

August 13, 2014

National List Manager
USDA/AMS/NOP, Standards Division
1400 Independence Ave. SW
Room 2648-So., Ag Stop 0268
Washington, DC 20250-0268

Subject: Petition to Request the Amendment of the National Organics Program's National List of Synthetic Substances Permitted in Organic Crop Production at §205.606
*Resubmission for correction of Errors

Dear Sir or Madam:

Amvac Chemical Corporation is respectfully requesting an amendment to §205.601 of the National List of Substances Allowed and Prohibited in Organic Production and Handling to include the synthetic substance 3-decene-2-one, so that it may be used for organic production. In support of this petition, the information below is being provided per the United States Department of Agriculture National Organics Program (NOP) guidance found in the Federal Register Notice of Thursday, January 18, 2007 (Vol. 72, No. 11, pp. 2167 – 2170, entitled "National Organic Program – Submission of Petitions of Substances for Inclusion on or Removal From the National List of Substances Allowed and Prohibited in Organic Production and Handling."

Thank you for your consideration of our petition. Please don't hesitate to contact me if you have questions, comments or need any additional information during your review. I can be reached at 949-221-6146 or via email me at Krystall@amvac-chemical.com.

Kind regards,

Krystal Jenkins, Regulatory Product Manager
AMVAC Chemical Corporation

ITEM A

Action being requested: Petitioner is requesting that the substance that is the subject of this petition be included in the National List in the section entitled "Synthetic Substances Allowed for Use in Organic Crop Production, §205.601."

ITEM B

1. The common name for the substance:

Chemical Name: 3-decen-2-one

Trade Name: SmartBlock®

CAS # 10519-33-2

2. The manufacturer's name, address and telephone number:

Manufactured for:

AMVAC Chemical Corporation 4695 MacArthur Court, Suite 1200 Newport Beach, CA 92660

Official Petition Contact Information:

Name: Krystal Jenkins Phone: 949-221-6146 FAX: 949-221-6196

E-mail: KrystalJ@amvac-chemical.com

3. The intended or current use of the substance:

SmartBlock, with active ingredient 3-decen-2-one is currently registered in the US (EPA Reg # 5481-571), Canada and is pending in the EU. It is labeled for postharvest use on stored potatoes as a sprout inhibitor.

3-decen-2-one is a naturally occurring substance that functions as a plant growth regulator, affecting plant growth by increasing tuber respiration. Data indicates that SmartBlock interferes with membrane integrity, which results in increased oxidative stress, desiccation, and rapid necrosis of the meristems and surrounding sprout tissues. Thus, SmartBlock inhibits sprouting, with no observed adverse effects on the potato, potato sweetening, or processing quality. 3-decen-2-one is approved by the U.S. Food and Drug Administration (FDA) for use as a synthetic agent and adjuvant that may be directly added to food under 21 CFR § 172.515.

Please see "Exhibit A" Product label for additional details.

4. A list of the crop, livestock or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance's mode-of-action must be described.

Crop and Rate: SmartBlock provides effective long-term sprout control by destroying the growing meristem of sprouting ("peeping") potato tubers and "burning off" sprouts. Further sprouting of potatoes in prevented for 1-3 months depending on potato variety and storage temperatures. It is applied via thermal fogging and the use rate is not to exceed 16.8 fl. oz./ton in any storage season. This product can effectively leverage the natural dormancy of potatoes when used in accordance with label directions. See attached product label for additional details.

Mode of Action: 3-decen-2-one acts only on the exposed rapidly growing meristematic tissue. It destroys membrane integrity, increases oxidative stress and inhibits the ability of cells to neutralize reactive oxygen species. The collapse of cell structure leads to the sprouts exhibiting a "burnt out" appearance due to pigmentation produced by the accumulation of polyphenols. -Dr. Rick Knowles, Washington State University

3-decen-2-one, the active ingredient in SmartBlock, is approved by the U.S. Food and Drug Administration (FDA) for use as a synthetic agent and adjuvant that may be directly added to food under 21 CFR § 172.515.

Please see "Exhibit A" Product label for additional details.

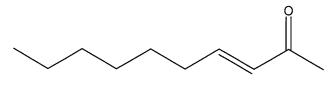
5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product.

Please see "Exhibit B" Confidential Statement of Formula

Description of the Production Process Used to Produce SmartBlock Potato Sprout Inhibitor Technical Grade

3-Decen-2-one (CAS RN 10519-33-2), the active ingredient in Amvac SmartBlock[®] Potato Sprout Inhibitor, is a naturally occurring compound¹. However, isolation of it from these sources would prove to be very difficult due to the low concentrations which are found in the natural matrix.

¹ 3-Decen-2-one (CAS RN 10519-33-2) has been found to be a flavor compound in the edible porcini mushroom, *Boletus edulis*: Thomas, A.F., 1973, J. Agric. Food Chem. 21(6) p. 955-958.



3-Decen-2-one (3D2)

There are several possible standard organic synthetic routes which could be used to make 3-Decen-2-one starting from readily available raw materials. Included in these possible methods which were screened by Amvac are: Aldol condensation^{2,3}, Wittig reaction⁴, catalytic rearrangements⁵, acylation of olefins⁶, reduction methodologies⁷, or some other more esoteric methods, such as olefin metathesis type reactions⁸. Most of these are chain elongation techniques. The Aldol condensation was chosen by Amvac as our method of choice for this synthesis due to the low cost and high availability of the raw materials.

The Aldol Condensation as practiced in the Amvac SmartBlock® synthetic process is based on the reaction of an alpha-keto active methylene group with n-heptaldehyde. Further transformations may be required depending on the reactant chosen, including decarboxylation, phase separation, filtration and fractional distillation, to form the active ingredient, 3-Decen-2-one. A catalyst is sometimes employed to facilitate the reaction. An example of this process is shown in the following reaction equation.

The raw materials for the Amvac SmartBlock process, n-Heptaldehyde and Acetone, were chosen based on both their applicability in the Aldol reaction, as well as their ready availability on the world market and their "natural" character. n-Heptaldehyde is produced industrially from natural product castor oil throughout the world by several manufacturers. Acetone is one of the most widely used industrial solvents and intermediates throughout the world. It has low

² Aldol Condensation: see for example: List, et al, Organic Letters (2001), 3(4), 573-575.

³ Knoevenagel Condensation: see for example: Fr Pat. 2481701 A1 to Nippon Soda Co. (1981).

⁴ For an excellent review of the Wittig reaction see, House, "Modern Synthetic Reactions", 1972, p. 682-709.

⁵ Ger. Pat.DE 2518031 A1 to Hoffmann-La Roche (1975).

⁶ Vukicevic, et al, Bulletin of the Chemical Society of Japan (1998), 71(4), 899-904.

⁷ Alper, et al, Tetrahedron Letters (1995), 36(32), 5673-6.

⁸ Grubbs, Robert H. (2003). Handbook of Metathesis (1st ed.). German: Wiley-VCH.

⁹ Trivedi, et al, JAOCS <u>66</u>, 938 (1989).

toxicity and is a natural product of the human body's metabolic processes.¹⁰ Acetone also has the advantages of having a low boiling point and is easy to recycle.

The process employed to manufacture Amvac SmartBlock® Potato Sprout Inhibitor Technical Grade can be broken down into several distinct processing steps and is described in the following paragraphs. The process can be sequential in nature which can be operated in one vessel or several vessels depending upon the available equipment. A block flow diagram for the process is attached.

<u>Process Step 1</u>: Formation of 3-Decen-2-one (3D2): Acetone is reacted with n-heptaldehyde (aka, 1-heptanal, n-heptanal or heptanal) in the presence of a catalyst in a batch reactor to produce the active ingredient, 3-Decen-2-one. No gaseous by-products are formed in this reaction. Several other condensation by-products are formed and must be separated from the active ingredient in further unit operations.

Acetone is charged to the reactor along with the catalyst. The reaction is exothermic, but must be initially heated to induce the reaction. The reactor is normally made of glass-lined steel, but suitable corrosion resistant metal reactors can also be used (such as 316 stainless steel or Hasteloy). Heptanal is metered into the reactor over 2-4 hours. Due to the flammable nature of the reactants and solvents the reaction is run under inert Nitrogen atmosphere. The reactor is equipped with a condenser on the vent to prevent loss of acetone. At the completion of the heptanal addition, the mixture is held until sampling shows the reaction to be complete. Reaction samples are analyzed by Gas Chromatography to show reaction completion. After completion of the reaction, the excess acetone is distilled out of the reactor. After Acetone recovery is complete, the reaction mass is cooled to 25°C.

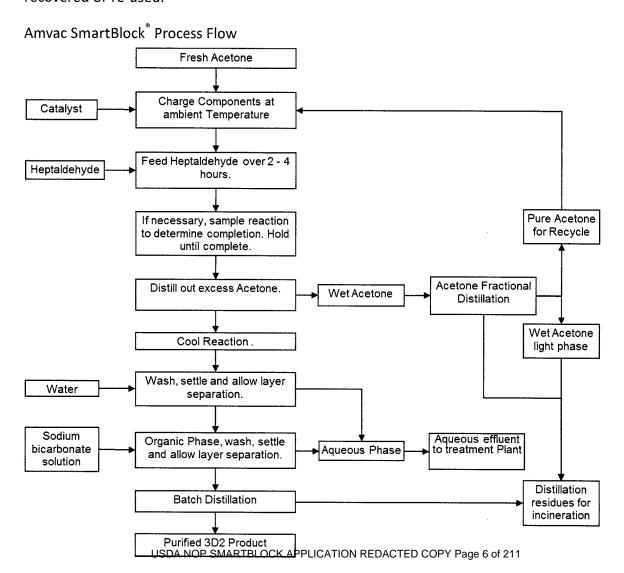
<u>Process Step 2</u>: Washing of 3-Decen-2-one (3D2): The reaction mass is washed to remove impurities and any acetone left after the distillation. Generally the ratio of aqueous to organic is optimized between 1:1 to 1:6 [water:organic]. The wash vessel must be outfitted with a method to determine the interface between the aqueous and organic layers (e.g. sight glass) for the purpose of good phase splitting. The vessel is normally made of glass-lined steel, but suitably corrosion resistant metal reactors can also be used (such as Hasteloy). The aqueous phase is drawn off (normally the bottom phase) and is sent to the effluent treatment plant. pH Analysis of the aqueous phase normally gives indication as to how the rest of the wash operation is to be done. If the batch has $pH \le 6$ then it is washed with sodium bicarbonate solution. If the batch is $pH \le 7$ it is passed on to the distillation step.

¹⁰ Please refer to the Dow Chemical internet page (http://www.dow.com/productsafety/finder/acetone.htm).

<u>Process Step 3</u>: Fractional Vacuum Distillation of 3-Decen-2-one: Crude reaction mixture is fractionally distilled under high vacuum to separate the undesired reaction by-products from the purified active ingredient, 3-decen-2-one. The distillation equipment is normally made of glass-lined steel, but suitably corrosion resistant metal systems can also be used (such as 316 stainless steel or Hasteloy). The rate of distillation is dependent upon the exact equipment used. When conducted at 3 - 5 torr the product distills at about 82 - 83°C.

Purified 3-decen-2-one is analyzed by gas chromatography. If it passes the required specifications, it is packaged as Amvac SmartBlock® Potato Sprout Inhibitor Technical Grade. If slightly out of specification it can be blended with other (better quality) product, rewashed or redistilled. After any of these re-work conditions is performed, the product is re-checked for quality.

<u>Process Step 4</u>: Recycle of Raw Materials: The excess acetone, as it comes from the process, can contain water and impurities and is recovered by distillation so as to recover acetone having the same specifications as the purchased material. No other raw material used in the process is recovered or re-used.



Please see "Exhibit C" Heptanal Citation; "Exhibit O" Acetone MSDS; "Exhibit P" Heptanal MSDS

6. A summary of any available previous reviews by state or private certification programs or other organizations of the petitioned substance.

OMRI:

An application for this substance was submitted to OMRI. The application was rejected on the sole basis that this was a synthetic compound that does not appear on the National List. There have been no other reviews conducted for this substance by State or other Organic Certification Programs.

7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers.

EPA:

This substance is registered with the EPA. The technical active ingredient has been assigned EPA Reg. No. 5481-568, initial product label dated February 5, 2013. The end-use product, which is identical in composition to the technical active ingredient, has been assigned EPA Reg. No. 5481-571, initial product label dated February 5, 2013. Please see enclosed Biopesticide Registration Action Document.

Please see "Exhibit D" Original EPA Stamped Technical Product label for additional details.

Please see "Exhibit E" Original EPA Stamped Product label for additional details.

Please see "Exhibit F" Biopesticide Registration Action Document (BRAD) 3-decen-2-one PC Code: 068403, dated February 4, 2013

PMRA:

An application for this substance was approved by the Health Canada Pest Management Regulatory Agency. The Agency assigned Registration No. 30889.

Please see "Exhibit G" PMRA Approval documentation.

FDA: FDA reviewed and classified 3-decen-2-one as a synthetic flavoring compound under 21 CFR 172.515 for use as a direct food additive.

FEMA GRAS:

3-decen-2-one has been reviewed by the Flavor and Extract Manufacturers Association (FEMA) Expert Panel and determined to be GRAS (Generally Recognized as Safe). FEMA GRAS Substances articles present the results of safety evaluations of flavoring ingredients performed

by an expert panel in response to the 1958 Food Additives Amendment to the Federal Food Drug and Cosmetics Act (FFDCA). The maximum concentrations of 3-decen-2-one in various foods considered by the expert panel to be GRAS are presented in the GRAS Substances 11 article published in Food Technology (Oser & Ford, 1978). These maximum concentrations included: 19 ppm in baked goods, 5.8 ppm in frozen dairy products and 4.8 ppm in gelatins and puddings.

Substance Number: 3532

Please see "Exhibit H" GRAS Substances (Page 2) February 1978.

8. The Chemical Abstract Service (CAS) Number.

3-Decen-2-one CAS Number: 10519-33-2

EINICS Number: 234-059-0

9. The substance's Physical Properties and Chemical Mode of Action.

		TABLE 4. Physical and Chemical Properties for 3-decen-2-one (40 CFR§ 158.2030)				
OCSPP Guideline Reference No./Property Description of Result MRID						
830.6302	Color	Colorless to pale yellow	47942607			
830.6303	Physical State	Clear Liquid	47942607			
830.6304	Odor	Pleasant	47942607			
830.6313	Stability to normal and elevated temperatures, metals and metal ions	The stability of the active ingredient of the test substance untreated and in presence of metals and metal ions (iron powder, iron acetate, aluminum powder, and aluminum acetate) stored for 1, 2, 7 and 14 days was determined at ambient (21 0 23°C) and elevated temperature (54°C). A significant decrease in the concentration of the active ingredient was observed at elevated temperatures for all treatments and with the samples treated with iron acetate at ambient temperature after 7 days.	47942607			
830.6315	Flammability	Flash Point =91°C	From Confidential Statement of Formula (CSF)			
830.6317	Storage Stability	Not required for TGAI. MP is stable during one year storage stability study.	48970301			
830.6319	Miscibility	N/A, not an emulsifiable liquid and is not to be diluted with petroleum solvents	47942607			
830.6320	Corrosion Characteristics	Not required for TGAI. MP showed no signs of corrosion (cracking, pitting, or discoloration) during one year storage stability study.	48970301			
830.7000	рН	4.33 of 1% w/w suspension in water at 23°C	47942607			

830.7050	UV/Visible light absorption	$\frac{\text{pH}}{\text{Neutral}}$ $\frac{\lambda_{\text{max(nm)}}}{\text{229.0}}$ $\frac{\epsilon(\text{L/mol*cm})}{\text{14408.1}}$ Acidic 229.0 16464.7 Alkaline 229.0 9330.6	47942607
830.7100	Viscosity	2.211 mm ² /s at 25°C	48156401
830.7200	Melting Range	N/A, not a solid	47942607
830.7220	Boiling Range	224.0°C	47942607
830.7300	Density/Relative Density/Bulk Density	0.845 g/mL at 20°C	47942607
830.7520	Particle size, fiber length, and diameter distribution	N/A, not insoluble in water and not a fiber	47942607
830.7550	partition Coefficient	Log P _{ow} = 3.45	47942607
830.7560	(n-Octanol/Water)	2 5"	
830.7570			
830.7840	Water Solubility	0.140 g/L at 24°C	47942607
830.7950	Vapor Pressure	430 Pa at 25°C	47942608

Please see "Exhibit F" Biopesticide Registration Action Document (BRAD) 3-decen-2-one PC Page 24 of 30.

Mode of Action: 3-decen-2-one acts only on the exposed rapidly growing meristematic tissue. It destroys membrane integrity, increases oxidative stress and inhibits the ability of cells to neutralize reactive oxygen species. The collapse of cell structure leads to the sprouts exhibiting a "burnt out" appearance due to pigmentation produced by the accumulation of polyphenols. -Dr. Rick Knowles, Washington State University

(a) Chemical interactions with other substances, especially substances used in organic production

This product is not expected to interact with other organic products used on potatoes during post-harvest storage being used commercially.

(b)Toxicity and Environmental Persistence;

Study/OCSPP Guideline No.	Results	Toxicity Category/Description	MRID
Avian acute oral toxicity (850.2100)	Not required. Significant exposure to birds is not expected due to the proposed indoor use only as a sprout inhibitor on potatoes. In addition, 3-decen-2-one is applied and released as a vapor and is not expected to be available to birds via the oral route.	Significant exposure not expected	47942617

Avian dietary toxicity (850.2200)	Not required. Significant exposure to birds is not expected due to the proposed indoor use only as a sprout inhibitor on potatoes. In addition, 3-	Significant exposure not expected	47942617
	decen-2-one is applied and released as a vapor	·	
	and is not expected to be available to birds via		
	the oral route.		
Aquatic invertebrate	Not required. Significant exposure to aquatic	Significant exposure	47942617
acute toxicity,	invertebrates is not expected due to the	not expected	
freshwater	proposed indoor use only as a sprout inhibitor on	·	
(850.1010)	potatoes. In addition, 3-decen-2-one is applied		
	and released as a vapor and is not expected to		
	enter surface water in amounts sufficient to		
	impact aquatic life.		
Fish acute toxicity,	Not required. Significant exposure to fish is not	Significant exposure	47942617
freshwater	expected due to the proposed indoor use only as	not expected	
(850.1075)	a sprout inhibitor on potatoes. In addition, 3-		
	decen-2-one is applied and released as a vapor		
	and is not expected to enter surface water in		
	amounts sufficient to impact aquatic life.		
Terrestrial plant	Not required. Significant exposure to terrestrial	Significant exposure	47942617
toxicity, seedling	plants is not expected due to the proposed	not expected	
emergence/Vegetative	indoor use only as a sprout inhibitor on potatoes.		
vigor	In addition, 3-decen-2-one is applied and released		
(850.4100 and	as a vapor during winter months when terrestrial		
850.4150)	plants are generally dormant and when seedlings		
	are not emerging.		
Nontarget insect	Not required. Significant exposure to insects is	Significant exposure	47942617
testing	not expected due to the proposed indoor use only	not expected	
(880.4350)	as a sprout inhibitor on potatoes. In addition, 3-	;	
	decen-2-one is applied and released as a vapor		
	during winter months when non-target insects		
	are generally dormant.		

Please see "Exhibit F" Biopesticide Registration Action Document (BRAD) 3-decen-2-one PC Page 26 of 30.

(c) Environmental impacts from its use or manufacture;

The need for Environmental Fate and Groundwater Data is not required based on the approved indoor use pattern of 3-decen-2-one.

(e) Effects on human health;

This substance is to be used only in potatoes post-harvest that have been placed in storage. Therefore, environmental impact is minimal and not expected to cause any negative impacts.

(d) Effects on soil organisms, crops or livestock.

Please see "Exhibit I" Federal Register Notice (Vol. 78, No. 34, February 20, 2013, pp11760 – 11766, entitled "3-decen-2-one; Exemption from the Requirement of a Tolerance") for a summary of human health effects.

10. Safety Information about the substance.

A US Material Safety Data Sheet (MSDS) is attached as "Exhibit J." A Canadian Material Safety Data Sheet (MSDS) is attached as "Exhibit K." An EU Material Safety Data Sheet (MSDS) is attached as "Exhibit L."

This product has "GRAS" classification as described in item 7 and detailed in "Exhibit H," and a further search of the public domain as attached in "Exhibit M" concludes that no clinical cases of poising incidents have occurred with 3-decen-2-one.

11. Research information about the substance that includes comprehensive substance research reviews and research bibliographies, including reviews on bibliographies that present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List.

Research Information: Please refer to the information below in the Petition Justification Statement in No. 12 below.

Further efficacy data and information is attached as "Exhibit N."

12. A "Petition Justification Statement" which provides justification for the inclusion of 3-decen-2-one (the active ingredient in SmartBlock) on the National List.

Petition Justification Statement:

SmartBlock (3-decen-2-one) is a unique sprout control product which has been determined to be naturally-occurring in many common foods such as yogurt, tuna, carp, mushrooms, soy and various spices. The chemically synthesized form has been used in the flavoring and fragrance industry for many decades and is approved as a direct food additive by the FDA (21 CFR 172.515) and has been determined to be GRAS by FEMA (Exhibit H). Many common foods such as baked goods or non-alcoholic beverages use 3-decen-2-one as a flavoring food additive up to 5 to 15 ppm. In other words, this compound is already present in the average American diet both in the synthetic and natural forms. SmartBlock is synthesized at a very high level of purity (>98%) and do not utilize any toxic solvents or adjuvants in the manufacturing process.

SmartBlock as a sprout suppressant is very unique. It is quite different from essential oils such as clove oil, mint oil, caraway seed oil etc. which act by "burning off" the growing (budding) tips of the potato sprouts. The residual activity of such essential oils is very short (often 2-3 weeks) and these do not control sprouts which are longer than 0.5cm. Recently, the supply of clove oil globally has been erratic leading to price spikes of imports which are subject to supply and demand. Taint (taste) of the potato tubers can also be an issue. SmartBlock is very effective in not only the budding sprouts but also eliminates sprouts which are up to 2.5cm long (or even longer) and in addition, provides a much longer residual control (in many cases, up to 3-4 months). SmartBlock treated potatoes also have a better shelf life (defined as the period from the time tubers come out of storage till consumption). We believe that SmartBlock provides the potato growers with an essential tool to provide quality potatoes to the consumer. The reducing sugar levels (important for potato fries and chips) are not adversely affected and the taste and texture of the tubers has been determined to be very good.

Organic growers who wish to export their tubers are often at a disadvantage because of the lack of proper sprout control products and they will benefit immensely if SmartBlock is added to the National List. Culturally, cold storage (around 40 to 42°F) helps to delay dormancy break, but storing at such temperatures induces "cold sweetening" leading to loss of taste and loss of quality (darker chips and French fries). Many growers are shifting away from cold storage because of high cost of energy (refrigeration) and also the risk of acrylamide formation in high-sugar chip/French fry stock.

In short, SmartBlock is a "green" fresh alternative and promises to provide the potato grower quality potatoes, requiring far fewer treatments than the current option (clove oil) while providing longer sprout-free residual activity and better shelf life for the consumers.

Please see "Exhibit 1 - 3" of letters of support and further justification from prominent US Potato Growers.

13. Confidential Business Statement Information: Pursuant to 7 CFR 1.27(d), some of the information in this petition is Confidential Business Information based upon it being Trade Secret Information that is commercially valuable, used in the course of Amvac Chemical Corporation's business and is maintained in secrecy. Confidential Information has been marked as such and a redacted copy of this petition has been included. If a determination is made by USDA to deny CBI treatment, Amvac respectfully requests notice of this determination prior to any publication of this submitted material.



FOR USE AS A POTATO SPROUT INHIBITOR For Indoor Use Only FOR USE THOUGH FOGGING EQUIPMENT ONLY

Active Ingredient: 3-decen-2-one	 98.0%
Inert Ingredients	
	100.0%

Contains 7.05 lbs (3.2kg) 3-decen-2-one per gallon

WARNING - AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

	FIRST AID
If on skin	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respirat preferably mouth-to-mouth if possible. Call a poison control center or doctor for treatment advice. 	
	EMERGENCY INFORMATION
treatment.	duct container or label with you when calling a poison control center or doctor, or going for LLOWING EMERGENCIES, PHONE 24 HOURS A DAY:
For Medical E	mergencies phone:
For Transpor	tation Emergencies, including spill, leak or fire, phone: CHEMTREC®800-424-9300
For Product U	Jse Information phone: AMVAC®888-462-6822
EPA Reg. No	EPA Est. No.: 5481-ID-001

Net Contents: As marked on container (5 gallons or 12.5 gallons)

Manufactured by:

AMVAC Chemical Corporation 4100 E. Washington Boulevard Los Angeles, CA 90023 U.S.A. 888-462-6822

Batch Code:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes skin irritation and substantial but temporary eye injury. Harmful if inhaled. Do not get on skin or on clothing. Avoid contact with eyes. Avoid breathing vapor.

Personal Protective Equipment (PPE):

Wear coveralls worn over long sleeve shirt and long pants, socks, chemical resistant footwear, chemical-resistant gloves, goggles, face shield, or shielded safety glasses and respirator. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables are available, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Non-Agricultural Use Requirements

The requirements in this box apply to uses of this product that are **not** within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried or dusts have settled. Do not enter the treatment area during application. Unless equipped with the required PPE, do not reenter the treatment area for 24 hours (Restricted-entry interval: 24 hours) after treatment and until the ventilation period is completed. PPE required is: coveralls worn over long sleeve shirt and long pants, socks, chemical resistant footwear, chemical-resistant gloves, goggles, face shield, or shielded safety glasses and a NIOSH approved respirator with any N, R, P or HE filter (or MSHA/NIOSH approval number prefix TC-21C).

General: SMARTBLOCK EP provides effective long-term sprout control by destroying the growing meristem of sprouting potato tubers and "burning off" sprouts. Further sprouting of potatoes is prevented for up to three (3) months or more depending on variety, sprout length, use rate and storage conditions.

Use Precautions:

- Do not make applications to potatoes in the field.
- Do not use on seed potatoes. Do not allow the thermal fog to come into contact with or to enter
 areas used for storage of seed potatoes, potato handling or cutting equipment. Seed potatoes
 can be safely stored in potato storage which were previously treated with SMARTBLOCK EP only
 after full ventilation and clean out procedures have been followed. The air system including ducts,
 plenums and the storage building itself must be thoroughly ventilated prior to storing seed
 potatoes.
- Follow all application equipment manufacturers' use directions.

20140327-571.SmartBlock.general revisions

• Do not enter the treatment area during application. Unless equipped with the required PPE, do not reenter the treatment area for 24 hours after treatment and until the ventilation period is completed. Continue to run ventilation fans as necessary to introduce fresh air into the storage.

Directions for Use:

SMARTBLOCK EP can effectively leverage the natural dormancy of potatoes when used according to label directions. SMARTBLOCK EP is generally used just prior to or during the time when the tuber dormancy period is ending. An application should preferably be made when the tubers display "peeping" sprouts but more advanced sprouting can also be treated and controlled (see Sprout Control Programs below). The interval between harvest and the onset of sprouting is dependent on the cultivar and storage temperature.

The preferred method of application is through standard aerosol (thermal fogging) equipment. Thermal fogging provides the most efficacious and consistent sprout control.

Excellent movement of the fog or vapor through the potato pile is also important for consistent efficacy.

Procedure for Thermal Fogging with SMARTBLOCK EP:

- 1. Calculate the quantity of SMARTBLOCK required based on total tonnage and condition of tubers in storage prior to application.
- 2. Prepare aerosol/fog/vapor generating equipment and insert intake hose into the container with SMARTBLOCK EP.
- 3. Configure settings such that the ventilation fans are set at proper speeds to re-circulate with adequate pressure to move the fog or vapor through the potato pile. Turn off all humidifier units and ensure a good seal of the storage to prevent leakage. These steps will ensure good distribution of SMARTBLOCK EP inside the storage.
- 4. Place the exhaust end of the aerosol/fog or vapor generator into the air mixing chamber. Potato storages vary greatly in design and air movement patterns. It is therefore advisable to work with your local custom applicator to ensure accurate applications under optimal conditions are made.
- 5. Adjust flow rate of SMARTBLOCK EP through the equipment to match the appropriate fogging temperature. Do not allow the product to dribble out at the introduction point. Important: Follow all equipment safety precautions.
- 6. For best results, restrict or avoid intake of outside air into the storage during SMARTBLOCK EP application.
- 7. Turn on the fogging equipment and allow the SMARTBLOCK aerosol, fog or vapor into the storage facility's mixing chamber or plenum. Operate the ventilation fans to cycle and recirculate the fog through the pile for up to 24 hours. For processing varieties, recirculating vapor for a period of 8 to 12 hours may be adequate prior to resuming the normal ventilation schedule.
- 8. After the recirculation period is complete, return the ventilation system to the desired operational mode and allow fresh air or outside air into the potato storage facility.
- 9. Within 1-5 days following application, buds or sprouts on tubers should exhibit a blackened or "burnt" appearance. However, depending on the potato variety, sprout size and use rate of SMARTBLOCK EP, it may take up to 7 to 10 days after treatment to observe full effects (including extended shelf life of tubers).

Sprout Control Programs with SMARTBLOCK EP:

General Use Directions

SMARTBLOCK EP treatments should preferably be made towards the end of tuber dormancy and to effectively leverage the natural, sprout-free dormancy period. Non-sprouting tubers may also be treated in anticipation of dormancy break as well. For best results, make the first application when approximately

20140327-571.SmartBlock.general revisions

75% of tubers show visible signs of sprouting (peeping) or exhibit signs of early dormancy break (swollen buds). An SMARTBLOCK EP treatment program can effectively provide season-long sprout control. SMARTBLOCK EPSMARTBLOCK EPSMARTBLOCK EPPotatoes can be removed or unloaded from storages and shipped 24 hours after ventilation is resumed. For full effect, unload the storages 7 to 10 days after treatment to ensure that sprouts are sufficiently blackened and adequate shelf life is achieved.

Combinations of SMARTBLOCK EP with other Sprout Control Products:

SMARTBLOCK EPSMARTBLOCK EP can also be used effectively with other sprout control products such as chlorpropham (CIPC), diisopropyl naphthalene (DIPN) or dimethyl naphthalene (DMN) products. When mixing other sprout control products, especially during the early period of the storage season, or as part of a planned sequential program, lower rates of SMARTBLOCK EP may be used. Follow all product label instructions. Consult your local custom applicator for more information.

(i) SMARTBLOCK EP Sprout Control Programs with Chlorpropham (CIPC) or DIPN (Amplify®) or DMN (1,4 Sight®)

During the storage cycle, when sprouting is observed on tubers treated earlier with CIPC, DIPN or DMN, SMARTBLOCK EP can be applied to burn off sprouts and extend the sprout control period. Alternatively, CIPC, DIPN or DMN can be mixed with SMARTBLOCK EP or applied sequentially. Either product may be applied first, followed by the other product or co-injected or applied as a mixture into the fogging equipment. Follow all use directions and product precautions.

- (ii) <u>SMARTBLOCK EP Sprout Control Programs with Maleic Hydrazide (Royal MH-30®):</u> At early dormancy break, potatoes treated with Royal MH-30 prior to harvest can be treated with SMARTBLOCK EP later in storage to further extend the sprout-free period of tubers. Depending on storage conditions and potato variety, up to an additional 3 months of sprout control may be achieved. Make additional applications as needed.
- (iii) Sprout Control in Potatoes undergoing Reconditioning:

When stored at low temperatures, reducing sugars increase in tubers and decrease the fry quality of potatoes. Such tubers can be reconditioned by raising the storage temperature and lower reducing sugar content. Such conditions, however, favor sprouting. SMARTBLOCK EP can be used effectively to burn off sprouts during the reconditioning phase prior to shipment. For best results, do not allow sprouts to exceed 1 inch (2.5 cm) on average, at the time of treatment.

(iv) <u>Rescue of Potatoes with Excessive Sprouting in Storage:</u> In cases where storage conditions lead to undesirable sprouting, especially during late in the storage cycle, SMARTBLOCK EP can be effectively used to "burn off" sprouts which on average, measure up to 1 inch (2.5cm) and restore dormancy.

<u>Application Rate</u>: Apply SMARTBLOCK EP up to a maximum of 4.20 fl oz. per ton or 0.21 fl oz/cwt potatoes. One gallon of SMARTBLOCK EP will treat 610 cwt. potatoes at the maximum use rate. Reapply SMARTBLOCK EP as needed. Use lower rates when sprouts are small or when a shorter period of sprout control is acceptable or when used in combination with other sprout control products.

Minimum re-application interval is 7 days.

Do not apply more than 16.8 fl oz/ton potatoes (0.84 fl oz/cwt) per storage season.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in cool dry area.

Pesticide Disposal: Wastes resulting from use of this product may be disposed of on site or at an

approved waste disposal facility.

Container Handling: Nonrefillable Container. Do not reuse or refill this container. Then offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

LIMITED WARRANTY AND DISCLAIMER

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is reasonably fit for the purposes set forth in the directions for use, subject to the inherent risks referred to herein, when it is used in accordance with such directions; and (c) that the directions, warnings, and other statements on this label are based upon responsible experts' evaluations of reasonable tests of effectiveness, of toxicity to laboratory animals and upon reports of field experience. Tests have not been made on all varieties of potatoes, or in all states or under all conditions.

THERE ARE NO WARRANTIES OTHER THAN THOSE EXPRESSLY SET FORTH HEREIN. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW THE MANUFACTURER NEITHER MAKES NOR INTENDS, NOR DOES IT AUTHORIZE ANY AGENT OR REPRESENTATIVE, TO MAKE, ANY OTHER WARRANTIES, EXPRESS OR IMPLIED AND IT EXPRESSLY EXCLUDES AND DISCLAIMS ALL IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION, THOSE OF MERCHANTABILITY. THIS WARRANTY DOES NOT EXTEND TO, AND THE BUYER SHALL BE SOLELY RESPONSIBLE FOR, ANY AND ALL LOSS OR DAMAGE WHICH RESULTS FROM THE USE OF THIS PRODUCT IN ANY MANNER WHICH IS INCONSISTENT WITH THE LABEL DIRECTIONS, WARNINGS OR CAUTIONS.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW BUYER'S EXCLUSIVE REMEDY AND MANUFACTURER'S OR SELLER'S EXCLUSIVE LIABILITY FOR ANY AND ALL CLAIMS, LOSSES, DAMAGES, OR INJURIES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER OR NOT BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY IN TORT OR OTHERWISE, SHALL BE LIMITED, AT THE MANUFACTURER'S OPTION, TO REPLACEMENT OF, OR THE REPAYMENT OF THE PURCHASE PRICE FOR, THE QUANTITY OF PRODUCT WITH RESPECT TO WHICH DAMAGES ARE CLAIMED. TO THE EXTENT PERMITTED BY WITH APPLICABLE LAW MANUFACTURER OR SELLER SHALL NOT BE LIABLE FOR SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

AMVAC offers this product, and Buyer accepts it, subject to the foregoing Limited Warranty which may be varied only by agreement in writing signed by an authorized representative of AMVAC.

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Exhibit B CBI - Deleted

HEPTANAL

Synonyms: Aldehyde C-7; Eanthal; Enanthaldehyde; Enanthic aldehyde; Enanthole; Heptaldehyde; n-Heptanal (8CI)(9CI); n-Heptanal; n-Heptanal; Heptanaldehyde; Heptylaldehyde; Oenanthal; Oenanthaldehyde; Oenanthic aldehyde; Oenanthol

CAS No.:	111-71-7	FL No.:	05.031	FEMA No.:	2540 N	AS No.:	2540
CoE No.:	117	EINECS No.:	203-898-4	JECFA No.:	95	**************************************	

Description: Heptanal has a very strong, fatty, harsh, pungent odor and an unpleasant, fatty

Consumption: Annual: 61.67 lb Individual: 0.00005225 mg/kg/day

Regulatory Status:

CoE: Approved. Bev.: 5 ppm; Food: 12 ppm

FDA: 21 CFR 172,515 FDA (other): n/a

JECFA: ADI: Acceptable. No safety concern (1997) Trade association guidelines: FEMA PADI: 1.792 mg

IOFI: Nature Identical

Empirical Formula/MW:

C7H14O/114.18

CH3-(CH2)5-CHO

Specifications: (FCC, 1996)

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	Refractive index 1.412-1.420
Acid value 10.0 (max)	Retractive index 1.417-1.420
Acid value 10 0 (max)	

(Part 1 of 2)

752 Fenaroli's Handbook of Flavor Ingredients

Specifications: (FCC, 1996) (Continued)

Appearance	Colorless to slightly yellow liquid
Assay	92% of C ₇ H ₁₄ O
Boiling point	153°C

Solubility	Slightly soluble in water, miscible in alcohol, ether fixed oils; 1:2 in 70% alcohol
Specific gravity	0.814-0.819

(Part 2 of 2)

Reported uses (ppm): (FEMA, 1994)

Food Category	Usual	Max.
Baked goods	7.74	11.60
Chewing gum	0.07	0.07
Frozen dairy	3.31	5.24
Gelatins, puddings	3.31	5.10

Food Category	Usual	Max.
Imitation dairy	5.00	50.00
Meat products	2.55	10.00
Nonalcoholic beverages	3.23	5.09
Soft candy	6.51	8.77

Synthesis: Obtained by distilling castor oil, preferably under reduced pressure.

Aroma threshold values: Detection: 3 to 60 ppb

Taste threshold values: n/a

Natural occurrence: Heptanal is a constituent of the essential oils of ylang-ylang, clary sage, California lemon, bitter orange, rose and hyacinth. Also reported found in cocoa, buckwheat, elderberry fruit and juice and babaco fruit (Carica pentagona Heilborn).

Burdock, George A. (2004) Fenaroli's Handbook of Flavor Ingredients, Fifth Edition, CRC Press



U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7511P) 1200 Pennsylvania Avenue NW Washington, DC 20460

EPA Reg. Number:

Date of Issuance:

5481-568

FEB - 5 2013

Term of Issuance:

Unconditional

Name of Pesticide Product

AMV-1018 Technical

NOTICE OF PESTICIDE:

X Registration
Reregistration

Name and Address of Registrant (include ZIP Code):

AMVAC Chemical Corporation 4695 MacArthur Court

Suite 1200

Newport Beach, CA 92660

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his/her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA. This product is unconditionally registered in accordance with FIFRA Sec. 3(c)(5) provided you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2. Revise the EPA Registration Number to read, "EPA Reg. No. 5481-568".
- 3. Submit two (2) copies of the final printed labeling before you release the product for shipment.

A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

Date

05 Delover 2013

Keith A. Matthews, Director,

Biopesticides and Pollution Prevention Division

EPA Form 8570-6

AMV-1018 Technical

For Manufacturing Use Only

Active Ingredient: 3-decen-2-one......98.0% Inert Ingredients......2.0% TOTAL

KEEP OUT OF REACH OF CHILDREN

WARNING

See (back) (side) panel for first aid, additional precautionary statements, and directions for use

EPA Reg. No.: 5481-LAI

EPA Est. No.: XXXXX-XXX

Net Contents: XXXX

Manufactured by:

AMVAC Chemical Corporation 4100 E. Washington Boulevard Los Angeles, CA 90023 U.S.A.

1-888-462-6822

ACCEPTED

FEB - 5 2013

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 5481-568

Batch Code:

AMV1018.tech.20130115

	FIRST AID
lf on skin	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If inhaled	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for treatment advice.
	EMERGENCY INFORMATION
	Section 1 at 1 mark 1 at 1 mark mark 1 at 1 a
doctor, or go	oduct container or label with you when calling a poison control center or ing for treatment.
doctor, or go	oduct container or label with you when calling a poison control center or
for the Fo	oduct container or label with you when calling a poison control center or ing for treatment.
FOR THE FOR Medical For Transpo	oduct container or label with you when calling a poison control center or ing for treatment. OLLOWING EMERGENCIES, PHONE 24 HOURS A DAY:

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes skin irritation and substantial but temporary eye injury. Harmful if inhaled. Do not get on skin or on clothing. Avoid contact with eyes. Avoid breathing vapor. Wear coveralls worn over long sleeve shirt and long pants, socks, chemical resistant footwear, chemical-resistant gloves, goggles, face shield, or shielded safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously

AMV1018.tech.20130115

notifying the local sewage treatment plant authority. For guidance contact your State Water Board of Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

FOR MANUFACTURING USE ONLY. Only for formulation into registered enduse products for use in or on stored potatoes. Formulators are responsible for obtaining EPA registration of their end-use products. Not for direct treatment of pests. Do not use from damaged, punctured or unsealed containers

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in cool dry area.

Pesticide Disposal: Wastes resulting from use of this product may be

disposed of on site or at an approved waste disposal facility.

Container Handling: Nonrefillable Container. Do not reuse or refill this container. Then offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by

state and local authorities, by burning. If burned, stay out of smoke.

LIMITED WARRANTY AND DISCLAIMER

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is reasonably fit for the purposes set forth in the directions for use, subject to the inherent risks referred to herein, when it is used in accordance with such directions; and (c) that the directions, warnings, and other statements on this label are based upon responsible experts' evaluations of reasonable tests of effectiveness, of toxicity to laboratory animals and upon reports of field experience. Tests have not been made on all varieties of potatoes, or in all states or under all conditions.

THERE ARE NO WARRANTIES OTHER THAN THOSE EXPRESSLY SET FORTH HEREIN. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW THE MANUFACTURER NEITHER MAKES NOR INTENDS, NOR DOES IT AUTHORIZE ANY AGENT OR REPRESENTATIVE, TO MAKE, ANY OTHER WARRANTIES, EXPRESS OR IMPLIED AND IT EXPRESSLY EXCLUDES

AMV1018.tech.20130115

AND DISCLAIMS ALL IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION, THOSE OF MERCHANTABILITY. THIS WARRANTY DOES NOT EXTEND TO, AND THE BUYER SHALL BE SOLELY RESPONSIBLE FOR, ANY AND ALL LOSS OR DAMAGE WHICH RESULTS FROM THE USE OF THIS PRODUCT IN ANY MANNER WHICH IS INCONSISTENT WITH THE LABEL DIRECTIONS, WARNINGS OR CAUTIONS.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW BUYER'S EXCLUSIVE REMEDY AND MANUFACTURER'S OR SELLER'S EXCLUSIVE LIABILITY FOR ANY AND ALL CLAIMS, LOSSES, DAMAGES, OR INJURIES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER OR NOT BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY IN TORT OR OTHERWISE, SHALL BE LIMITED, AT THE MANUFACTURER'S OPTION, TO REPLACEMENT OF, OR THE REPAYMENT OF THE PURCHASE PRICE FOR, THE QUANTITY OF PRODUCT WITH RESPECT TO WHICH DAMAGES ARE CLAIMED. TO THE EXTENT PERMITTED BY WITH APPLICABLE LAW MANUFACTURER OR SELLER SHALL NOT BE LIABLE FOR SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

AMVAC offers this product, and Buyer accepts it, subject to the foregoing Limited Warranty which may be varied only by agreement in writing signed by an authorized representative of AMVAC.



U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7511P) 1200 Pennsylvania Avenue NW Washington, DC 20460

EPA Reg. Number:

Date of Issuance:

5481-571

FEB - 5 2013

Term of Issuance:

Unconditional

Name of Pesticide Product:

AMV-1018 EP

NOTICE OF PESTICIDE:

X Registration

Reregistration (under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

AMVAC Chemical Corporation 4695 MacArthur Court Suite 1200

Newport Beach, CA 92660

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his/her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA. This product is unconditionally registered in accordance with FIFRA Sec. 3(c)(5) provided you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2. Revise the EPA Registration Number to read, "EPA Reg. No. 5481-571".
- 3. Submit two (2) copies of the final printed labeling before you release the product for shipment.

A stamped copy of the label is enclosed for your records.

Signature of Approxing Official

Keith A. Matthews, Director,

Biopesticides and Pollution Prevention Division

Date:

8 For 2013

EPA Form 8570-6

AMV-1018 EP

FOR USE AS A POTATO SPROUT INHIBITOR

For Indoor Use Only

FOR USE THOUGH FOGGING EQUIPMENT ONLY

Active Ingredient: 3-decen-2-one	98.0%
Inert Ingredients	
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING - AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See (back) (side) panel for first aid, additional precautionary statements, and directions for use

EPA Reg. No.: 5481-LTR

EPA Est. No.: XXXXX-XXX-XXX

Net Contents: XXXX

Manufactured by:

AMVAC Chemical Corporation 4100 E. Washington Boulevard Los Angeles, CA 90023 U.S.A. 1-888-462-6822

ACCEPTED FEB - 5 2013

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. \$481-57.1

Batch Code:

FIRST AID		
lf on skin	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. 	
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. 	
If inhaled	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for treatment advice. 	
	EMERGENCY INFORMATION	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. FOR THE FOLLOWING EMERGENCIES, PHONE 24 HOURS A DAY:		
For Medical	Emergencies phone:1-888-681-4261	
For Transportation Emergencies, including spill, leak or fire, phone: CHEMTREC1-800-424-9300		
For Product Use Information phone : AMVAC1-888-462-682		

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes skin irritation and substantial but temporary eye injury. Harmful if inhaled. Do not get on skin or on clothing. Avoid contact with eyes. Avoid breathing vapor.

Personal Protective Equipment (PPE):

Wear coveralls worn over long sleeve shirt and long pants, socks, chemical resistant footwear, chemical-resistant gloves, goggles, face shield, or shielded safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables are available, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Non-Agricultural Use Requirements

The requirements in this box apply to uses of this product that are **not** within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried or dusts have settled. Do not enter the treatment area during the time of application. Do not reenter until the ventilation period is complete. If early reentry is required, the PPE required is coveralls worn over long sleeve shirt and long pants, socks, chemical resistant footwear, chemical-resistant gloves, goggles, face shield, or shielded safety glasses and a respirator.

General: AMV-1018 provides effective long-term sprout control by destroying the growing meristem of sprouting ("peeping") potato tubers and "burning off" sprouts. Further sprouting of potatoes is prevented for 1-3 months depending on variety and storage temperatures.

Use Precautions:

- Do not make applications to potatoes in the field.
- Do not use on seed potatoes. Do not allow the thermal fog to come into contact with or to enter areas used for storage of seed potatoes, potato handling or cutting equipment. Seed potatoes can be safely stored in potato storage which were previously treated with AMV-1018 only after full ventilation and clean out procedures have been followed. The air system including ducts, plenums and the storage building itself must be thoroughly ventilated prior to storing seed potatoes.
- Follow all application equipment manufacturers' use directions.
- Do not enter the treatment area during the time of application. Do not reenter until the ventilation period is complete. If early reentry is required, the PPE required is coveralls worn over long sleeve shirt and long pants, socks, chemical resistant footwear, chemical-resistant gloves, goggles, face shield, or shielded safety glasses and a respirator.

Directions for use

AMV-1018 can effectively leverage the natural dormancy of potatoes when used according to label directions. AMV-1018 is generally used only when the dormancy period has ended. An application should preferably be made when the tubers display "peeping" sprouts but more advanced sprouting can also be treated and controlled (see Sprout Control Programs below). The interval between harvest and the onset of sprouting is dependent on the cultivar and storage temperature.

The preferred method of application is through standard aerosol (thermal fogging) equipment. Thermal fogging provides the most efficacious and consistent sprout control.

Excellent movement of the fog through the potato pile is important for consistent efficacy.

Do not apply more than 16.8 fl oz/ton (0.84 fl oz/cwt) per storage season.

Procedure for Thermal Fogging with AMV-1018:

- Do not enter the treatment area during the time of application. Do not reenter until the ventilation period is complete. If early reentry is required, the PPE required is coveralls worn over long sleeve shirt and long pants, socks, chemical resistant footwear, chemical-resistant gloves, goggles, face shield, or shielded safety glasses and a respirator.
- 2. Calculate the quantity of product required based on total tonnage of tubers in storage prior to application.
- 3. Prepare aerosol/fog generating equipment and insert intake hose into the container with AMV-1018.
- 4. Configure settings such that the air-ducts are set to re-circulate with adequate pressure to move the fog through the potato pile. Turn off all humidifier units. These steps will ensure good distribution of AMV-1018 inside the storages.
- 5. Place the exhaust end of the aerosol/fog generator in the center of the air mixing chamber or plenum pointed in the direction of the air flow. Potato storages vary greatly in design and air movement patterns. It is therefore advisable to work with your local custom applicator to ensure accurate applications.
- 6. Adjust flow rate of AMV-1018 through the equipment to match the appropriate aerosol/fogging temperature. Do not allow the product to dribble out at the injection point.
- 7. Close off the ventilation system and turn on the fans/re-circulation system.
- 8. Turn on the fogging equipment and allow the fog into the mixing chamber. Operate the fans to continuously re-circulate the fog through the pile for 24 hours.
- 9. After recirculation is completed, open the ventilation louvers and allow fresh air to move back into the potato storage unit.

10. Within 3-5 days following application, tubers should exhibit "burnt out" or darkened sprouts.

Sprout Control Programs with AMV-1018:

(a) General Use Directions

AMV-1018 can effectively leverage the natural dormancy of stored potatoes when used according to label directions. Make first application when 75% of tubers show visible signs of sprouting (peeping). Apply AMV-1018 at the rate of 4.20 fl oz. per ton or 0.21 fl oz/cwt. One gallon of AMV-1018 will treat 610 cwt. Reapply AMV-1018 as necessary when tubers show visible signs of re-sprouting. Minimum reapplication interval is 7 days. Potatoes can be removed from storages and shipped 24 hours after ventilation is resumed.

(b) Combinations of AMV-1018 with other Sprout Control Products:

AMV-1018 can be used effectively as part of a program which combines other sprout control products. However, AMV-1018 is effective only after sprouting has commenced and can be used in combination programs such as chlorpropham (CIPC), diisopropyl naphthalene (DIPN) or dimethyl naphthalene (DMN) products. Follow all product label instructions.

(i) AMV-1018 Sprout Control Programs with Chlorpropham (CIPC) or DIPN (Amplify®) or DMN (1,4 Sight®)

During the storage cycle, when sprouting is observed on tubers where CIPC, or DIPN or DMN applications were made earlier, these can be treated with AMV-1018 to burn off the sprouts. The best timing of application is when at least 75% of the tubers show visible signs of sprouting ("peeping"). Alternatively, CIPC, DIPN or DMN and AMV-1018 can also be applied sequentially on the same day, when visible sprouting is observed. Either product may be applied first, immediately followed by the other product or co-injected into the fogging equipment. Follow all use directions and product precautions.

- (ii) AMV-1018 Sprout Control Programs with Maleic hydrazide (Royal MH-30®): At dormancy break, potatoes treated with Royal MH-30 prior to harvest can be treated with AMV-1018 later in storage to further extend the sprout-free period of tubers. Depending on storage temperature and potato variety, an additional 1-3 months of sprout control may be achieved. Make additional applications as needed.
- (c) <u>Sprout Control in Potatoes undergoing Reconditioning</u>: When stored at low temperatures, reducing sugars increase in tubers and affects the fry quality of potatoes. Such tubers can be reconditioned by raising the storage temperature leading to lower reducing sugar content. Such conditions, however, favor sprouting. AMV-1018 can be used effectively to burn off sprouts

during the reconditioning phase, or even just prior to shipment. For best results, do not allow potato sprouts to exceed 1 inch (2.5 cm) at the time of treatment.

(d) <u>Rescue of Storage Potatoes with Excessive Sprouting:</u> In cases where storage conditions lead to undesirable sprouting, especially during late in the storage cycle, AMV-1018 can be effectively used to "burn off" sprouts which are up to 1 inch (2.5cm). Apply AMV1018 at the rate of 4.2 fl oz per ton (0.21 fl oz per cwt).

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store in cool dry area.

Pesticide Disposal: Wastes resulting from use of this product may be disposed

of on site or at an approved waste disposal facility.

Container Handling: [For containers less than 30 gallons] (Nonrefillable Container. Do not reuse or refill this container. Then offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.)

[For containers equal to or greater than 30 gallons] (Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10% full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.)

LIMITED WARRANTY AND DISCLAIMER

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is reasonably fit for the purposes set forth in the directions for use, subject to the inherent risks referred to herein, when it is used in accordance with such directions; and (c) that the directions, warnings, and other statements on this label are based upon responsible experts' evaluations of reasonable tests of effectiveness, of toxicity to laboratory animals and upon reports of field experience. Tests have not been made on all varieties of potatoes, or in all states or under all conditions.

THERE ARE NO WARRANTIES OTHER THAN THOSE EXPRESSLY SET FORTH HEREIN. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW THE MANUFACTURER NEITHER MAKES NOR INTENDS, NOR DOES IT AUTHORIZE ANY AGENT OR REPRESENTATIVE, TO MAKE, ANY OTHER WARRANTIES, EXPRESS OR IMPLIED AND IT EXPRESSLY EXCLUDES AND DISCLAIMS ALL IMPLIED WARRANTIES INCLUDING WITHOUT

LIMITATION, THOSE OF MERCHANTABILITY. THIS WARRANTY DOES NOT EXTEND TO, AND THE BUYER SHALL BE SOLELY RESPONSIBLE FOR, ANY AND ALL LOSS OR DAMAGE WHICH RESULTS FROM THE USE OF THIS PRODUCT IN ANY MANNER WHICH IS INCONSISTENT WITH THE LABEL DIRECTIONS, WARNINGS OR CAUTIONS.

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BIOPESTICIDES REGISTRATION ACTION DOCUMENT

3-decen-2-one **PC Code**: 068403

U.S. Environmental Protection Agency Office of Pesticide Programs Biopesticides and Pollution Prevention Division

February 4, 2013

TABLE OF CONTENTS

I.	EXECUTIVE SUMMARY:	5
II.	ACTIVE INGREDIENT OVERVIEW	7
III.	REGULATORY BACKGROUND	7
A.	Classification	7
В.	Food Clearances/Tolerances	8
IV.	RISK ASSESSMENT	9
A.	Active Ingredient Characterization	9
В.	Human Health Assessment	. 10
1.	Toxicology	_
2.	Dose Response Assessment	13
3.	Food Quality Protection Act (FQPA) Considerations	
4.	Occupational, Residential, School and Day Care Exposure and Risk Characterization	
5.	Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation	
6.	Cumulative Effects	
7.	Risk Characterization	19
C.	Environmental Assessment	. 19
1.	Ecological Hazards	
2.	Environmental Fate and Ground Water Data	
3.	Ecological Exposure and Risk Characterization	
4.	Endangered Species Assessment	
D.	Efficacy Data	. 20
V.	RISK MANAGEMENT DECISION	. 21
A.	Determination of Eligibility for Registration	. 21
В.	Regulatory Decision	. 21
C.	Environmental Justice	. 21
VI.	ACTIONS REQUIRED BY REGISTRANTS	. 22
A.	Reporting of Adverse Effects	
В.	Reporting of Hypersensitivity Incidents	

3-decen-2-one
Page 3 of 30
Biopesticides Registration Action Document

VII.	. APPENDIX A. DATA REQUIREMENTS (40 CFR PART 158-SUBPART U)	. 22
VII	I. APPENDIX B	. 27
IX.	APPENDIX C.	. 27
Χ.	GLOSSARY OF ACRONYMS AND ABBREVIATIONS	. 28

BIOPESTICIDES REGISTRATION ACTION DOCUMENT (BRAD) TEAM

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I. EXECUTIVE SUMMARY:

3-decen-2-one is a new biochemical pesticide active ingredient intended for postharvest use on stored potatoes as a sprout inhibitor. 3-decen-2-one is a naturally occurring biochemical substance, with a history of unremarkable human exposure. 3-decen-2-one functions as a plant growth regulator, affecting plant growth by increasing tuber respiration. Data on file indicate that 3-decen-2-one interferes with membrane integrity, which results in increased oxidative stress, desiccation, and rapid necrosis of the meristems and surrounding sprout tissues. Thus, 3-decen-2-one inhibits sprouting, with no observed affects on the potato, potato sweetening, or processing quality. Based on this information, the Agency considers the mode of action to be non-toxic (EPA, 2011).

The Biopesticides and Pollution Prevention Division (BPPD) determined that the data and information submitted for product chemistry and Tier I acute toxicity for 3-decen-2-one satisfy the current guideline requirements. Based on the primary eye and dermal irritation acute toxicity data for 3-decen-2-one, the active ingredient is toxicity category II. A subchronic 90-day oral toxicity study (OCSPP 870.3100) on the active ingredient (a.i.) was not conducted. In lieu of the study, EPA used a weight-of-the-evidence (WOE) approach to estimate the likelihood of potential of toxicity from repeat oral exposure to this substance (EPA, 2013). First, using an expert system computer program (DEREK Nexus), EPA identified two potential toxicological endpoints for 3-decen-2-one (potential dermal sensitization and in vitro chromosome damage); however, follow-up studies did not support these as toxicological endpoints. Second, the metabolic pathways of 3-decen-2-one have been characterized and demonstrate that the biochemical is metabolized into innocuous compounds that are either excreted or further metabolized in the fatty acid pathway or citric acid cycle. Third, 3-decen-2-one occurs naturally in some foods and has been used as a food additive without specific reports of adverse effects. Finally, U.S. Food and Drug Administration (FDA) has approved the use of 3-decen-2-one as a synthetic flavoring agent and adjuvant that may be directly added to food under 21 CFR § 172.515. Based on this evidence, EPA concluded that 3-decen-2-one has relatively low toxicity via the repeated oral exposure route. BPPD granted waivers from conducting subchronic 90-day dermal (OCSPP 870.3250) and 90-day inhalation (OCSPP 870.3465) studies based on the fact that prolonged dermal exposure is not expected because 3-decen-2-one is not purposely applied to the skin and repeated inhalation exposure is unlikely due to 3-decen-2-one being applied by a thermal fog generator in a closed system. In addition, significant exposure to humans is not anticipated for 3-decen-2-one based on its indoor use pattern in a closed system and appropriate Personal Protective Equipment (PPE) requirements on the product label. BPPD received data for the prenatal developmental data requirement (OCSPP 870.3700), Tier I mutagenicity studies [bacterial reverse mutation test (OCSPP 870.5100) and in vitro mammalian cell assay (OCSPP 870.5300)], and a Tier II mutagenicity study [in vivo mammalian erythrocyte micronucleus test assay (OCSPP 870.5395)]. The prenatal developmental toxicity study showed a no-observedadverse-effects-level (NOAEL) of 1,000 mg/kg/day (highest dose tested) for maternal and fetal toxicity. EPA's WOE approach showed that 3-decen-2-one was not a mutagen based on the results of the Tier I and Tier II mutagenicity data. Although the data requirements were satisfied for the new active ingredient, 3-decen-2-one, BPPD notes that should future intended end-use product (EP) applications result in different anticipated exposures to humans, these data requirements may need to be readdressed.

For nontarget organisms and environmental fate data requirements (OCSPP 850.1010 to 850.4450), the nontarget organism data requirements for 3-decen-2-one were waived based on the proposed indoor use pattern. 3-decen-2-one is proposed for use in end-use formulations that are applied indoors only as sprout inhibitors on potatoes. The end-use formulations will be introduced and dispersed as a vapor through air circulation systems in potato storage warehouse facilities and is not expected to be available to nontarget organisms. Based on the indoor use pattern, exposure of 3-decen-2-one to nontarget organisms is expected to be minimal.

EPA has not identified any toxic endpoints for nontarget mammals, birds, plants, aquatic, or soil organisms. Based on the information provided, EPA has no concerns, at this time, for any nontarget organisms exposed to 3-decen-2-one when used in accordance with approved label directions. Given that 3-decen-2-one is applied indoors in a closed system, has low toxicity and presents little, if any, risk to nontarget organisms, EPA has concluded that it is in the best interests of the public to issue the registration for the manufacturing-use product (MP), AMV-1018 Technical (EPA File Symbol No. 5481-LAI) and the EP, AMV-1018 EP (EPA File Symbol No. 5481-LTR), which contain this new active ingredient, 3-decen-2-one.

BPPD has reviewed the data and information in support of the requirements for granting registration under Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). BPPD has determined that the data and information submitted adequately satisfy current data requirements (please refer to 40 CFR Subpart U § 158.2000).

On October 1, 2009, EPA announced a new policy to provide a more meaningful opportunity for the public to participate on major registration decisions before they occur. According to this policy, EPA provides a public comment period prior to making a registration decision for the following types of applications: new active ingredients, first food use, first outdoor use, first residential use; and any registration decisions for which the Agency believes there may be substantial public interest.

Consistent with the policy of making registration actions more transparent, 3-decen-2-one was subject to a 15-day comment period as a "new active ingredient." EPA established a comment period of 15 days on the basis of 3-decen-2-one's minimal toxicity, the determination that 3-decen-2-one presents low risk of any adverse effects to human health and the environment, and critical need for this active ingredient. The notice for this comment period included the draft Biopesticides Registration Action Document (BRAD) and draft product labels for the MP, AMV-1018 Technical, and EP, AMV-1018 EP, which contain this new active ingredient, 3-decen-2-one. The docket identification (ID) number is EPA-HQ-OPP-2010-0064. The Agency did not receive any comments on the registration of 3-decen-2-one during this 15-day comment period. The Agency believes that based on the risk assessment and information submitted in support of the registration of the MP and EP containing 3-decen-2-one, it is in the best interests of the public to issue the registration for AMV-1018 Technical and AMV-1018 EP. The basis for this decision can be found in the risk assessment for 3-decen-2-one, which is characterized in this BRAD.

II. **ACTIVE INGREDIENT OVERVIEW**

Common Name:

3-decen-2-one

Chemical Names:

3-decen-2-one; Heptylidene acetone; Oenanthylidene acetone

Trade & Other Names: AMV-1018 Technical

CAS Registry Number: 10519-33-2

OPP Chemical Code:

068403

Type of Pesticide:

Plant Growth Regulator (Sprout Inhibitor)

Ш. **REGULATORY BACKGROUND**

On December 8, 2009, EPA received an application filed by Technology Sciences Group, Inc. (TSG), 1150 18th Street, NW, Suite 1000, Washington, DC 20036, on behalf of Amvac Chemical Corporation (AMVAC), 4695 MacArthur Court, Ste. 1250, Newport Beach, CA 90660, to register the products, AMV-1018 Technical (EPA File Symbol No. 5481-LAI), AMV-1018 EP (EPA File Symbol No. 5481-LTR), AMV-1018 90EC (EPA File Symbol No. 5481-LTN), and AMV-1018 67.5EC (EPA File Symbol No. 5481-LAO) containing the new biochemical active ingredient, 3-decen-2-one. The applicant withdrew AMV-1018 90EC (EPA File Symbol No. 5481-LTN) and AMV-1018 67.5EC (EPA File Symbol No. 5481-LAO) from consideration by EPA with the letter dated March 2, 2011. A notice of receipt (NOR) of this application, allowing for a 30-day comment period, was published in the Federal Register on March 10, 2010 (75 FR 11175). No comments were received following this publication.

A. Classification

On September 22, 2008, EPA's Biochemical Classification Committee determined that 3-decen-2-one is a biochemical pesticide. The biochemical classification committee indicated that 3decen-2-one is a plant growth regulator and the mode of action is to induce a transient increase in tuber respiration rate and seemed to interfere with membrane integrity, resulting in increased oxidative stress, dessication, and rapid necrosis of meristem and surrounding sprout tissues. The observed effect is primarily mechanical damage to sprout cell membranes. Sweetening and processing quality of potatoes and the mature tuber were unaffected. 3-decen-2-one is related to class of secondary alcohols, ketones, and related esters naturally occurring in foods, flavor additives, and fragrances. No safety concerns were identified and the substance is rapidly metabolized and excreted from mammals. 3-decen-2-one is approved for use as a synthetic flavor under 21 CFR § 172.515.

B. Food Clearances/Tolerances

The applicant filed a petition (PP 9F7670) proposing to establish an exemption from the requirement of a tolerance for residues of 3-decen-2-one in or on all food commodities. A notice of filing (NOF), allowing for a 30-day comment period, was published in the *Federal Register* on March 10, 2010 (75 FR 11171). One comment was received following this publication and is described below.

A comment was posted to the NOF docket ID number EPA-HQ-OPP-2010-0065 from Michael J. Keim, Keim Aerosol Technologies, on April 21, 2010. Mr. Keim believes that EPA has not been adequately informed by the registrants with respect to the use of chemicals for the postharvest treatment of stored potatoes and that 3-decen-2-one does pose a risk to humans and the environment. Mr. Keim's states that the primary reason for his claim stems from the registrant's use of the same equipment to apply the proposed product, AMV-1018 EP, as conventional products containing Chlorpropham (CIPC). Mr. Keim has concerns with EPA's evaluation of the proposed 3-decen-2-one products and the following year's (2011) registration review of CIPC applications because there is no mention of the significant displacement and degradation of the chemicals to the outside atmosphere during the application process. Mr. Keim indicates that he believes that half of the applied CIPC to stored potatoes does not deposit on the potatoes and. therefore, is expelled to the outside environment. Mr. Keim estimates that approximately 227,500 pounds of CIPC and over 900,000 pounds of 3-decen-2-one are lost to the outside environment in the U.S. each year and believes that this displacement must be evaluated in order to determine what testing must be performed to insure no harm comes to humans and the environment. Mr. Keim also provided copies of his communications to Canada's Pesticide Management Regulatory Authority (PMRA) during its re-evaluation decision for CIPC in 2007-2009, where he did not agree with PMRA's approval of CIPC. In summary, Mr. Keim indicated that the following data must be submitted due to the gross displacement and degradation of the proposed product, AMV-1018 EP: 1) product performance data, 2) mammalian toxicity data, 3) nontarget organism data, 4) post-application exposure data, 5) applicator/user exposure data, 6) spray drift evaluation, 7) environmental fate data, and 8) residue chemistry data.

EPA thanks Keim Aerosol Technologies for its comment regarding the NOF for 3-decen-2-one. Documents in the docket for the Registration Review of CIPC (docket ID number EPA-HQ-OPP-2010-0923) prepared by the Agency's Health Effects Division (HED) and Environmental Fate and Effects Division (EFED) have already responded to Mr. Keim's comments about the application equipment used for CIPC products and the potential for exposure based on the displacement and degradation of CIPC. Moreover, with respect to 3-decen-2-one, the Agency has received and reviewed product chemistry, mammalian toxicity, and nontarget organism data and/or information for this new a.i., 3-decen-2-one, as outlined in 40 CFR §§ 158.2030, 158.2050, and 158.2060 (see infra, Section IV). Based on the risk assessment discussed in the subsequent sections, the Agency has concluded that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result from the use of 3-decen-2-one as a pesticide when label instructions are followed. The data and information submitted to the Agency indicate that 3-decen-2-one is of low acute and subchronic toxicity, with the exception that it is a primary eye and dermal irritant, is not a developmental toxicant, and is not mutagenic. With regard to worker exposure, the thermal fogging application method on the

proposed product label used for stored potatoes is an automated system and as such, the Agency considers this method a closed-delivery system and does not expect occupational handler exposure. The only occupational exposure expected is the handling of the product prior to application, which is mitigated by appropriate precautionary statements and PPE requirements listed on the label. The Agency has not identified any toxic endpoints for nontarget mammals, birds, plants, aquatic, or soil organisms; therefore, EPA has no concerns for any nontarget organisms exposed to 3-decen-2-one when used in accordance with approved label directions. The applicant did submit information that estimated the physical and chemical properties for 3decen-2-one by using QSAR modeling based on the Estimation Programs Interface Model (EPI SuiteTM 4.0). Using Henry's Law, which states that the solubility of a gas in a liquid is directly proportional to the partial pressure of the gas above the liquid, 3-decen-2-one is estimated to be 5.4 x 10⁻⁴ atm·m³/mol and indicates that the a.i. has a potential for volatility from water or moist soil. In soil, the estimated K_{oc} of 165.2 - 860.9 L/kg indicates that the active would have medium to low mobility in soil. In water, an estimated log Kow of 3.28 and an estimated bioconcentration factor (BCF) of 67.41 L/kg wet-wt indicate that bioaccumulation in aquatic organisms is unlikely. In the air, atmospheric oxidation by reaction of hydroxyl radicals is expected to occur with estimated half-lives of 1.9 - 2.2 hours. The probability of biodegradation of 3-decen-2-one was evaluated using EPI SuiteTM 4.0 in the BIOWIN module. Various models in the BIOWIN module predicted rapid biodegradation of 3-decen-2-one. Based on a total air volume in potato warehouse of 1910 m³ and total applied 3-decen-2-one of 122,475 g calculated by the applicant, the maximum air concentration of 3-decen-2-one in warehouse was estimated to be 64.14 mg/L of air. With an estimated ventilation rate of 825 m³ of air/min, the air volume in a warehouse will be exchanged within 2.5 minutes when the vents to the outdoors are opened. Thus, the concentration emitted will be rapidly diluted in the outside air, which further demonstrates insignificant exposure to nontarget organisms. In summary, given that 3-decen-2-one is applied indoors in a closed system, has low toxicity, and presents little, if any risk to nontarget organisms, the Agency has concluded that products containing this new a.i., 3-decen-2-one, are not expected to cause unreasonable adverse effects to humans, including infants and children, and nontarget organisms.

EPA determined during the initial review of the petition that the data and/or information submitted was insufficient to support the use of the active ingredient, 3-decen-2-one, in or on all food commodities. The applicant filed a revised petition (PP 9F7670) proposing to establish an exemption from the requirement of a tolerance for residues of 3-decen-2-one in or on stored potatoes only. A NOF, allowing for a 30-day comment period, was published in the Federal Register on March 14, 2012 (77 FR 15012). No comments were received following this publication.

IV. RISK ASSESSMENT

A. Active Ingredient Characterization

3-decen-2-one is a new biochemical pesticide active ingredient intended for postharvest use on stored potatoes as a sprout inhibitor. 3-decen-2-one is a naturally occurring biochemical substance, with a history of unremarkable human exposure. 3-decen-2-one functions as a plant

growth regulator, effecting plant growth by increasing tuber respiration. Data on file indicate that 3-decen-2-one interferes with membrane integrity, which results in increased oxidative stress, desiccation, and rapid necrosis of the meristems and surrounding sprout tissues. Thus, 3-decen-2-one inhibits sprouting, with no observed affects on the potato, potato sweetening, or processing quality. Based on this information, the Agency considers the mode of action to be nontoxic (EPA, 2011).

3-decen-2-one has been found to naturally occur in yogurt, skipjack tuna, edible porcini mushrooms, and Iberian ham (EPA, 2013). Additionally, in a 2003 report, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) indicated that 3-decen-2-one is one in a group of compounds that have been identified in fruits, vegetables, spices, cocoa, coffee, and tea (JECFA, 2003). JECFA also concluded in their report that there is no safety concern at current intake levels when the chemical is used as a flavoring agent. The chemical has been approved by FDA as a food additive without limitation under 21 CFR § 172.515. According to a report by an independent panel of experts retained by the Flavor and Extract Manufacturer's Association (FEMA), 3-decen-2-one is considered safe for its intended use when added at an average maximum level of 19 ppm in baked goods, 7.8 ppm in soft candy, 5.8 ppm in frozen dairy products, 4.8 ppm in gelatins and puddings, 4.3 ppm in non-alcoholic beverages, and 4.0 ppm in alcoholic beverages (EPA, 2013).

Descriptions of the product formulation and production process, formation of impurities, and physical and chemical characteristics were examined by BPPD and found to be acceptable in meeting current guideline standards.

All product chemistry data requirements for registration of 3-decen-2-one have been satisfied.

For more information regarding product chemistry data requirements, refer to Tables 3 and 4 in Appendix A.

B. Human Health Assessment

1. Toxicology

For acute toxicity data requirements, toxicity categories are assigned based on the hazard(s) identified from studies and/or information on file with the Agency. The active ingredient is classified into Toxicity Category I, II, III or IV where Toxicity Category I indicates the highest toxicity and Toxicity Category IV indicates the lowest toxicity.

Adequate mammalian toxicology data/information is available to support registration of 3-decen-2-one. All toxicology data requirements for 3-decen-2-one have been satisfied.

a. Acute Toxicity

Acute toxicity testing is required to: 1) determine systemic toxicity from acute exposure via the dermal, inhalation, and oral routes; 2) determine irritant effects from exposure to the eyes; and 3) determine the potential for skin sensitization (allergic contact dermatitis).

Tier I acute toxicity studies submitted and reviewed showed that 3-decen-2-one is moderately irritating to the eye and severely irritating to the skin based on the results of primary eye irritation and primary dermal irritation studies in rabbits, respectively (toxicity category II). 3-decen-2-one is a toxicity category III (slightly toxic) compound via the inhalation route of exposure, based on LC_{50} 0.52-2.04 mg/L in male rats and > 2.04 mg/L in female rats. 3-decen-2-one falls in toxicity category IV (not toxic) for acute oral toxicity and acute dermal toxicity. 3-decen-2-one is not a dermal sensitizer.

For more information regarding acute toxicity data requirements, refer to Table 5 in Appendix A.

b. Subchronic Toxicity

Subchronic data are required to determine a no-observed-effect-level (NOEL) and any toxic effects associated with repeated or continuous exposure to a test substance for a period of 90 days.

A subchronic 90-day oral toxicity study (OCSPP 870.3100) on the a.i. was not conducted. In lieu of the study, EPA used a WOE approach to estimate the likelihood of potential of toxicity from repeat oral exposure to this substance. EPA considered the following evidence: (1) lack of toxicological endpoints; (2) metabolic pathways, (3) lack of incidents associated with naturally occurring levels of 3-decen-2-one in foods, and (4) FDA's approval of this biochemical as a direct food additive. This evidence is further expanded on below.

- i. Using an expert system computer program (DEREK Nexus), EPA identified two potential toxicological endpoints for 3-decen-2-one (potential dermal sensitization and in vitro chromosome damage); however, follow-up studies did not support these as toxicological endpoints.
- ii. The metabolic pathways of 3-decen-2-one have been characterized and demonstrate that the biochemical is metabolized into innocuous compounds that are either excreted or further metabolized in the fatty acid pathway or citric acid cycle.
- iii. 3-decen-2-one occurs naturally in some foods and has been used as a food additive without specific reports of adverse effects.
- iv. FDA has approved the use of 3-decen-2-one as a synthetic flavoring agent and adjuvant that may be directly added to food under 21 CFR § 172.515.

Based on the above evidence, EPA concluded that 3-decen-2-one has relatively low toxicity via the repeated oral exposure route and 90 day oral toxicity data requirement for this a.i. has been satisfied.

Waiver requests for the subchronic 90-day dermal toxicity (OCSPP 870.3250) and 90-day inhalation toxicity (OCSPP 870.3465) data requirements were granted by BPPD, based on the 3-decen-2-one's toxicological and exposure profile, summarized below.

i. Prolonged dermal exposure is not expected because 3-decen-2-one is not purposely applied to the skin and do not result in comparable human exposure to the

product.

ii. Repeated inhalation exposure is unlikely because 3-decen-2-one is applied by a thermal fog generator in a closed system. Personnel are not allowed in the potato storage facilities during application and evacuation of the product. In addition, any unlikely inhalation exposure will be mitigated on the label by precautionary statements and PPE requirements.

For more information regarding the subchronic toxicity data requirements, refer to Table 5 in Appendix A.

c. Developmental Toxicity and Mutagenicity

The Tier I prenatal developmental toxicity study (OCSPP 870.3700) submitted and reviewed showed that the maternal and fetal (developmental) toxicity NOAEL was 1,000 mg/kg/day (the highest dose tested). A lower bodyweight gain effect was seen in the highest-dose group (1,000 mg/kg/day) for maternal rats; however, the bodyweight gain effect is considered to be attributable to the palatability of the test substance and not toxicologically significant.

The Tier I mutagenicity studies [bacterial reverse mutation test (OCSPP 870.5100) and *in vitro* mammalian cell assay (OCSPP 870.5300)] and Tier II mutagenicity study [in vivo mammalian erythrocyte micronucleus test assay (OCSPP 870.5395)] submitted and reviewed showed that 3-decen-2-one is not mutagenic. Results were negative in the bacterial reverse mutation test. In an *in vitro* mammalian gene mutation assay (mouse lymphoma cell), results were positive without metabolic activation and results were equivocal with metabolic activation. These results are considered equivocal because it was not clear whether the positive results would translate into an *in vivo* system based on the increased osmotic pressure and marked cytotoxicity noted during the experiment. Results of an *in vivo* mammalian erythrocyte micronucleus test assay were negative for the a.i.; therefore, the WOE approach indicates that 3-decen-2-one is not likely to be mutagenic.

For more information regarding developmental and mutagenicity data requirements, refer to Table 5 in Appendix A.

d. Tier II/Tier III

No data were required, except to confirm that 3-decen-2-one is not a mutagen (see section B.1.c above) due to the nature of the active ingredient and its intended indoor uses in potential new EP products (potato sprout inhibitor).

e. Effects on the Endocrine System

As required under Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to

making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and nine inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

3-decen-2-one is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Under FFDCA section 408(p) the Agency must screen all pesticide chemicals. Accordingly, EPA anticipates issuing future EDSP test orders/data call-ins for all pesticide active ingredients.

For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: http://www.epa.gov/endo/.

2. Dose Response Assessment

Because no toxicological endpoints were identified for this active ingredient, a dose-response assessment was not required.

3. Food Quality Protection Act (FQPA) Considerations

a. Dietary Exposure and Risk Characterization

Human exposure to 3-decen-2-one may occur via dietary exposure to treated potatoes. A qualitative risk assessment was conducted for the chemical to assess potential risks (if any) from dietary exposure. Although dietary exposure to humans may occur, the Agency has determined that there is reasonable certainty of no harm to humans when exposed to residues of the active ingredient from pesticidal use when label instructions are followed. This conclusion is based on the following: 1) available toxicology data and information indicate that the active ingredient is of low acute toxicity (with the exception that it is an eye and skin irritant) and not likely to be a developmental toxicant, a mutagen or toxic via repeat oral exposure, 2) humans are already exposed to 3-decen-2-one in the diet from foods that naturally contain the chemical and from foods to which the chemical has been added as a food additive, 3) metabolism data and information on the chemical indicate that it is metabolized into innocuous substances in humans, and 4) simplistic exposure analyses suggest that dietary exposure to the chemical as a pesticide is likely to be less than dietary exposure to the chemical as a natural

constituent in foods and pesticidal use of 3-decen-2-one is not likely to result in a significant increase in overall dietary exposure (EPA, 2013). A detailed discussion of how the Agency arrived at its conclusion is provided in the subsequent paragraphs.

Residues

Previous residue data submitted by the applicant indicate that residues of 3-decen-2-one persist in treated potatoes for up to 61 days post-treatment (after one application), although there is a substantial reduction over time (EPA, 2011). In support of the revised petition, a new residue study was conducted on stored Ranger Russet potatoes treated with one application of AMV-1018 (the end-use product containing 98% 3-decen-2-one; EPA File Symbol No. 5481-LTR) at twice the maximum application label rate. Potatoes were analyzed for residues when raw, steamed and baked at 1, 3, 5, 7 and 14 days after treatment. The study was terminated after day 14. Prior to cooking and/or analysis, potatoes were "gently" washed with a vegetable brush. Tubers were prepared by quartering each potato, chopping one of the quarters into cubes, mixing the cubes for random distribution and then storing at -80°C. The residue data are summarized in Table 1 below.

Table 1: 3-Decen-2-one Residues in Raw, Steamed, and Baked Potatoes Treated with 230 mg/kg AMV-1018 (98% 3-decen-2-one)								
Days After Treatment	Raw (ppm)	Steamed (ppm)	Baked (ppm)					
i i	2.224	0.256	0.550					
3	1.262	0.255	0.548					
7	0.747	0.193	0.347					
14	0.459	0.112	0.274					

The residue study demonstrated that 3-decen-2-one residues are reduced when potatoes are cooked. Residues remained on all forms of potatoes through 14 days, when the study was terminated. Based on the results of the previously submitted residue study, residues of 3-decen-2-one are likely to persist longer than 14 days, although they decrease over time. It is noted that since potatoes were "gently" washed with a vegetable brush prior to residue analysis, some residues of the active ingredient were likely washed off. Per the applicant, potatoes were washed to simulate normal behavior of consumers who generally wash potatoes prior to cooking and eating.

Comparison of Dietary Exposure from Different Sources of 3-Decen-2-One

A simplistic quantitative evaluation of potential dietary exposure to children from consumption of pesticide-treated potatoes was conducted and compared to estimated dietary exposure to 3-decen-2-one as a natural constituent of food and as a food additive. Children (1 to 2 years old) were chosen as a representative group to assess exposure due to likely consumption of potatoes and potato-products and because children are considered a sensitive subgroup of the population. The assessment indicates that overall dietary exposure to the chemical as a naturally-occurring component in foods and as a food additive is not likely to substantially increase from exposure via consumption by children of potatoes treated with the active ingredient as a pesticide when label instructions are followed (EPA, 2013).

Dietary exposure to 3-decen-2-one as a natural constituent in foods was evaluated by using a quantitative estimation of the amount of the chemical likely found in fermented milk (yogurt) and calculating the potential exposure to children, aged 1-2 years. The applicant identified two scientific articles where information to calculate the naturally occurring amount of 3-decen-2one was taken. The active ingredient has been identified by gas chromatography (GC) as a volatile constituent in four types of yogurt (Patrignani et al., 2009); however, the amount was not quantified. In another study where some volatile constituents of yogurt were analyzed (Ott et al., 2000), the amount of acetaldehyde present in five different types of yogurt was quantified and found to be at an average concentration of 10.82 ppm. Acetaldehyde was also identified in the Patrignani study, but not quantified. Because acetaldehyde was the only volatile constituent found in both studies, it was used as a surrogate to estimate the amount of 3-decen-2-one found in the Patrignani study. The average amount of acetaldehyde in the Ott study was assumed to be the same in the Patrignani study. The relationship between the peak areas of 3-decen-2-one and acetaldehyde measured using GC was considered to be equivalent to the relationship between the average concentration of 3-decen-2-one and acetaldehyde. The amount of the active ingredient was then estimated by dividing the 3-decen-2-one peak area by the acetaldehyde peak area for each of the four yogurt types in the Patrignani study. For the purposes of this assessment, the Agency considers this a reasonable approach for estimation of 3-decen-2-one concentration in yogurt. Since the yogurts were analyzed after one day and then after 14 days of storage, instead of four concentration estimates, eight estimates of 3-decen-2-one concentrations were calculated. These concentrations ranged from 2.15-11.15 ppm with the average of 7.64 ppm. To estimate the average amount of yogurt consumed by children per day, EPA's Exposure Factors Handbook (U.S. EPA, 2011) was consulted which indicated that the mean per capita yogurt intake by children aged 1-2 years is 12 g/day; the consumer-only intake was not available. The Exposure Factors Handbook (EFH) indicates that approximately 8.4% of the age group consumes yogurt. It is anticipated that the consumer-only intake is considerably higher (for perspective, a 3.5 oz container of yogurt weighs approximately 100 g). With regard to this assessment, the per capita intake is the average yogurt consumed per person in a population of both individuals who ate yogurt during a specified time and those who did not and the consumer-only intake is the average yogurt consumed per person in a population composed only of people who ate yogurt during a specified period. Using the average estimated concentration of 3-decen-2-one in yogurt and the average amount of yogurt consumed by children per day, an estimate of dietary exposure was calculated. The concentration of the active ingredient (ppm, or µg/g) is multiplied by the grams of yogurt consumed per day; the resulting number is then adjusted for inclusion of body weight (the average body weight of a child aged 1-2 years is 11.4 kg (U.S. EPA, 2011)). Assuming consumption of 12 g yogurt/day, the dietary exposure for children is as follows:

 $7.64 \mu g$ 3-decen-2-one/g yogurt × 12 g yogurt consumed/day = 91.68 μg 3-decen-2-one/day;

91.68 μ g/day ÷ 11.4 kg bodyweight = 8.04 μ g 3-decen-2-one/kg body weight/day

Thus, the estimated exposure to 3-decen-2-one of a child consuming 12 g of yogurt per day is $8.04 \,\mu g/kg$ bw/day. To account for the lack of consumer-only intake data and to use a more conservative approach, an estimate of 50 g yogurt (which is approximately half of a 3.5 oz container of yogurt) consumed per day was employed. Using this consumption amount and the

3-decen-2-one
Page 16 of 30
Biopesticides Registration Action Document

same calculation presented above, the estimated exposure of a child consuming 50 g of yogurt per day is 33.5 μ g/kg bw/day. Based on these data, the amount of the chemical consumed by children aged 1-2 years is estimated to range from 8.04-33.5 μ g/kg bw/day

Dietary exposure to 3-decen-2-one as a food additive was also evaluated using the same methodology and calculations presented above and the levels of the chemical added to food as described by Oser and Ford (1978). According to this report, the chemical is considered safe for its intended use when added to baked goods at an average maximum of 19 ppm and to nonalcoholic beverages at an average maximum of 4.3 ppm. According to the EFH, the average daily per capita intake of bread (includes breads, rolls, muffins, bagels, biscuits, combread and tortillas) for children aged 1-2 years is 2 g/kg bw/day. The average per capita intake of non-citrus juices and nectars and citrus juices is 132 g/day and 49 g/day, respectively. The juice intake values were chosen as reasonable representations for nonalcoholic beverages that children may ingest. Because the amounts of 3-decen-2-one added to food are considered maximum amounts, two calculations for each food group were performed to create a range of dietary exposure estimates. The first estimate is based on exposure to the maximum amount of the chemical added to the specific food group and the second estimate is based on the maximum amount of the chemical divided in half. The division is considered a reasonable estimate for levels of 3-decen-2-one that may be generally added to food and is useful in creating a range of possible dietary exposures. For example, for baked goods, the maximum amount of the chemical added can be 19 ppm; to estimate dietary exposures, concentrations of 19 ppm and 9.5 ppm were used in the calculations. Assessments similar to those discussed regarding dietary exposure to 3-decen-2-one in yogurt suggest a range of dietary exposures of 19.0-38.0 µg/kg bw/day in baked goods and 9.24-49.8 μg/kg bw/day (24.9-49.8 μg/kg bw/day in non-citrus juices and nectars and 9.2 - 18.5 μg/kg bw/day in citrus juices) in nonalcoholic beverages.

Dietary exposure to 3-decen-2-one from use as a pesticide was evaluated by using the residue data presented in Table 2 and similar calculations to those discussed above. Residues in the amount of 0.550 ppm 3-decen-2-one were identified in potatoes that were baked one day after treatment with double the application rate on the label. The residue value for baked potatoes was selected since children are not likely to eat raw potatoes. The label indicates that 4 applications of the pesticide can be made in 7-day increments. A conservative estimate of potential residues after four pesticide applications was conducted by using the residue value for baked potatoes at day 1 and multiplying that value by four. The estimate is conservative because it is assumed that four applications of the pesticide will be made all at one time and potatoes will be consumed at day 1 after treatment when in reality, the pesticide will not be applied all in one interval and residue data indicate that levels of 3-decen-2-one decline in potatoes over time. According to the EFH, the average consumer-only intake of white potatoes by children aged 1-2 years is 1.86 g/kg bw/day (uncooked weight). Using the type of calculations discussed above, the estimated dietary exposure to children from exposure to 3-decen-2-one as a pesticide is 4.1 μg/kg bw/day. The estimated dietary exposures for children aged 1-2 years as calculated and discussed above are summarized in Table 2 below.

Table 2: Estimated Dietary Exposures t	Table 2: Estimated Dietary Exposures to 3-decen-2-one for Children Aged 1-2 Years							
Source of 3-decen-2-one	Estimated Dietary Exposure (μg/kg bw/day)							
Naturally-occurring constituent of yogurt	8.0 - 33.5							
Food additive in baked goods	19.0 – 38.0							
Food additive in nonalcoholic beverages: Non-citrus juices and nectars Citrus juices	24.9 – 49.8 (non-citrus) 9.24 -18.5 (citrus)							
Pesticide residues on baked potatoes	4.1							

The information presented above suggests that dietary exposure to residues of 3-decen-2-one used as a pesticide is likely to be less than dietary exposure to the chemical as a naturally occurring constituent in food and/or as a food additive. Further, when compared to the amount of the chemical that is likely already consumed in the human diet, pesticidal use is not anticipated to significantly increase overall human dietary exposure to 3-decen-2-one as a food additive and a natural constituent in food (EPA, 2013).

b. Drinking Water Exposure and Risk Characterization

Based on the proposed use pattern of the active ingredient as a potato sprout inhibitor used in indoor settings, residues in drinking water are not anticipated if products are used according to label instructions. Products containing the active ingredient will be used in indoor commercial settings only; therefore, 3-decen-2-one residues in drinking water are highly unlikely. In the unlikely event that exposure via drinking water does occur, the health risk would be expected to be minimal based on the low acute oral toxicity of 3-decen-2-one.

c. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

The Agency has determined that there are no foreseeable dietary risks to sensitive subpopulations, including infants and children, from the use of 3-decen-2-one as a pesticide on stored potatoes when label instructions are followed. The available data and information indicate that the chemical: 1) is of low toxicity and is not a developmental toxicant; 2) naturally occurs in the human diet; 3) has been approved for use in foods as a food additive by the FDA; and 4) is metabolized into innocuous substances. Additionally, basic exposure analyses that were specifically conducted for children aged 1-2 years suggest that dietary exposure from ingestion of the chemical as a pesticide is likely to be less that dietary exposure from ingestion of the chemical as a food additive and/or as a constituent that naturally occurs in foods. When compared to the amount of 3-decen-2-one that is likely already consumed in the human diet, dietary exposure from pesticidal use is not anticipated to significantly increase overall dietary exposure of infants and children.

4. Occupational, Residential, School and Day Care Exposure and Risk Characterization

a. Occupational Exposure and Risk Characterization

An occupational exposure assessment was not conducted for 3-decen-2-one, and is not required.

Significant occupational exposure is not expected when 3-decen-2-one is used according to label instructions. Products containing this active ingredient are intended for indoor use as a sprout inhibitor on stored potatoes. The application method is a thermal fog generator in a closed system. The end-use product is fogged into the storage area by way of the ventilation ducts and re-circulated through the air by the ventilation system for 24 hours. After the re-circulation is complete, the ventilation louvers will be opened and the air in the storage area will be evacuated to the outside. The only occupational exposure expected is the handling of the product prior to application, which is mitigated by appropriate precautionary statements and PPE requirements listed on the label. This will include instructions for applicator PPE, which includes: coveralls worn over long sleeve shirt and long pants, socks, chemical resistant footwear, chemical-resistant gloves, face shield or shielded safety glasses, and appropriate PPE for potential exposure via the inhalation route. Additionally, no relevant toxicological endpoints have been identified. Based on the data and information available to the Agency, anticipated exposure is not likely to result in unreasonable risk to humans.

b. Residential, School and Day Care Exposure and Risk Characterization

Exposure to 3-decen-2-one will be minimal in residential, school, and day care areas, as the enduse product containing this active ingredient is intended for use as a sprout inhibitor on stored potatoes in a closed system.

5. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

There is reasonable certainty that no harm to the U.S. population will result from aggregate exposure to 3-decen-2-one. This includes all exposures for which there is reliable information. Based on the use pattern of the chemical as a sprout inhibitor on stored potatoes in a closed system and appropriate personal PPE requirements on the label, significant exposure via the dermal and inhalation routes is not anticipated when label instructions are followed. Dietary (oral) exposure has been identified as the only likely route of exposure. Exposure is not anticipated in drinking water based on the use pattern and the pesticide is not to be used in residential settings. The chemical's highly specific mode of action as a sprout inhibitor, its low toxicity (with the exception that 3-decen-2-one is an eye and skin irritant) further support the EPA's conclusion. In consideration of the above information, the Agency has determined the risk from aggregate exposure (via oral, dermal, and inhalation exposures) is negligible.

6. Cumulative Effects

Pursuant to FFDCA section 408(b)(2)(D)(v), EPA has considered available information concerning the cumulative effects of 3-decen-2-one residues and other substances that have a common mechanism of toxicity. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, the Agency has not made a common mechanism of toxicity finding for 3-decen-2-one and any other substances and 3-decen-2-one does not appear to produce a toxic metabolite produced by other substances. The active ingredient is a biopesticide that has a nontoxic mode of action. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by the Agency's Office

of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

7. Risk Characterization

EPA has considered human exposure to 3-decen-2-one in light of the relevant safety factors in FQPA and FIFRA and has determined that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result from the use of 3-decen-2-one as a pesticide when label instructions are followed.

C. Environmental Assessment

1. Ecological Hazards

The nontarget organism data requirements for 3-decen-2-one are waived based on the proposed indoor use pattern. 3-decen-2-one is proposed for use in end-use formulations that are applied in indoors only as sprout inhibitors on potatoes. The end-use formulations will be introduced and dispersed as a vapor through air circulation systems in potato storage warehouse facilities and is not expected to be available to nontarget organisms. Based on the indoor use pattern, exposure of 3-decen-2-one to nontarget organisms is expected to be minimal. All nontarget toxicology data requirements for 3-decen-2-one have been **satisfied**.

For more information regarding nontarget organism toxicity data requirements, refer to Table 6 in Appendix A.

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data is not required based on the proposed indoor use pattern of 3-decen-2-one and the information submitted for the nontarget organism toxicology data requirements, which did not trigger additional Tier I studies. The applicant did submit information that estimated the physical and chemical properties for 3-decen-2-one by using QSAR modeling based on the Estimation Programs Interface Model (EPI SuiteTM 4.0). Using Henry's Law, which states that the solubility of a gas in a liquid is directly proportional to the partial pressure of the gas above the liquid, 3-decen-2-one is estimated to be 5.4 x 10⁻⁴ atm·m³/mol and indicates that the a.i. has a potential for volatility from water or moist soil. In soil, the estimated K_{oc} of 165.2 - 860.9 L/kg indicates that the a.i. would have medium to low mobility in soil. In water, an estimated log K_{ow} of 3.28 and an estimated BCF of 67.41 L/kg wetwt indicate that bioaccumulation in aquatic organisms is unlikely. In the air, atmospheric oxidation by reaction of hydroxyl radicals is expected to occur with estimated half-lives of 1.9 – 2.2 hours. The probability of biodegradation of 3-decen-2-one was evaluated using EPI Suite™ 4.0 in the BIOWIN module. Various models in the BIOWIN module predicted rapid biodegradation of 3-decen-2-one. Based on a total air volume in potato warehouse of 1,910 m³ and total applied 3-decen-2-one of 122,475 g calculated by the applicant, the maximum air concentration of 3-decen-2-one in warehouse was estimated to be 64.14 mg/L of air. With an estimated ventilation rate of 825 m³ of air/min, the air volume in a warehouse will be exchanged

within 2.5 minutes when the vents to the outdoors are opened. Thus, the concentration emitted will be rapidly diluted in the outside air, which further demonstrates insignificant exposure to nontarget organisms.

3. Ecological Exposure and Risk Characterization

Significant exposure and risk to nontarget organisms is not expected because of the proposed indoor use pattern as a sprout inhibitor on potatoes for 3-decen-2-one. The end-use formulations will be introduced and dispersed as a vapor through air circulation systems in potato storage warehouse facilities and are not expected to be available to nontarget organisms. In addition, the estimated ventilation rate of 825 m³ of air/min in the potato storage warehouse facilities will exchange the air volume in the warehouse within 2.5 minutes when the vents to the outdoors are opened; therefore, the concentration emitted will be rapidly diluted in the outside air.

4. Endangered Species Assessment

Tier I studies were not submitted for 3-decen-2-one, but are not required. Based on its use pattern and use instructions as a sprout inhibitor on stored potatoes intended for use in indoor, enclosed potato storage facilities, exposure to nontarget organisms is not expected. Based on its use pattern and use instructions, EPA has determined 3-decen-2-one will have "No Effect" on any currently listed threatened or endangered species or any designated critical habitat.

D. Efficacy Data

Product performance data must be developed for all pesticides to ensure that pesticide products will perform as intended and that unnecessary pesticide exposure to the environment will not occur as a result of the use of ineffective products. The Agency reserves the right to require on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration that are intended to be used to control a pest of significance public health importance and a public health pest as defined in FIFRA section 28(d) and section 2(nn). For further guidance on product performance requirement, refer to Pesticide Registration Notice (PR) Notices 96-7, 2002-1 and Explanation of Statutory Framework for Risk-Benefit Balancing for Public Health Pesticides (http://www.epa.gov/PR_Notices/pr2002-1.pdf) and (http://www.epa.gov/PR_Notices/pr2002-1.pdf) and (http://www.epa.gov/PR_Notices/pr2002-1.pdf) and (http://www.epa.gov/pesticides/health/risk-benefit.htm).

The EPs submitted with this new active ingredient did not list pests of significance public health importance or a public health pest as defined in FIFRA section 28(d) and section 2(nn). Therefore, product performance (efficacy) was not evaluated.

V. RISK MANAGEMENT DECISION

A. Determination of Eligibility for Registration

Section 3(c)(5) of FIFRA provides for the registration of a new active ingredient if it is determined that: (A) its composition warrants proposed claims; (B) its labeling and other materials comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.

The four criteria of the Eligibility Determination for Pesticidal Active Ingredients are satisfied by the science assessments supporting products containing the technical grade active ingredient, 3-decen-2-one. Such products are not expected to cause unreasonable adverse effects. Therefore, 3-decen-2-one as a technical grade active ingredient is eligible for registration for the labeled uses.

B. Regulatory Decision

The data submitted fulfill the registration requirements of 3-decen-2-one for use as a potato sprout inhibitor. Refer to Appendix B for product-specific information.

Conditional/Unconditional Registration

All data requirements are fulfilled, and EPA determined that an unconditional registration of 3-decen-2-one is appropriate.

Consistent with the policy of making registration actions more transparent, 3-decen-2-one was subject to a 15-day comment period as a "new active ingredient." EPA established a comment period of 15 days on the basis of 3-decen-2-one's minimal toxicity, the determination that 3-decen-2-one presents low risk of any adverse effects to human health and the environment, and critical need for this active ingredient. The notice for this comment period included the draft Biopesticides Registration Action Document (BRAD) and draft product labels for the MP, AMV-1018 Technical, and EP, AMV-1018 EP, which contain this new active ingredient, 3-decen-2-one. The docket identification (ID) number is EPA-HQ-OPP-2010-0064. The Agency did not receive any comments on the registration of 3-decen-2-one during this 15-day comment period. The Agency believes that based on the risk assessment and information submitted in support of the registration of the MP and EP containing 3-decen-2-one, it is in the best interests of the public to issue the registration for AMV-1018 Technical and AMV-1018 EP. The basis for this decision can be found in the risk assessment for 3-decen-2-one, which is characterized in this BRAD.

C. Environmental Justice

EPA seeks to achieve environmental justice—the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income—with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. At this time,

EPA does not believe that use of 3-decen-2-one pesticide products will cause harm or a disproportionate impact on at-risk communities. For additional information regarding environmental justice issues, please visit EPA's website at http://www.epa.gov/compliance/environmentaljustice/index.html.

VI. ACTIONS REQUIRED BY REGISTRANTS

EPA evaluated all data submitted in connection with the registration of the 3-decen-2-one pesticide products and determined that these data are sufficient to satisfy current registration data requirements. At this time, no additional data must be submitted to EPA for these particular products. For new uses and/or changes to existing uses, EPA may require additional data.

Notwithstanding the information stated in the previous paragraph, it should be clearly understood that certain specific data are required to be reported to EPA as a requirement for maintaining the Federal registration for a pesticide product. A brief summary of these types of data are listed below.

A. Reporting of Adverse Effects

Pursuant to FIFRA section 6(a)(2), reports of all incidents of adverse effects to the environment must be submitted to EPA.

B. Reporting of Hypersensitivity Incidents

Additionally, all incidents of hypersensitivity (including both suspected and confirmed incidents) must be reported to the Agency under the provisions of 40 CFR Part 158.2050(d).

VII. APPENDIX A. DATA REQUIREMENTS (40 CFR PART 158-SUBPART U)

*NOTE: Master Record Identification (MRID) numbers listed in the following tables are representative of supporting data/information for the original registration of the product containing this active ingredient. Subsequent to this registration, there may be additional MRIDs that support registration of other products containing this active ingredient.

TABLE 3. Product Chemistry Data Requirements for 3-decen-2-one (40 CFR § 158.2030)										
OCSPP	Guideline Reference No./Study	Description of Result	MRID							
880.1100	Product identity and composition	The product identity and composition were adequately addressed. Confidential Business Information (CBI).	47942601							
880.1200	Description of starting materials, production, and formulation process	The description of the starting materials, production, and formulation process were adequately addressed. CBI.	47942602 47942603							
880.1400	Discussion of formation of impurities	The discussion of formation of impurities was adequately addressed. CBI.	47942604							
830.1700	Preliminary analysis	The preliminary analysis of the product was acceptable. CBI.	47942605							
830.1750	Certified limits	The certified limits listed on the CSF are acceptable.	47942606							
830.1800	Enforcement analytical method	The enforcement analytical method was adequately addressed. CBI.	47942605							

TABLE 4. Physical and Chemical Properties for 3-decen-2-one (40 CFR § 158.2030)										
OCSPP (Guideline Reference No./Property	Description of Result	MRID							
830.6302	Color	Colorless to pale yellow	47942607							
830.6303	Physical State	Clear liquid	47942607							
830.6304	Odor	Pleasant	47942607							
830.6313 Stability to normal and elevated temperatures, metals and metal ions		The stability of the active ingredient of the test substance untreated and in presence of metals and metal ions (iron powder, iron acetate, aluminum powder, and aluminum acetate) stored for 1, 2, 7 and 14 days was determined at ambient (21 - 23°C) and elevated temperature (54°C). A significant decrease in the concentration of the active ingredient was observed at elevated temperatures for all treatments and with the samples treated with iron acetate at ambient temperature after 7 days.	47942607							
830.6315	Flammability	Flash point = 91°C	From Confidential Statement of Formula (CSF)							
830.6317	Storage Stability	Not required for TGAI. MP is stable during one year storage stability study.	48970301							
830.6319	Miscibility	N/A, not an emulsifiable liquid and is not to be diluted with petroleum solvents	47942607							
830.6320	Corrosion Characteristics	Not required for TGAI. MP showed no signs of corrosion (cracking, pitting, or discoloration) during one year storage stability study.	48970301							
830.7000	pH	4.33 of 1% w/w suspension in water at 23°C	47942607							
830.7050	UV/Visible light absorption	pH λ _{max} (nm) ε (L/mol*cm) Neutral 229.0 14408.1 Acidic 229.0 16464.7 Alkaline 229.0 9330.6	47942607							
830.7100	Viscosity	2.211 mm ² /s at 25°C	48156401							
830.7200	Melting Range	N/A, not a solid	47942607							
830.7220	Boiling Range	224.0°C	47942607							
830.7300	Density/Relative Density/Bulk Density	0.845 g/mL at 20°C	47942607							
830.7520	Particle size, fiber length, and diameter distribution	N/A, not insoluble in water and not a fiber	47942607							
830.7550 830.7560 830.7570	Partition Coefficient (n-Octanol/ Water)	Log P _{ow} = 3.45	47942607							
830.7840	Water Solubility	0.140 g/L at 24°C	47942607							
830.7950	Vapor Pressure	430 Pa at 25°C	47942608							

Table 5: Mammalian Toxicology Data Requirements for 3-decen-2-one (40 CFR § 158.2050)									
Study/OCSPP Guideline No.	Results	Toxicity Category/Description	MRID						
Acute oral toxicity (rat) (870.1100)	LD ₅₀ > 5,000 mg/kg body weight in female rats	Toxicity Category IV	47942609						
Acute dermal toxicity (rat) (870.1200)	LD ₅₀ > 5,000 mg/kg body weight in male and female rats	Toxicity Category IV	47942610						
Acute inhalation toxicity (rat) (870.1300)	LC ₅₀ 0.52-2.04 mg/L in male rats and > 2.04 mg/L in female rats	Toxicity Category III	47942611						
Primary eye irritation (rabbit) (870.2400)	One hour after test substance instillation, all three treated eyes exhibited corneal opacity and conjunctivitis, and two treated eyes exhibited iritis. Severity decreased over time, with all animals free of ocular irritation by Day 10. Test substance is classified as moderately irritating to the eye.	Toxicity Category II	47942612						
Primary dermal irritation (rabbit) (870.2500)	Animals exhibited severe irritation (severe erythema and moderate edema) through 72 hours post patch removal. Irritation was no longer observed by Day 14. Test substance is classified as severely irritating to the skin.	Toxicity Category II	47942613						
Dermal sensitization (guinea pig) (870.2600)	Not a dermal sensitizer.	-	47942614						
90-Day oral toxicity (870.3100)	A subchronic 90-day oral toxicity study (OCSPP 870.3100) on the active ingredient (a.i.) was not conducted. In lieu of the study, EPA used a WOE approach to estimate the likelihood of potential of toxicity from repeat oral exposure to this substance. First, using an expert system computer program (DEREK Nexus), EPA identified two potential toxicological endpoints for 3-decen-2-one (potential dermal sensitization and in vitro chromosome damage); however, follow-up studies did not support these as toxicological endpoints. Second, the metabolic pathways of 3-decen-2-one have been characterized and demonstrate that the biochemical is metabolized into innocuous compounds that are either excreted or further metabolized in the fatty acid pathway or citric acid cycle. Third, 3-decen-2-one occurs naturally in some foods and has been used as a food additive without specific reports of adverse effects. Finally, FDA has approved the use of 3-decen-2-one as a synthetic flavoring agent and adjuvant that may be directly added to food under 21 CFR § 172.515. Based on this evidence, EPA concluded that 3-decen-2-one has relatively low toxicity via the repeated oral exposure route.	-	47942617 48422301						
90-Day dermal toxicity (870.3250)	Not required. Proposed uses not to involve purposeful application to human skin and do not result in comparable human exposure to the product.	-	47942617						
90-Day inhalation toxicity (870.3465)	Not required. Repeated inhalation exposure is unlikely due to product being applied by a thermal fog generator in a closed system. Personnel are not allowed in the potato storage facilities during application and	-	47942617; 48422301						

Table 5: Mammalian Toxicology Data Requirements for 3-decen-2-one (40 CFR § 158.2050)									
Study/OCSPP Guideline No.	Results	Toxicity Category/Description	MRID						
v	evacuation of the product. In addition, any unlikely inhalation exposure will be mitigated on the label by precautionary statements and PPE requirements.								
Developmental toxicity (870.3700)	Maternal and fetal NOAEL = 1,000 mg/kg/day (the highest dose tested).								
	A lower bodyweight gain effect was seen in the highest-dose group (1,000 mg/kg/day) for maternal rats; however, the bodyweight gain effect is considered to be attributable to the palatability of the test substance and not toxicologically significant.	-	48970303						
Mutagenicity – Tier I (870.5100, 5300 and 5375)	Test substance is negative in bacterial reverse mutation assay with and without metabolic activation.		47942616						
	Test substance positive in 24-hr exposure without metabolic activation and equivocal results with metabolic activation in an <i>in vitro</i> mammalian gene mutation assay (mouse lymphoma cell). Mouse lymphoma results are considered equivocal because it is not clear whether the positive results would translate into an <i>in vivo</i> system based on the increased osmotic pressure and marked cytotoxicity noted during the experiment.	•	47942615						
Mutagenicity – Tier II (870.5395)	Test substance is considered non-mutagenic based on <i>in vivo</i> mammalian erythrocyte micronucleus test assay results.		48412402						

Table 6: Nontarget Org	Table 6: Nontarget Organism Toxicity Data Requirements for 3-decen-2-one (40 CFR § 158.2060)									
Study/OCSPP Guideline No.	Results	Toxicity Category/Description	MRID							
Avian acute oral toxicity (850.2100)	Not required. Significant exposure to birds is not expected due to the proposed indoor use only as a sprout inhibitor on potatoes. In addition, 3-decen-2-one is applied and released as a vapor and is not expected to be available to birds via the oral route.	Significant exposure not expected	47942617							
Avian dietary toxicity (850.2200)	Not required. Significant exposure to birds is not expected due to the proposed indoor use only as a sprout inhibitor on potatoes. In addition, 3-decen-2-one is applied and released as a vapor and is not expected to be available to birds via the oral route.	Significant exposure not expected	47942617							
Aquatic invertebrate acute toxicity, freshwater (850.1010)	Not required. Significant exposure to aquatic invertebrates is not expected due to the proposed indoor use only as a sprout inhibitor on potatoes. In addition, 3-decen-2-one is applied and released as a vapor and is not expected to enter surface water in amounts sufficient to impact aquatic life.	Significant exposure not expected	47942617							

Table 6: Nontarget Organism Toxicity Data Requirements for 3-decen-2-one (40 CFR § 158.2060)									
Study/OCSPP Guideline No.	Results	Toxicity Category/Description	MRID						
Fish acute toxicity, freshwater (850.1075)	Not required. Significant exposure to fish is not expected due to the proposed indoor use only as a sprout inhibitor on potatoes. In addition, 3-decen-2-one is applied and released as a vapor and is not expected to enter surface water in amounts sufficient to impact aquatic life.	Significant exposure not expected	47942617						
Terrestrial plant toxicity, Seedling emergence/Vegetative vigor (850.4100 and 850.4150)	Not required. Significant exposure to terrestrial plants is not expected due to the proposed indoor use only as a sprout inhibitor on potatoes. In addition, 3-decen-2-one is applied and released as a vapor during winter months when terrestrial plants are generally dormant and when seedlings are not emerging.	Significant exposure not expected	47942617						
Nontarget insect testing (880.4350)	Not required. Significant exposure to insects is not expected due to the proposed indoor use only as a sprout inhibitor on potatoes. In addition, 3-decen-2-one is applied and released as a vapor during winter months when nontarget insects are generally dormant.	Significant exposure not expected	47942617						

VIII. APPENDIX B.

For product specific information, please refer to http://www.epa.gov/pesticides/pestlabels.

IX. APPENDIX C.

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EPA. 2013. Memorandum from Angela L. Gonzales thru Felecia A. Fort to Colin G. Walsh. Joint Science Review with Health Canada Pest Management Regulatory Agency (PMRA) in Support of the Registration of AMV-1018 Technical Containing 98.0% of 3-Decen-2-One as its Active Ingredient. U.S. Environmental Protection Agency Office of Pesticide Programs. January 3, 2013.

X. GLOSSARY OF ACRONYMS AND ABBREVIATIONS

active ingredient

a.i.

AMVAC	Amvac Chemical Corporation
BPPD	Biopesticides and Pollution Prevention Division
BRAD	Biopesticide Registration Action Document
bw	body weight
CBI	Confidential Business Information
CFR	Code of Federal Regulations
CIPC	Chlorpropham
cm ³	cubic centimeter
CSF	Confidential Statement of Formula
°C	degrees Celsius
EC ₅₀	median effective concentration. A statistically derived single concentration in
	environmental medium that can be expected to cause an effect in 50% of the test
	animals when administrated by the route indicated (inhalation). It is expressed

Biopesticides Registration Action Document

as a concentration in air or water (e.g. mg/L).

EDSP Endocrine Disruptor Screening Program

EDSTAC Endocrine Disruptor Screening and Testing Advisory Committee

EFH Exposure Factors Handbook

EP end-use product

EPA Environmental Protection Agency (the "Agency")

FDA Food and Drug Administration

FEMA Flavor and Extract Manufacturer's Association

FFDCA Federal Food, Drug, and Cosmetic Act

FIFRA Federal Insecticide, Fungicide, and Rodenticide Act

FQPA Food Quality Protection Act

FR Federal Register

g gram ha hectare

JECFA Joint FAO/WHO Expert Committee on Food Additives

kg kilogram

Kow octanol-water partition coefficient

L liter

LC₅₀ median lethal concentration. A statistically derived single concentration in air or

water that can be expected to cause death in 50% of the test animals when administrated by the route indicated (inhalation and environment). It is

expressed as a concentration in air or water (e.g. mg/L).

LD₅₀ median lethal dose. A statistically derived single dose that can be expected

to cause death in 50% of the test animals when administered by the route

indicated (oral and dermal). It is expressed as a weight of

substance per unit weight of animal (e.g., mg/kg).

MRID No. Master Record Identification Number

mg milligram mPa millipascal mL milliliter

MP manufacturing-use product

N/A not applicable NE "No Effect"

NIOSH National Institute for Occupational Safety and Health

nm nanometer

NOAEL no-observed-adverse-effect-level

NOEL no-observed-effect-level

NOF notice of filing NOR notice of receipt

OPP Office of Pesticide Programs

OCSPP Office of Chemical Safety and Pollution Prevention

pa pascal

PADI possible average daily intake

PMRA Canada's Pesticide Management Regulatory Authority

PPE personal protective equipment PR Notice Pesticide Registration Notice

3-decen-2-one Page 30 of 30 Biopesticides Registration Action Document

TGAI technical grade of the active ingredient TSG Technology Sciences Group, Inc.

ug microgram

USDA United States Department of Agriculture

UV ultra-violet

WOE weight of the evidence

3-decen-2-one (068403) Fact Sheet

Summary

3-decen-2-one is a biochemical pesticide active ingredient intended for postharvest use on stored potatoes as a sprout inhibitor. 3-decen-2-one is a naturally occurring biochemical substance that functions as a plant growth regulator, affecting plant growth by increasing tuber respiration. The use of 3-decen-2-one as a potato sprout inhibitor is not expected to cause any unreasonable adverse effects to human health or the environment.

I. Description of the Active Ingredient

3-decen-2-one is a biochemical pesticide active ingredient intended for postharvest use on stored potatoes as a sprout inhibitor. 3-decen-2-one is a naturally occurring biochemical substance, with a history of unremarkable human exposure. 3-decen-2-one functions as a plant growth regulator, affecting plant growth by increasing tuber respiration. Data on file indicate that 3-decen-2-one interferes with membrane integrity, which results in increased oxidative stress, desiccation, and rapid necrosis of the meristems and surrounding sprout tissues. Thus, 3-decen-2-one inhibits sprouting, with no observed affects on the potato, potato sweetening, or processing quality. 3-decen-2-one is approved by the U.S. Food and Drug Administration (FDA) for use as a synthetic agent and adjuvant that may be directly added to food under 21 CFR § 172.515.

II. Use Sites, Target Pests, and Application Methods

Use Sites: Stored potatoes

Target Pests: Plant growth regulator (sprout inhibitor)

Application Methods: Thermal fog generator in a closed system

III. Assessing Risks to Human Health

Review of the required toxicity testing data and information indicate that 3-decen-2-one is of low acute toxicity (with the exception that it is an eye and skin irritant) and is not a developmental toxicant, a mutagen, or toxic via repeat oral exposure. There have been no reports of hypersensitivity incidents for 3-decen-2-one. Based on this information, no human health risks are expected when pesticide products containing 3-decen-2-one are used according to their respective label directions.

IV. Assessing Risks to the Environment

Significant exposure and risk to nontarget organisms is not expected for 3-decen-2-one because of the proposed indoor use pattern as a sprout inhibitor on potatoes. The end-use formulations will be introduced and dispersed as a vapor through air circulation systems in potato storage warehouse facilities and are not expected to be available to nontarget organisms.

V. Regulatory Information

This is the first registration of a product containing the new active ingredient, 3-decen-2-one. On December 8, 2009, EPA received an application filed by Technology Sciences Group, Inc. (TSG), 1150 18th Street, NW, Suite 1000, Washington, DC 20036, on behalf of Amvac Chemical Corporation (AMVAC), 4695 MacArthur Court, Ste. 1250, Newport Beach, CA 90660, to register the products, AMV-1018 Technical (EPA File Symbol No. 5481-LAI), AMV-1018 EP (EPA File Symbol No. 5481-LTR), AMV-1018 90EC (EPA File Symbol No. 5481-LTN), and AMV-1018 67.5EC (EPA File Symbol No. 5481-LAO) containing the new biochemical active ingredient, 3-decen-2-one under the provisions of section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The applicant withdrew AMV-1018 90EC (EPA File Symbol No. 5481-LTN) and AMV-1018 67.5EC (EPA File Symbol No. 5481-LAO) from consideration by EPA with the letter dated March 2, 2011. A notice of receipt (NOR) of this application, allowing for a 30-day comment period, was published in the *Federal Register* on March 10, 2010 (75 FR 11175) pursuant to the provisions of FIFRA section 3(c)(4). No comments were received following this publication.

VI. Applicant Information

Technology Sciences Group, Inc. 1150 18th Street, NW Suite 1000 Washington, DC 20036

Amvac Chemical Corporation 4695 MacArthur Court Suite 1250 Newport Beach, CA 90660

VII. Additional Contact Information

Ombudsman
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460



Health Canada Santé Canada

Pest Management Regulatory Agency Agence de réglementation de la lutte antiparasitaire

JUL 3 0 2013

John A. Immaraju AMVAC Chemical Corporation Suite 1250, 4695 MacArthur Court Newport Beach, CA 92660 USA

Dear Mr. Immaraju:

Re: SmartBlock®, containing 3-decen-2-one, EP Submission Number: 2010-0035

The review of your application to register SmartBlock[®], containing 3-decen-2-one, has been completed. The Pest Management Regulatory Agency has carried out an evaluation of available information in accordance with section 7 of the *Pest Control Products Act* (PCPA) and has found it sufficient to allow a determination of the health and environmental risks and value of SmartBlock[®]. The purpose of this application is to register the subject product. The Agency has concluded that use of SmartBlock[®] in accordance with the enclosed approved label has value and will not pose unacceptable health or environmental risk.

Pursuant to subsection 8(1) of the PCPA, this product has been granted Full Registration for a validity period to December 31, 2018.

The Agency has assigned **Registration No. 30889**.

Please note, a condition of the full registration for this product is the submission of the operational efficacy trials by September 1, 2017, as outlined in Attachment 1.

Conditions of Full Registration

In order to address the conditions of full registration, you must submit an application for amended registration by the date indicated, consisting of:

- a covering letter explaining the purpose of the application and the information/data included. The letter should state "Submission to fulfill condition(s) of Full Registration";
- application form for new or amended registration indicate "Category B Other":



2720 promenade Riverside Drive, Ottawa, Ontario K1A 0K9

Page 2 of 4 Mr. Immaraju

- fee form indicating "1(b) Label..." (CAD\$262.00) plus any other appropriate
 Part and Component and their associated fees;
- 10% of the total fees payable (or 100% if total fees payable is less than CAD\$1000.00);
- an electronic proposed text label, consistent with the most recently approved label, in Word format (separate files for English and French text);
- an electronic index in the XML format (please refer to Regulatory Directive 2006-05, Requirements for Submitting Data Index, Documents and Forms);
- one copy of any required information (e.g. data/studies) organized by Data Code (DACO) in correct format (please refer to Regulatory Directive 2003-01, Organizing and Formatting a Complete Submission for Pest Control Products and Regulatory Directive 2006-05, Requirements for Submitting Data Index, Documents and Forms);
- one copy of the Statement of Product Specification Form (please refer to Regulatory Directive 2006-05, Requirements for Submitting Data Index, Documents and Forms).

Should you have any questions regarding this letter, please contact the Administrative Coordinator, Katarzyna Gulajska, at 613-736-3640, or e-mail Katarzyna.Gulajska@hc-sc.gc.ca.

Your Registration Certificate and a copy of the approved text label are enclosed. This application is now complete. Please note that this decision is subject to the filing of a Notice of Objection subject to subsection 35(1) of the PCPA.

Yours truly,

Marion Law

Chief Registrar

PEST MANAGEMENT REGULATORY AGENCY

cc: Laurie Tyo, Technology Sciences Group (TSG) Canada Inc.,

the submission contact

encl.: Attachment 1: Conditions of Full Registration

Registration Certificate (expires December 31, 2018)

Approved label (SmartBlock®)

Attachment 1:

Conditions of Full Registration SmartBlock[®], Reg. No. 30889

Submission No. 2010-0035

During the full registration period, the following information is to be generated and must be provided to the Agency by September 1, 2017, and should indicate the DACO numbers specified below. A partial response to the outlined Conditions of Full Registration will not be accepted.

PART 0

INDEX

DACO:

0

Title:

Index

Required Data:

Please submit an electronic index of the data package submitted in response to this letter. Please refer to Regulatory Directive 2006-05, Requirements for Submitting Data Index, Documents and Forms, for additional information.

Page 3 of 4

PART 10

VALUE

DACO:

10.2.3.4

Title:

Operational efficacy trials

Deficiencies:

The efficacy of SmartBlock® must be confirmed when applied in accordance with the label in a commercial storage facility.

Required Data:

Efficacy data are required from at least two trials in which SmartBlock® is applied in accordance with the label by means of thermal fogging equipment (minimum one trial) and by means of cold fogging (misting) equipment (minimum one trial) to potatoes

that have not been previously treated with CIPC.

In <u>each</u> trial, efficacy must be assessed throughout the pile to examine the degree of sprout control. A sufficient number of samples of potatoes are to be removed from the storage prior to treatment and kept separately under the same conditions to serve as an untreated control treatment. Data (sprout weight, number and rating) must be taken from random samples of potatoes from various locations in the pile (over the area of the storage and at various

depths from near the top of the pile to the bottom).

Data (sprout weight, number and rating) must be collected over a sufficient period of time (e.g. at least three months or until Attachment 1:

Conditions of Full Registration SmartBlock®, Reg. No. 30889

Submission No. 2010-0035

untreated potatoes are sprouting extensively, whichever is longer).

The applicant is advised to submit the trial protocols for PMRA review prior to initiating the trials.

USDA NOP SMARTBLOCK APPLICATION REDACTED COPY Page 68 of 211

Page 4 of 4

Recent Progress in the Consideration of Flavoring Ingredients Under the Food Additives Amendment

11. GRAS Substances

BERNARD L. OSER and RICHARD A. FORD

☐ THIS PAPER is the latest in a series reporting the results of deliberations of the independent panel of experts retained by the Flavor and Extract Manufacturers' Association (FEMA) for evaluation of GRAS (Generally Recognized as Safe) status of new flavoring substances. This panel consists of members chosen as described before (Hall and Oser, 1961) and is made up of experts who are qualified by training and years of experience in pharmacology and toxicology as well as in the safety evaluation of flavors. The criteria used by the Expert Panel in arriving at judgements of GRAS status have been discussed in a recent publication (Oser and Hall, 1977). The Panel currently consists of: Dr. Anthony M. Ambrose, Medical College of Virginia; Dr. John Doull, University of Kansas Medical Center; Dr. David W. Fassett; Dr. Howard C. Spencer; Prof. R. Tecwyn Williams, St. Mary's Hospital Medical School, University of London; and Dr. Lauren A. Woods, Virginia Commonwealth University. Dr. Doull only recently joined the Panel and was not a member during the discussion of the GRAS status of the substances listed herein.

SACCHARIN

The Expert Panel has not modified or retracted its GRAS determination of saccharin (Hall and Oser, 1965), despite the announced proposal of FDA to ban its use (FDA, 1977). It has taken cognizance of the three F₀/F₁ generation feeding studies, in particular that of the Canadian Health Protection Branch, which formed the basis for FDA's regulatory decision. It was noted that neither the WARF nor the FDA study were regarded as conclusive by the NAS/NRC Subcommittee on Non-Nutritive Sweeteners, (Safety of Saccharin and Sodium Saccharin in the Human Diet. Subcommittee on Non-Nutritive Sweeteners. Committee on Food Protection. Food and Nutrition Board. National Research Council/National Academy of Sciences, Washington, D.C. 1974) for several reasons, including uncertainty with respect to the suspected impurity, orthotoluene sulfonamide. Whereas the HPB study exonerated this impurity, the results of its single level (5%) test of saccharin were reported to have satisfied FDA of the carcinogenicity of this artifical sweetener.

The panel noted certain questionable aspects of

The authors are respectively with Bernard L. Oser Associates, Inc., Food and Drug Consultants, 108-18 Queens Blvd., Forest Hills, NY 11375; and Consultants to the Flavor and Extract Manufacturers' Association, 900 17th St. N.W., Washington, DC 20006

0015-6639/78/0002-0060\$02.25/0 ©1978 Institute of Food Technologists these 2-generation studies, viz. a) the rationale for, and consequences of the use of the "maximum tolerated dose"; b) the excessive dietary dose levels (7.5% in the FDA study and 5% in the other two) at which malignant neoplasms were reported, as contrasted with human exposure levels; c) the significantly higher incidence of tumors in the second generation (F₁) rats than in the parent generation; d) uncertainty (and appropriateness) concerning the dosages to which the F₁ rats were exposed in utero, during lactation, and during the post-weaning period of normally high food consumption relative to body weight; e) the higher incidence of tumors in male rats than in female rats; and f) the absence of control groups to clarify the effect of sodium intake of the high test groups compared to that of the animals receiving the unsupplemented basal diets.

Because of these questions concerning the Canadian study (stemming in part from the methodology employed), and viewed against the total present information on the tests and use of saccharin, the Expert Panel concludes that it should not change its present GRAS classification until research and review now planned permit further clarification.

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GRAS FLAVORING INGREDIENTS AND USAGE LEVELS

Flavor and Extract Manufacturer's Association average maximum levels (in ppm) on which the Expert Panel based its judgments that the substances are generally recognized as safe for their intended uses

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soūps	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies -	Other use Categories
Acetoin acetate see 3526								·			
3526											
2-ACETOXY-3-BUTANONE	49.3	20.0		47.8	00.0			00.0	00.0		
9-Acetoxy-1-p-menthene	43.3	20.0	_	41.0	20.0		_	20.0	20.0	_	
see 3566											
3-Acetoxyoctene											
see 3582											
3527											
3-ACETYL-2,5-DIMETHYL-	2.0	0.6	1.0	1.5	1.5	1.0	_	1.0	1.0	_	Milk
THIOPHENE											products-0.6
Acetyl ethyl carbinol ,											-
see 3550											
Acetyl methyl carbinyl											
acetate see 3526											
o-Acetylphenol see 3548											
Amyl ethyl carbinol											•
see 3581											
Amyl ethyl carbinyl											
acetate see 3583											
iso-Amyl acetoacetate											
see 3551											
Amyl vinyl carbinyl											
acetate see 3582											
1,3-Benzenediol											
see 3589											
3528	0.0		0.2				0.0			0.0	37 .
1,2-BUTANEDITHIOL ⁴¹	0.2	_	0.2	_	_	0.2	0.2		_	0.2	Nut products=0.2
3529											products-0.2
.3-BUTANEDITHIOL(*)	0.2	_	0.2	_	_	0.2	0.2	_	_	0.2	Nut
•											products-0.2
2-Butanon-3-yl acetate											•
see 3526											
Butyl ethyl carbinol											
see 3547											
Campholenic aldehyde											
see 3592											
Carvomenthol see 3562											
Celery ketone										6. 2	
see 3577											
3530											
m-CRESOL	1.0	_	0.5	_	_	0.5	0.5	-	_	0.5	Nut
											products-0.5;
											Instant coffee
											& tea-0.5;
											Household
											seasonings &
3531											flavorings-0.5;
CYCLOHEXANECARBOXYLIC	2.0	1.0		_	1.0			1.0	_		Fruit ices-1.0;
ACID ^(b)	2.0	1.0	_	_	1.0		-	1.0	_	_	Confectionery
, neip											& frost-
1974 B. D											ing-2.0;
											Chewing
											gum-1.5
3532											
3-DECEN-2-ONE	19	5.8	-	7.8	4.8		-	4.3	4.0	-	
Dallyl di-, tri-, tetra-, and pentasulfides											
see 3533											
3533			. ^				٥.			٥.	D
DIALLYL POLYSULFIDES	1.0	_	1.0		_		0.1	-	_	0.1	Processed
The second secon											vegetables 1.0; House-
Contract Section 1											hold season-
											ings & flavor-
											ings-1.0
											ings-1.0

^{&#}x27;a'Total dithiol added to any food not to exceed 1.0 ppm.

⁽b) Substance has not been covered in a Scientific Literature Review nor is it presently scheduled for future coverage.

(c) To be used at not more than 10.0 ppm in the finished food.

^{&#}x27;4'To be used in cocoa substitute only.

⁻Continued on page 62

Substance	Baked Goods		Meat Products	Soft Candy	Gelatins & Puddings	Soups		Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other use Categories
3534 1,2-DI[(1'-ETHOXY)-ETHOXY] PROPANE	330	54.9	-	137	273	Soups	-	62.5	54.8	Gravies	Milk products—54.9; Processed fruit—54.9; Fruit ices—54.9; Condiments & relishes—273; Confectionery & frosting— 137; Jams & jellies—273; Sweet sauce—273; Nut prod- ucts—62.5; Imitation dairy—54.9; Hard can- dy—137; Chewing gum—1546; Household
1, 3-Diethylacetonyl 3-methyl-3-furyl sulfide see 3570 sis-Dihydrocarvone see 3565 Dihydrocuminyl acetate see 3561 3,7-Dihydro-3,7-dimethyl- 1H-purine-2,6-dione see 3591 Dihydrojasmone see 3552 m-Dihydroxybenzene see 3589											seasonings & flavors—273
Disobutyl ketone see 3537 ,3-Disopropylacetonyl 2-methyl-3-furyl sulfide see 3538 ,2-Dimercaptobutane see 3528 ,3-Dimercaptobutane see 3529										×	
,3-Dimercaptopropane see 3588 2,5-Dimethyl-3- acetylthiophene see 3527 3535 2,3-DIMETHYLBENZOFURAN	2.0		1.0	_	_	1.0	_	_	_		Condiments &
0500											relishes—1.0; Household seasonings & flavorings—1.0
3536 DIMETHYL DISULFIDE	16.9	4.8	2.2	9.4	8.3	•	-	4.8	2.0	-	Condiments & relishes—3.8; Sweet sauce—0.007
3537 2,6-DIMETHYL-4-HEPTANONE 6,6-Dimethyl-3-hydroxy- 2-methylenebicyclo [3.1.1]heptane see 3587	5.0	2 .0	-	5.0	1.1	-	-	0.8	1.1	-	
3538 2,6-DIMETHYL-3-[(2- METHYL-3-FURYL)THIO]- 4-HEPTANONE	1.0	-	1.0	-	-	1.0	1.0	· <u>-</u>	-	1.0	Nut products=1.0

⁽a)Total dithiol added to any food not to exceed 1.0 ppm.

(b)Substance has not been covered in a Scientific Literature Review nor is it presently scheduled for future coverage.

(c)To be used at not more than 10.0 ppm in the finished food.

(d)To be used in cocoa substitute only.

⁻Continued on page 64

11. GRAS Substances . . .

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other use Categories
3539 3,7-DIMETHYL-1,3,6- OCTATRIENE 2,5-Dimethylphenol see 3595 3,4-Dimethylphenol see 3596	15.2	7.7	-	15.2	4.0		-	2.3	4.0	-	
3540 2,6-DIMETHYLPYRIDINE	10.0		5.0	-	3.0	5.0	10.0	-	-	5,0	Confectionery & frost- ings-3.0; Nut products-5.0; Instant coffee & tea-0.15
3541 3,5-DIMETHYL-1,2,4-TRITHIOLANE	-	-	0.3	_	-	0.3	-	-	-	0.3	Milk products-0.3
3542 6,10-DIMETHYL-5,9- UNDECADIEN-2-ONE 3,7-Dimethylxanthine see 3591 1,3-Dipropylacetonyl 2-methyl-3-furyl sulfide see 3571	10.0	10.0	-	10.0	10.0	_	_	10.0	-	-	
3543 ETHYLENE BRASSYLATE Ethylene glycol brassylate cyclic diester see 3543	2.0	2.0		2.0	2.0	-	-	2.0	-	-	
3544 ETHYL CYCLOHEXANE- CARBOXYLATE ⁽⁺⁾	0.01	0.01	-	~	0.01	-	-	0.01	-	-	Fruit ices-0.01; Confectionery & frost- ing-0.05
3545 ETHYL 3-HYDROXYHEXANOATE	5.0	1.0	_	-	1.0	-	-	1.0	1.0	v	Breakfast cereals-5.0; Other grains-5.0; Milk products-1.0; Fruit ices-1.0; Confectionery & frostings-1.0; Jams & jellies-1.0; Chewing gum-1.0
3546 5-ETHYL-2-METHYLPRIDINE Ethyl vinyl carbinol see 3584 2-Furfurylidenephenyl- acetaldehyde see 3586 Geranyl acetone see 3542	1.5	-	1.0	-	-	0.5	-	-		0.5	Breakfast cereals—1.0; Nut products—1.0; Instant coffee & tea—0.05
3547 3-HEPTANOL Hexahydrocarvacrol see 3562 2-Hexyl-2-cyclopenten-1- one and 2-hexylidene- cyclopentanone mixture see 3552	18.5	8.8	-	13.5	8.2	-	-	7.8	6.3	_	
3548 2-HYDROXYACETOPHENONE	0.2	-	0.1	-	-	0.1	0.2	-		0.1	Poultry-0.1; Condiments & relishes-0.1; Instant coffee & tea-0.1; Household seasoning & flavors-0.1

^{**}Total dithiol added to any food not to exceed 1.0 ppm.

**Substance has not been covered in a Scientific Literature Review nor is it presently scheduled for future coverage.

**To be used at not more than 10.0 ppm in the finished food.

**To be used in cocoa substitute only.

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other use Categories
3549											
-HYDROXYDIHYDROTHEA- SPIRANE	_	0.2	-	0.2	0.2	_	-	0.05	-	-	
-Hydroxy-2,5-dimethyl-											
benzene see 3595 -Hydroxy-3,4-dimethyl-											
benzene see 3596											
3550 -HYDROXY-2-PENTANONE	10.0	10.0		10.0	10.0			10.0			
-Hydroxytetradecanoic	10.0		_	10.0	10.0	_	_	10.0	_		
acid lactone see 3590									•	•	
-Hydroxy-2,6,10,10-											
tetramethyl-1-oxaspiro- [4.5]decane see 3549								,			
-Hydroxytoluene											
see 3530 -Hydroxy-2,6,6-trimethyl-											
bicyclo[3.1.1]hept-2-ene see 3594					•.		٠				
3551 SOAMYL ACETOACETATE	166	83.2	_	106	81.6	_		80.8	54.0	_	
soamyl 3-oxobutanoate see 3551	100	00.2		200	01.0			00.0	04.0		
3552 SOJASMONE 3553	2.3	1.9	-	2.5	1.9	_	-	1.6	10.0	_	
SOPHORONE	50.0	4.7	-	50.0	50.0	_	-	10.0	-	-	Condiments relishes—1.0
											Chewing gum-1.0;
											Household
											seasoning & flavors-1.0
-Isopropenyl-1-cyclohexene carbinyl acetate											
see 3561 -Isopropenyl-I-cyclohexene- 1-carboxaldehyde											
see 3557 -Isopropenyl-1-methyl- 1-cyclohexanol											
see 3564											
-Isopropenyl-6- methylcyclohexanone											
see 3565 -Isopropyl-6-methyl-										#2"	
cyclohexanol see 3562											
-Isopropyl-1-methyl-3-											
cyclohexen-1-01 see 3563											
3554 -ISOPROPYL-2- METHYLPYRAZINE™	4.0	4.0	-	4.0	4.0	_	-	4.0	_	-	
3555											
-ISOPROPYL-4-METHYL- THIAZOLE		. -	-	1.0	1.5	_	-	1.0	2.0	_	& frosting- & frosting- 2.0; Jams & jellies-2.0; Sweet
											sauce-1.5; Imitation dairy-2.0;
											Hard candy -2.0; Chewir gum-4.0; In stant coffee tea-2.0
3556	E0.0	20.0		50.0	50.0			20.0			tea-2.0
SOPROPYL MYRISTATE sopropyl tetradecanoate see 3556	50.0	30.0	-	50.0	50.0	_	_	30.0	-	_	

(d) To be used in cocoa substitute only.

[&]quot;Total dithiol added to any food not to exceed 1.0 ppm.
"Substance has not been covered in a Scientific Literature Review nor is it presently scheduled for future coverage." To be used at not more than 10.0 ppm in the finished food.

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other use Categories
3557											
p-MENTHA-1,8-DIEN-7-AL 3558	4.5	6.3	20.0	9.7	4.5		_	4.0	6.0	-	
p-MENTHA-1,3-DIENE 3559	21.5	11.5	20.0	17.8	12.0	-	-	12.0	10.0	-	
p-MENTHA-1,4-DIENE	13.6	8.6	20.0	10.3	8.6	_	_	8.5	10.0	_	Hard can- dy-50.0; Chewing gum-25.0
3560 p-MENTHA-1,4(8)- DIEN-3-ONE	5.0	5.0	~ ~	5.0	5.0	-	-	5.0	-		
3561 -MENTHA-1,8-DIEN- 7-YL ACETATE	16.0	8.0	3.0	16.0	4.0	-	-	2.0	4.0		
3562 MENTHAN-2-OL	14.8	7.6		14.8	4.1	-	_	2.2	4.0	-	
3563 p-MENTH-3-EN-1-OL	30.0	10.0		25.0	20.0	_	-	10.0	_	-	
3564 D-MENTH-8-EN-1-OL	47.5	20.0	10.0	37.5	20.0	-	_	14.6	10.0	_	
3565 p-MENTH-8-EN-2-ONE	15.7	7.3	_	14.0	4.7		_	2.7	4.0	-	
3566 L-p-MENTHEN-9-YL ACETATE	9.0	4.5	_	7.0	4.0	-	<u> </u>	4.0	-	-	
3567 p-METHOXYCINNAMALDEHYDE 3-Methylbutyl 3-oxobutanoate	5.0	_	2.0	-	5.0	-	-	-	_	-	Milk products—2. Condiments relishes—4.0 Confectione & frosting-5.0; Jams & jellies—5.0 Sweet sauce—4.0; Household seasoning & flavors—5.0
see 3551 3568 METHYL CYCLOHEXANE- CARBOXYLATE***	0.1	0.01	-	-	0.1	_	-	0.01	-	-	Fruit ices-0.01; Confectione & frost- ing-0.05; In itation
Methyl disulfide see 3536 Methyldithio-1-propene see 3576 3569 2-METHYL-3,5 or 6-ETHOXY- PYRAZINE**** 2-Methyl-5-ethylpyridine see 3546 3-{(2-Methyl-3-furyl)thio}- 2,6-dimethyl-4-heptanone	-	0.5	-	-	3.0	-		0.5		_	dairy-0.0' Confectione
see 3538 3570 3-[(2-METHYL-3-FURYL)- THIO] 4 UPPTANONE	1.0	_	1.0	-	_	1.0	1.0		_	1.0	Nut products—1
THIO]-4-HEPTANONE 3571 I[(2-METHYL-3-FURYL)- THIO]-5-NONANONE	1.0	-	1.0	_	_	1.0	1.0	-	_	1.0	Nut products—1
3572 5-METHYLHEXANOIC ACID®	10.0	_	_	-	-	3.0	5.0	_	-	_	Imitation
I-Methyl-3-hydroxybenzene see 3530 I-Methyl-4-isopropenylcyclo- hexan-1-ol see 3564							·				dairy—5.0

-Continued on page 68

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**To be used at not more than 10.0 ppm in the finished food.

**To be used in cocoa substitute only.

Substance	Baked Goods		Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other use Categories
-Methyl-4-isopropyl- 1,3-cyclohexadiene see 3558											
-Methyl-4-isopropyl-1,4- cyclohexadiene											
see 3559 -Methyl-4-isopropyl-2-											
cyclohexanol see 3562											
-Methyl-4-isopropyl-3- cyclohexen-1-ol see 3563											
Methyl-4-isopropylidene- 1-cyclohexen-3-one see 3560											
-Methyl-5-isopropylpyrazine see 3554 3573											
SETHYL 2-METHYL-3-FURYL DISULFIDE 3574	0.5	-	0.5	-	-	0.5	0.5	-	-	0.5	Nut products—0
METHYLNONANOIC ACID	10.0	-	5.0	-	-	2.5	10.0	-		2.5	Milk products-5. Imitation dairy-5.0
3575 METHYLOCTANOIC ACID®	_	3.0	0.15	_	0.15	0.15	3.0		_	0.15	Milk
											products—3. Cheese—3. Confections & frosting—
Methylphenol see 3530 3576											J
ETHYL 1-PROPENYL DISULFIDE 3577	1.0	1.0	-	1.0	1.0	-	-	1.0	_	-	
METHYL-5-PROPYL-2- CYCLOHEXEN-1-ONE 3578	14.7	6.5	9.3	10.5	4.0	-	~	5.9	-	-	
METHYL-4-PROPYL-1,3- OXATHIANE	0.1	0.1	0.1	0.1	0.1	-	-	0.05		-	
3579 4-NONANEDIOL DIACETATE 3580	9.0	7.0	-	7.0	7.0			· · · 7.0	_	_	
s-6-NONENAL	1.0	0.3	-	-	0.5	_	-	0.2	0.1	er er	Breakfast ceals—0.1; Frices—0.3; Codiments & rishes—0.1 Confection
											& frost- ing-1.5; Chewing gum-1.0
rans-β-Ocimene see 3539 3581											
OCTANOL 3582	4.8	4.0		4.0	4.0	-	10.0	4.0	1.0		Chewing gum-11.
-OCTEN-3-YL ACETATE 3583	4.8	4.0	12.0	4.0	4.0	-	10.0	4.0	-	-	
OCTYL ACETATE	4.4	4.0	2.6	4.0	4.0	-	10.0	4.0	_	-	Chewing gum=2.6
3584 PENTEN-3-OL erillaldehyde see 3557 erillyl acetate	8.8	4.3	-	5.0	4.3	-	-	3.5	2.0	-	
see 3561 3585 -PHENYLALANINE' ⁴	110	60.0	10.0	268	60.0	_	_	-	_	_	Milk
					-						products-6 Condiment relishes-10 Confection

 $^{^{\}rm (c)}{\rm To}$ be used at not more than 10.0 ppm in the finished food. $^{\rm (d)}{\rm To}$ be used in cocoa substitute only.

Sweet sauce-220

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other use Categories
3586											
2-PHENYL-3-(2-FURYL)- PROP-2-ENAL 3587	2.0	1.0	-	_	2.0	-	-	1.0	-	-	Confectionery & frosting-2.0
2(10)-PINEN-3-OL 2-Pinen-4-ol	1.0	1.0	-	1.0	1.0	-		1.0	-	-	
see 3594 Pinocarveol see 3587 Piperitenone											
see 3560 3588 1,3-PROPANEDITHIOL ⁽⁴⁾	0.2	_	0.2	_	_	0.2	0.2	_		0.2	Nut
1-Propenyl methyl disulfide see 3576 2-Propenyl polysulfides see 3533 3589											products-0.2
RESORCINOL	15.0	-	5.0	-	-	5.0	10.0	-	-	5.0	Condiments & relishes—5.0; Household seasoning & flavors—10.0
Tirpilene see 3558 α-Terpinene see 3558 γ-Terpinene see 3559 1-Terpineol see 3563 β-Terpineol see 3564											
3590 ∆-TETRADECALACTONE	40.0	_	30.0	30.0	-	15.0	30.0	-	-	15.0	Fats & oils-30.0; Milk products-20.0; Cheese-30.0; Poultry-30.0; Confectionery & frost- ing-30.0; Im-
									,	e?	itation dairy products—40.0; Hard can- dy—15.0; Household seasoning & flavors—15.0
3591 THEOBROMINE ¹⁴⁷	1050	-	-	4020	795	_		-	-		Milk products—990; Confectionery & frost- ing—4020; Sweet sauces—3300
Tetradecanedioic acid cyclic ethylene glycol diester see 3543 3,5,5-Trimethyl-2-cyclo- hexen-1-one see 3553											
3592 2,2,3-TRIMETHYLCYCLOPENT- 3-EN-1-YLACETALDEHYDE	8.0	-	-	-	-	-	-	-	5.0	-	Condiments & relishes-5.0; Reconstituted vegetables-5.0

-Concluded on page 70

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(*)Substance has not been covered in a Scientific Literature Review nor is it presently scheduled for future coverage.
(*)To be used at not more than 10.0 ppm in the finished food.
(*)To be used in cocoa substitute only.

11. GRAS Substances . . .

Substance		Frozen Dairy	Meat Products	Soft Candy	Gelatins & Puddings	Soups	Snack Foods	Nonalcoholic Beverages	Alcoholic Beverages	Gravies	Other use Categories
3593 1,2,3-TRIS [1'-ETHOXY) ETHOXY]-PROPANE	308	51.3	_	128	255	_	-	58.3	51.1	-	Milk products—51.3; Processed fruit—51.3; Fruit ices—51.3; Condiments & relishes—255; Confectionery & frost- ing—128; Jams & jellies—255; Sweet sauce—255; Nut products—58.3; Imitation dai- ry products—51.3; Hard can- dy—128; Chewing gum—1442; Household seasoning & flavors—255
3594 VERBENOL	1.0	1.0	-	1.0	1.0	-	-	1.0	_	-	
3595 2,5-XYLENOL	4.0	_	2.0	-		2.0	-	-	-	2.0	Nut products—2.0; Instant coffee & tea—2.0; Household seasoning & flavors—2.0
3596 3,4-XYLENOL	4.0	_	2.0	-	-	2.0		-	-	2.0	Nut products—2.0; Instant coffee & tea—2.0; Household seasoning & flavors—2.0

⁽a) Total dithiol added to any food not to exceed 1.0 ppm.
(b) Substance has not been covered in a Scientific Literature Review nor is it presently scheduled for future coverage.
(c) To be used at not more than 10.0 ppm in the finished food.
(d) To be used in cocoa substitute only.

EPA-APPROVED MISSOURI REGULATIONS—Continued								
1	Missouri citation		Title	State effec- tive date	EF	Explanation		
106.400		* .	* Restriction of Emission late Matter from Ind esses.		02/28/11		* insert FEDERAL REGISTER imber where the docu- ins].	*
*		*	*	*		*	*	*

[FR Doc. 2013-03769 Filed 2-19-13; 8:45 am] BILLING CODE 6560-50-P

Exhibit I

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0065; FRL-9378-1]

3-decen-2-one; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA). ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical pesticide, 3-decen-2-one, in or on potatoes when applied as a postharvest potato sprout inhibitor and used in accordance with label directions and good agricultural practices. On behalf of AMVAC Chemical Corporation (AMVAC), Technology Sciences Group, Inc. (TSG) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum

DATES: This regulation is effective February 20, 2013. Objections and requests for hearings must be received on or before April 22, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

permissible level for residues of 3-

decen-2-one under the FFDCA.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2010-0065, is available at http://www.regulations.gov or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through

Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at http://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT:

Colin G. Walsh, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 308-0298; email address: walsh.colin@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS) code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http:// www.ecfr.gov/cgi-bin/textidx?&c=ecfr&tpl=/ecfrbrowse/Title40/ 40tab 02.tpl. To access the OCSPP test guidelines referenced in this document electronically, please go to http://www.epa.gov/ocspp and select "Test Methods and Guidelines."

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0065 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 22, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0065, by one of the following methods:

- Federal eRulemaking Portal: http:// www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- Mail: OPP Docket, Environmental Protection Agency Docket Center (EPA/ DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.
- Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at http:// www.epa.gov/dockets/contacts.htm.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at http://www.epa.gov/dockets.

II. Background and Statutory Findings

In the Federal Register of March 10, 2010 (75 FR 11171) (FRL–8810–8), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 9F7670) by TSG, 1150 18th Street NW., Suite 1000, Washington, DC 20036, on behalf of AMVAČ, 4695 MacArthur Court, Suite 1250, Newport Beach, CA 90660. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of 3-decen-2-one. This notice referenced a summary of the petition prepared by the petitioner, TSG (on behalf of AMVAC), which is available in the docket via http:// www.regulations.gov. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit VII.C.

During the initial review of the petition, EPA determined that the data and/or information submitted was insufficient to support the use of the active ingredient, 3-decen-2-one, in or on all food commodities. The petitioner submitted additional data and filed a revised petition (PP 9F7670), proposing to establish an exemption from the requirement of a tolerance for residues of 3-decen-2-one in or on stored potatoes only. A Notice of Filing, allowing for a 30-day comment period, was published in the Federal Register of March 14, 2012 (77 FR 15012) (FRL-9335-9). No comments were received following this publication.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance exemption and to "ensure that there is a reasonable certainty that no

harm will result to infants and children from aggregate exposure to the pesticide chemical residue. * * *" Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider "available information concerning the cumulative effects of [a particular pesticide's] * * * residues and other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information to human risk. EPA also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A. Overview

3-decen-2-one is a naturally occurring biochemical substance, as defined in 40 CFR 158.2000(a)(1), with a history of unremarkable human exposure. 3decen-2-one functions as a plant growth regulator, affecting plant growth by increasing tuber respiration. Data on file indicate that 3-decen-2-one interferes with membrane integrity, which results in increased oxidative stress, desiccation, and rapid necrosis of the meristems and surrounding sprout tissues. Thus, 3-decen-2-one inhibits sprouting with no observed effects on the potato, potato sweetening, or processing quality. Based on this information, EPA considers the mode of action to be non-toxic (Ref. 1).

3-decen-2-one is approved by the U.S. Food and Drug Administration (FDA) as a synthetic flavoring agent and adjuvant that may be directly added to food (21 CFR 172.515). A report by an independent panel of experts retained by the Flavor and Extract Manufacturer's Association (FEMA) states 3-decen-2-one is considered safe for its intended use when added at an average maximum level of 19 ppm in baked goods, 7.8 ppm in soft candy, 5.8 ppm in frozen dairy products, 4.8 ppm in gelatins and puddings, 4.3 ppm in non-alcoholic beverages, and 4.0 ppm in alcoholic beverages (Oser & Ford, 1978) (Ref. 2).

3-decen-2-one has been well characterized and studied with respect to its metabolism and, more importantly, its natural occurrence in many foods that are common in the human diet including yogurt, skipjack tuna, edible porcini mushrooms and Iberian ham (Ref. 2). Additionally, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has reported that 3-decen-2-one, a structural class II flavoring agent, is one in a group of compounds that have been identified in fruits, vegetables, spices, cocoa, coffee and tea. JECFA concluded that there are no safety concerns at current intake levels when 3-decen-2-one is used as a flavoring agent (Ref. 2).

As stated previously in this unit, 3decen-2-one is a substance that exhibits a non-toxic mode of action. In humans, this substance readily metabolizes into innocuous compounds (Ref. 1). Based on information submitted in support of this petition (summarized in Unit III.B.) and the comprehensive risk assessment conducted by the Agency, EPA concludes that there is a reasonable certainty of no harm from aggregate exposures to 3-decen-2-one, including the consumption of potatoes treated with this active ingredient in accordance with label directions and good agricultural practices. EPA has made this determination for the following reasons:

- 1. Available toxicology data and information indicate that the active ingredient is of low acute toxicity (with the exception that it is an eye and skin irritant) and is not a developmental toxicant, a mutagen, or toxic via repeat oral exposure;
- 2. Available information from the scientific literature indicate humans are already exposed to 3-decen-2-one in the diet from foods that naturally contain the chemical and from foods to which the chemical has been added as a food additive at levels higher than what will occur from pesticide use;
- 3. Metabolism data and information on the chemical indicate that it is metabolized into innocuous substances in humans that present no toxicological or dietary concern; and
- 4. Deterministic exposure analyses suggest that dietary exposure to the chemical as a pesticide is likely to be less than dietary exposure to the chemical as a food additive, thus as a natural constituent in foods, the pesticidal use of 3-decen-2-one is not likely to result in a significant increase in overall dietary exposure (Ref. 2).

B. Toxicity

The following is a summary of EPA's review of the toxicity profile of this biochemical.

1. Acute toxicity (OCSPP Guideline Nos. 870.1100, 870.1200, 870.1300, 870.2400, 870.2500, and 870.2600; Master Record Identification (MRID) Nos. 47942609, 47942610, 47942611, 47942612, 47942613, and 47942614). The petitioner submitted acute toxicity studies conducted on the technical grade material to EPA. Results of the acute toxicity testing indicate that 3decen-2-one is of low acute toxicity with the exception that the substance is an eye and skin irritant. Acute oral toxicity (rat): $LD_{50} > 5,000$ mg/kg; Acute dermal toxicity (rat): $LD_{50} > 5,000 \text{mg/kg}$; Acute inhalation toxicity (rat): LC₅₀ = 0.52-2.04 mg/L (male) and LC₅₀ > 2.04mg/L (female); Primary eye irritation (rabbit): moderately irritating; Primary dermal irritation (rabbit): Severely irritating; Dermal sensitization (guinea pig): not a dermal sensitizer (Ref. 3).

2. 90-day oral toxicity (OCSPP Guideline No. 870.3100; MRID Nos. 47942617 and 48422301). A subchronic 90-day oral toxicity study on the technical grade material was not conducted. In lieu of the study, EPA used a weight-of-the-evidence (WOE) approach to estimate the likelihood of potential of toxicity from repeat oral exposure to this substance (Ref. 2). EPA considered the following evidence:

Lack of toxicological endpoints;

ii. Metabolic pathways;

iii. Lack of incidents associated with naturally occurring levels of 3-decen-2one in foods; and

iv. FDA's approval of this biochemical as a direct food additive.

First, using an expert system computer program (DEREK Nexus), EPA identified two potential toxicological endpoints for 3-decen-2-one (potential dermal sensitization and in vitro chromosome damage); however, followup studies did not support these as toxicological endpoints. Second, the metabolic pathways of 3-decen-2-one have been characterized and demonstrate that the biochemical is metabolized into innocuous compounds that are either excreted or further metabolized in the fatty acid pathway or citric acid cycle. Third, 3-decen-2-one occurs naturally in some foods and has been used as a food additive without specific reports of adverse effects. Finally, as noted in this unit, FDA has approved the use of 3-decen-2-one as a synthetic flavoring agent and adjuvant that may be directly added to food. Based on this evidence, EPA concludes that 3-decen-2-one has relatively low toxicity.

3. Prenatal developmental toxicity (OCSPP Guideline Ño. 870.3700; MRID No. 48970303). An acceptable prenatal developmental toxicity study was submitted. In the study, Crl:CD Sprague-Dawley rats were administered doses of AMV-1018 (99.81% purity 3-decen-2one) by gavage at 0, 100, 300 or 1,000 mg/kg/day from day 6 to day 19 of gestation. Each treatment group consisted of 24 female rats:

i. The control group which received

corn oil and

ii. The test substance vehicle group. No maternal deaths or clinical signs related to treatment were observed in the study. Salivation was observed in all animals in the intermediate- and highdose groups during the treatment period. Chin rubbing, which is associated with salivation, was observed in some animals in the high-dose group. These observations were considered to be attributable to the palatability of the test substance and not toxicologically significant. Bodyweight gain in the lowand intermediate-dose groups was not affected by treatment. When compared to the control group, overall mean bodyweight gain in the high-dose group was slightly low during gestation, which was associated with slightly lower food consumption in the high-dose group. The bodyweight gain effect is considered to be attributable to the palatability of the test substance and not toxicologically significant. Food consumption in the low- and intermediate-dose groups was unaffected by treatment. Gravid uterine weights were not affected by treatment in any group. There were no maternal treatment-related macroscopic effects. All females in each test group were pregnant. Mean corpora lutea, implantations, early, late and total resorption counts, live young, sex ratio, pre- and post-implantation loss, litter weight, placental weight, male and female fetal weight and overall fetal weight were all considered to be unaffected by treatment at all doses. In all dose groups, no relationship to treatment was observed in the incidence of major and minor fetal abnormalities and skeletal variants. There was a slight increase in the percentage of incidences of fetuses with 13/14 and 14/14 ribs in all dose groups when compared to the control group, but the incidences were similar to historical control data, and in the absence of other related findings in the study, the observations were not considered to be treatment related. Based on the lack of systemic maternal and fetal toxicity, the no-observedadverse-effect-level (NOAEL) for maternal and fetal (developmental) toxicity is 1,000 mg/kg/day (Ref. 2).

4. Mutagenicity (OCSPP Guideline Nos. 870.5100, 870.5300, and 870.5395; MRID Nos. 47942616, 47942615, and 48412402). Three mutagenicity studies were submitted. In a reverse mutation assay, AMV-1018, containing 98% of the active ingredient 3-decen-2-one, was investigated for its potential to induce gene mutations via a plate incorporation test and a pre-incubation test. Each experiment was conducted with five tester strains of Salmonella typhimurium, six different test substance concentrations (0.0316, 0.100, 0.316, 1.0, 2.5 and 5.0 μL/plate, and control scenario), and with and without metabolic activation. According to the results of this study, no biologically relevant increases in revertant colony numbers of any of the five tester strains were observed following treatment with AMV-1018 at any concentration level, neither in the presence or absence of metabolic activation, in either experiment. In the pre-incubation experiments, cytotoxicity was noted in all five tester strains at a dose concentration of 5.0 µL/plate without metabolic activation and in tester strain TA 102 at a dose concentration of 5.0 μL/plate with metabolic activation. The reference mutagens employed in the control scenarios induced a distinct increase in revertant colonies, indicating the validity of the experiments. Therefore, the test substance is considered to be nonmutagenic in this bacterial reverse mutation assay (Ref. 3).

In a mammalian cell gene mutation assay, mouse lymphoma cells cultured in vitro were exposed to AMV-1018 (3decen-2-one; 98.57% active ingredient) in dimethyl sulfoxide (DMSO) at the various concentrations for 4 and 24 hours with and without metabolic activation. The S9 fraction (for metabolic activation) was derived from the livers of male Wistar rats induced with phenobarbital (80 mg/kg bw) and β-Naphthoflavone (100 mg/kg bw). The solvent DMSO served as a negative control in the presence and absence of S9. Benzo(α)pyrene (BP) served as a positive control in the presence of S9. Ethylmethanesulfonate (EMS) and methylmethanesulfonate (MMS) served as positive controls in the absence of S9. Selection of test substance concentrations were based on a preexperiment for cytotoxicity. No precipitation of the test substance was noted in the experiments. Growth inhibition was noted in all experiments (+/-S9), with marked cytotoxicity seen in several cases (one incident less than 10%, several less than 20%). The pH values for the highest concentrations

tested were within the physiological range. The osmolality for the solvent controls as well as for the highest test concentrations was found to be 465 mosmol/kg. Thus, the osmolality was above the physiological range. Test substance was positive for mutagenicity in the 24 hour exposure without metabolic activation and equivocal results with metabolic activation. The mouse lymphoma results are considered equivocal because it is not clear whether the positive results would translate into an in vivo system based on the increased osmotic pressure and marked cytotoxicity noted during the experiment (Ref. 3).

A Tier II in vivo mammalian erythrocyte micronucleus test guideline study was submitted due to the equivocal results found in the mouse lymphoma assay. The test substance for the study was AMV-1018, containing 98.0% 3-decen-2-one. The test substance was prepared with cottonseed oil and the volume administered intraperitoneal to the 5 male and 5 female mice was 10 mL/kg bw. A range finding study was performed prior to the experiment to determine the maximum tolerable dose (MTD). The MTD was determined to be 50%/kg bw, which is equivalent to an application of 10 mL/kg bw of 5% v/v test item solution. The three dose levels used in the experiment were 1 MTD, 0.5 MTD, and 0.2 MTD, which is equivalent to 50%/kg bw, 25%/kg bw, and 10%/kg bw, respectively. The animals treated with a dose of 0.2 MTD showed no signs of systemic toxicity after treatment, whereas the animals at 1 MTD and 0.5 MTD showed signs of toxicity including reduction of spontaneous activity, prone position, clonic convulsion, ataxia, constricted abdomen, piloerection, half eyelid closure, diarrhea, cramps, and loss of weight. Peripheral blood samples were taken at 44 and 68 hours after a single application of the test item solution for micronuclei analysis. All mean values of micronuclei were within range or decreased compared to the corresponding negative control in all dose groups. The positive control used cyclophosphamide (40 mg/kg bw), which showed significant increase in micronucleus frequency and was used to validate the assay. A nonparametric Mann-Whitney Test was performed and showed no statistically significant increase (p<0.05) of micronuclei cells in any dose group. The test material, AMV-1018 (98% 3-decen-2-one), is considered non-mutagenic with respect to clastogenicity and aneugenicity based on the test item material showing no signs of induction of structural or

numerical chromosomal damage in the immature erythrocytes of the mice (Ref. 1).

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

In addition to the natural presence and the deliberate addition of 3-decen-2-one in other foods, people will be exposed 3-decen-2-one through the consumption of treated potatoes. A qualitative risk assessment was conducted for the chemical to assess potential risks (if any) from dietary exposure.

1. Food. Dietary exposure to 3-decen-2-one is already occurring, given that this substance is a component of and/or is used as a flavoring agent in many foods that are commonly consumed by humans. When 3-decen-2-one is applied as a potato sprout inhibitor and used in accordance with good agricultural practices and label directions, the aforementioned dietary exposure is not likely to be substantially increased.

A deterministic quantitative evaluation of potential dietary exposure to children (1 to 2 years) from consumption of pesticide-treated potatoes was conducted and compared to estimated dietary exposure to 3decen-2-one as a natural constituent of food and as a food additive. Based on the results of the analysis, EPA has concluded that dietary exposure to residues of 3-decen-2-one when used as a pesticide will be considerably less than dietary exposure to the chemical as a naturally occurring constituent in food and/or as a food additive. This conclusion is supported by data obtained from the residue study specifically on baked potatoes, which demonstrated that residues of 3-decen-2-one decline over time and are reduced when potatoes are cooked (Ref. 2).

Based on the information in this unit, which includes an estimation of potential dietary exposure to 3-decen-2-one from the consumption of treated potatoes, the Agency concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from dietary exposure to the pesticidal residues of 3-decen-2-one in food.

2. Drinking water exposure. Based on the proposed use pattern of the active ingredient as a potato sprout inhibitor used in indoor settings, residues in drinking water are not anticipated if products are used according to good agricultural practices and label instructions. Products containing the active ingredient will be used in indoor commercial settings only; therefore, 3decen-2-one residues in drinking water are highly unlikely. In the unlikely event that exposure via drinking water does occur, the health risk would be expected to be minimal based on the low acute oral toxicity of 3-decen-2-one.

B. Other Non-Occupational Exposure

Non-occupational exposure is not expected from the postharvest use of 3-decen-2-one on stored potatoes via a closed system. Any exposure is expected to be occupational in nature.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance exemption, EPA consider "available information concerning the cumulative effects of [a particular pesticide's] * * residues and other substances that have a common mechanism of toxicity."

EPA has not found 3-decen-2-one to share a common mechanism of toxicity with any other substances, and 3-decen-2-one does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 3-decen-2-one does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine chemicals that have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at http://www.epa.gov/pesticides/ cumulative.

VI. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an

additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X, or uses a different additional or no safety factor when reliable data are available to support a different additional or no safety factor.

Because there are no threshold effects associated with this biochemical, an additional margin of safety for infants and children is not necessary.

EPA has determined that there are no foreseeable dietary risks to the U.S. population, including infants and children, from the use of 3-decen-2-one as a pesticide on stored potatoes when label instructions and good agricultural practices are followed. The available data and information indicate that the chemical:

- 1. Is of low toxicity and is not a developmental toxicant;
 - 2. Naturally occurs in the human diet;
- 3. Has been approved by FDA for use in foods as a food additive without limitation; and
- 4. Is metabolized into innocuous substances.

Additionally, basic exposure analyses that were specifically conducted for children aged 1–2 years suggest that dietary exposure from ingestion of the chemical as a pesticide is likely to be less than dietary exposure from ingestion of the chemical as a food additive and/or as a constituent that naturally occurs in foods (Ref. 2). When compared to the amount of 3-decen-2-one that is likely already consumed in the human diet, dietary exposure from pesticidal use is not anticipated to significantly increase overall dietary exposure of infants and children.

Therefore, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of 3-decen-2one when it is used as labeled and in accordance with good agricultural practices. Such exposure includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion because the data and information available on 3-decen-2-one do not demonstrate significant toxic potential to mammals, including infants and children.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes for the reasons stated in Unit VI. and because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. In this context, EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for 3-decen-2-one.

C. Response to Comments

In response to a Notice of Filing that published in the Federal Register of March 10, 2010, EPA received a comment from Michael J. Keim (Keim Aerosol Technologies) in docket ID number EPA-HQ-OPP-2010-0065. Mr. Keim believes that EPA has not been adequately informed [by the petitioner] with respect to the use of chemicals for the postharvest treatment of stored potatoes and that such use poses a risk to humans and the environment. His conclusion is based on his experience with the use of chlorpropham (CIPC), a conventional chemical that is applied (via thermal fog generator) in the same manner as the proposed product. Mr. Keim states that half of CIPC applied to stored potatoes does not deposit on the potatoes and, therefore, is expelled to the outside environment. As a result of this application method, Mr. Keim contends that EPA has not adequately assessed the risks to non-target organisms and worker/handlers.

EPA notes that the comment from Mr. Keim pertains mainly to the application equipment used on the proposed label, which would be more applicable to the Notice of Receipt (see the **Federal Register** of March 10, 2010 (75 FR 11175) (FRL-8811-6)) for 3-decen-2-one, and to the conventional chemical, CIPC, which, from a toxicological perspective, is quite different from 3-decen-2-one. Nonetheless, EPA will address Mr. Keim's comment in this document.

EPA would first direct the commenter to the documents in the docket for the Registration Review of CIPC (docket ID number EPA-HQ-OPP-2010-0923) as the Agency's Health Effects Division (HED) and Environmental Fate and Effects Division (EFED) have already responded to Mr. Keim's comments regarding the application equipment used for CIPC products and the potential for exposure based on the displacement and degradation of CIPC.

As stated in the EPA memoranda listed in Unit IX., the Agency received and reviewed product chemistry, residue, mammalian toxicity, and nontarget organism data and/or information for this new active ingredient, 3-decen-2-one, as outlined in 40 CFR 158.2030, 158.2040, 158.2050, and 158.2060. The data and information submitted to EPA indicate that 3-decen-2-one is of low toxicity (with the exception that it is an eye and dermal irritant), no developmental effects were found at the highest dose tested (NOAEL = 1,000 mg/ kg/day), and 3-decen-2-one is not mutagenic. With regard to worker exposure, the thermal fogging application method on the proposed product label used for stored potatoes is an automated system and, as such, EPA considers this method a closed-delivery system and does not expect occupational handler exposure. The only occupational exposure expected is the handling of the product prior to application, which is mitigated by appropriate precautionary statements and personal protective equipment (PPE) requirements listed on the label. EPA has not identified any toxic endpoints for non-target mammals, birds, plants, aquatic, or soil organisms and has no concerns for any non-target organisms exposed to 3-decen-2-one when used in accordance with approved label directions. The petitioner did submit information that estimated the physical and chemical properties for 3decen-2-one by using QSAR modeling based on the Estimation Programs Interface Model (EPI SuiteTM 4.0). Using Henry's Law, which states that the solubility of a gas in a liquid is directly proportional to the partial pressure of the gas above the liquid, 3-decen-2-one is estimated to be 5.4×10^{-4} atm·m³/ mol and indicates that the active ingredient has a potential for volatility from water or moist soil. In soil, the estimated Koc of 165.2-860.9 L/kg

indicates that 3-decen-2-one would have medium to low mobility in soil. In water, an estimated log K_{ow} of 3.28 and an estimated bioconcentration factor (BCF) of 67.41 L/kg wet-wt indicate that bioaccumulation in aquatic organisms is unlikely. In the air, atmospheric oxidation by hydroxyl radicals' reaction is expected to occur with estimated halflives of 1.9–2.2 hours. The probability of biodegradation of 3-decen-2-one was evaluated using EPI SuiteTM 4.0 in the BIOWIN module. Various models in the BIOWIN module predicted rapid biodegradation of 3-decen-2-one. Based on a total air volume in a potato warehouse of 1,910 m³ and the total applied 3-decen-2-one of 122,475 g calculated by the petitioner, the maximum air concentration of 3-decen-2-one in a potato warehouse was estimated to be 64.14 mg/L of air. With an estimated ventilation rate of 825 m3 of air/min, the air volume in a potato warehouse will be exchanged within 2.5 minutes when the vents to the outdoors are opened. Thus, the concentration emitted will be rapidly diluted in the outside air, which further demonstrates insignificant exposure to non-target organisms. In summary, given that 3decen-2-one is applied indoors in a closed system, has low toxicity, is naturally occurring in foods that are common in the human diet, and presents little, if any, risk to non-target organisms, EPA concludes that pesticide products containing this new active ingredient, 3-decen-2-one, are not expected to cause unreasonable adverse effects on the environment (includes consideration of risks to workers/ handlers and non-target organisms).

VIII. Conclusion

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of 3-decen-2-one. Therefore, an exemption from the requirement of a tolerance is established for residues of the biochemical pesticide, 3-decen-2-one, in or on potatoes when applied as a postharvest potato sprout inhibitor and used in accordance with label directions and good agricultural practices.

IX. References

The references used in this document are available as "Supporting & Related Material" within docket ID EPA-HQ-OPP-2010-0065 at www.regulations.gov.

 U.S. EPA. 2011. Memorandum from Colin G. Walsh thru Angela L. Gonzales to Linda A. Hollis. Joint Science Review with Health Canada Pest Management

- Regulatory Agency (PMRA) in Support of the Registration of AMV-1018 Technical (EPA File Symbol No. 5481-LAI), a Manufacturing-Use Product (MP), Containing 98.0% of 3-decen-2-one as its Active Ingredient and Tolerance Exemption Petition Review in Support of 3-decen-2-one. U.S. Environmental Protection Agency, Office of Pesticide Programs. December 20, 2011.
- U.S. EPA. 2013. Memorandum from Angela L. Gonzales thru Felecia A. Fort to Colin G. Walsh. Joint Science Review with Health Canada Pest Management Regulatory Agency (PMRA) in Support of the Registration of AMV-1018 Technical Containing 98.0% of 3-decen-2-one as its Active Ingredient. U.S. Environmental Protection Agency, Office of Pesticide Programs. January 3, 2013.
- 3. U.S. EPA. 2010. Memorandum from Gina M. Casciano and Colin G. Walsh thru Russell S. Jones to Driss Benmhend. Revised Hazard Assessment for Tier I Human Health Toxicity in Support of the Registration of AMV–1018 Technical, Containing 3-decen-2-one as its Active Ingredient (Amends EPA Memorandum from Gina M. Casciano and Colin G. Walsh through Russell S. Jones to Driss Benmhend dated June 16, 2010). U.S. Environmental Protection Agency, Office of Pesticide Programs. December 7, 2010.

X. Statutory and Executive Order Reviews

This final rule establishes a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the

Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 et seq.).

This action does not involve any technical standards that would require EPA consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 5, 2013.

Steven Bradbury,

 $Director,\,Office\,of\,Pesticide\,Programs.$

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In subpart D, add § 180.1318 to read as follows:

§ 180.1318 3-decen-2-one; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide, 3-decen-2-one, in or on potatoes when applied as a potato sprout inhibitor and used in accordance with label directions and good agricultural practices.

[FR Doc. 2013–03758 Filed 2–19–13; 8:45 am] BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R7-ES-2012-0009; 4500030113]

RIN 1018-AY40

Endangered and Threatened Wildlife and Plants; Special Rule for the Polar Bear Under Section 4(d) of the Endangered Species Act

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule; availability of environmental assessment and Finding of No Significant Impact.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), amends it regulations which implement the Endangered Species Act of 1973, as amended (ESA), to create a special rule under authority of section 4(d) of the ESA that provides measures that are necessary and advisable to provide for the conservation of the polar bear (*Ursus maritimus*), while also including appropriate prohibitions from section 9(a)(1) of the ESA.

DATES: This rule becomes effective on March 22, 2013.

ADDRESSES: Document Availability: The final rule, final environmental assessment, and finding of no significant impact are available for viewing on http://www.regulations.gov under Docket No. FWS—R7—ES—2012—0009. Supporting documentation we used in preparing this final rule is available for public inspection, by appointment, during normal business hours, at the Marine Mammal Management Office, U.S. Fish and Wildlife Service, 1011 East Tudor Road, Anchorage, AK 99503.

FOR FURTHER INFORMATION CONTACT: Charles Hamilton, Marine Mammals Management Office, U.S. Fish and Wildlife Service, Region 7, 1011 East Tudor Road, Anchorage, AK 99503; telephone 907–786–3309. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, 24 hours a day, 7 days a week.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why We Need To Publish a Final Rule

The Service was challenged via litigation on our December 16, 2008, final special rule under section 4(d) of the ESA (hereafter referred to as 4(d) special rule) (16 U.S.C. 1531 et al), for the polar bear. The District Court for the District of Columbia (Court) found that, although the final 4(d) special rule published December 16, 2008 (73 FR 76249) for the polar bear was consistent with the ESA, the Service violated the National Environmental Policy Act (42 U.S.C. 4321 et seq.) (NEPA) and the Administrative Procedure Act (5 U.S.C. 500 et seq.) by failing to conduct a NEPA analysis when it promulgated the final rule. On November 18, 2011, the Court vacated the final 4(d) special rule and ordered that the May 15, 2008, interim 4(d) special rule take effect until superseded by a new final 4(d) special rule. The Service is therefore promulgating a new final 4(d) special rule with appropriate NEPA analysis. Through the NEPA process, the Service fully considered a suite of alternatives for the special rule.

What is the effect of this rule?

The 2008 listing of the polar bear as a threatened species under the ESA is not affected by this final rule. In addition, nothing in this rule affects requirements applicable to polar bears under any other law such as the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 et seq.). On-the-ground conservation management of the polar bear under both the May 15, 2008, interim 4(d) special rule and the December 16, 2008, final 4(d) special rule, were substantively similar; this final 4(d) special rule reinstates the regulatory parameters afforded the polar bear under the December 16, 2008 rule, which was in place until November 18, 2011. Because this rule adopts a regulatory scheme that has governed polar bear management for over 30 years, the requirements placed on individuals, local communities, and industry are not substantively changed.

The Basis for Our Action

Under section 4(d) of the ESA, the Secretary of the Interior (Secretary) has discretion to issue such regulations as he deems necessary and advisable to provide for the conservation of threatened species. The Secretary also has the discretion to prohibit by regulation with respect to a threatened species any act prohibited by section 9(a)(1) of the ESA.

Exercising this discretion, which has been delegated to the Service by the Secretary, the Service has developed general prohibitions that are appropriate for most threatened species in 50 CFR 17.31 and exceptions to those prohibitions in 50 CFR 17.32. But for the polar bear, the Service has determined that a 4(d) special rule is appropriate. This 4(d) special rule adopts the existing conservation regulatory requirements under the MMPA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES; 27 U.S.T. 1087) as the primary regulatory provisions for the polar bear. If an activity is authorized or exempted under the MMPA or CITES, no additional authorization under the ESA regulations is required, although consultation under section 7 of the ESA will also still be required if there is a Federal nexus. But if the activity is not authorized or exempted under the MMPA or CITES, and that activity would result in an act otherwise prohibited under the general ${\tt ESA}$ regulatory prohibitions for threatened species, then the general prohibitions at 50 CFR 17.31 would apply, and we would require a permit for the activity as specified in our ESA regulations.

Under this rule, incidental take caused by activities within the United States but outside the current polar bear range would not be subject to the takings prohibition under 50 CFR 17.31 as it is for most threatened species, but would remain subject to the taking prohibition in the MMPA and, if there is a Federal nexus, to the consultation requirement of section 7 of the ESA.

Previous Federal Actions

On May 15, 2008, the Service published a final rule listing the polar bear (*Ursus maritimus*) as a threatened species under the ESA (73 FR 28212). At the same time, the Service also published an interim special rule for the polar bear under authority of section 4(d) of the ESA that provided measures necessary and advisable for the conservation of the polar bear and prohibited certain acts covered in section 9(a)(1) of the ESA (73 FR 28306);

Page 1 of 7

AMVAC MSDS No.: 369_6

2

MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: SmartBlock®; SmartBlock® 98% Technical

GENERAL USE: Potato Sprout Inhibitor

PRODUCT DESCRIPTION: Clear colorless liquid with a fruity, jasmine-like

odor

ACTIVE COMPOUND: 3-Decen-2-one MOLECULAR FORMULA (a.i.): C10H18O **MOLECULAR WEIGHT(a.i.): 154.25**

EPA REGISTRATION NUMBER: 5481-568; 5481-571

HEALTH CANADA REGISTRATION NUMBER: 30889; 39888

MSDS NUMBER: 369 6

CURRENT REVISION DATE: 16 AUGUST 2013

SUPPLIER:

AMVAC CHEMICAL CORPORATION

4100 E. Washington Blvd. Los Angeles, CA 90023-4406

PHONE: 323-264-3910

FAX: 323-268-1028

EMERGENCY TELEPHONE NUMBERS:

PRODUCT USE:

888-462-6822 **TRANSPORTATION (24 HOURS)**

CHEMTREC:

800-424-9300

OTHER (24 HOURS)

MEDICAL:

888-681-4261

COMPOSITION/INFORMATION ON INGREDIENTS 2.

COMPONENT	CAS No.	WT %
3-Decen-2-one	10519-33-2	98+%
Inert Ingredients		< 2%

OSHA HAZARDOUS COMPONENTS (29 CFR1910.1200)

COMPONENT	HAZARD	OSHA PEL*/ACGIH TLV*
3-Decen-2-one	None established	Not established. A PEL of 200 mg/m³ is suggested by Amvac until an actual PEL can be established.
¥	T::4-01 TYY/A	

Exposure Limits 8 hrs. TWA

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

WARNING! Causes skin irritation and substantial but temporary eye injury. Harmful if inhaled. Do not get on skin or on clothing. Avoid contact with eyes. Avoid breathing vapor.

KEEP OUT OF REACH OF CHILDREN.

Do not contaminate bodies of water.

POTENTIAL HEALTH EFFECTS

ROUTE(S) OF ENTRY: Ingestion, inhalation, eye contact, and skin contact.

SIGNS OF ACUTE OVEREXPOSURE: Contact with the skin may cause skin irritation. Contact with the eyes causes tearing and pain that will subside after a short period of time. Inhalation may cause shortness of breath.

SIGNS OF CHRONIC OVEREXPOSURE: None are known.

OTHER POTENTIAL EFFECTS: None are known.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: None are known.

4. FIRST AID MEASURES

EYES: Immediately flush the eyes with copious amounts of clear, cool running water for a minimum of 15 minutes. Hold the eyelids apart during the flushing to ensure rinsing of the entire surface of the eyes and lids with water. Contact a physician immediately. If there will be a delay in getting medical attention, rinse the eyes for at least another 15 minutes.

INHALATION: Remove victim to fresh air. If breathing has ceased, clear the victim's airway and start artificial respiration, preferably mouth-to-mouth. If breathing is difficult, give oxygen. Contact a physician immediately.

INGESTION: Do not induce vomiting. Administer water and call a physician or poison control center immediately. Never give anything by mouth to an unconscious person.

SKIN: Remove contaminated clothing. Wash thoroughly with soap and clean water. If a rash or skin irritation appear, contact a physician immediately.

NOTE TO PHYSICIANS: Treat symptomatically. For further medical information, contact your local poison control center. For other questions AMVAC Chemical Corporation is available 24 hours/day to answer questions on this product. The telephone number is 1-323-264-3910.

AMVAC MSDS No.: 369 6

5. FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES:

Flash Point: 197°F (91°C)

Autoignition Temperature: Not determined

Flammable Limits:

Lower flammable limit: Not determined Upper flammable limit: Not determined

Flammability: This is a combustible liquid that will support fire if it is preheated

(NFPA rating = 1)

EXPLOSIVITY:

Mechanical Impact: Not explosive Static Discharge: Not determined

HAZARDOUS COMBUSTION PRODUCTS: This product may emit hazardous fumes when it is heated excessively or burned. WEAR SELF-CONTAINED BREATHING APPARATUS.

EXTINGUISHING MEDIA: Dry chemical, foam, or carbon dioxide.

FIRE FIGHTING INSTRUCTIONS: Do not breathe fumes. Wear complete firefighting gear, including protective gloves, eye protection and self-contained breathing apparatus. Wash clothing before reuse.

6. ACCIDENTAL RELEASE MEASURES

GENERAL: Keep out of water sources. Wear appropriate personal protective equipment (PPE, Section 8).

SMALL OR LARGE SPILL: Absorb small spills on standard absorbents. Dike large spills and siphon the spill into a container. Clean up residual amounts as a small spill. Wash the location with soap and water. Collect the washings in a hazardous waste container and dispose as a hazardous waste.

7. HANDLING AND STORAGE

HANDLING: Keep this product cool and dry. Keep container closed. Store away from feed, non-target food, and drink. Keep away from children and pets. Wash thoroughly after handling this product.

STORAGE: Store product in its original container in a cool, dry, locked place out of the reach of children.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: Ventilation should be sufficient to minimize exposure to this product.

RESPIRATORY PROTECTION: A properly <u>FIT-TESTED</u> NIOSH/MSHA approved respirator fitted with organic vapor cartridges may be required when working with this product. Specific use regulations are listed on the label.

SKIN PROTECTION: Applicators and other handlers should wear coveralls over long-sleeved shirt and long pants; chemical resistant gloves; socks and chemical resistant footwear. Follow manufacturer's instructions for cleaning/maintaining personal protection equipment (PPE). If no such instructions are available, use detergent and hot water. Keep and wash PPE separately from other laundry.

EYE PROTECTION: Safety glasses with sideshields should be used whenever chemicals are being handled. If there is a possibility of eye contact from splashing or misting, goggles or a full face shield should also be worn.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:

Liquid

APPEARANCE:

Clear colorless liquid

ODOR:

Fruity, jasmine-like odor Not established

ODOR THRESHOLD:

125-126°C (257-259°F)

BOILING POINT: FREEZING/MELTING POINT:

Not determined

SPECIFIC GRAVITY:

0.80 - 0.81 g/mL @ 25°C

BULK DENSITY:

6.68 - 6.76 lb/gal

VAPOR PRESSURE (mm/Hg):

Not determined

PERCENT VOLATILE BY VOL:

> 99%

SOLUBILITY IN WATER:

Insoluble

PARTITION COEFFICIENT (O/W):

Not determined Not determined

pH (5% dispersion): EVAPORATION RATE:

Not determined

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY (Conditions to avoid): This product is stable under normal storage and use conditions.

INCOMPATIBILITY: Strong oxidizing agents

HAZARDOUS DECOMPOSITION PRODUCTS: This product may emit hazardous fumes when it is heated excessively or burned. WEAR SELF-CONTAINED BREATHING APPARATUS when these conditions are present.

HAZARDOUS POLYMERIZATION: This product will not polymerize.

11. TOXICOLOGICAL INFORMATION

GENERAL: Acute toxicological and mutagenicity data for this product are given below. The long-term toxicological properties of this potato sprout inhibitor have not been determined. Care should be taken with chemicals that have not been thoroughly investigated.

INGESTION:

Oral LD₅₀ (female rat):

> 5000 mg/kg (Tox Cat IV)

INHALATION:

Inhalation LC₅₀ (male rat):

> 0.52 < 2.04 mg/l (Tox Cat III)

(female rat):

>2.04 mg/l

DERMAL:

Skin LD₅₀ (rat):

> 5000 mg/kg (Tox Cat IV)

IRRITATION:

Eye irritation (rabbit):

Moderate irritant. (Tox Cat III)

Skin irritation (rabbit):

Severe Irritant (Tox Cat II)

SENSITIZATION:

Sensitizer (guinea pig):

Not a skin sensitizer

TERATOGENICITY: No data are available.

MUTAGENICITY: Non-mutagenic in bacterial reverse mutation assay and no evidence of clastogenicity or aneugenicity in the mouse micronucleus assay. Mouse lymphoma assay showed limited evidence of mutagenicity i.e. without metabolic activation only.

CARCINOGENICITY: No data are available.

REPRODUCTIVE TOXICITY: No data are available.

TOXICOLOGICALLY SYNERGISTIC PRODUCTS: No data are available.

12. ECOLOGICAL INFORMATION

GENERAL: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

13. DISPOSAL CONSIDERATIONS

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed on site (by use according to the label) or in a sanitary landfill or by incineration. Further information can be obtained from the EPA or the equivalent state and local agencies.

CONTAINER DISPOSAL: The containers for this product should be triple-rinsed and disposed in a sanitary landfill or offered back to the refiller for reuse (see the label for more information). Check with EPA, state, and local authorities for the current regulations applicable to your area.

14. TRANSPORTATION INFORMATION

SHIPPING INFORMATION: Based on the hazard information this product is nonhazardous for transport and is not regulated by DOT or ICAO/IATA. The classification of this product is based on the fact that the mist criteria found in 49CFR§173.132(b)(3) will not be met during transportation and therefore the LC₅₀ is not applicable.

TYPICAL PACKAGING:

12.5 gallon drum

15. REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS: This product is registered under EPA/FIFRA Regulations. It is a violation of Federal Law to use this product in any manner inconsistent with its labeling. Read and follow all label directions. This product is excluded from listing requirements under EPA/TSCA.

CANADIAN REGULATIONS: This product is registered under the Pest Control Product Act of Canada. It is a violation of Canadian Law to use this product in any manner inconsistent with its labeling. Read and follow all label directions.

This product has been classified according to the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

SARA TITLE III DATA

Section 311 & 312 Hazard Categories:

Immediate Health Hazard:YesDelayed Health Hazard:NoFire Hazard:NoReactive Hazard:NoSudden Pressure Release Hazard:No

Section 302 Extremely Hazardous Substances: None

Section 313 Toxic Chemicals: None

CERCLA Reportable Quantity (RQ): None

STATE REGULATIONS:

CALIFORNIA (Proposition 65): None

16. OTHER INFORMATION

MSDS STATUS:

Date This Revision: 16 August 2013 Date Previous Revision: 7 February, 2013

Person Responsible for Preparation: Gary A. Braden

REASONS FOR REVISION: Registration of this product in Canada has been completed. Information has been included in sections 1 and 15 to reflect this registration. A typographical error in the transportation information (section 14) has been corrected.

believes that the information is provided for the limited guidance to the user. While AMVAC believes that the information is, as of the date hereof, reliable, it is the user's responsibility to determine the suitability of the information for its purposes. The user is advised not to construe the information as absolutely complete since additional information may be necessary or desirable when particular, exceptional, or variable conditions or circumstances exist (like combinations with other materials), or because of applicable regulations. No express or implied warranty of merchantability or fitness for a particular purpose or otherwise is made hereunder with respect to the information or the product to which the information relates.

AMVAC MSDS No.: 369_6

16. OTHER INFORMATION, cont'd

ABBREVIATIONS:

a.i.	-	Active ingredient
ACGIH	=.	American Conference of Governmental Industrial Hygienists
CAS		Chemical Abstracts Services
CERCLA	-	Comprehensive Environmental Response, Compensation, and
		Liability Act
EINICS	_	European Inventory of Existing Chemical Substances
EPA	-	Environmental Protection Agency
FEMA	_	Federal Emergency Management Agency
FIFRA	_	Federal Insecticide, Fungicide, and Rodenticide Act
IARC	_	International Agency for Research on Cancer
JECFA	-	Joint FAO/WHO Expert Committee on Food Additives
NTP	_	National Toxicology Program
OSHA	-	Occupational Safety and Health Administration
SARA	-	Superfund Amendments and Reauthorization Act
TSCA	-	Toxic Substances Control Act

This is the last page of this MSDS. There should be 7 pages.

AMVAC CHEMICAL CORPORATION

SmartBlock®; SmartBlock® 98% Technical

Page 1 of 7

AMVAC MSDS No.: 369_6

MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: SmartBlock®; SmartBlock® 98% Technical

GENERAL USE: Potato Sprout Inhibitor

PRODUCT DESCRIPTION: Clear colorless liquid with a fruity, jasmine-like

odor

ACTIVE COMPOUND: 3-Decen-2-one MOLECULAR FORMULA (a.i.): C₁₀H₁₈O MOLECULAR WEIGHT (a.i.): 154.25

EPA REGISTRATION NUMBER: 5481-568; 5481-571

HEALTH CANADA REGISTRATION NUMBER: 30889; 39888

MSDS NUMBER:

369 6

CURRENT REVISION DATE: 16 AUGUST 2013

SUPPLIER:

AMVAC CHEMICAL CORPORATION

4100 E. Washington Blvd. Los Angeles, CA 90023-4406 PHONE: 323-264-3910

FAX: 323-268-1028

EMERGENCY TELEPHONE NUMBERS: PRODUCT USE: 888-462-6822

PRODUCT USE: 888-462-68 TRANSPORTATION (24 HOURS)

800-424-9300

CHEMTREC: OTHER (24 HOURS)

MEDICAL:

888-681-4261

2. <u>COMPOSITION/INFORMATION ON INGREDIENTS</u>

COMPONENT	CAS No.	WT %
3-Decen-2-one	10519-33-2	98+%
Inert Ingredients		< 2%

OSHA HAZARDOUS COMPONENTS (29 CFR1910.1200)

COMPONENT	HAZARD	OSHA PEL*/ACGIH TLV*
3-Decen-2-one	None established	Not established. A PEL of 200 mg/m³ is suggested by Amvac until an actual PEL can be established.

* Exposure Limits 8 hrs. TWA

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

WARNING! Causes skin irritation and substantial but temporary eye injury. Harmful if inhaled. Do not get on skin or on clothing. Avoid contact with eyes. Avoid breathing vapor.

KEEP OUT OF REACH OF CHILDREN.

Do not contaminate bodies of water.

POTENTIAL HEALTH EFFECTS

ROUTE(S) OF ENTRY: Ingestion, inhalation, eye contact, and skin contact.

SIGNS OF ACUTE OVEREXPOSURE: Contact with the skin may cause skin irritation. Contact with the eyes causes tearing and pain that will subside after a short period of time. Inhalation may cause shortness of breath.

SIGNS OF CHRONIC OVEREXPOSURE: None are known.

OTHER POTENTIAL EFFECTS: None are known.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: None are known.

4. FIRST AID MEASURES

EYES: Immediately flush the eyes with copious amounts of clear, cool running water for a minimum of 15 minutes. Hold the eyelids apart during the flushing to ensure rinsing of the entire surface of the eyes and lids with water. Contact a physician immediately. If there will be a delay in getting medical attention, rinse the eyes for at least another 15 minutes.

INHALATION: Remove victim to fresh air. If breathing has ceased, clear the victim's airway and start artificial respiration, preferably mouth-to-mouth. If breathing is difficult, give oxygen. Contact a physician immediately.

INGESTION: Do not induce vomiting. Administer water and call a physician or poison control center immediately. Never give anything by mouth to an unconscious person.

SKIN: Remove contaminated clothing. Wash thoroughly with soap and clean water. If a rash or skin irritation appear, contact a physician immediately.

NOTE TO PHYSICIANS: Treat symptomatically. For further medical information, contact your local poison control center. For other questions AMVAC Chemical Corporation is available 24 hours/day to answer questions on this product. The telephone number is 1-323-264-3910.

5. FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES:

Flash Point: 197°F (91°C)

Autoignition Temperature: Not determined

Flammable Limits:

Lower flammable limit: Not determined Upper flammable limit: Not determined

Flammability: This is a combustible liquid that will support fire if it is preheated

(NFPA rating = 1)

EXPLOSIVITY:

Mechanical Impact: Not explosive Static Discharge: Not determined

HAZARDOUS COMBUSTION PRODUCTS: This product may emit hazardous fumes when it is heated excessively or burned. WEAR SELF-CONTAINED BREATHING APPARATUS.

EXTINGUISHING MEDIA: Dry chemical, foam, or carbon dioxide.

FIRE FIGHTING INSTRUCTIONS: Do not breathe fumes. Wear complete firefighting gear, including protective gloves, eye protection and self-contained breathing apparatus. Wash clothing before reuse.

6. ACCIDENTAL RELEASE MEASURES

GENERAL: Keep out of water sources. Wear appropriate personal protective equipment (PPE, Section 8).

SMALL OR LARGE SPILL: Absorb small spills on standard absorbents. Dike large spills and siphon the spill into a container. Clean up residual amounts as a small spill. Wash the location with soap and water. Collect the washings in a hazardous waste container and dispose as a hazardous waste.

7. HANDLING AND STORAGE

HANDLING: Keep this product cool and dry. Keep container closed. Store away from feed, non-target food, and drink. Keep away from children and pets. Wash thoroughly after handling this product.

STORAGE: Store product in its original container in a cool, dry, locked place out of the reach of children.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: Ventilation should be sufficient to minimize exposure to this product.

RESPIRATORY PROTECTION: A properly <u>FIT-TESTED</u> NIOSH/MSHA approved respirator fitted with organic vapor cartridges may be required when working with this product. Specific use regulations are listed on the label.

SKIN PROTECTION: Applicators and other handlers should wear coveralls over long-sleeved shirt and long pants; chemical resistant gloves; socks and chemical resistant footwear. Follow manufacturer's instructions for cleaning/maintaining personal protection equipment (PPE). If no such instructions are available, use detergent and hot water. Keep and wash PPE separately from other laundry.

EYE PROTECTION: Safety glasses with sideshields should be used whenever chemicals are being handled. If there is a possibility of eye contact from splashing or misting, goggles or a full face shield should also be worn.

Liquid

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:

APPEARANCE: Clear colorless liquid

ODOR: Fruity, jasmine-like odor

ODOR THRESHOLD: Not established

BOILING POINT: 125-126°C (257-259°F)

FREEZING/MELTING POINT: Not determined

SPECIFIC GRAVITY: 0.80 - 0.81 g/mL @ 25 °C

BULK DENSITY: 6.68 - 6.76 lb/gal

VAPOR PRESSURE (mm/Hg): Not determined

PERCENT VOLATILE BY VOL: > 99%

SOLUBILITY IN WATER: Insoluble
PARTITION COEFFICIENT (O/W): Not determined

pH (5% dispersion): Not determined Not determined EVAPORATION RATE: Not determined

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY (Conditions to avoid): This product is stable under normal storage and use conditions.

INCOMPATIBILITY: Strong oxidizing agents

HAZARDOUS DECOMPOSITION PRODUCTS: This product may emit hazardous fumes when it is heated excessively or burned. WEAR SELF-CONTAINED BREATHING APPARATUS when these conditions are present.

HAZARDOUS POLYMERIZATION: This product will not polymerize.

Page 5 of 7

AMVAC MSDS No.: 369 6

11. TOXICOLOGICAL INFORMATION

GENERAL: Acute toxicological and mutagenicity data for this product are given below. The longterm toxicological properties of this potato sprout inhibitor have not been determined. Care should be taken with chemicals that have not been thoroughly investigated.

(female rat):

INGESTION:

Oral LD_{50} (female rat):

> 5000 mg/kg (Tox Cat IV)

INHALATION:

Inhalation LC₅₀ (male rat):

> 0.52 < 2.04 mg/l (Tox Cat III)

DERMAL:

Skin LD₅₀ (rat):

> 5000 mg/kg (Tox Cat IV)

IRRITATION:

Eye irritation (rabbit):

Moderate irritant. (Tox Cat III) Severe Irritant (Tox Cat II)

Skin irritation (rabbit): SENSITIZATION:

Sensitizer (guinea pig):

Not a skin sensitizer

>2.04 mg/l

TERATOGENICITY: No data are available.

MUTAGENICITY: Non-mutagenic in bacterial reverse mutation assay and no evidence of clastogenicity or aneugenicity in the mouse micronucleus assay. Mouse lymphoma assay showed limited evidence of mutagenicity i.e. without metabolic activation only.

CARCINOGENICITY: No data are available.

REPRODUCTIVE TOXICITY: No data are available.

TOXICOLOGICALLY SYNERGISTIC PRODUCTS: No data are available.

12. **ECOLOGICAL INFORMATION**

GENERAL: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

13. **DISPOSAL CONSIDERATIONS**

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed on site (by use according to the label) or in a sanitary landfill or by incineration. Further information can be obtained from the EPA or the equivalent state and local agencies.

CONTAINER DISPOSAL: The containers for this product should be triple-rinsed and disposed in a sanitary landfill or offered back to the refiller for reuse (see the label for more information). Check with EPA, state, and local authorities for the current regulations applicable to your area.

14. TRANSPORTATION INFORMATION

SHIPPING INFORMATION: Based on the hazard information this product is nonhazardous for transport and is not regulated by DOT or ICAO/IATA. The classification of this product is based on the fact that the mist criteria found in 49CFR§173.132(b)(3) will not be met during transportation and therefore the LC_{50} is not applicable.

TYPICAL PACKAGING:

12.5 gallon drum

15. REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS: This product is registered under EPA/FIFRA Regulations. It is a violation of Federal Law to use this product in any manner inconsistent with its labeling. Read and follow all label directions. This product is excluded from listing requirements under EPA/TSCA.

CANADIAN REGULATIONS: This product is registered under the Pest Control Product Act of Canada. It is a violation of Canadian Law to use this product in any manner inconsistent with its labeling. Read and follow all label directions.

This product has been classified according to the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

SARA TITLE III DATA

Section 311 & 312 Hazard Categories:

Immediate Health Hazard: Yes
Delayed Health Hazard: No
Fire Hazard: No
Reactive Hazard: No
Sudden Pressure Release Hazard: No

Section 302 Extremely Hazardous Substances: None

Section 313 Toxic Chemicals: None

CERCLA Reportable Quantity (RQ): None

STATE REGULATIONS:

CALIFORNIA (Proposition 65): None

16. OTHER INFORMATION

MSDS STATUS:

Date This Revision: 16 August 2013
Date Previous Revision: 7 February, 2013

Person Responsible for Preparation: Gary A. Braden

REASONS FOR REVISION: Registration of this product in Canada has been completed. Information has been included in sections 1 and 15 to reflect this registration. A typographical error in the transportation information (section 14) has been corrected.

DISCLAIMER: This information is provided for the limited guidance to the user. While AMVAC believes that the information is, as of the date hereof, reliable, it is the user's responsibility to determine the suitability of the information for its purposes. The user is advised not to construe the information as absolutely complete since additional information may be necessary or desirable when particular, exceptional, or variable conditions or circumstances exist (like combinations with other materials), or because of applicable regulations. No express or implied warranty of merchantability or fitness for a particular purpose or otherwise is made hereunder with respect to the information or the product to which the information relates.

AMVAC CHEMICAL CORPORATION SmartBlock®; SmartBlock® 98% Technical

Page 7 of 7

AMVAC MSDS No.: 369_6

16. OTHER INFORMATION, cont'd

ABBREVIATIONS:

a.i.	-	Active ingredient
ACGIH	-	American Conference of Governmental Industrial Hygienists
CAS	-	Chemical Abstracts Services
CERCLA	-	Comprehensive Environmental Response, Compensation, and
		Liability Act
EINICS	-	European Inventory of Existing Chemical Substances
EPA	-	Environmental Protection Agency
FEMA	-	Federal Emergency Management Agency
FIFRA	_	Federal Insecticide, Fungicide, and Rodenticide Act
IARC	_	International Agency for Research on Cancer
JECFA	_	Joint FAO/WHO Expert Committee on Food Additives
NTP	-	National Toxicology Program
OSHA	-	Occupational Safety and Health Administration
SARA	-	Superfund Amendments and Reauthorization Act
TSCA	-	Toxic Substances Control Act

This is the last page of this MSDS. There should be 7 pages.

AMVAC CHEMICAL CORPORATION SMARTBLOCK®: 3-Decen-2-one

Page 1 of 7

AMVAC SDS No. 369

SAFETY DATA SHEET

Identification of the substance/mixture and of the company/undertaking **SECTION 1.**

Product Identifier

Trade Name or designation

SmartBlock®; SmartBlock® Technical; 3-Decen-2-one; 3-Decen-2-one Technical

of the mixture

Synonyms SDS number

369

OAD number Issue date

12551 08-01-2014

Version number

01* (see section 16)

1.2.

Relevant identified uses of the substance or mixture and uses advised against

Identified uses

Potato sprout inhibitor

Uses advised against

None known.

1.3. Details of the supplier of the safety data sheet

Supplier

Company name

AMVAC Chemical Corporation

Address

4100 E Washington Blvd., Los Angeles, CA 90023

US

Division

Telephone

Amvac Chemical Corp.

323-264-3910

Amvac Chemical Corp.

323-268-1028 (FAX)

e-mail

Not available

Contact person

Not available

1.4. Emergency telephone number

Medical

888-681-4261

CHEMTREC(US & Canada) CHEMTREC(Outside US & Canada) 800-424-9300 +1-703-527-3887 (collect calls accepted)

Product Use

888-462-6822

SECTION 2: Hazards Identification

Classification of the mixture 2.1

> The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Xn: R20: R38: R43

The full text for all R-phrases is displayed in section 16. Classification according to Regulation (EC) No 1272/2008 as amended

Health hazards

Acute toxicity, inhalation

Category 4

H330 - harmful if inhaled

H315 - Causes skin irritation

Hazard summary

Physical hazards

Not classified for physical hazards

Health hazards Environmental hazards Harmful by inhalation

Not classified for hazards to the environment

Specific hazards

Not available Not available

Main symptoms 2.2 Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

3-Decen-2-one, Inert Ingredients

Hazard Pictograms



Signal word

Warning

Material Name: SmartBlock®; SmartBlock® 98% Technical; 3-Decen-2-one 12551 Version #: 01 Issue Date: 13-01-2014

Hazard statements

H332 Harmful if inhaled H315 Causes skin irritation

Precautionary statements

Prevention

Avoid breathing dust/fume/gas/mist/vapour/spray. P261 P271 Use only outdoors or in a well-ventilated area.

Wear protective gloves/protective clothing/eye protection/face protection. P280

Wash contaminated clothing before reuse P363

Response

P304 + P340If INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing P312 Call a POISON CENTER or doctor/physician if you feel unwell

Storage

P402 + P404Store in a cool, dry area P403 + P233 Store in a well-ventilated place.

P405 Store locked up.

Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations P501

Supplemental label information Not applicable.

2.3 Other hazards

None known.

SECTION 3: Composition/information on ingredients

3.1 Substances

General Information

Chemical Name CAS-No./EC No. **REACH Registration No.** Index No. Notes 10519-33-2 3-Decen-2-one >98.00

Classification:

DSD: Xn; R20, R38, R43 CLP: H332, H315, H317

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limits(s).

Composition comments

The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General Information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves

4.1. Description of first aid measures

Inhalation

Remove victim to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a physician or poison control center immediately.

Skin contact

Wash off with soap and water. Get medical attention if irritation develops and persists.

Eve contact

Rinse with water about 15-20 minutes. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Get medical attention if symptoms occur.

4.2 Most important symptoms May cause skin irritation.

and effects, both acute and

delayed

4.3. Indication of any immediate medical attention

Provide general supportive measures and treat symptomatically. In case of shortness of breath, give oxygen. Keep victim warm. Keep victim under observation. Symptoms may be delayed.

and special treatment needed

SECTION 5: Firefighting measures

General fire hazards No unusual fire or explosion hazards noted.

5.1 Extinguishing media

Suitable extinguishing Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing Do not use water jet as an extinguisher, as this will spread the fire.

media

Page 3 of 7

AMVAC SDS No. 369

5.2 Special hazards arising During fire, gases hazardous to health may be formed.

from the substance or mixture 5.3 Advice for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire. Special protective

equipment for firefighters

Special fire fighting Move containers from fire area if you can do so without risk.

procedures

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Immediately evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. For non-emergency Keep out of low areas. Wear appropriate personal protective equipment. Ventilate closed spaces personnel

Before entering them. Local authorities should be advised if significant spillages cannot be contained.

For personal protection, see section 8 of the SDS.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

Methods and material for Large spills: Stop the flow of material, if this is without risk, to prevent entry into waterways, sewer,

containment and cleaning up basements or confined areas. Dike the spilled material, where this is possible, to prevent

contamination of local water sources. Siphon the majority of the liquid into drums for use or Disposal, depending on the circumstances. Clean the area as described for a small spill. Small Spills: Cover with absorbent (clay, sawdust, straw, kitty litter, etc.) to absorb the liquid. Sweep or shovel into an open drum. Clean surface thoroughly with soap and water to remove residual contamination. Absorb and sweep into the same open drum. Close the drum and dispose of properly,

according to hazardous waste disposal procedures for your locality.

Never return spills in original containers for re-use.

6.4 Reference to other sections

For personal protection, see section 8 of the SDS. For waste disposal, see section 13.

SECTION 7: Handling and storage

Do not breathe vapor. Use only outdoors or in a well-ventilated area. Wear appropriate personal 7.1 Precautions for safe

protective equipment recommended in section 8. Observe good industrial hygiene practices. handling

7.2 Conditions for safe Store locked up. Keep container tightly closed. Store in a cool, dry place out of direct sunlight.

storage, including any Store in a well-ventilated place.

incompatibilities

7.3 Specific end uses(s) Potato sprout inhibitor

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits No exposure limits noted for ingredient(s).

Biological limit values No biological exposure limits noted for the ingredient(s).

Recommended monitoring Follow standard monitoring procedures.

procedures

Derived no-effect level (DNEL) Not available Predicted no effect Not available

concentrations (PNECs)

Amvac recommended PEL = 200 mg/m3 Exposure guidelines

8.2 Exposure controls

Ventilation should be sufficient to effectively remove and prevent buildup of any dusts or fumes Appropriate engineering

that may be generated during handling or thermal processing. controls

Individual protection measures, such as personal protective equipment Personal protection equipment should be chosen according to the CEN standards and in General information

Discussion with the supplier of the personal protective equipment.

Eye/face protection Skin protection

Wear safety glasses with side shields (or goggles). Wear a full-face respiratory, if needed.

To prevent skin contact use suitable protective gloves. - Hand protection - Other

Wear suitable protective clothing. Wear suitable respiratory protection. Respiratory protection

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Always observe good personal hygiene measures, such as washing after handling the material and Hygiene measures

Before eating, drinking, and/or smoking. Routinely wash work clothing and protective

Equipment to remove contaminants.

Environmental exposure

Environmental manager must be informed of all major releases.

controls

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance Physical state A colorless to slightly yellow colored liquid

Form

Liquid. Liquid.

Color

Colorless to light yellow.

Odor

Jasmine

Odor threshold

Not established 4.33 (1% dispersion) not determined

Melting point/freezing point Initial boiling point and

435.2 °F (224°C)

boiling range

Flash point

224.6 °F (107°C) Cleveland Open Cup 210.2 °F (99°C) Penske Closed Cup

Evaporation rate Flammability (solid, gas) Not determined Not applicable

Upper/lower flammability or explosive limits Flammability limit -

Not available

lower (%)

Flammability limit -

upper (%)

Vapor pressure

430 Pa (3.23 mm Hg) at 25 °C Not available

Not available

Vapor density Relative density

Not available

Solubility (ies)

0.1 g/l in water

Partition coefficient

3.45

(n-octanol/water)

527 °F (275°C)

Auto-ignition temperature Decomposition temperature

Not available Not available

Viscosity

This product has been tested and has no explosive properties.

Explosive properties Oxidizing properties

No oxidizing properties.

9.2 Other Information

Specific gravity **Bulk density** Percent volatile 0.845 0.845 kg/l > 99%

SECTION 10: Stability and reactivity

10.1 Reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport.

10.2 Chemical stability

Material is stable under normal conditions.

10.3 Possibility of hazardous

No dangerous reaction known under conditions of normal use.

reactions

10.4 Conditions to avoid

Avoid temperatures exceeding the flash point.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous

No hazardous decomposition products are known

decomposition products

11. Toxicological information

General Information

Not available Information on likely routes of exposure

Ingestion

Based on available data, the classification criteria are not met.

Inhalation

Harmful if inhaled. May be irritating to the skin.

Skin contact Eye contact

Not irritating to the eyes.

Symptoms

No data available

11.1 Information on toxicological effects

Acute toxicity

Harmful if inhaled. Acute and toxicological and mutagenicity data for this product are given below.

The long-term toxicological properties of this potato sprout inhibitor have not been determined.

Care should be taken with chemicals that have not been thoroughly investigated.

Product	Species	Test Results							
3-Decen-2-one (SmartBlock® 9	8% Technical, CAS 10519-33-2)								
Acute									
Dermal									
LD50	Rat	> 5000 mg/kg, female (Tox Cat IV)							
Inhalation									
LC50	Rat	>1.00 mg/l, 4 hours, male (Tox Cat IV)							
LC50	Rat	> 2.04 mg/l, female							
Oral									
LD50	Rat	> 5000 mg/kg (Tox Cat IV)							
* Estimates for product ma	ay be based on additional component data no	ot shown.							
Skin corrosion/irritation	Causes skin irritation.								
Serious eye damage/eye	Not an eye irritant.								
Irritation									
Respiratory sensitization	No data available. Due to lack of data the	classification is not possible.							
Skin sensitization	Not a skin sensitizer.								
Germ cell mutagenicity	an in vivo Liver unscheduled DNA Synthe	enic. Non-mutagenic in bacterial reverse mutation assay, in sis assay and no evidence of clastogenicity or aneugenicity ymphoma assay showed limited evidence of mutagenicity,							
Carcinogenicity		ck of data the classification is not possible.							
Reproductive toxicity		to lack of data the classification is not possible.							
single exposure		to lack of data the classification is not possible.							
Specific target organ toxicity repeated exposure	No data are available on this product. Due	to lack of data the classification is not possible.							
Aspiration hazard	No data are available on this product. Due	to lack of data the classification is not possible.							
Mixture versus substance	Not applicable								
information									
Other information	No data are available.								

SECTION 12: Ecological information

12.1 Toxicity

Product	Species	Test Results	
3-Decen-2-one (Smart)	Block® 98% Technical, CAS 10519-	33-2)	
Acute			
Fish			
LC50	Fish	1.50 mg/L (96-hr)	
Daphnia			
EC50	Daphnia	1.68 mg/L (48-hr)	
Algae			
EyC50	algae	0.90 mg/L (72-hr)	
Lemna			
EC50	Lemna	1.69 mg/L (7-day)	

12.2 Persistence and degradability

3-Decen-2-one is considered to be readily biodegradable, but fails the 10-day window.

12.3 Bioaccumulative potential No data available for this product.

Partition coefficient

n-octanol/water (log Kow)

3-Decen-2-one

Bioconcentration factor (BCF) Not available. 12.4 Mobility in soil Not available

12.5 Results of PBT

and vPvB assessment

Not available.

12.6. Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential

Endocrine disruption, global warming potential) are expected from this product.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

AMVAC CHEMICAL CORPORATION SMARTBLOCK®; 3-Decen-2-one

Page 6 of 7

AMVAC SDS No. 369

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some

product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

EU waste code

The Waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Disposal methods/information Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material

and its container must be disposed as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international

regulations.

SECTION 14: Transportation information

ADR

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

AND

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7 Transport in bulk This

This substance/mixture is not intended to be transported in bulk.

according to Annex II of MARPOL 63/78 and the IBC

Code

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture EU regulations

Regulation (EC) No. 1005/2009 on substance that deplete the ozone layer, Annex I

Not listed

Regulation (EC) No. 1005/2009 on substance that deplete the ozone layer, Annex II

Not listed

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended Not listed

Not listed

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex Vas amended

Not listed

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed

Authorizations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed

Restrictions on use
Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are

breastfeeding

Not listed

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed

Material Name: SmartBlock®; SmartBlock® 98% Technical; 3-Decen-2-one

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed

Directive 94/33/EC on the protection of young people at work

Not listed

The product is classified and labeled in accordance with EC directives or respective national laws. Other regulations

This Safety Data Sheet complies with the requirements of Regulation (EC) No. 1907/2006.

National regulations Young people under 18 years old are not allowed to work with this product according to EU

Directive 94/33/EC on the protection of young people at work.

15.2 Chemical Safety

Assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

Not available

References

Not available

Information on evaluation method leading to the classification of mixture Full text of any statements or The classification for health and environmental hazards is derived by a combination of calculation

methods and test data, if available

R-phrases and H-statements under Sections 2 to 15

R-phrases

R20

Harmful by inhalation

R38

Irritating to skin

R43

May cause sensitization by skin contact

H-phrases

H332

Harmful if inhaled

H315

Causes skin irritation

Revision information

Because new software has been used to create this SDS, the revision number has been changed to 01.

It replaces the former revision number of 369_06 issued on 13/08/2013.

Training information

Disclaimer

Follow training instructions when handling this material.

This information is provided for the limited guidance to the user. While AMVAC believes that the information is, as of the date hereof, reliable, it is the user's responsibility to determine the suitability of the information for its purposes. The user is advised not to construe the information as absolutely complete since additional information may be necessary or desirable when particular, exceptional, or variable conditions or circumstances exist (like combinations with other materials), or because of applicable regulations. No express or implied warranty of merchantability or fitness for a particular purpose or otherwise is made hereunder with respect to the information or the product to which the

information relates.

Appendix A Search Results: 3-Decen-2-one, 2-Decanol, 2-Decanone



JOXNEL Toxicology Data Network

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Env. Health & Toxicology D TOXNET

TOXNET - Databases on toxicology, hazardous chemicals, environmental health, and toxic releases.

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Select Database

• ChemIDplus de la company	2
• HSDBHILL AND THE STATE OF THE	2
• TOXLINE	2
FOCCRIS CONTRACTOR	[2]
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● GENETOX	2
• IRIS	[7]
• TIERS IN THOSE STREET	[2]
• LaciMed	[2]
 Multi-Database 	2
• TRI	[2]
• Haz-Map	?
• Household Products	2
• TOXMAP	[7]
	Aurola Sala

Additional Resource

Env. Health & Toxicology



Portal to environmental health and toxicology resources.

Products

Support Pages

- <u>Help</u>
- **TOXNET FAQ**
- **TOXNET Update Status**
- Fact Sheet
- **Database Description**
- Training Manuals
- News

Search All Databases

2-decanone Search Clear Help							
(€	e.g. asthma air pollution, ibuprofen fever, vinyl	chloride)					
References f	rom Biomedical Literature						
TOXLINE	Toxicology Literature Online	<u>41</u>					
DART	Developmental Toxicology Literature	0					
Chemical, To	oxicological, and Environmental Health Dat	:a					
<u>ChemIDplus</u>	Chemical Identification/Dictionary	<u>1</u>					
<u>HSDB</u>	Hazardous Substances Data Bank	<u>1</u>					
CCRIS	Chemical Carcinogenesis Information	0					
CPDB	Carcinogenic Potency Database	0					
GENETOX	Genetic Toxicology Data	0					
CTD	Comparative Toxicogenomics Database	0					
IRIS	Integrated Risk Information	0					
ITER	International Toxicity Estimates for Risk	0					
LactMed	Drugs and Lactation Database	0					
TRI	Toxics Release Inventory	0					
TOXMAP	Environmental Health e-Maps	0					
<u>Haz-Map</u>	Occupational Exposure/Toxicology	Show me					
Household	Health & Safety Information on Household	0					

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2-decano	ne <u>Search Clear</u> Limits	Print this
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Include Pt	ubMed records: Yes No	
records are	ough 20 of 41 e sorted in <u>relevancy ranked</u> order and not by date . ort to change the order of the retrieved records.	Pages: <u>123</u>
Select Record	record	
1 2	Growth kinetics of preexposed and naive populations of Tetra 2-decanone and acetone. BEARDEN AP; GREGORY BW; SCHULTZ TW ECOTOXICOLOGY AND ENVIRONMENTAL SAFETY; 37 (3). 199	
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records are sorted in relevancy ranked order and not by date.

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Select Record	record				
21	REGRESSION AND CLUSTER ANALYSIS OF THE ACUTE TOXICITY OF 267 CHEMICALS TO SIX SPECIES OF BIOTA AND THE OCTANOL-WATER PARTITION COEFFICIENT KAISER K LE; ESTERBY SR HERMENS, J. L. M. AND A. OPPERHUIZEN (ED.). QSAR (QUANTITATIVE STRUCTURE-ACTIVITY RELATIONSHIPS) IN ENVIRONMENTAL TOXICOLOGY-IV; FOURTH INTERNATIONAL WORKSHOP, VELDHOVEN, NETHERLANDS, SEPTEMBER 16-20, 1990. XXI+705P. ELSEVIER SCIENCE PUBLISHERS B.V.: AMSTERDAM, NETHERLANDS; (DIST. IN THE USA AND CANADA BY ELSEVIER SCIENCE PUBLISHING CO., INC.: NEW YORK, NEW YORK, USA). ILLUS. ISBN 0-444-89471-3.; 0 (0). 1991. 499-514. [BIOSIS]				
22	Structure-toxicity relationship of monoketones: In vitro effects on beta-adrenergic receptor binding and Na+-K+-ATPase activity in mouse synaptosomes. HUANG J; TANII H; OHYASHIKI T; HASHIMOTO K NEUROTOXICOLOGY AND TERATOLOGY; 15 (5). 1993. 345-352. [BIOSIS]				
23 🗔	REGRESSION AND CLUSTER ANALYSIS OF THE ACUTE TOXICITY OF 267 CHEMICALS TO SIX SPECIES OF BIOTA AND THE OCTANOL WATER PARTITION COEFFICIENT KAISER K LE; ESTERBY SR FOURTH INTERNATIONAL WORKSHOP ON QSAR (QUANTITATIVE STRUCTURE-ACTIVITY RELATIONSHIPS) IN ENVIRONMENTAL TOXICOLOGY, VELDHOVEN, NETHERLANDS, SEPTEMBER 16-20, 1990. SCI TOTAL ENVIRON; 109-110 (0). 1991. 499-514. [BIOSIS]				
24	Application of QSARs, extrapolation and equilibrium partitioning in aquatic effects assessment: I. Narcotic industrial pollutants. VAN LEEUWEN CJ; VAN DER ZANDT P TJ; ALDENBERG T; VERHAAR H JM; HERMENS J LM ENVIRON TOXICOL CHEM; 11 (2). 1992. 267-282. [BIOSIS]				
25 🗔	OCCURRENCE AND RATES OF CHEMICAL BIODEGRADATION IN SUPERIOR HARBOR USA WATER VAISHNAV DD; BABEU L J GREAT LAKES RES; 12 (3). 1986. 184-191. [BIOSIS]				
26	Ketone EC50 values in the Microtox test. Chen HF; Hee SS Ecotoxicol Environ Saf. 1995, Mar; 30(2):120-3. [Ecotoxicology and environmental safety] [PubMed]				

	PubMed Citation
27	Mutagenicity and chemical analysis of fumes from cooking meat. THIEBAUD HP; KNIZE MG; KUZMICKY PA; FELTON JS; HSIEH DP JOURNAL OF AGRICULTURAL AND FOOD CHEMISTRY; 42 (7). 1994. 1502-1510. [BIOSIS]
28	A survey of antifungal compounds from higher plants, 1982-1993. GRAYER RJ; HARBORNE JB PHYTOCHEMISTRY (OXFORD); 37 (1). 1994. 19-42. [BIOSIS]
29	EFFECTS OF CHEMICALS ON MICROORGANISMS WALKER JD J WATER POLLUT CONTROL FED; 59 (6). 1987. 614-625. [BIOSIS]
30 🗵	TOTAL TOTAL IN THE STATE OF THE
31	Anesthetic activity of monoketones in mice: Relationship to hydrophobicity and in vivo effects on Na++-ATPase activity and membrane fluidity. TANII H TOXICOLOGY LETTERS (SHANNON); 85 (1). 1996. 41-47. [BIOSIS]
32 🗵	A TANKE COMPOUNDS IN ANITA POTIO MADDIE OF DIMENTS
33 🔼	Toxicity of organic chemicals to fathead minnow: A united quantitative structure. Activity relationship model and its application. FENG L; HAN S; ZHAO Y; WANG L; CHEN J CHEMICAL RESEARCH IN TOXICOLOGY; 9 (3). 1996. 610-613. [BIOSIS]
34 📃	
35 🗔	Development of an in vitro competitive binding assay to predict alpha2u-globulin nephropathy. LEHMAN-MCKEEMAN LD; CAUDILL D IN VITRO & MOLECULAR TOXICOLOGY; 12 (2). 1999. 83-95. [BIOSIS]
36	Population growth impairment of sulfur-containing compounds to Tetrahymena pyriformis. Schultz TW; Sinks GD; Miller LA Environ Toxicol. 2001; 16(6):543-9. [Environmental toxicology] [PubMed] PubMed Citation
37 🗵	Structure-toxicity relationships for the fathead minnow, Pimephales promelas: Narcotic industrial chemicals. VEITH GD; CALL DJ; BROOKE LT CAN J FISH AQUAT SCI; 40 (6). 1983. 743-748. [HEEP]
38	CHROMATOGRAPHIC MASS SPECTROMETRIC STUDY OF TOXIC SUBSTANCES ADSORBED ON DUST DMITRIEV MT; RASTYANNIKOV EG; ETLIN SN; MALYSHEVA AG GIG SANIT; 0 (1). 1984. 44-47. [Russian] [HEEP]
39	Bowen RD; Maccoll A Organic Mass Spectrometry, Vol. 18, No. 12, pages 576-581, 20 references, 19831983 [NIOSH]
40	STUDIES ON CELL DIVISION: THE EFFECT OF ALDEHYDES, KETONES AND ALPHA-KETO-ALDEHYDES ON THE PROLIFERATION OF ESCHERICHIA COLI EGYUED LG CURR MOD BIOL 1:14-20,1967 [EMIC]

Items 21 through 40 of 41

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Select record Record 41

Repellency property of long chain aliphatic methyl ketones against Anopheles gambiae s.s.

Innocent E; Gikonyo NK; Nkunya MH Tanzan J Health Res. 2008, Jan; 10(1):50-4. [Tanzania journal of health research]

[PubMed]

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24 TOXLINE Subset - toxicology citations

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O DIRLINE - Directory of Health Organizations

0 Genetics Home Reference

O Household Products Database

Other Information Resources i

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0 HSRProj - Health Services Research Projects

2 OMIM - Online Mendelian Inheritance in Man

1 HSDB - Hazardous Substances Data Bank

0 IRIS - Integrated Risk Information System

0 ITER - International Toxicity Estimates for Risk

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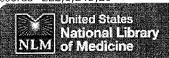
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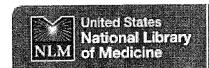
References from Biomedical Literature

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Chemical, Toxicological, and Environmental Health Data

Circimical, 102		
ChemIDplus	Chemical Identification/Dictionary	1
HSDB	Hazardous Substances Data Bank	0
CCRIS	Chemical Carcinogenesis Information	0
CPDB	Carcinogenic Potency Database	0
GENETOX	Genetic Toxicology Data	0
IRIS	Integrated Risk Information	0
ITER	International Toxicity Estimates for Risk	0
LactMed	Drugs and Lactation Database	0
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Full Record

3-Decen-2-one RN: 10519-33-2

Structure Descriptors

InChl=1/C10H18O/c1-3-4-5-6-7-8-9-10(2)11/h8-9H,3-7H2,1-2H3/b9-8+

Download | View Full InChl

Smiles

 $C(CCCC)\C=C\C(C)=O$

Download

Names and Synonyms

Synonyms

i 3-Decen-2-one

i EINECS 234-059-0

Enanthylidene acetone

FEMA No. 3532

I Heptylidene acetone

1 Oenanthylidene acetone

Systematic Name

3-Decen-2-one

Superlist Name

i 3-Decen-2-one

Registry Numbers

CAS Registry Number

i 10519-33-2

System Generated Number 1 010519332

Formulas

Molecular Formula

i C10-H18-O

Locators

File Locator

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NIST WebBook

I NIST Chemistry WebBook

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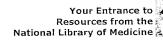
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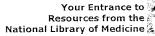
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IRIS	Integrated Risk Information	0
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Exhibit N

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Pages 123-189



Material Safety Data Sheet

Acetone

CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME:

Acetone

OTHER/GENERIC NAMES:

2-Propanone, β-Keptopropane, Dimethylformadlehyde, Dimethyl Ketone, Methyl

Ketone, Propanonene, Pyroacetic Ether

PRODUCT USE: Solvent

MANUFACTURER:

Honeywell

1953 South Harvey Street

Muskegon, MI 49442

DISTRIBUTOR:

VWR International

1310 Goshen Parkway

West Chester, PA 19380

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(Monday-Friday, 8:00am-5:00pm)

1-800-932-5000

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(24 Hours/Day, 7 Days/Week) 1-800-424-9300 (USA Only)

For Transportation Emergencies:

1-800-424-9300 (CHEMTREC - Domestic) 1-613-996-6666(CANUTEC- Canada)

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COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT NAME

Acetone

CAS NUMBER

WEIGHT %

67-64-1

100

Component Information/Information on Non-Hazardous Components

This product is considered to be hazardous according to the criteria specified in 29 CFR 1910.1200 (Hazard Communication Standard) and the Canadian Controlled Product Regulations.

Trace impurities and additional material names not listed above may also appear in Section 15 toward the end of the MSDS. These materials may be listed for local "Right-To-Know" compliance and for other reasons.

HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: This product is a clear, volatile, flammable liquid. Has a sweet, mint-like odor. Highly flammable. Vapours may form explosive mixtures with air. The product causes irritation of eyes, skin and mucous membranes. Repeated exposure may cause skin dryness or cracking. Harmful by inhalation. Harmful: may cause lung damage if swallowed. Causes headache, drowsiness or other effects to the central nervous system. Do not allow product to contact skin, eyes and clothing. Do not breathe vapours.

MSDS Number:

BDH-110

Page 1 of 9

Current Issue Date:

January 6, 2006

USDA NOP SMARTBLOCK APPLICATION REDACTED COPY Page 190 of 211



Acetone

POTENTIAL HEALTH HAZARDS

SKIN: Irritating to skin. Skin absorption may cause toxic effects similar to those described for inhalation. Repeated or extended contact may cause erythema (reddening of the skin) or dermatitis, resulting from a defatting action on tissue.

Irritating to eyes. Symptoms include itching, burning, redness and tearing.

Harmful by inhalation. Vapours may cause drowsiness and dizziness. Inhalation of high INHALATION: vapour concentrations can cause CNS-depression and narcosis. Severe overexposure may

produce more serious symptoms, including coma and risk of kidney damage.

INGESTION: Harmful: may cause lung damage if swallowed. Ingestion causes burning sensation in the

mouth, throat and stomach and gastrointestinal disturbances. Ingestion of this product may result in central nervous system effects including headache, sleepiness, dizziness, slurred speech

and blurred vision.

DELAYED EFFECTS: Repeated or prolonged exposure may cause damage to the liver and kidney.

MEDICAL CONDITIONS Pre-existing respiratory diseases, liver or kidney dysfunctions, or central

AGGRAVATED BY EXPOSURE: nervous system disorders may be aggravated by exposure.

HMIS Ratings: Health: 2 Fire: 3 Physical Hazard: 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

Ingredients found on one of the OSHA designated carcinogen lists are listed below.

INGREDIENT NAME NTP STATUS IARC STATUS **OSHA LIST**

No component of this product at levels greater than or equal to 0.1% is identified as a carcinogen by ACGIH, IARC, NTP or OSHA.

FIRST AID MEASURES

Wash off immediately with soap and plenty of water. Take off contaminated clothing and shoes SKIN: immediately. Wash contaminated clothing before re-use. Obtain medical attention.

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical EYES: attention.

INHALATION: Move to fresh air in case of accidental inhalation of vapours. If not breathing, give artificial

respiration. If breathing is difficult, give oxygen, provided a qualified operator is available. Call

a physician immediately.

Page 2 of 9 MSDS Number: **BDH-110**

Current Issue Date: January 13 2006 NARTBLOCK APPLICATION REDACTED COPY Page 191 of 211



Acetone

INGESTION: DO NOT induce vomiting. Immediate medical attention is required. If vomiting occurs naturally,

have victim lean forward to reduce risk of aspiration.

ADVICE TO PHYSICIAN: Treat symptomatically.

5. FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES

FLASH POINT: -4°F (-20°C)

FLASH POINT METHOD: Closed Cup

AUTOIGNITION TEMPERATURE: 869°F (465°C) UPPER FLAME LIMIT (volume % in air): 13 LOWER FLAME LIMIT (volume % in air): 2.5

FLAME PROPAGATION RATE (solids): Not applicable

OSHA FLAMMABILITY CLASS: Class 1B Flammable Liquid

EXTINGUISHING MEDIA:

Use alcohol-resistant foam, carbon dioxide (CO2) or dry chemical.

UNUSUAL FIRE AND EXPLOSION HAZARDS:

Highly flammable. Vapours may form explosive mixtures with air. Vapours are heavier than air and may travel along the ground to some distant source of ignition and flash back.

Hazardous combustion products may include carbon monoxide, carbon dioxide (CO2).

SPECIAL FIRE FIGHTING PRECAUTIONS/INSTRUCTIONS:

Water may be ineffective. Fire-fighters should wear self-contained, NIOSH-approved breathing apparatus and full protective clothing. Fire or intense heat may cause violent rupture of packages. In the event of fire, cool tanks with water spray. Do not use a solid water stream as it may scatter and spread fire. After fire, flush area with water to prevent re-ignition. Do not allow run-off from fire fighting to enter drains or water courses.

NFPA Ratings: Health: 1 Fire: 3 Reactivity: 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

6. ACCIDENTAL RELEASE MEASURES

IN CASE OF SPILL OR OTHER RELEASE:

Containment Procedures: Use personal protective equipment. Ensure adequate ventilation. Remove all sources of ignition. Stop flow of material, if this is without risk.

Cleanup Procedures: Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Shovel into suitable container for disposal. Do not use sparking tools. Do not allow product to enter sewer or waterways.

Evacuation Procedures: Keep unnecessary people away. Isolate area.

Special Procedures: Use personal protective equipment. Remove all sources of ignition. Ensure adequate ventilation.

MSDS Number: BDH-110 Page 3 of 9

Current Issue Date: January 13, 2006

USDA NOP SMARTBLOCK APPLICATION REDACTED COPY Page 192 of 211



Acetone

Spills and releases may have to be reported to Federal and/or local authorities. See Section 15 regarding reporting requirements.

HANDLING AND STORAGE

NORMAL HANDLING: (Always wear recommended personal protective equipment.)

Ensure all equipment is electrically grounded before beginning transfer operations. Ensure adequate ventilation. Do not allow product to contact skin, eyes and clothing. Do not breathe vapours. Keep away from fire, sparks and heated surfaces. Keep container tightly closed in a dry and well-ventilated place.

STORAGE RECOMMENDATIONS:

Keep in a well-ventilated place. Empty containers may retain product residue including Flammable or Explosive vapours. Do not cut, drill, grind, or weld near full, partially full, or empty product containers. Keep away from heat and sources of ignition. Store away from incompatible substances. Re-open used containers with caution. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Store in area designed for storage of flammable liquids.

EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:

Provide local and general exhaust ventilation to effectively remove and prevent buildup of any vapours or mists generated from the handling of this product. Use product only in closed system. Prevent electrostatic charge build-up by using common bonding and grounding techniques. Local exhaust ventilation is preferred.

PERSONAL PROTECTIVE EQUIPMENT

SKIN PROTECTION:

Wear impervious gloves and flame retardant antistatic protective clothing. Gloves must be inspected prior to use. For leak, spills, or other emergency, use full protective equipment.

EYE PROTECTION:

For handling in closed ventilation system, wear safety glasses with side-shields. For leak, spill or other emergency, use chemical goggles and face-shield. Remove contact lenses.

RESPIRATORY PROTECTION:

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

ADDITIONAL RECOMMENDATIONS:

Provide eyewash stations and quick-drench shower facilities.

Current Issue Date: January 13020 ARTBLOCK APPLICATION REDACTED COPY Page 193 of 211



Acetone

EXPOSURE GUIDELINES

Acetone (67-64-1)

ACGIH: 500 ppm TWA

750 ppm STEL

OSHA (Final):

1000 ppm TWA; 2400 mg/m3 TWA

OSHA (Vacated):

750 ppm TWA; 1800 mg/m3 TWA

1000 ppm STEL; 2400 mg/m3 STEL (The acetone STEL does not apply to the cellulose

acetate fiber industry. It is in effect for all other sectors)

NIOSH: Alberta: 250 ppm TWA; 590 mg/m3 TWA 750 ppm TWA; 1800 mg/m3 TWA

1000 ppm STEL; 2400 mg/m3 STEL

British Columbia:

250 ppm TWA 500 ppm STEL

Manitoba:

750 ppm TWA; 1780 mg/m3 TWA

1000 ppm STEL; 2375 mg/m3 STEL

New Brunswick:

500 ppm TWA; 1188 mg/m3 TWA 750 ppm STEL; 1782 mg/m3 STEL

Northwest Territories:

1000 ppm TWA; 2370 mg/m3 TWA

1250 ppm STEL; 2970 mg/m3 STEL

Nova Scotia:

500 ppm TWA 750 ppm STEL

Nunavut:

1000 ppm TWA; 2370 mg/m3 TWA

1250 ppm STEL; 2970 mg/m3 STEL

Ontario:

500 ppm TWAEV 750 ppm STEV

Quebec:

750 ppm TWAEV; 1780 mg/m3 TWAEV

1000 ppm STEV; 2380 mg/m3 STEV

Saskatchewan:

1780 mg/m3 TWA; 750 ppm TWA 2380 mg/m3 STEL; 1000 ppm STEL

Yukon:

1000 ppm TWA; 2400 mg/m3 TWA 1250 ppm STEL; 3000 mg/m3 STEL

PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: Clear, colorless liquid

PHYSICAL STATE: Liquid **MOLECULAR WEIGHT: 58.05** CHEMICAL FORMULA: C₃H₆O

ODOR: Sweet mint-like odor detectable at 20 ppm

SPECIFIC GRAVITY (water = 1.0): 0.79

SOLUBILITY IN WATER (weight %): Complete

pH: Not applicable

BOILING POINT: 133°F (56°C) **MELTING POINT:** -138.6°F (-94.8°C)

VAPOUR PRESSURE: 180 mm Hg at 68°F (20°C)

MSDS Number:

BDH-110

Current Issue Date: January 13, 2006

USDA NOP SMARTBLOCK APPLICATION REDACTED COPY Page 194 of 211

Page 5 of 9



Acetone

VAPOUR DENSITY (air = 1.0): 2.0

EVAPORATION RATE: 12

COMPARED TO: Butyl Acetate = 1

% VOLATILES: 100

FLASH POINT: -4°F (-20°C)

(Flash point method and additional flammability data are found in Section 5.)

10. STABILITY AND REACTIVITY

NORMALLY STABLE? (CONDITIONS TO AVOID):

Stable under recommended storage conditions.

Avoid: Heat, flames and sparks. Incompatible products

INCOMPATIBILITIES:

Keep away from oxidising agents, strongly alkaline and strongly acid materials in order to avoid exothermic reactions.

HAZARDOUS DECOMPOSITION PRODUCTS:

Hazardous decomposition products include carbon monoxide and carbon dioxide (CO2).

HAZARDOUS POLYMERISATION:

Hazardous polymerisation does not occur.

11. TOXICOLOGICAL INFORMATION

Component Analysis - LD50/LC50

Acetone (67-64-1)

LD50 - Route: Inhalation; Dose: 76 mg/L/4H Rat:

LD50 - Route: Oral; Dose: 1800 mg/kg Rabbit: LD50 - Route: Dermal; Dose: 20000 mg/kg

IMMEDIATE (ACUTE) EFFECTS:

The product causes irritation of eyes, skin and mucous membranes. Repeated exposure may cause skin dryness or cracking. Harmful by inhalation. Harmful: may cause lung damage if swallowed. Causes headache, drowsiness or other effects to the central nervous system.

DELAYED (SUBCHRONIC AND CHRONIC) EFFECTS:

Repeated or prolonged exposure may cause damage to the liver and kidney.

8-Week Inhalation Toxicity Study (rat): 19,000 ppm acetone 5days/week for 8 weeks produced no signs of toxicity other than slightly reduced weight gain compared to controls.

90-Day Oral Toxicity Study (rat): The no-observed effect level is 100 mg/kg/day and the low-observed effect level is 500 mg/kg/day based on increased liver and kidney weights and nephrotoxcity.

Page 6 of 9 MSDS Number: BDH-110

Current Issue Date: January 1302006 APPLICATION REDACTED COPY Page 195 of 211



Acetone

OTHER DATA:

This material is not known or reported to be carcinogenic by any reference source including IARC, OSHA, NTP, or EPA.

Ames Assay (S. typhimurium): Negative

Chromosome Aberrations and Sister Chromatid Exchange Assays: Negative

Point Mutation in Mouse Lymphoma Cells: Negative

DNA Cell-binding Assay: Negative

12. ECOLOGICAL INFORMATION

Prevent from entering sewer or waterway. This material is not expected to be harmful to aquatic life.

Component Analysis - Ecotoxicity - Aquatic Toxicity

Acetone (67-64-1)

Test & Species Conditions

96 Hr LC50 rainbow trout 5540 mg/L static

96 Hr LC50 fathead minnow 6210 mg/L flow-through

96 Hr LC50 bluegill 8300 mg/L static

48 Hr LC50 water flea 0.0039 mg/L

48 Hr EC50 water flea 12700 mg/L Static

Accumulation in terrestrial organisms is unlikely. Bioaccumulation is unlikely.

13. DISPOSAL CONSIDERATIONS

WASTE INFORMATION: Waste Code: U002. This product is a D001 ignitable waste in supplied form. Dispose of as special waste in compliance with local and national regulations. Waste codes should be assigned by the user based on the application for which the product was used. Incineration of waste material in an EPA-approved facility is recommended, allowing a solid, inert residue to form.

OTHER DISPOSAL CONSIDERATIONS: Observe all Federal, State, and Local Environmental regulations.

The information offered here is for the product as shipped. Use and/or alterations to the product such as mixing with other materials may significantly change the characteristics of the material and alter the RCRA classification and the proper disposal method.

14. TRANSPORT INFORMATION

US DOT PROPER SHIPPING NAME: Acetone

US DOT HAZARD CLASS: 3 PACKING GROUP: II

US DOT ID NUMBER: UN1090

TDG PROPER SHIPPING NAME: Acetone

TDG HAZARD CLASS: 3 PACKING GROUP: II

TDG ID NUMBER: UN1090

MSDS Number: BDH-110 Page 7 of 9

Current Issue Date: January 13, 2006
USBA NOP SMARTBLOCK APPLICATION REDACTED COPY Page 196 of 211



Acetone

North American Emergency Response Guide (ERG) Number: 127

For additional information on shipping regulations affecting this material, contact the information number found in Section 1.

15. REGULATORY INFORMATION

TOXIC SUBSTANCES CONTROL ACT (TSCA)

TSCA INVENTORY STATUS: All components are on the U.S. EPA TSCA Inventory List.

OTHER TSCA ISSUES: TSCA 4(a) Final Test Rules & Testing Consent Orders.

TSCA 8(a) Inventory Update Rule. (1998 EPA form U Instructions, App.A)

SARA TITLE III/CERCLA

"Reportable Quantities" (RQs) and/or "Threshold Planning Quantities" (TPQs) exist for the following ingredients.

INGREDIENT NAME

SARA/CERCLA RQ (lb)

SARA EHS TPQ (lb)

Acetone

5000

None

Spills or releases resulting in the loss of any ingredient at or above its RQ requires immediate notification to the National Response Center [(800) 424-8802] and to your Local Emergency Planning Committee.

SECTION 311 HAZARD CLASS: Immediate. Fire.

SARA 313 TOXIC CHEMICALS:

The following ingredients are SARA 313 "Toxic Chemicals". CAS numbers and weight percents are found in Section 2.

INGREDIENT NAME

COMMENT

No ingredients listed in this section.

STATE RIGHT-TO-KNOW

In addition to the ingredients found in Section 2, the following are listed for state right-to-know purposes.

INGREDIENT NAME

WEIGHT %

COMMENT

Acetone (67-64-1)

100 CA, MA, MN, NJ, PA, RI

ADDITIONAL REGULATORY INFORMATION:

Acetone is a DEA Listed Precursor and Essential Chemical (List II) subject to certain import, export recordkeeping and reporting requirements. 21 CFR 1310.04 (f),-(g).

Acetone is a Volatile organic compound (VOC) with negligible photochemical reactivity and thus excluded from the definition of volatile organic compounds for the purposes of preparing State implementation plans to attain the national ambient air quality standards for ozone under title I of the Clean Air Act. 40 CFR 51.100(s).

MSDS Number:

BDH-110

Page 8 of 9

Current Issue Date: January 13 2006 APPLICATION REDACTED COPY Page 197 of 211



Acetone

WHMIS CLASSIFICATION (CANADA):

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all information required by CPR.

WHMIS Classification:

B2- Flammable Liquid D2B-Toxic Material

FOREIGN INVENTORY STATUS:

Component Analysis - Inventory

Component	CAS#	TSCA	CAN	EEC	AUST	PHIL	MITI	KOREA	CHINA
Acetone	67-64-1	Yes	DSL	EINECS	Yes	Yes	Yes	Yes	Yes

16. OTHER INFORMATION

CURRENT ISSUE DATE:

January 13, 2006

PREVIOUS ISSUE DATE: New MSDS.

CHANGES TO MSDS FROM PREVIOUS ISSUE DATE ARE DUE TO THE FOLLOWING:

New MSDS.

OTHER INFORMATION:

As per the OSHA Hazard Communication Standard, 1910.1200, the information contained within this MSDS must be given to those persons using this material. For

laboratory use only. Not for food or drug use. Do not store with foodstuffs.

KEY/LEGEND:

ACGIH = American Conference of Governmental Industrial Hygienists; CAS = Chemical Abstracts Service; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CFR = Code of Federal Regulations; CPR = Controlled Products Regulations; DOT = Department of Transportation; DSL = Domestic Substances List; EINECS = European Inventory of Existing Commercial Chemical Substances; EPA = Environmental Protection Agency; IARC = International Agency for Research on Cancer; IATA = International Air Transport Association; mg/Kg = milligrams per Kilogram; mg/L = milligrams per Liter; mg/m3 = milligrams per Cubic Meter; MSHA = Mine Safety and Health Administration; NA = Not Applicable or Not Available; NIOSH = National Institute for Occupational Safety and Health; NJTSR = New Jersey Trade Secret Registry; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; SARA = Superfund Amendments and Reauthorization Act; TDG = Transport Dangerous Goods; TSCA = Toxic Substances Control Act; WHMIS = Workplace Hazardous Materials Information System.

End of Sheet #BDH-110

MSDS Number: Page 9 of 9 **BDH-110**

Current Issue Date: January 13020 MARTBLOCK APPLICATION REDACTED COPY Page 198 of 211

Heptaldehyde MSDS



Material Safety Data Sheet

Heptanal

SECTION 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Heptanal

Other/generic Names: Heptaldehyde, Enanthaldehyde, 1-Heptanal, Aldehyde Cz

Chemical Formula: C7H14O

Chemical Structure:

/ / / 50

Company Identification:

ARKEMA Rotterdam B.V.

Tankhoofd 10, 3196 KE

P.O. Box 6030, 3196 XH

The Netherlands Harbour no. 3255

Tel: +31 (0) 10 472 51 00 Fax: +31 (0) 10 438 26 13

www.arkema.com

SECTION 2 - COMPOSITION, INFORMATION ON INGREDIENTS

CAS No	Chemical/Product Name	Percent	EINECS/ELINCS
111-71-7	Heptanal	99	

1/9

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SECTION 3 - HAZARDS IDENTIFICATION

Flammable liquid, Irritant

Potential Health Effects

Eye: Causes eye imitation.

Skin: May be harmful if absorbed through skin. Causes skin irritation.

Ingestion: May be harmful if swallowed.

Inhalation: May be harmful if inhaled. Causes respiratory tract irritation.

Chronic: No information found

SECTION 4 - FIRST AID MEASURES

Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

Ifinhaled

If breathed in, move person into fresh air. If not breathing give artificial respiration Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

SECTION 5 - FIRE FIGHTING MEASURES

2/9

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For small (incipient) fires, use media such as "alcohol" foam, dry chemical, or carbon dioxide. For large fires, apply water from as far as possible. Use very large quantities (flooding) of water applied as a mist or spray, solid streams of water may be ineffective. Cool all affected containers with flooding quantities of water.

Special protective equipment for fire-fighters

Wear self contained breathing apparatus for fire fighting if necessary.

Further information

Use water spray to cool unopened containers.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions

Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

Methods and materials for containment and cleaning up

Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). Keep in suitable, closed containers for disposal.

SECTION 7 - HANDLING AND STORAGE

3 / 9
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Precautions for safe handling

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist. Keep away from sources of ignition - No smoking. Take measures to prevent the build up of electrostatic charge.

Conditions for safe storage

Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Store in cool place. Handle and store under inert gas.

SECTION 8 - EXPOSURE CONTROLS, PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection

Handle with gloves.

Eye protection

Face shield and safety glasses

Skin and body protection

4/9
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Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical State: liquid

Appearance: light yellow

pH: no data available

Boiling Point: 153 deg C @ 760 mm Hg

Melting Point: -43 deg C

Ignition Temperature: Not applicable.

Flash Point: 35 deg C-closed cup

Explosion Limits, Lower: 1.1%(V). Upper: 5.2%(V)

Water Solubility: slight soluble.

Density: 0.817 g/cm3 at 25 degree C

Molecular Weight: 114,19

SECTION 10 - STABILITY AND REACTIVITY

Chemical stability

Stable under recommended storage conditions:

5/9

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Aldrich - W254002 Page 4 of 6

Possibility of hazardous reactions

Vapours may form explosive mixture with air.

Conditions to avoid

Heat, flames and sparks.

Materials to avoid

Oxidizing agents, Strong bases, Strong reducing agents

Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides

SECTION 11 - TOXICOLOGICAL INFORMATION

LD50 Oral - rat - 3,200 mg/kg

Remarks: Behavioral:Muscle weakness.

LD50 Dermal - rabbit - > 5,000 mg/kg

Skin corrosion/irritation

Serious eye damageleye irritation

Eyes - rabbit - Severe eye irritation

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

TARC. No component of this product present at levels greater than or equal to 0.1% is

6 / 9
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identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

no data available

Specific target organ toxicity - single exposure (GHS)

inhalation - May cause respiratory irritation.

Specific target organ toxicity - repeated exposure (GHS)

no data available

Aspiration hazard

no data available

Potential health effects

Inhalation May be harmful if inhaled. Causes respiratory tract irritation.

Ingestion May be harmful if swallowed.

Skin May be harmful if absorbed through skin. Causes skin irritation.

Eyes Causes eye irritation.

Additional Information

RTECS MI6900000.

SECTION 12- ECOLOGICAL INFORMATION

7 / 9
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No data available

Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

SECTION 13 - DISPOSAL CONSIDERATIONS

Product

Burn in a chemical incinerator equipped with an afterburner and scrubber but exert extra care in igniting as this material is highly flammable. This combustible material may be burned in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging

Dispose of as unused product.

SECTION 14 - TRANSPORT INFORMATION

Proper Shipping Name: n-Heptaldehyde

UN#: UN3056

Hazard Class: 3

Packing Group: |||

Additional Information: None

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SECTION 15 - REGULATORY INFORMATION

We have not found regulatory information.

SECTION 16 - OTHER INFORMATION

The information contained in the Material Safety Data Sheet is correct to the best of our knowledge at the date of issue. It is intended as a guide for the safe use, handling, disposal, storage and transportation and is not intended as a warranty or as a specification. The information relates only to the product specified and may not be suitable for combinations with other materials or in processes other than those specifically described herein.

HISTROY

Date of printing

Date previous issue

Date of issue

9/9
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Nelson's Vegetable Storage Systems inc.

P.O. BOX 215 N7158 6TH DRIVE PLAINFIELD. WI 54966

OFFICE: (715) 335-6660 FAX: (715) 335-6661

E-Mail: dale@nelsonsveg.com

March 7, 2014

National List Manager USDA/AMS/NOP, Standards Division 1400 Independence Ave SW Room 2648-So, Ag Stop 0268 Washington, DC 20250-0268

RE: NOP List Approval
SmartBlock Potato Sprout Inhibitor (EPA Reg. No. 5481-571)

To Whom It May Concern:

I am writing to you in support of AMVAC Chemical Corporation on its petition to the NOSB. My company performs sprout inhibiting and was fortunate enough to help bring clove oil and SmartBlock to the potato industry.

We have been using clove oil for many years and have been somewhat effective in sprout control. Although the organic market is not very large here, there have been some opportunities on organic chip stock. The clove oil treatments for the chip stock were not very successful. We had to make multiple applications of clove oil. The more applications of clove oil that were done, the more the sugars would spike and turn the potato chip to an undesirable color. We were forced to have the growers move them earlier than what they wanted. The sprout control and potato chip color was marginal.

We have had some opportunities on potato chip stock with SmartBlock; not on organic potatoes, but on potatoes that the grower did not want the traditional sprout inhibitor, CIPC, applied. This was because he was going to put seed potatoes in the storage after the current potatoes were processed and did not want the CIPC residue in the storage. We were very successful on burning off sprouts up to 1" long. There were no sugar spikes. Therefore, no potato chip color problems. The grower was very impressed with how well SmartBlock worked on sprout control compared to using clove oil in the past.

AGRI-VENTILATION SALES & SERVICES

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The other opportunity we had was on some fresh pack potatoes in Nebraska for Elkhorn River Farms, owned by R.D. Offut Company, the largest farmer in the United States. These were not organic potatoes but the grower was putting seed potatoes back into the shed so didn't want the carryover of CIPC residue. The grower was willing to write a letter explaining his experience with SmartBlock vs clove oil. I have attached the letter for your review.

As an applicator and as someone who has firsthand experience with SmartBlock and clove oil, there is no doubt that SmartBlock does a better job with fewer applications for controlling sprouts for both immediate and long term.

Sincerely,

Dale E. Nelson

Nelson's Vegetable Storage Systems, Inc.

Jah 3. Mun

Ekhorn River

March 4, 2014

To Whom It Concerns:

I was asked to compose a letter concerning the AMVAC Chemical Corporation product SmartBlock. We are a fresh pack operation and pack Norkotah potatoes raised and stored on our farm. SmartBlock was used to treat one of our storage sheds this year as a trial. The shed is divided into two bins that were filled between 9/30/13 and 10/9/13 and have 225,000 cwt total. SmartBlock was applied 12/3/13 when the tubers were just starting to become active. The last storage sprouting inspection performed on 2/20/14 showed that there are still less than 5% of the tubers active and no peeping. This is actually better than our farm's standard sprout inhibitor treatment program at this point. The rest of our storage sheds that received our standard program, which includes 1,4-Sight and CIPC, have between 35-70% of the tubers active with between 1-5% peeping.

In the absence of 1,4-Sight and CIPC for sprout control, the other option is clove oil. Our experience with clove oil shows sprouts and peeps will burn back within a few days to a week after application, depending on the size, but the longevity of control is limited to about 4-6 weeks. There were a few tubers with sprouts in the SmartBlock treated shed that I marked prior to application. The sprouts were completely burned off the day after application and continue to be inactive to date. Since there is very minimal tuber activity in this shed to date, 13 weeks after application and 21 weeks after door closure, I would say efficacy of SmartBlock for long term sprout control far exceeds that of clove oil. In short, I am very impressed with SmartBlock so far and would certainly recommend it over clove oil for extended and immediate sprout control.

Sincerely,

Paul Seger Agronomist

Elkhorn River Farms

Nick David

Midwest Regional Agronomist

R.D. Offutt Company

Exhibit 3



National List Manager

2/28/14

USDA/AMS/NOP, Standards Division

1400 Independence Ave SW

Room 2648-So, Ag Stop 0268

Washington, DC 20250-0268

RE: NOF

NOP List Approval

SmartBlock Potato Sprout Inhibitor (EPA Reg. No. 5481-571)

I am writing to fully support AMVAC Chemical Corporation's petition to the NOSB for the inclusion of the product SmartBlock® (3-decen-2-one, 98% purity) to be listed as an approved substance for stored potatoes under the National Organic Program. As a grower of 1200 acres of organic potatoes, we typically store 500,000 CWT each storage season. We currently lack effective tools to control sprouting in stored potatoes and definitely need new products and technology. Sprout control is the corner stone to ensure a dependable supply of organic potatoes into the marketplace. Without any treatment, we average a loss of around 20% which means that unless we treat for sprout control, it results in a significant economic loss to our business.

We ship organic potatoes to the Pacific Rim countries, which takes about three to four weeks just to get the potatoes to those countries and with the high temperature/humidity climates potatoes can sprout quickly, reducing shelf life. The demand for organic potatoes has been steadily increasing and as we grow to meet this demand, we will definitely need Smartblock to stay competitive in the marketplace.

Although clove oil (eugenol) which is a NOP- listed material is available for this use, we have since discovered that it is not as efficacious as SmartBlock. To control sprouting over the course of a storage season, we typically have to make 1 to 3 applications of clove oil which involve product and manpower to make the treatments, and the potatoes will still sprout. Additionally, with 1 treatment we believe that Smartblock-treated potatoes will last a lot longer without sprouting in grocery stores or consumer homes than when treated with clove oil.

I understand that 3-decen-2-one is also on the approved FDA's EAFUS Direct Food Additive List and also classified as GRAS, which gives us confidence on the safety of the product, and overall comfort with its use in our organic potato business.

Please feel free to contact me if you have additional questions or concerns of if you require additional information.

Sincerely.

Daniel Chin

President Wong Potatoes, Inc./ Chin Family Farms Organic, LLC

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