ORO AGRI
ORO AGRI INCORPORATED

PETITION TO ADD POTASSIUM SORBATE TO §205.601(e) AND §205.601(i) OF THE NATIONAL LIST

Submitted by:
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NOP – NATIONAL LIST PETITION

ITEM A

Item A.1 – Synthetic substances allowed for use in organic crop production §205.601(e) and §205.601(i).

Item A.2 – OFPA Category: Potassium sorbate will fall under Production aids.

ITEM B

1. Substance Name

Chemical Name: Potassium Sorbate

Other names: K sorbate
Sorbic acid, potassium salt
Potassium salt of 2,4-hexadienoate
2,4-Hexadienoic acid, potassium salt

2. Petitioner and Manufacturer Information

Petitioner: Oro Agri, Inc., 2788 S. Maple Ave., Fresno, CA 93725
(559)442-4996

Manufacturer: Celanese Sales Germany GmbH
Am Unisys-Park 1
65843 Sulzabach (Taunus)
German

3. Intended or Current Use

Potassium sorbate is an allowed active ingredient in 25(b) minimal risk pesticide formulations. Oro Agri is petitioning potassium sorbate as an active ingredient for plant disease and insect control/suppression under §205.601(e) and §205.601(i).

4. Intended Activities and Application Rate

Intended for organic crop production: Potassium sorbate as a minimal risk active ingredient used as a fungicide and insecticide with intended uses in field and greenhouse applications. Potassium sorbate is exempt from requirement of tolerance on crops.

OR-159-B, the proposed end-use fungicide/insecticide contains 45% potassium sorbate to be

tank mixed at 1% v/v solution to target crop disease and insects such as powdery mildew, downey mildew and whitefly. The product is used on a wide range of crops including grapes, cucurbits, roses, stone fruit, pome fruit, nuts, solanaceae vegetables and cannabaceae plants. Refer to Appendix I for OR-159-B product label for information on mode of action, use sites and directions.

5. Manufacturing Process of Potassium Sorbate

Sorbic acid was found and extracted from mountain-ash berries in 1859. The first uses of sorbic acid for antimicrobial properties began in 1939/1940. Today, sorbic acid is produced synthetically by using ketene and crotonaldehyde. Potassium sorbate is the potassium salt of the output of neutralization of sorbic acid with potassium hydroxide. The preparation method of a kind of sorbic acid and potassium sorbate is characterized in the following comprising steps[1]:

1) Acetic acid generates ketene gas through Pintsch process, obtains polyester with the crotonic aldehyde condensation reaction;
2) Polyester depolymerizes to crude product Sorbic Acid and tar under the condition that hydrochloric acid exists;
3) Remove tar by washing with alcohol, obtain the crude product Sorbic Acid;
4) Crude product Sorbic Acid and salt of wormwood reaction obtains potassium sorbate solution, adds Gấc and removes pigment in the potassium sorbate solution, fall Gấc through filtering separation after, become colourless, clarification, transparent potassium sorbate liquid;
5) Potassium sorbate liquid obtains the potassium sorbate powder by the mode drying of high speed centrifugation spraying;
6) The potassium sorbate powder becomes the potassium sorbate granule of bar column through the tablets press granulation;
7) Again by fluidised bed drying, screening, obtain the product potassium sorbate.

Information on the source of potassium sorbate:

Nutrinova® Sorbic Acid (E 200) is manufactured synthetically according to a process developed by former Hoechst AG / Celanese Food Ingredients, Germany, using ketene and crotonaldehyde.

Nutrinova® Potassium Sorbate (E 202) is manufactured synthetically through neutralization of Nutrinova® Sorbic Acid with potassium hydroxide.

The source of potassium sorbate is food grade and manufactured in a closed system, waste disposal certified and chlorine-free production with multiple accreditations such as Food Safety System Certification, HACCP, and ISO 9001. Manufacturing of the potassium sorbate is done according to cGMP 21 CFR Part 110 and 21 CFR part 117. The potassium sorbate raw material and packaging suppliers are qualified per supplier company protocols. This ensures for high quality potassium sorbate that is consistent in purity and stability. The potassium sorbate source has high solubility and fast dissolution when dissolved will produce crispy clear solution as compared to other sources. Natural contaminants such as mycotoxins are excluded since potassium sorbate is synthetically manufactured, and not derived from natural agriculture materials. It is not genetically modified or derived from genetically modified materials.

[1] Referenced from “https://patents.google.com/patent/CN1634844A/en”

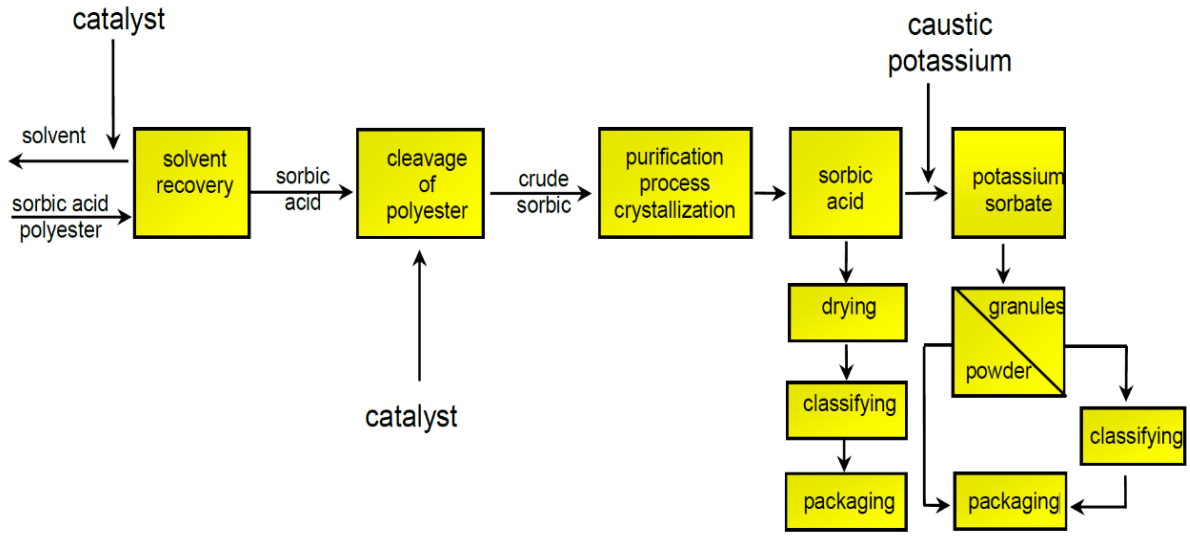

Figure 1Production Flow Chart of Nutrinova® Potassium Sorbate and Nutrinova® Sorbic Acid.

6. Ancillary Substances

Oro Agri is petitioning 100% food grade potassium sorbate. There are no known ancillary substances.

7. Previous Reviews

2002 Crops, 205.601: Petitioned for use in seed film coating as a preservative
Conclusion: Not enough information was provided to justify the use of potassium sorbate as a preservative in seed coating. Potassium sorbate is a weak acid antimicrobial known to cause resistance and is used in the food industry. Although, the possibility of potassium sorbate as a preservative in biological and microbial soil amendments was entertained in this review, it was concluded that potassium sorbate will not be allowed as a synthetic substance for use as a preservative.

2002 Livestock, 205.603: Petitioned for use in organic livestock production as a mold inhibitor
Conclusion: Potassium sorbate is appropriate for use in organic products considering potassium sorbate is a low toxicity profile substance. Additional information of the ingredients in manufacturing of potassium sorbate is questioned however, the reviewers would allow use in organic livestock production with the exception of lifting the regulations about chemical preservatives.

8. Regulatory Authority

IARC: Not listed

Prop 65: Not listed

FDA: GRAS (Generally Regarded As Safe) listed 21 CFR 182.3640; 21 CFR 182.90

EPA:

- TSCA listed CAS 24634-61-5; 2,4-Hexadienoic acid, potassium salt (1:1), (2E,4E)-
- 40 CFR 180.1233 Exempt from requirement of tolerance
- Listed on EPA list 4A minimal risk inert ingredient
- Allowed Minimum Risk Pesticide Active under 40 CFR 152.25(f)
- Allowed Minim Risk Pesticide Inert ingredient under 40 CFR 152.25(f)
- Safer Choice: CAS 24634-61-5; Potassium (E,E)-sorbate; preservatives and antioxidants
- Pesticide active: Sorbic acid, potassium salt (PC 075902)

FAO/WHO Expert Committee on food additives (JECFA): ADI 0-25 mg/kg bw

9. Chemical Abstracts Service (CAS) Number and Product Labels

CAS No.: 24634-61-5, 590-00-1
OR-159-B end-Use label (see Appendix I)

10. Physical/Chemical Properties and Mode of action

Physical/Chemical Properties

Form: Solid, granules
Color: White/ white to yellow
Odor: Odorless
Density: 1.36 @ 20°C
pH: 7 @ 20°C
Water solubility: 58.2% at 20°C
Alcohol solubility: 6.5%
Molecular formula: $C_6H_7KO_2$
Shelf life: 3 years

Mode of Action

Potassium sorbate has a contact mode of action. For example, mold inhibitors such as potassium sorbate cannot be effective unless they are completely and thoroughly distributed

throughout the feed. Ideally, this means that the entire infested surface of each feed particle or crop should come in contact with the inhibitor and that the inhibitor should also penetrate so that interior molds will be inhibited. The particle size of the carriers for mold-inhibiting chemicals should be small so that as many particles of feed as possible are contacted.

Chemical interactions with other substances, especially substances used in organic production:

"The main types of mold inhibitors are (1) individual or combinations of organic acids (for example, propionic, sorbic, benzoic, and acetic acids), (2) salts of organic acids (for example, calcium propionate and potassium sorbate), and (3) copper sulfate. Solid or liquid forms work equally well if the inhibitor is evenly dispersed through the feed. Generally, the acid form of a mold inhibitor is more active than its corresponding salt. Many factors influence the effectiveness of mold inhibitors, and proper attention to these factors can enhance the benefits they provide. In general, the smaller the inhibitor particles the greater the effectiveness. Some propionic acid inhibitors rely on the liberation of the chemical in the form of a gas or vapor from fairly large particle carriers. Presumably, the inhibitor then penetrates the air spaces between particles of feed to achieve even dispersion. (K-Sorbate Organic Petition Technical Advisory Report)

"Potassium sorbate goes into solution as ionic potassium and sorbic acid. The degradation products are more hazardous than the product itself (Binas, 2001). Like potassium sorbate, sorbic acid has antifungal and antimicrobial activities. Sorbic acid is reported to have synergistic effects with sodium nitrite (Banerjee and Giri, 1986). Sorbate and nitrite form several species of direct acting mutagens and genotoxic agents, including ethylnitrolic acid and 1,4-dinitro-2-methylpyrrole (Hartman, 1983). Various microorganisms play a role in this transformation (Shu et al., 1991). This has been studied primarily in the context of sodium nitrite and potassium sorbate as food additives, and not under field conditions. However, sodium nitrate is used as a fertilizer on some organic farms in the United States. Nitrite can be formed reduced by denitrification and reduction of sodium nitrate under conditions of poor drainage and anaerobic conditions (see Brady, 1974.)"[1]

Toxicity and environmental persistence:

"Potassium sorbate is the potassium salt of sorbic acid. Both potassium sorbate and sorbic acid are novel, highly efficient, safe and nonpoisonous food preservatives recognized internationally as a best series. It is the substitute for the sodium benzoate as a traditional preservative. Potassium sorbate is the potassium salt of an unsaturated fatty acid, which participates in the normal fat metabolism in human body and will be oxidated into carbon dioxide and water finally. It will not be accumulated in human body." "Potassium sorbate is a naturally occurring unsaturated fatty acid and is completely safe with regard to health and have the lowest allergenic potential of all food preservatives." (Technical Advisory Panel, 2002)

Acute and sub-chronic toxicity of potassium sorbate are outlined in table 1 and 2.

[1] Directly referenced from http://www.omri.org/Ksorbate_final.pdf (TAP report for crop use)

Table 1: Acute Toxicity of Potassium Sorbate[2]		
Study	**Results**	**Source**
Acute oral toxicity	Rat: 4, 920 – 6, 170 mg/kg	(JECFA 1966; Walker 1990)
Acute dermal toxicity	Not found	
Acute inhalation	Not found	
Acute eye irritation	Not found	
Acute dermal irritation	Not found	
Skin sensitization	Not found	

Table 2: Sub-chronic Toxicity of Potassium Sorbate[2]		
Study	**Results**	**Source**
Repeated Dose 28-day Oral Toxicity Study in Rodents	Not found	
90-Day oral toxicity in rodents	Mice: No adverse effects (sorbic acid) Rats: Slight enlargement of liver	(Hendy et al. 1976; LSRO 1975)
90-Day oral toxicity in non-rodents	Dog: No adverse effects	(Walker 1990)
90-Day dermal toxicity	Not found	
90-Day inhalation toxicity	Not found	
Reproduction/development toxicity screening test	Rat: No significant difference from control	(JECFA 1974)
Combined repeated dose toxicity with reproduction/ development toxicity screening test	Not found	
Prenatal developmental toxicity study	Not found	
Reproduction and fertility effects	Not found	

Although allergic reactions to potassium sorbate can be described as unusual, there has been a reported incident of repeated occupational exposure in a dairy plant leading to severe rashes in an exposed worker (Le Coz 2005).

The chronic toxicity of potassium sorbate is described in table 3.

Table 3: Chronic Toxicity of Potassium Sorbate[3]		
Study	**Results**	**Source**
Chronic toxicity	Ames: Negative	(Walker 1990)
Carcinogenicity	Mouse: Negative	(JECFA 1974; LSRO 1975)

[2] Directly referenced from https://ecommons.cornell.edu/bitstream/handle/1813/56136/potassium-sorbate-MRP-NYSIPM.pdf?sequence=1&isAllowed=y
[3] Directly referenced from https://ecommons.cornell.edu/bitstream/handle/1813/56136/potassium-sorbate-MRP-NYSIPM.pdf?sequence=1&isAllowed=y

Combined chronic toxicity & carcinogenicity	Not Found	

During the evaluation of potassium sorbate as GRAS (Generally Regarded As Safe) status, the FDA reviewed four animal studies for carcinogenesis. One was inconclusive and three had no carcinogenesis in the test animals (LSRO 1975). Potassium sorbate is not identified as carcinogens by the International Agency for Research on Cancer (IARC 2014), is not on the California Proposition 65 list of known carcinogens (Cal-EPA 1997) and does not appear on the Toxics Release Inventory (TRI) Basis of OSHA Carcinogens (US EPA Toxics Release Inventory Program 2015).

Environmental impacts from its use and/or manufacture:

"Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Potassium sorbate is considered a low-risk pesticide. therefore, the chances of environmental contamination if used in feed or medication are minimal. Potassium sorbate is non-toxic."[4]

Effects on human health:

"Potassium sorbate is the potassium salt of sorbic acid and is much more soluble in water than the acid. Potassium sorbate will produce sorbic acid once it is dissolved in water and is the most widely used food preservative in the world. It is effective up to pH 6.5 but effectiveness increases as the pH decreases. Potassium sorbate has about 74% of the antimicrobial activity of the sorbic acid, thus requiring higher concentrations to obtain the same results that pure sorbic acid provides. Potassium sorbate is effective against yeasts, molds, and select bacteria, and is widely used at 0.025 to 0.10 % levels in cheeses, dips, yogurt, sour cream, bread, cakes, pies and fillings, baking mixes, doughs, icings, fudges, toppings, beverages, margarine, salads, fermented and acidified vegetables, olives, fruit products, dressings, smoked and salted fish, confections and mayonnaise." "Maximum level allowable by law is 0.1%. It is important to know that the addition of sodium benzoate and/or potassium sorbate to a food product will raise the pH by approximately 0.1 to 0.5 pH units depending on the amount, pH, and type of product. Additional adjustment of the pH might be needed to keep the pH at a safe level."[5]

Although sorbic acid is not qualified as an active ingredient in minimum risk pesticides, potassium sorbate is because it can instantly isolate into sorbic acid in solution. Toxicology studies of sorbic acid will generally be buffered with either sodium or potassium in solution, and sorbic acid has low mammalian toxicity, including for humans. However, an analysis of the literature concluded that "a small but ill-defined subgroup may suffer idiosyncratic reactions to this preservative [sorbic acid]" (Walker, 1990). For example, contact dermatitis (Le Coz 2005), urticaria (hives) (Hannuksela and Haahtela 1987), stinging sensations, and 'burning mouth syndrome' (Lamey et al. 1987; Haustein 1988)

[4] From 2002 Potassium Sorbate Livestock CFNP TAP Review: https://www.ams.usda.gov/sites/default/files/media/P%20Sor%20technical%20advisory%20panel%20report.pdf; Directly referenced from http://www.jtbaker.com/msds/p6135.htm

[5] Directly referenced from http://www.ferlowbrothers.com/potassium_sorbate.htm

Effects on soil organisms, crops or livestock:

"Sorbic acid is readily metabolized. Both man and rat appear to utilize identical metabolic mechanisms for oxidation of sorbate. The long-term studies suggest that the same no-effect level applies to the salts as to the free acid. Sorbic acid and K-sorbate corresponding to the specifications do not cause tumours when administered orally or subcutaneously. The earlier results of s.c. injection with an unidentified sample remain unexplained. Long-term studies on parasorbic acid which, it has been claimed, may be produced from sorbic acid, also produce no evidence of carcinogenic potential when given orally." "There have been many studies investigating the migration of antimicrobials such as sodium benzoate, benzoic acid, propionic acid, and potassium sorbate from coatings into food. It appears that the most advantageous use of these films for antimicrobial properties would be the formation of a monolayer lipid and sorbic acid film, or a bilayer film composed of a hydrophilic base layer coated with a thin layer of lipid containing sorbic acid. The main issue involves the production of coatings with good surface tension that will stick to produce."[6]

"Unfortunately, grain and feed provides an ideal environment for molds to proliferate. Raw materials or feeds in bulk storage are rich sources of energy, proteins and moisture and, thus, are highly conducive to mold growth."[7] "Toxins produced by molds are called mycotoxins. Mold growth and toxin production is favored by warm temperatures and high humidity typical of tropical and subtropical regions, including the southern United States. Some types of mycotoxin cause cancer in animals. Aflatoxin, a type of mycotoxin, is a potent liver toxin in all animals in which it has been tested. Of all the mycotoxins, aflatoxin is of greatest concern because it is highly toxic and potentially carcinogenic. Peanuts, corn, and cottonseed are the U.S. commodities which are most susceptible to contamination with aflatoxin. The Food and Drug Administration monitors foods for the presence of aflatoxin."[8] Swine are sensitive to mycotoxins, especially nursing or nursery-age swine. In general, mycotoxins cause reductions in feed intake, growth performance, and immune function when levels are relatively low. Producers must be aware that if one toxin is identified in a sample, the chances are high that other toxins are present. Some toxins may not have been identified yet, but research on known mycotoxins provides insight into the expected effects in swine and potential methods to reduce those effects.

Aflatoxin-contaminated feed not only reduces animal performance and overall health, but it also creates risks of residues in milk. Aflatoxin is secreted into milk in the form of aflatoxin M1 with residues approximately equal to 1 to 2 percent (1.7 percent average) of the dietary level. This ratio is not influenced greatly by milk production level since higher producing cows consume more feed and have a slightly higher transmission rate. Due to risks of milk residues, dietary aflatoxin should be kept below 25 ppb. This level is conservative due to: (1) nonuniform distribution of aflatoxin in grain and feed, (2) uncertainties in sampling and analysis, and (3) the potential for having more than one source of aflatoxin in the diet. Replacement animals may tolerate 50 to 100 ppb aflatoxin. (K-Sorbate Organic Petition Technical Advisory Report)

[6] Directly referenced from http://www.cfsan.fda.gov/~comm/ift3exec.html#stp
[7] Directly referenced from http://www.kemin.com/livestock-feed-ingredients/mold-antimicrobials.shtml
[8] Directly referenced from http://spokane-county.wsu.edu/food/topic1.htm

11. Safety Information

Potassium sorbate is a category 2B serious eye damage/eye irritation health hazard with a WARNING signal word. If in eyes or exposed, rinse cautiously with water for several minutes. Medical attention is advised if irritation persists. Potassium sorbate is stable under normal conditions. See SDS appendix II

OR-159-B end-use product with potassium sorbate 45% is not hazardous according to OSHA Hazard Communication Standards (29 CFR 1910.1200). See SDS appendix III

NTP technical report for potassium sorbate is not available.

12. Research Information on Potassium Sorbate

Sorbic acid should inhibit the growth of soil bacteria and fungi. It would also inhibit the growth of yeast that contaminated stored seed coated with a protein/carbohydrate polymer. Potassium sorbate is petitioned as a shelf-life extender for a seed coating. The microbial growth inhibition comes at a cost, however, exposure of microbes to weak acids and bases can turn on resistance genes and "train" the organisms to resist other environmental stresses (Russell, 1991; Piper et al., 2001). Mild acid treatment of Vibro parahaemolyticus, using hydrochloric acid at a pH of 5, has been shown to increase the bacteria's resistance to lower pH and give cross protection against heat stress (Wong, 1998). Leyer & Johnson (1993) reported similar findings on Salmonella typhimurium. Taormina and Beuchat (2001) also show that exposing Listeria monocytogenes to mild alkali or chlorine induces resistance to strong disinfectants agents and heat.

Short chain fatty acid preservatives like sorbic and propionic acid have been specifically shown to induct resistance to environmental stresses in Salmonella typhimurium and yeasts in the genus Saccharomyces (Piper et al., 2001; Stratford & Anslow, 1996; Kwon & Ricke, 1998). Kwon & Ricke (1998) show that exposure of Salmonella typhimurium to propionic acid can induce acid resistance in as little as 30 minutes. Weak acid resistance is becoming a problem in the food industry where acids such as sorbic and propionic are widely used to preserve food against yeast and fungi spoilage (Piper et al., 2001). Propionic acid is currently being phased into the meat packing industry as an antibacterial spray for beef carcasses (Hardin et al., 1995). Weak organic acid antimicrobials are important to the food industry, and April 4, 2002 Page 3 of 11 NOSB TAP Review Compiled by OMRI Potassium Sorbate Crops manufacturers should use them wisely. Indiscriminate use can lead to widespread acid tolerance in microbial populations (Levy, 2001).[9] On the contrary, "[T]here has been no evidence to indicate that microorganisms can develop resistance to sorbates, as occurs with antibiotics and certain other antimicrobial chemicals. However, there is variation in the sorbate sensitivity of microorganism from one genus to another, between different species in the same genus, and even between different strains of the same species." (Dorko, C. L., et al, 2000)

<u>Crop use - seed coating:</u>

[10] Directly referenced from https://www.ams.usda.gov/sites/default/files/media/Pot%20sor1%20technical%20advisory%20panel%20report%202002.pdf

"The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock.

Potassium sorbate is used for its antimicrobial activity. Therefore, it is reasonable to expect that it would inhibit the growth of soil microorganisms. Dorko (1997) contains a summary table of over 150 different bacteria, molds, and yeasts inhibited by sorbates. Many of these are human or plant pathogens. In particular, sorbic acids and its salts suppress a significant number of organisms regarded as beneficial, such as Aspergillus niger—generally non-pathogenic and active in making phosphorous and trace elements more available (Alexander, 1977); Bacillus subtilis—an antagonist used to suppress pathogenic strains of Alternaria, Aspergillus, Fusarium, and Rhizotonia (Meister, 2001); Trichoderma viride, an antagonist of Pythium and Rhizoctonia (Horst, 1990); and Saccharomyces cerevisiae—brewer's yeast and an organism identified as playing a potential role in the sulfur cycle (Alexander, 1977). However, solutions that contain potassium sorbate adjusted to an acid pH using acetic acid and other ingredients were found to be selective in favor of certain Sporolactobacillus (Doores and Westhoff, 1983)."[10]

"The alternatives to using the substance in terms of practices or other available materials.

The petitioned use, and the only crop application supported in the literature, is as a seed treatment. This is tied to the practice of coating the seed. One alternative is to not coat the seed. Admixtures are documented to decrease the storage life 182 of seeds, particularly those that absorb moisture and serve as a substrate for plant pathogens (Agrawal and Sinclair, 1996). By not coating the seed with such substances, one could effectively increase the storage life. If coating the seed is desirable, then timing the treatment to within two weeks of planting should be sufficient to avoid infection, based on the information provided in the petition (Patil, 2001). This would preclude saving coated seed for more than a season.

Proper seed storage begins at planting. Some varieties are more prone to seed-borne diseases than others (Agrawal and 188 Sinclair, 1996). By sowing disease-free seed, one is more likely to reap disease-free seed. Techniques are available to exclude, quarantine, and reduce inoculum (Maude, 1996). Selecting a field that has not grown a host crop for a suitable period reduces the chance of soil-borne infection (Agrawal and Sinclair, 1996). Preventing infection in the field is an important step to maintaining disease-free seeds.

Harvest is a critical stage for preventing seed-borne diseases. Timing must be right. Delayed harvest favors seed infection (Agrawal and Sinclair, 1996). Yet seed should not be harvested too soon either. Seeds should be harvested when the moisture levels are low enough to prevent the growth of mold. Care should be taken in harvesting to not damage the seeds in a way that permits opportunistic infection by mold or bacteria. Test methods are available to help predict and ensure storability (Neergaard, 1977). Once harvested, seeds need to be maintained in cool, dry conditions (Copeland and McDonald, 1995). Insect damage can also create opportunities for infection (Neergaard, 1977; Agrawal and Sinclair, 1996). Construction and maintenance of

[10] Directly referenced from https://www.ams.usda.gov/sites/default/files/media/Pot%20sor1%20technical%20advisory%20panel%20report%202002.pdf

appropriate storage containers and facilities can also regulate conditions so that they favor long-term seed storage (Neergaard, 1977).

A number of biological control agents are commercially available to protect seeds from microbial pathogens, including Bacillus subtilis, Trichoderma spp., and Gliocladium spp. (Campbell, 1989; OMRI, 2001). Biological control methods are compatible and are particularly well suited for use with coating technology (Campbell, 1989). Copper sulfate [7 CFR 205 205.601(i)(2)] and elemental sulfur [7 CFR 205.601(i)(8)] both appear on the National List and are both effective as seed treatments (Maude, 1996). Various natural edible plant extracts show equal or greater efficacy as antimicrobial agents, including Chinese chive, cinnamon, and Corni fructus when compared with potassium sorbate (Mau, Chen, and Hsieh, 208 2001)."[11]

Food use:

"The three most common preservatives are sorbates, propionates, and benzoates. Choosing from these alternatives is highly dependent on the pH of your product. In general, the effective upper pH limit is about 6.5 for sorbates, 5.5 for propionates, and 4.5 for benzoates. When used at the pH levels of most mildly acidic food products (pH 5.5 - 6.0), sorbates are the more effective preservative against a wider spectrum of food spoilage microorganisms than benzoates or propionates. Sorbates' effectiveness increases with greater acidity. Above pH 4.0, sorbates are more effective than sodium benzoate and sodium or calcium propionate. At pH 2.5 to 3.0, sorbates are still somewhat more effective than sodium benzoate as a yeast and mold inhibitor, and more than twice as potent as propionates. Sorbates are at their optimum effectiveness when used below pH 6.0. However, they function up to pH 6.5 but are relatively ineffective at pH 7.0 and above." [12]

"Sorbates are compounds like potassium sorbate, calcium sorbate or sodium sorbate. Another name for these compounds is sorbic acid. These compounds prevent the growth of mold on/in cheeses, jelly, cake, syrup, dried fruits and wine. Sorbic acids are naturally found in plants and have been found to be safe for human consumption. They inhibit microbial growth in the same way that benzoates do. Propionates also inhibit microbial growth by inhibiting energy production. However, they do not require low pH's to inhibit the microbes. Compounds like sodium propionate and calcium propionate are placed in bread, biscuits, cakes, pastries and other flour products to prevent that ubiquitous mold from destroying them. As a result, bread does not have to be purchased every day to keep away the mold forming. Calcium propionate is used more often than sodium propionate because it increases the amount of calcium people consume and keeps down the amount of sodium people eat in the product. Propionates have been found to also be safe for human consumption. The next two members of the food preservation family are not as human-friendly as the preservatives mentioned above. Nitrates have, for a long time, been used in various meat products such as bacon, ham, sausage, beef jerky and hot dogs. Sodium nitrate is the most common compound used and it, along with the salt in the meat, keeps Clostridium botulinum from growing deep in the center of the meat

[11] Directly referenced from https://www.ams.usda.gov/sites/default/files/media/Pot%20sor1%20technical%20advisory%20panel%20report%202002.pdf

[12] Directly referenced from https://www.ams.usda.gov/sites/default/files/media/P%20Sor%20technical%20advisory%20panel%20report.pdf

product. Clostridium botulinum is a dangerous bacterium that produces a protein toxin that causes paralysis and in some cases death. Preventing its growth is very important to food processors and consumers alike. Unfortunately, when nitrites are cooked, they form compounds called nitrosamines. Nitrosamines have been shown to cause cancer – which can be very dangerous. With all the bad press nitrates get, it is possible to assume that processors would get rid of them from their products. Good refrigeration would slow the growth of microbes enough to make the product safe. However, nitrates do a couple of things to the meat that food processors have found consumers like. Nitrates keep the meat a nice red color instead of the gray it would normally turn, and it gives the meat a flavor that consumers are used to in the products. Another food preservative that gives some people problems are the sulphites (sulfites). These compounds include the sodium or potassium salts of sulfite, bisulfite, or metabisulfite. These compounds are used in dried fruit, lemon juice, molasses, wine and processed potatoes. They prevent the growth of bacteria. Unfortunately, they also destroy vitamin B-1 and are not to be used in foods rich in this vitamin (meats, for example). Sulfites can also be a problem for people with asthma. Other people can become allergic to this compound and have a very severe reaction to it. If you are one of those people you should not consume anything preserved with sulphites."[13] See table 4.

Table 4: Common food preservatives and their uses[14]

Preservative	Effective Concentration	Uses
Propionic acid and propionates	0.32%	Antifungal agent in breads, cake, Swiss cheeses
Sorbic acid and sorbates	0.2%	Antifungal agent in cheeses, jellies, syrups, cakes
Benzoic acid and benzoates	0.1%	Antifungal agent in margarine, cider, relishes, soft drinks
Sodium diacetate	0.32%	Antifungal agent in breads
Lactic acid	Unknown	Antimicrobial agent in cheeses, buttermilk, yogurt, and pickled foods
Sulfur dioxide, sulfites	200-300 ppm	Antimicrobial agent in dried fruits, grapes, molasses
Sodium nitrite	200 ppm	Antibacterial agent in cured meats, fish, etc.
Sodium chloride	Unknown	Prevents microbial spoilage of meats, fish, etc
Sugar	Unknown	Prevents microbial spoilage of preserves, jams, syrups, jellies, etc
Wood smoke	Unknown	Prevents microbial spoilage of meats, fish, etc.

Potassium sorbate is used as a mold inhibitor in liquid aloe vera juice. Liquid aloe vera juice

[13] Directly referenced from https://www.ams.usda.gov/sites/default/files/media/P%20Sor%20technical%20advisory%20panel%20report.pdf
[13] Directly referenced from https://www.ams.usda.gov/sites/default/files/media/P%20Sor%20technical%20advisory%20panel%20report.pdf

using potassium sorbate is currently certified organic by the Texas Department of Agriculture, a certification that is recognized by the USDA. The aloe vera juice containing the potassium sorbate is in compliance with the FDA for human use as a dietary juice and the aloe vera juice is recognized as a GRAS product.

Aloe vera juice is a good substitute for the use of antibiotics and hormones in livestock therapy. The aloe vera juice cannot be made to provide adequate shelf life without the use of potassium sorbate to prevent mold growth. The aloe vera juice is a very important holistic medicinal therapy for livestock producers to use on livestock for scours prevention on young calves, topical therapy for cuts, sore teat ends, uterine infections, local irrigation of surgical wounds, pneumonia, shipping fever, immune support, topical treatment of pinkeye, etc. Livestock producers need a clean, safe source of aloe vera and potassium sorbate makes that possible.

Feed use:

"Detoxification of feed is still an elusive goal. However, certain feed additives have been successfully used to inhibit mold growth and to reduce the incidence of aflatoxicosis in animals. Organic acids such as propionic, sorbic and benzoic acids, as well as their salts such as calcium propionate and potassium sorbate, and copper sulfate can be used to inhibit mold growth in feed. Mineral clays such as zeolite and bentonite as well as hydrated sodium calcium aluminosilicate (HSCAS) can bind to aflatoxin, protecting animals from absorbing the toxin that may be in the feed. These products, according to FDA rules, cannot as yet be labeled as mycotoxin binders, and are sold as anticaking and free-flow feed additives."[15]

Efficacy of OR-159-B product (45% potassium sorbate):

OR-159-B product has been tested against industry standards both allowed for organic and conventional crop production. The following is a summary of trials showing efficacy on powdery mildew, downy mildew and whitefly.

Powdery Mildew
End-use product was evaluated as '159-B' for powdery mildew (*Erysiphe necator*) control on wine grapes by Crop Matters. The trial was conducted on an eleven-year-old block of Chardonnay wine grapes in Grandview, WA. The treatments were replicated four times. Applications were initiated from 5-12-inch shoots and continued through veraison until a total of 10 applications were made. The applications were done by backpack mist blower at 50 gallons per acre until June 6th, 100 gallons per acre on June 16, and 150 gallons per acre for the rest of the applications. Powdery mildew incidence was extremely high due to artificial inoculation of the trial site, averaging 99-100% in leaf and berry clusters on all plots.

[15] Directly referenced from
https://www.ams.usda.gov/sites/default/files/media/P%20Sor%20technical%20advisory%20panel%20report.pdf

159-B was applied at 0.25% v/v, 0.5% v/v, 1% v/v and 2% v/v. The pH of the spray solution was brought to 5-5.5 by addition of OR-278 acidifier. The standard treatments for comparison was an industry standard at the labeled rate of 20 oz. per acre and the same rate with the addition of an adjuvant.

Twenty-five leaves from each plot were evaluated for incidence and severity of powdery mildew. Twenty-five clusters from each plot were evaluated for incidence and severity of powdery mildew.

Treatments statistically reduced disease severity in leaf and clusters compared to the untreated control. 159-B at the rate of 1% v/v had the best control and significantly reduced severity in leaves and clusters compared to untreated and the standard, Serenade Opti (QST 713 strain of *Bacillus subtilis*). These results are summarized in **table 5** and supports the claim of powdery mildew control in grapes as stated on the end-use label.

Table 5: Effect on Powdery Mildew in Chardonnay wine grapes

Rating type			% incidence	% severity	% incidence	% severity
Rating date			16-Aug	16-Aug	16-Aug	16-Aug
Rating Unit			25 leaves	25 leaves	25 clusters	25 clusters
Days after last application			1 DA	1 DA	1 DA	1 DA
Trt No.	**Treatment**	**Rate**				
1	untreated	-	100 a	74.1 e	100 a	36.5 e
2	159-B	0.25% v/v	100 a	47.4 a	100 a	24.2 ab
3	159-B	0.5% v/v	99 a	41.3 abc	99 a	24.2 ab
4	159-B	1% v/v	100 a	33.0 d	99 a	9.6 f
5	159-B	2% v/v	99 a	34.8 bcd	99 a	13.5 cd
6	Serenade Opti*	20 oz /acre	100 a	48.3 a	99 a	29.6 a
7	Serenade Opti* + adjuvant	20 oz /acre + 0.25 v/v	99 a	36.3 bcd	100 a	20.5 bc

Mean values followed by the same letter indicates no significant difference as determined by ANOVA (α=0.10)

*Industry Standard (Organic Input Mateiral)-QST 713 strain of Bacillus subtilis

Phytotoxicity ratings were made in-season before every application. No phytotoxicity was observed at any time on leaves or fruit, even at the double rate of 159-B (2% v/v).

Powdery Mildew and Downey Mildew

End-use product was evaluated as 'OR-159' for downy mildew (*Plasmopara viticola*) and powdery mildew (*Erysiphe necator*) on Niagara grapes by Michigan State University. The trial was conducted on a mature vineyard in Clarksville, MI. The treatments were replicated four times. Treatments were applied 8 times from 4-6 inch through 5th post bloom spray with 7-14-day spray intervals. The applications were done by research sprayer with a 5ft boom at 40 gallons per acre. Downy mildew and powdery mildew disease pressure was moderate to high on leaves and/or clusters.

OR-159 was applied at 0.5% v/v, 1% v/v and 2% v/v along with OR-278 acidifier at equal rates. The industry standard treatments for comparison are Kaligreen (potassium bicarbonate) at 2.5lbs per acre, Microthiol Disperss (sulfur) at 3lbs per acre, PREV-AM (sodium tetraborohydrate decahydrate), at 0.4% v/v, Revus (mandipropamid) 8 fl.oz per acre and Quintec at 4 fl. oz per acre. The trial also included a standard program which data was not summarized.

Twenty-five randomly selected leaves and/or clusters were evaluated from each plot. Downy mildew on leaves was rated on September 19. Powdery mildew on leaves and clusters was rated October 16.

Treatments statistically controlled overall disease severity for both diseases in leaf and clusters compared to the untreated control. In both cases of disease severity control on leaves and/or clusters, OR-159 at 1% v/v was comparable to Revus, Quintec and PREV-AM while Kaligreen and Microthiol Disperss had poor control of downy mildew. Results as summarized in **table 6** support the claim of powdery and downy mildew control in grapes**.**

Table 6. Control of various diseases on Niagara grapes

Disease name			Downy mildew	Powdery Mildew	Powdery Mildew
Rating date			Oct-1	Oct-10	Oct-10
Rating Unit			25 leaves	25 clusters	25 leaves
Days after last application			41 DA	51 DA	51 DA
Treatment No.	**Treatment**	**Rate**	Untreated: % Overall severity Trt 2-7: % control vs Untreated		
1	Untreated	-	54.6 a	30.9 a	35.9 a
2	OR-159 + OR-278	0.5% v/v	90.7 c	96.4 bc	91.9 bc
3	OR-159 + OR-278	1% v/v	94.3 cd	99.0 c	95.8 cd
4	OR-159 + OR-278	2% v/v	97.6 ef	99.4 c	98.6 cd
5	PREV-AM	0.4% v/v	90.5 c	96.4 bc	88.9 b
6	Kaligreen*	2.5 lbs/ acre	36.1 b	94.8 bc	89.1 b
7	Microthiol Disperss*	3 lbs/are	44.0 b	92.9 b	87.7 b
8	Revus	8 fl. oz. /acre	97.8 f	99.9 c	99.7 d
9	Quintec	4 fl. oz. /acre	98.5 f	99.7 c	98.9 d

Letters behind means indicate statistical differences based on % overall severity data.
Means with the same letter are not significantly different according to Fisher's Protected LSD test (P≤0.05).
*Industry Standard (Organic Input Mateiral)-QST 713 strain of Bacillus subtilis

The vines were monitored throughout the season for signs of phytotoxicity. No phytotoxicity due to OR-159 with the addition of OR-278 acidifier was observed even at the high rate of 2% v/v.

Whitefly
The end-use product was evaluated as 'OR-159-B' for the comparison of efficacy against silverleaf whitefly (SLWF) on Prestige Red poinsettia by Crop Inspection Services. The trial was conducted at a greenhouse in Valley Center, CA. The treatments were replicated five times. Treatments were applied 2 times on November 1 and 9 of 2018 with a 7-day spray interval. The applications were done by backpack sprayer at 150 gallons per acre. Counts of nymph and adult stages of SLWF infestations were used for rating. Infestation was considered high.

OR-159-B was applied at 0.5% v/v, 1% v/v and 2% v/v along with an acidifier at equal rates. The industry standard treatments for comparison were SAFARI 20SG (dinotefuran) at 8 oz per100 gallons with the addition of CAPSIL (adjuvant) at 6 fl. oz. per 100 gallons. Additional products were included in the trial that will not be summarized and deemed irrelevant for comparison.

SLWF nymphs were rated before each application and 4 and 7 days after each application. SLWF adults were rated only before and on the day of each application.

There was significant statistical difference in the control of adults when all treatments were compared to the untreated control on the day of each application. Infestation of SLWF increased during days after each application, causing no statistical difference in control of nymphs at 4 or 7 days after each application. On the first application, OR-159-B at 1%v/v and SAFARI 20SG both showed equal control of SLWF adults, however, on the second application, SAFARI 20SG performed statistically better than 1%v/v of OR-159-B. Results as summarized in **Table 7** support the claim of suppression of white fly as no evidence of any residual control has been presented**.**

Table 7. Effects of OR-159-B product on silverleaf whitefly on Prestige Red poinsettia

Rating type			Counts	Counts	Counts	Counts	Phytotoxicity
Pest stage			adult	nymph	nymph	adult	N/A
Rating date			Nov-1	Nov-5	Nov-8	Nov-9	Nov-5, 15, 26
Days after application			0 DA-A	4 DA-A	7 DA-A	0 DA-B	4 DA-A, 6 DA-A, 6 DA-B
Trt No.	**Treatment**	**Rate**	**Pest numbers**				**Avg score over three dates**
1	untreated	-	64.4 a	108.4 a	274.9 a	87.8 a	0
2	OR-159-B + acidifier	0.5% v/v	7.8 d-h	102.1 a	150.0 a	7.8 de	0.7
3	OR-159-B + acidifier	1% v/v	6.6 ghi	123.1 a	115.0 a	14.2 bcd	2.7
4	OR-159-B + acidifier	2% v/v	7.3 e-i	98.6 a	153.0 a	8.5 de	5.7
5	SAFARI 20SG + CAPSIL	8 oz/100 gal	3.2 i	89.5 a	129.0 a	3.6 e	0
Means with the same letter are not significantly different according to LSD test (P≤0.05).							

General phytotoxicity on the Prestige Red poinsettia was rated on a scale of 1-10 on November 5, 15 and 26 of 2018. Phytotoxicity symptoms increased with increasing dose of OR-159-B,

however, at the recommended rate of 1% v/v, very low levels of phytotoxicity were observed.Phytotoxicity results for the poinsettia trial are summarized in **Table 7**.

13. Petition Justification Statement

Potassium sorbate is necessary as an organic input pesticide active because it has a contact mode of action where organic crop farmers in the US can use OR- 159-B in a disease resistance management program rotating with fungicides having different modes of action while suppression insects as summarized in section 12. OR-159-B can be used for late season diseases as potassium sorbate is exempt from requirement of tolerance and pre-harvest restrictions. It is found to have no phytotoxicity effects when used as directed.

Potassium sorbate is already used in organic crop production as it is an allowed substance for use in organic crop production under 205.601(m); “[A]s synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances”.

Potassium sorbate is on EPA list 4A known to be ingredients of minimal concern alongside of other natural occurring substances. Furthermore, EPA have reviewed ingredients that pose littleto no risk to human health or the environment and have allowed potassium sorbate as a minimalrisk active ingredient and/or inert ingredient whereas registration of these types are products arenot required under 40 CFR 152.25(f) of the FIFRA act.

On the contrary, there are currently non-synthetic and natural substances that could be used in place of potassium sorbate. NOP list of allowed and prohibited substances, 7 CFR 205.601(e) lists additional actives approved for use as insecticide actives and 7 CFR 205.601(i) as plant disease control. Additionally, a search in the OMRI approved product database was conducted under “Crop Pest, Weed and Disease Control” keyword “fungicide” to find that 464 fungicide products are currently available in the market through OMRI certification. The following passages are examples of these actives, one from 7 CFR 205.601(i) as a plant disease control and one natural extract.

Potassium Bicarbonate 7 CFR 205.601(i)(9):

Potassium bicarbonate is one of the currently available active ingredients listed on 7 CFR 205.601(i) and used in end-use product Kaligreen, an OMRI certified contact fungicide. Potassium bicarbonate is also listed under 7 CFR 205.601 (i) Synthetic substances allowed for use in organic crop production as plant disease control. According to an experiment done in article “Comparative Efficacy of Potassium Salts Against Soil-borne and Air-borne Fungi and Their Ability to Suppress Tomato Wilt and Fruit Rots,” by Jabnoun-Khiareddine H tested Potassium sorbate (PS), potassium bicarbonate (PB), and dipotassium hydrogenphosphate (DPHP) and were assessed for their antifungal activity against *Fusarium oxysporum* f. sp. *lycopersici* (FOL), *F. oxysporum* f. sp. *radicis-lycopersici* (FORL), F. *solani, Verticillium dahliae* (VD), *Rhizoctonia solani, Colletotrichum coccodes, Pythium aphanidermatum, Sclerotinia sclerotiorum, Botrytis cinerea and Alternaria solani*. They were screened for their ability to suppress Verticillium and Fusarium wilts, and Fusarium Crown and Root Rot (FCRR), for their effects on tomato growth, and for their potential control of Botrytis, Alternaria, Rhizoctonia and

Anthracnose fruit rots. PS (0.25-1.5%), DPHP (0.1-0.6 M) and PB (0.1-0.6 M) inhibited fungal growth in a concentration-dependent manner, with the greatest inhibition achieved using the highest concentrations. Inter specific variations in sensitivity were detected with *P. aphanidermatum, S. Sclerotiorum* and *B. cinerea* being the most sensitive to all salts. Single treatments using PS (0.25%), PB (50 mM) and DPHP (50 mM) resulted in varied degree of protection against wilts. PS led to 50, 78.26 and 65% lower wilt severity as respectively compared to *VD-, FOL- and FORL-inoculated controls*. PS had *significantly increased plant height, root* and aerial part fresh weights by *20.61, 30.76 and 33.02%, respectively, compared to FORL-inoculated plants and had improved root fresh weight by 42.18 and 32.87% compared to FOL-and VD-inoculated plants, respectively*. PB-based treatment led to 60.86 and 30% lower Fusarium wilt and FCRR severity but did not suppress Verticillium wilt. DPHP suppressed only Fusarium wilt by 65.21%. *Used as fruit treatment*, DPHP and PS significantly decreased Botrytis, Rhizoctonia, Alternaria and Anthracnose fruit rots by 46.68 and 30.81%, 14.04 and 15.74%, 20 and 31.67%, and 19.17 and 25.24%, respectively, compared to inoculated and untreated controls. PB-based treatment resulted in 12.83% significantly lower Rhizoctonia fruit rot. These results showed that PS may be used as potential abiotic agent for successfully controlling fungal tomato diseases.

Journal of Microbial & Biochemical Technology based article also states, “when studying the *in vitro efficacy* of eight food additives as possible alternatives to synthetic fungicides for the control of soil-borne pathogens, Arslan U et al., [31] find that the minimum PS inhibitory concentrations are 0.1% for F. *oxysporum* f. sp. *melonis*, 0.2% for *M. phaseolina*, 0.6% for *R. solani*, and 0.05% for *S. sclerotiorum*, whereas the minimum fungicidal concentrations were > 2%, > 2%, 0.8% and 0.1%, respectively. In the same sense, Mecteau et al., [18] showed that the organic anions sorbate completely inhibit mycelial growth of F. *sambucinum*, the causal agent of potato dry rot, at 0.2 M, while for spore germination the ED50 was 0.56 mM. Sorbate has also shown toxicity on mycelium of *Helminthosporium solani*, an important potato pathogen and always ranked first in efficacy, since it was fungicidal at concentrations as low as 0.05 M [17]. Sorbate has also shown toxicity on mycelium of *Helminthosporium solani*, an important potato pathogen and always ranked first in terms of efficacy [17]. PS, which is the most commonly applied salt of sorbic acid, is reported to completely suppress growth of the banana pathogen *Colletotrichum musae* in vitro when used at 0.125% [43]. In this regards, Kader et al., [44] noticed that the reduction in mycelial growth of citrus and strawberry fruit decay pathogens (*Geotricum candidum, Penicillium digitatum, P. italicum* and *B. cinerea*) is correlated to the gradual increase in PS concentrations with the highest inhibition observed at 4%. Yildirim et al., found that among food additives, PS shows strong inhibitory against mycelial growth of *B. cinerea* at rising doses [45]. At increasing concentrations (from 600 to 1600 µg/ml), this salt shows the strongest inhibition on mycelial growth and pycnidia and pycnidiospores production of *Phomopsis viticola* [46]. In the same sense, Mills et al., also reported that PS has significantly inhibited the growth of *B. cinerea, F. solani* var. *coeruleum, Phytophthora erythroseptica* and *P. infestans* infecting potato while [47,48] found that PS has completely suppressed *V. dahliae* growth at 0.25%.” “PB was found to be ineffective against most tomato fruit rot pathogens even though bicarbonates were reported possess wide-spectrum antimicrobial properties; their efficacy in controlling postharvest fungal phytopathogens has been widely reported [17,20- 22,35,37,41,80].” [2]

2 Referenced from "https://www.longdom.org/open-access/comparative-efficacy-of-potassium-salts-against-soilborne-and-airbornefungi-and-their-ability-to-suppress-tomato-wilt-and-fruit-ro-1948-5948-1000261.pdf”

Reynoutria sachalinensis (Natural; Plant extract):

Reynoutria sachalinensis is a plant extract currently being used as active ingredient in end-use product, REGALIA. In an article “Efficiency of plant extract from Reynoutria sachalinensis (Milsana) to control powdery mildew on tomato (Oïdium neolycopersici)”[3] by Tannie Trottin-Caudal, Reynoutria sachalinensis (a plant extract from the giant knotweed) has shown a high efficiency to control powdery mildew caused by Oidium neolycopersici on tomato crops grown in greenhouse conditions. Experiments on tomato grown in greenhouse conditions have been conducted during a 3-year period (1999-2001) to test the efficiency of this product for the control of O. neolycopersici. Several frequencies of application (7, 14 and 21 days) have been tested. Results obtained were compared with water-treated plants and with a fungicide control (Anvil, 0.6 l/ha). Whatever the frequency of application, plant extract gave a good protection of plants by reducing the number of leaflets attacked and especially by reducing the severity of the disease. Moreover, protection due to the plant extract sprayed every 7 days appeared to be not significantly different from the reference fungicide.

The conclusion of this study showed the plant extract from R. sacchalinensis significantly reduced the incidence of powdery mildew due to O. neolycopersici in the 6 greenhouses trials conducted between 1999 and 2001. Efficiency of this product was consistent whatever the levels of disease pressure and the cultivars of tomato tested. This product has also shown a good efficacy to control the other agent of powdery mildew on tomato, Leveillula taurica (Malathrakis et al., 2002). Moreover Nicot et al. have observed that the efficacy of Microdochium dimerum strain L13 to control Botrytis cinerea on tomato was not altered by the application of Milsana on leaves. It could then contribute to the management of tomato powdery mildews in organic farming.

As previously mentioned in table 6, treatments statistically controlled overall disease severity

for both diseases in leaf and clusterscompared to the untreated control. In both cases of disease severity control on leaves and/or clusters, OR-159 at 1% v/v was comparable to Revus, Quintec and PREV-AM while Kaligreen and Microthiol Disperss had poor control of downy mildew. In other words, potassium sorbate (the active ingredient in OR-159) had better results compared to potassium bicarbonate (the active ingredient in Kaligreen).

Conclusion: Beneficial Effects of Potassium Sorbate

Potassium sorbate is allowed in organic input materials for crop protection as an inert ingredient, therefore is already present in organic farming. It is exempt from requirement of tolerance and qualifies as a minimal risk pesticide active per 40 CFR 152.25(f). Potassium sorbate is generally recognized as safe (GRAS) in accordance with the FDA 21 CFR 582.3640 and CFR 182.90. It is used as food additives and does not accumulate in body.

Potassium sorbate will be an effective tool in a crop disease resistance program with its contact mode of action and it is not suspected to contribute to phytotoxicity of crops. For use as a fungicide and insect suppression, it produces comparable efficacy to conventional pesticides and carries a higher efficacy rate compared to other allowed organic or natural actives.

3 Referenced from “https://hal.inrae.fr/hal-02764311/document”

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APPENDIX I: OR-159-B End-Use Label

14. OR-159-B

FUNGICIDE and INSECT SUPPRESSION

Active Ingredient: Potassium Sorbate 45%
Inert Ingredients: Water, Urea, Citric Acid 55.0
Total: 100%

Keep Out of Reach of Children
CAUTION

Hazard & Precautionary statements: Wear eye protection and chemical resistant protective gloves. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product.
Environmental Hazards: Do not contaminate water sources by cleaning of equipment or disposal of wastewaters.

FIRST AID
Call a POISON CENTER or doctor/physician if you feel unwell. For Chemical Emergency (spill, leak, fire or accident), call CHEMTREC (800) 424-9300
IF SWALLOWED: Rinse mouth with plenty of water. Call a poison center/doctor if you feel unwell.
IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
IF INHALED: Provide fresh air and keep person comfortable for breathing.
IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Get medical attention if symptoms occur.

GENERAL INFORMATION: OR-159-B is a contact fungicide for field and greenhouse applications. Direct contact with the target organism is required for optimal control. Ensure application covers both sides of leaves. OR-159-B can be used in a disease resistance management program, rotating with fungicides having different modes of action. OR-159-B can also be used for late season disease infections when other fungicides may be limited due to pre-harvest interval restrictions.

Restricted Entry Interval: After a OR-159-B application, you may re-enter the area when the spray is dry.
Pre-Harvest Interval: OR-159-B can be applied up through harvest except where otherwise stated in the application rate comments.

DIRECTIONS FOR USE: Apply OR-159-B as a foliar treatment at the application rates listed below. For maximum effectiveness, apply OR-159-B at the first sign of disease. Spray intervals should be shortened if rain occurred within 48 hours after application or during fast growing stages to protect newly developed leaf or fruit surfaces. Also use shorter intervals when conditions are favorable for disease development or when high disease incidence is observed.

MIXING
Always clean tank, pump, and lines thoroughly before and after use. Add water to fill the tank to 90% of final volume and begin agitation. Gradually add OR-159-B to the tank mix. Ensure the pH of the spray solution is between 4.7 to 5 by adding an acidifier. Maintain agitation until spraying is completed. Spray until the tank is empty. Do not allow spray solution to sit overnight.

COMPATIBILITY
Test the tank mix compatibility, efficacy and crop sensitivity of a new tank mix combination before widespread use. OR-159-B is not compatible with alkaline chemicals or products that require a solution pH higher than 5, for example copper or potassium bicarbonate-based fungicides. Do not mix or apply within 14 days after the last copper fungicide application. Do a jar test on all new tank mix combinations. Do not add any additional adjuvants.

To make a 1% solution:

- 25 gallon spray volume: Use 32 fl. oz. OR-159-B
- 50 gallon spray volume: Use 64 fl. oz. OR-159-B
- 100 gallon spray volume: Use 128 fl. oz ORO-159-B

Application rates:
* Rate (%v/v) indicates the required concentration of OR-159-B. See dilution instructions above.

Crop	***Pest/Disease***	***Rates (% v/v) ****	***Comments***
Grapes (Table, wine, raisin and juice)	Powdery Mildew *(Erysiphe necator)* Downy Mildew *(Plasmopara viticola)* Sour rot disease complex	1%	Start application as soon as the first visual symptoms are observed and repeat every 7-10 days. When conditions are favorable for downy mildew development during pre-flowering through fruit set stages it is advisable to use OR-159-B in an integrated program with a residual contact or systemic product registered for downy mildew. Do not apply OR-159-B to wine grapes within 7 days of harvest.
Cucurbits including but not limited to melons, squashes, pumpkins, cucumbers	Powdery mildew *(Podosphaera xanthii)* White fly – suppression only	1%	Start application as soon as the first visual symptoms are observed and repeat every 5-7 days. Ensure thorough coverage on the underside of leaves. Where white flies are present during application, suppression can be expected.
Roses	Powdery mildew (*Podosphaera pannosa)* White fly – suppression only	*1%*	Start application as soon as the first visual symptoms are observed and repeat every 5-10 days. Some rose varieties and those grown in greenhouses may be sensitive to the spray mixture and should be tested before applying on a large scale. Where white flies are present during application, suppression can be expected.
Stone fruit, pome fruits and nuts including but not limited to peaches, nectarines, cherries, apples, pistachios, pecans	Powdery mildew: (*Podosphaera* spp.) (*Erysiphe pistaciae*) (*Microsphaera penicillata*)	1%	Start application as soon as the first visual symptoms are observed and repeat every 7-10 days.
Solanaceae, including but not limited to **tomato,**	Powdery mildew (*Leveillula taurica*) White fly – suppression only	1%	Start application as soon as the first visual symptoms are observed and repeat every 5-7 days. Ensure thorough penetration of plant foliage and cover on both sides of leaf surfaces. Where white flies are

eggplants, peppers			present during application, suppression can be expected.
Cannabaceae including but not limited to **hops, cannabis**	Powdery mildew (*Podosphaera* spp.) White fly – suppression only	1%	Start application as soon as the first visual symptoms are observed and repeat every 5-7 days. Where white flies are present during application, suppression can be expected.

STORAGE AND DISPOSAL: Do not contaminate ponds, waterways, ditches and food or feed by storage or disposal. Store in original container in a well-ventilated place away from children and pets. Dispose of contents/container in accordance with local/regional/national/international regulations.

CONDITIONS OF SALE-LIMITED WARRANTY AND LIMITATIONS OF LIABILITY AND REMEDIES: To be read prior to using this product. The directions should be followed carefully together with good application practice. Failure to do so may cause injury to crops, animals, man or the environment. Extraordinary or unusual weather conditions may affect product performance and/or crop injury which are beyond the control of Oro Agri, Inc. (the "Company") or seller. The Company warrants that this product conforms to the chemical description on the label and is reasonably fit for the purpose referred to in the Directions For Use. The Company makes no other warranties or representations of any kind, express or implied, concerning the product, including no implied warranty of merchantability or fitness for any particular purpose, and no such warranty shall be implied by law. The exclusive remedy against the Company for any cause of action relating to the handling or use of this product shall be limited to, at Company's election, ONE of the following: 1. Refund of the purchase price paid by buyer or user for product bought. 2. Replacement of the product used. To the extent allowed by law, the Company shall not be liable and any and all claims against the Company are waived for special, indirect, incidental, or consequential damages or expense of any nature, including, but not limited to, loss of profits or income. The Company/seller offer this product and the buyer/user accepts it, subject to the foregoing conditions of sale and limitation of warranty, liability and remedies.

This product has not been registered by the U.S. EPA. Oro Agri, Inc represents that this product qualifies for exemption from registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Section 25B.

For patent information contact legal@oroagri.com
ORO AGRI is a proprietary trademarks of Oro Agri, Inc.

Oro Agri, Inc. 2788 S Maple Ave Fresno, CA 93725
+1(559)442-4996

APPENDIX II: Potassium Sorbate SDS

Product Name	Nutrinova® Potassium Sorbate Granules		NAGH/EN
MSDS number	81043	**Revision Date**	Mar.05.2019
Revision Number	1.02	**Issuing date**	Mar.05.2019

1. Product and company identification

Trade Name

Nutrinova® Potassium Sorbate Granules

Manufacturer, importer, supplier
Celanese Sales Germany GmbH
Am Unisys-Park 1
65843 Sulzbach (Taunus)
Germany

Transportation emergency phone numbers:
For Chemical Emergency: Spill Leak Fire Exposure or Accident
Call CHEMTREC Day or Night
DOMESTIC NORTH AMERICA: 800-424-9300
INTERNATIONAL, CALL +1 703-527-3887 (collect calls accepted)

Identified uses
Preservative in the food industry, feed additive, pharmaceutical

2. Hazard Identification

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200:

GHS Classification

Hazards	**Category**
Serious eye damage/eye irritation	Category 2B

Label elements
No Pictogram Required.

Signal Word	Warning
Hazard Statements	Causes eye irritation

Precautionary statements
Wash face, hands and any exposed skin thoroughly after handling.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

Product Name	Nutrinova® Potassium Sorbate Granules		NAGH/EN
MSDS number	81043	**Revision Date**	Mar.05.2019
Revision Number	1.02	**Issuing date**	Mar.05.2019

3. Composition/information on ingredients

Components	CAS-No	Percent %
Potassium (E,E)-hexa-2,4-dienoate	24634-61-5	100

4. First aid measures

Skin
Wash off immediately with plenty of water. Get medical attention if irritation develops and persists.

Eyes
Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.

Inhalation
Get medical attention immediately if symptoms occur.

Ingestion
Do NOT induce vomiting. Call a physician immediately.

5. Fire-fighting measures

NFPA: **Health:** 2 **Flammability:** 0 **Instability:** 0

Suitable extinguishing media
Carbon dioxide (CO2), Water spray, Foam, Dry chemical

Special exposure hazards arising from the substance or preparation itself, its combustion products, or released gases
Under conditions giving incomplete combustion, hazardous gases produced may consist of
Carbon monoxide
Carbon dioxide (CO2)
Combustion gases of organic materials must in principle be graded as inhalation poisons

Special protective equipment for fire-fighters
Wear self-contained breathing apparatus and protective suit.

6. Accidental release measures

Personal precautions
Avoid contact with the skin and the eyes. Keep away from heat and sources of ignition. Provide adequate ventilation.

Environmental precautions
Prevent further leakage or spillage. Do not discharge into the drains/surface waters/groundwater.

Methods for cleaning up
Use mechanical handling equipment. Dispose of in accordance with local regulations.

7. Handling and storage

Advice on safe handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing.

Protection - fire and explosion:
Take measures to prevent the build up of electrostatic charge. Keep away from sources of ignition - No smoking.

Technical measures/Storage conditions
Keep tightly closed in a dry, cool and well-ventilated place.

Material storage
Keep in a dry, cool place. Protect against light.

Incompatible products
Keep away from:, Oxidizing agents

8. Exposure controls / personal protection

15. OSHA Exposure Limits
No exposure limits established.

ACGIH Exposure Limits
No exposure limits established.

Mexico National Exposure Limits
No exposure limits established

16. Exposure controls

Engineering measures
General or dilution ventilation is frequently insufficient as the sole means of controlling employee exposure. Local ventilation is usually preferred. Explosion-proof equipment (for example fans, switches, and grounded ducts) should be used in mechanical ventilation systems.

Protective equipment
A safety shower and eyebath should be readily available.

General advice
Avoid contact with skin and eyes. Do not breathe dust.

9. Physical and chemical properties

Appearance

Form	solid
Color	white
Odor	odorless
Flash point	Not applicable
Autoignition Temperature	178 °C
Method	A.16 (DI 92/69/EEC)
Boiling point/range	not applicable
Method	OECD 103
Density	1.36 g/ml @ 20°C
Method	OECD 109
pH	7 @ 20°C @ 543 g/l
Vapor pressure	1.0 x 10-7 hPa @ 20°C 1.0 x 10-7 hPa @ 50°C
Water solubility	1.95 g/l @ 20°C @ pH 4.0
Solubility in other solvents	30.5 g/l @ 20°C, Methanol, p-Xylene
Partition coefficient (n-octanol/water)	-1.72 @ 20°C (pH: 6.5)

10. Stability and reactivity

Reactivity
Stable under normal conditions of handling, use and transportation.

Conditions to avoid
Avoid dust formation.

Incompatible Materials
Keep away from:
Oxidizing agents

Hazardous Combustion or Decomposition Products:
Thermal decomposition products may include oxides of carbon.

Possibility of hazardous reactions
No hazards to be especially mentioned.

11. Toxicological information

17. Potential health effects

Routes of exposure Skin, eyes, inhalation.

Immediate effects

Skin Essentially non-irritating.

Eyes Causes eye irritation.

Inhalation No adverse health effects have been observed.

Potassium (E,E)-hexa-2,4-dienoate

Acute oral toxicity	LD50: > 10000 mg/kg, rat (Reference substance: Sorbic acid)
Acute dermal toxicity	LD50: > 2000 mg/kg, rat (Reference substance: Sorbic acid)
Acute inhalation toxicity	LC50 (4h): > 5.15 mg/l
Method	OECD 403
Skin corrosion/irritation	Not irritating
Species	rabbit
Method	OECD 404
Skin Sensitization	nonsensitizer (Reference substance: Sorbic acid)
Species	guinea pig
Method	Similar to: EEC 96/54, B.6
Serious eye damage/eye irritation	irritant
Species	rabbit eye
Method	OECD 405
Carcinogenic effects	No evidence of carcinogenicity (Reference substance: Sorbic acid)
Species	mice
Study	80-weeks long term study NOAEL: 1400 mg/kg/d
in vitro Mutagenicity	Ames Test: negative - with and without metabolic activation - Method: Similar to EC B.13/B.14 Chromosome aberration test: weak positive - without metabolic activation - Method: similar to EC B.10 (2000/32/EEC)
in vivo Mutagenicity	Mammalian Erythrocyte Micronucleus Test in mice: negative - Method: OECD 474 (Reference substance: Sorbic acid)
Reproductive toxicity	No toxicity to reproduction (Reference substance: Sorbic acid)
Routes of exposure	oral gavage

Species	rat
	NOAEL (P-generation): 3000 mg/kg/day; NOAEL (reproductive): 3000 mg/kg/day; NOAEL (offspring): 1000 mg/kg/day
Developmental effects	No developmental or reproductive effects
Routes of exposure	oral gavage
Species	rat
	NOAEL (parental): 340 mg/kg/day; NOAEL (embryonic/teratogenic effects): 340 mg/kg/day
Repeated exposure	No consistent differences between treated and control groups, although there were some statistically significant differences in the high dose males and/or females (Reference substance: Sorbic acid)
Routes of exposure	oral gavage
Species	rat
	NOAEL: 750 mg/kg bw/day
Type of study	2 years

12. Ecological Information

Potassium (E,E)-hexa-2,4-dienoate

Acute fish toxicity	LC50: > 1000 mg/l (96h)
Species:	Oncorhynchus mykiss (rainbow trout)
Method	OECD 203
Acute daphnia toxicity	EC50: 982 mg/l (48h)
Species:	Daphnia magna
Method	OECD 202
Toxicity to bacteria	EC50 (3h): > 100 mg/l (Reference substance: Sorbic acid)
Species:	in activated sludge
Method	OECD 209
Biodegradation	Readily biodegradable (Reference substance: Sorbic acid)
Method	OECD 301 D
Other potential hazards	The substance does not meet the criteria for PBT / vPvB according to REACH, Annex XIII

13. Disposal considerations

Disposal considerations

Dispose of spilled material in accordance with state and local regulations for waste that is non-hazardous by Federal definition. Note that this information applies to the material as manufactured; processing, use, or contamination may make this information inappropriate, inaccurate, or incomplete.

14. Transport information

US Department of Transportation Not regulated

TDG Not regulated

Mexico Transport Information Not regulated

ICAO/IATA Not restricted

IMDG Not regulated

15. Regulatory Information

US State Regulations
Chemicals associated with the product which are subject to the state right-to-know regulations are listed along with the applicable state(s):
none

U.S. FEDERAL REGULATIONS

TSCA Inventory:
We certify that all components are either on the TSCA inventory or qualify for an exemption.

Potassium sorbate is regulated by the Food, Drug and Cosmetics Act, GRAS status (21CFR 182.3640)

Environmental Regulations:

SARA 311:

Acute health:	Yes
Chronic health:	No
Fire:	No
Sudden release of pressure:	No
Reactive:	No

INTERNATIONAL REGULATIONS

Product Name	Nutrinova® Potassium Sorbate Granules		NAGH/EN
MSDS number	81043	**Revision Date**	Mar.05.2019
Revision Number	1.02	**Issuing date**	Mar.05.2019

International Inventories
Australia (AICS)
Canada (DSL)
China (IECSC)
Europe (EINECS)
Japan (ENCS)
Japan (ISHL)
Korea (KECI)
New Zealand (NZIoC)
Philippines (PICCS)
United States (TSCA)

16. Other information

NFPA:	Health: 2	Flammability: 0	Instability: 0
HMIS:	Health: 2	Flammability: 0	Physical Hazard: 0

Food / Feed Safety Emergency Contact: 24 h Food / Feed Safety Emergency No:
(Please contact only in emergency situations) +49 (0)69 305 6418

Prepared By
Product Stewardship Department
Celanese

Sources of key data used to compile the datasheet
Information contained in this safety data sheet is based on Celanese owned data and public sources deemed valid or acceptable.. The absence of data elements required by ANSI or 1907/2006/EC indicates that no data meeting these requirements is available..

Other Information:
Observe national and local legal requirements
Changes against the previous version are marked by ***

Abbreviation and Acronym:
ADR = Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
CAS = Chemical Abstracts Service (division of the American Chemical Society)
CLP = Classification, Labelling and Packaging
DNEL = Derived No Effect Level
EINECS = European Inventory of Existing Commercial Chemical Substances
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
ICAO = International Civil Aviation Organization
IMDG = International Maritime Code for Dangerous Goods
LC50 = Lethal Concentration
LD50 = Lethal Dose
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RID = Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
vPvB = very Persistent and very Bioaccumulative

Safety Data Sheet

Celanese

Product Name	Nutrinova® Potassium Sorbate Granules		NAGH/EN
MSDS number	81043	**Revision Date**	Mar.05.2019
Revision Number	1.02	**Issuing date**	Mar.05.2019

ORO AGRI
ORO AGRI INCORPORATED

APPENDIX III: OR-159-B SDS

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ORO AGRI
ORO AGRI INCORPORATED

SAFETY DATA SHEET

acc. to 29 CFR 1910.1200 App D

Version number: GHS 1.0

Date of compilation: 2021-07-21
OROAGRI 255:

SECTION 1: Identification

1.1 Product identifier

Product Name **OR-159-B**

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

Relevant identified uses Fungicide, insecticide

Uses advised against None.

1.3 Details of the supplier of the safety data sheet

Oro Agri, Inc.
2788 S. Maple Ave.
Fresno CA 93725
United States

e-mail: SDS-NA@oroagri.com

1.4 Emergency telephone number

Incident, Spill, Leak, Fire, Exposure or Accident
Call CHEMTREC Day or Night

Within USA and Canada:
1 (800) 424-9300

Outside USA:
+1 (703) 741-5970.

SECTION 2: Hazard(s) identification

2.1 Classification of the substance or mixture

Classification acc. to OSHA "Hazard Communication Standard" (29 CFR 1910.1200)

This mixture does not meet the criteria for classification.

2.2 Label elements

Labelling acc. to OSHA "Hazard Communication Standard" (29 CFR 1910.1200)

- Signal word not required
- Pictograms not required

2.3 Other hazards

There is no additional information.

SECTION 3: Composition/information on ingredients

3.1 Mixtures

Description of the mixture

Name of substance	Wt%
Potassium Sorbate	45

Components, CAS numbers and/or concentrations not listed are either non-hazardous, below reporting limits or have been withheld as trade secret.

SECTION 4: First-aid measures

4.1 Description of first-aid measures

General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing and wash it before reuse. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Provide fresh air.

Following skin contact

Take off immediately all contaminated clothing. Rinse skin with water/shower. If skin irritation or rash occurs: Get medical advice/attention.

Following eye contact

Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. In all cases of doubt, or when symptoms persist, seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Harmful if inhaled. Causes eye irritation. Localized redness, edema, pruritis and/or pain.

4.3 Indication of any immediate medical attention and special treatment needed

In case of burns and frostbite: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes. Symptoms may develop several hours following exposure; medical observation therefore necessary for at least 48 hours.

SECTION 5: Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water spray, BC-powder, Carbon dioxide (CO_2)

Unsuitable extinguishing media

Do not use water jet as this will spread the fire.

5.2 Special hazards arising from the substance or mixture

In case of fire and/or explosion do not breathe fumes.

Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO_2)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Coordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

Special protective equipment for firefighters

Protective clothing against liquid and gaseous chemicals, including liquid aerosols and solid particles, Wear self-contained breathing apparatus

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety. Ventilate affected area. Wear suitable protective clothing.

For emergency responders

Wear breathing apparatus if exposed to vapors/dust/aerosols/gases. Eliminate all ignition sources if safe to do so. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Wear suitable protective clothing.

6.2 Environmental precautions

Avoid release to the environment. Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Set up barriers, Covering of drains

Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece). Collect spillage: absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.)

Appropriate containment techniques

Use of adsorbent materials. Stop leak if safe to do so.

Equipment required for containment/clean-up

Non-sparking tools and equipment, Collecting basins for spills, Absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.), Personal protective equipment: see section 8

Other information relating to spills and releases

Ventilate affected area. Place in appropriate containers for disposal. Take any precaution to avoid mixing with combustibles.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations

- Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Use only in well-ventilated areas.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs. Avoid contact with eyes. Wear personal protective equipment/face protection. Avoid release to the environment. Employ good industrial hygiene practice.

7.2 Conditions for safe storage, including any incompatibilities

Control of the effects

Keep in a cool, well-ventilated place. Protect from sunlight. Store in a dry place. Store in a closed container. Take precautionary measures against static discharge. Ground/bond container and receiving equipment. Keep away from clothing as well as other incompatible materials. Incompatible materials: see section 10.

Protect against external exposure, such as

Frost, UV-radiation/sunlight

7.3 Specific end use(s)

See section 16 for a general overview.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

This information is not available.

8.2 Exposure controls

Appropriate engineering controls

Exhaust ventilation. Use explosion-proof electrical/ventilating/lighting/tooling /equipment.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection. Use safety goggle with side protection.

Skin protection

- Hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

- Other protection measures

Protective clothing against liquid chemicals. Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Thermal hazards

Wear protective gloves against thermal risks (heat and/or fire).

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

8.2.4 Advice on general occupational hygiene

Employ good industrial hygiene practice. Do not eat, drink or smoke when using this product. Wash contaminated clothing before reuse.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state	liquid
Color	amber
Particle	not relevant (liquid)
Odor	earthy
Odor threshold	no data available

Other safety parameters

pH (value)	6.79 (25 °C)
Melting point/freezing point	not determined
Initial boiling point and boiling range	not determined
Flash point	100.5 °C at 718.2 Pa (212.9 °F at 718.2 Pa)
Evaporation rate	Not determined
Flammability (solid, gas)	not relevant, (fluid)
Vapor pressure	not determined
Density	0.9982 $^{g}/_{cm^3}$ at 25 °C
Vapor density	this information is not available
Solubility(ies)	not determined

Partition coefficient

- n-octanol/water (log KOW)	this information is not available

	Auto-ignition temperature	not determined
	Decomposition temperature	no data available
	Viscosity	not determined
	Explosive properties	none
	Oxidizing properties	none
9.2	**Other information**	there is no additional information

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is not reactive under normal ambient conditions. Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials".

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure. Stable under normal conditions of use.

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid

Incompatible materials: see section 10.

10.5 Incompatible materials

Oxidizers

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Classification acc. to OSHA "Hazard Communication Standard" (29 CFR 1910.1200)

This mixture does not meet the criteria for classification.

Acute toxicity

Shall not be classified as acutely toxic.

GHS of the United Nations, annex 4: May be harmful if swallowed, in contact with skin or if inhaled.

Acute toxicity			
Exposure route	**Endpoint**	**Value**	**Species**
oral	LD50	5,000 $^{mg}/_{kg}$	rat
dermal	LD50	>2,000 $^{mg}/_{kg}$	rat
inhalation: dust/mist	LC50	>7.131 $^{mg}/_{l}$/4h	rat

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitization

Shall not be classified as a respiratory or skin sensitizer.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

12.2 Persistence and degradability

Data are not available.

12.3 Bioaccumulative potential

Data are not available.

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Endocrine disrupting properties

Information on this property is not available.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packages

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

SECTION 14: Transport information

14.1	**UN number**	not subject to transport regulations
14.2	**UN proper shipping name**	not relevant
14.3	**Transport hazard class(es)**	not assigned
14.4	**Packing group**	not assigned
14.5	**Environmental hazards**	non-environmentally hazardous acc. to the dangerous goods regulations

14.6 Special precautions for user

There is no additional information.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

The cargo is not intended to be carried in bulk.

Information for each of the UN Model Regulations

Transport of dangerous goods by road or rail (49 CFR US DOT) - Additional information

Not subject to transport regulations.

International Maritime Dangerous Goods Code (IMDG) - Additional information

Not subject to IMDG.

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Not subject to ICAO-IATA.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

National regulations (United States)

Toxic Substance Control Act (TSCA) all ingredients are listed

Superfund Amendment and Reauthorization Act (SARA TITLE III)

- The List of Extremely Hazardous Substances and Their Threshold Planning Quantities (EPCRA Section 302, 304)

none of the ingredients are listed

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

- List of Hazardous Substances and Reportable Quantities (CERCLA section 102a) (40 CFR 302.4)

none of the ingredients are listed

Clean Air Act

none of the ingredients are listed

Right to Know Hazardous Substance List

- Hazardous Substance List (NJ-RTK)

none of the ingredients are listed

California Environmental Protection Agency (Cal/EPA): Proposition 65 - Safe Drinking Water and Toxic Enforcement Act of 1987

none of the ingredients are listed

Industry or sector specific available guidance(s)

NPCA-HMIS® III

Hazardous Materials Identification System. American Coatings Association.

Category	Rating	Description
Chronic	/	none
Health	1	irritation or minor reversible injury possible
Flammability	0	material that will not burn under typical fire conditions
Physical hazard	0	material that is normally stable, even under fire conditions, and will not react with water, polymerize, decompose, condense, or self-react. Non-explosive
Personal protection	-	

NFPA® 704

National Fire Protection Association: Standard System for the Identification of the Hazards of Materials for Emergency Response (United States).

Category	Degree of hazard	Description
Flammability	0	material that will not burn under typical fire conditions
Health	1	material that, under emergency conditions, can cause significant irritation
Instability	0	material that is normally stable, even under fire conditions
Special hazard		

15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information, including date of preparation or last revision

Revision date 2021-07-21

Version number GHS 1.0

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
49 CFR US DOT	49 CFR U.S. Department of Transportation
DGR	Dangerous Goods Regulations (see IATA/DGR)
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
MARPOL	International Convention for the Prevention of Pollution from Ships (abbr. of "Marine Pollutant")
NPCA-HMIS® III	National Paint and Coatings Association: Hazardous Materials Identification System - HMIS® III, Third Edition
OSHA	Occupational Safety and Health Administration (United States)
PBT	Persistent, Bioaccumulative and Toxic
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

OSHA Hazard Communication Standard (HCS), 29 CFR 1910.1200.

Transport of dangerous goods by road or rail (49 CFR US DOT). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

Classification procedure

Physical and chemical properties: The classification is based on tested mixture.
Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

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