United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet
https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Document Type:

☐ **National List Petition or Petition Update**

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

☒ **Technical Report**

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

Microcrystalline Cheesewax

Crops

Identification of Petitioned Substance

Chemical Names:
Microcrystalline Cheesewax
Microcrystalline Wax
Paraffin Wax
Petrolatum

Other Name:
Micro wax
Cheese wax
Clay treated microcrystalline wax
Hydrocarbon waxes
Hydrotreated Heavy Naphtha
Petroleum Wax

Trade Names:
Parafflex 4669A
BW 100F01 cheesewax
Witcovar 146
Paramelt
BE SQUARE™ 175 Amber Wax
Vaseline®

CAS Numbers:
64742-42-3 (Microcrystalline Wax)
8002-74-2 (Paraffin Wax)
8009-03-8 (Petrolatum)

Other Codes:
EC: 232-373-2 (Petrolatum)
EINECS: 232-315-6 (Paraffin Wax)
EINECS: 232-373-2 (Petrolatum)

Summary of Petitioned Use

Microcrystalline cheesewax is currently listed under the National Organic Program (NOP) regulations at 7 CFR §205.601(o) as a synthetic substance allowed as a "production aid" for "use in log grown mushroom production," with the exception that the wax "must be made without either ethylene-propylene co-polymer or synthetic colors." The primary use of microcrystalline cheesewax in organic crop production is in log-based mushroom cultivation as a sealant for inoculation sites.

Characterization of Petitioned Substance

Composition of the Substance:

Microcrystalline cheesewax is a food-grade product which is composed of a blend of microcrystalline wax, paraffin wax, and petrolatum. These ingredients are blended in different amounts to achieve the desired characteristics (i.e., flexibility, melting point, etc.) for a range of applications (Heimbach et al., 2002). All three of the ingredients are derived from the refinement of crude oil, as mixtures of long-chain hydrocarbons with relatively high melting points (>51 °C) (Baker Hughes, 2010; Sigma-Aldrich, 2017a, b). Microcrystalline cheesewax is a complex combination of long chain (>12 C) hydrocarbons, and is differentiated from paraffin waxes due to their higher average molecular weight, longer hydrocarbon chains, and the increased branching of the alkane chains (SCF, 1995).

Source or Origin of the Substance:

The components of microcrystalline cheesewax are derived from mineral sources via the refinement of crude oil. During the refining process, these petroleum waxes are separated by fractional distillation followed by fractional crystallization. Once separated, the waxes are further processed by refining to remove residual oils, odors, and colors (EFSA, 2013).

Properties of the Substance:

The properties of microcrystalline cheesewax are summarized in Table 1.

Table 1. Properties or Microcrystalline wax, Petrolatum, and Paraffin Wax

Property	Microcrystalline Wax	Petrolatum	Paraffin Wax
CAS no.	64742-42-3	8009-03-8	8002-74-2
Appearance	Amber solid	Colorless paste	Colorless solid
Melting/ freezing point	81.7 to 87.2 °C	51 to 71 °C	58 to 62 °C
Initial boiling point and range	N/A	360 to 732 °C	341 to 665 °C
Relative Density	0.9 to 1 (25 °C)	0.865 to 0.886 g/cm^3 (15 °C)	N/A
Vapor Pressure	<0.1 mmHg	<0.2 mmHg (80 °C)	N/A
Chemical stability	Stable	Stable	Stable

Sources: Baker Hughes, 2010; Sigma-Aldrich, 2017a, b.

Specific Uses of the Substance:

The substance is used as a sealant in mushroom cultivation. In the cultivation process, a log is inoculated with spawn by drilling into the material and depositing the spawn. The microcrystalline cheesewax is then applied to the inoculation site to both secure the mushroom spawn, as well as to seal in the moisture required for successful cultivation (Kimmons, 2006).

Approved Legal Uses of the Substance:

Microcrystalline cheesewax has been approved by the United States Food and Drug Administration (FDA) at 21 CFR § 172.888 as a "synthetic petroleum wax," for use as a "masticatory substance," in chewing gum, a "protective coating," on cheese and raw fruits and vegetables, and a "defoamer in food." Microcrystalline cheesewax as a petroleum wax is also listed by the FDA at 21 CFR 178.3710 as an allowed "component of nonfood articles in contact with food."

Paraffin wax is allowed by the FDA at 21 CFR §172.250 as "synthetic paraffin," for use "as an impregnant in, coating on, or component of coatings on articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food." Paraffin wax has been approved by the FDA as a wood preservative for "wooden articles that are used or intended for use in packaging, transporting, or holding raw agricultural products," at 21 CFR §178.8300. The FDA has also approved the use of melted paraffin wax as a "paraffin bath," to be "maintained at an elevated temperature in which the patient's appendages (e.g., hands or fingers) are placed to relieve pain and stiffness."

Petrolatum, an ingredient of microcrystalline cheesewax, has been approved by the FDA at 21 CFR §172.880 as a "release agent and lubricant" in bakery products, a "release agent and as a sealing and polishing agent" in confectionaries, a "release agent" for dehydrated fruits and vegetables, egg white solids, a protective coating on raw fruits and vegetables, and as a "defoamer" in beet sugar and yeast. Petrolatum is approved for use as a "resinous and polymeric coating," that "may be safely used as the food-contact surface of articles for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food," listed at 21 CFR §175.300(3)(xxv) as a "release agent," and §175.300(3)(xxvii) as a "surface lubricant." Petrolatum is also allowed by the FDA at 21 CFR §175.105(c)(5) as "permitted for use in adhesives," and at 21 CFR 175.125 for use in "pressure-sensitive adhesives." Petrolatum has been approved for use in animal feed at 21 CFR §573.720. Petrolatum is allowed by the United States Environmental Protection Agency (EPA) at 40 CFR §180.910 as an "inert (or occasionally active) ingredient in pesticides formulations applied to growing crops or to raw agricultural commodities after harvest," as a "coating agent."

Action of the Substance:

The substance is used as a sealant in mushroom cultivation. In the cultivation process, a log is inoculated with spawn by drilling into the material and depositing the spawn. The microcrystalline cheesewax is then applied to the inoculation site to both secure the mushroom spawn, as well as to seal in the moisture required for successful cultivation (Kimmons, 2006).

Combinations of the Substance:

Microcrystalline cheesewax is a complex mixture of hydrocarbons formulated by the blending of several other components, primarily microcrystalline wax, petrolatum, and paraffin wax. However, due to the complex nature of the wax blend, and the components themselves, production formulas vary by vendor, as well as by batch. Due to the chemical stability of the substance, additional ingredients are not often added, although some formulations include small amounts of antioxidants (Kimmons, 2006).

Status

Historic Use:

Microcrystalline cheesewax has been used in the cultivation of organic mushrooms since the 1980s. The primary usage of the substance is as a sealant, which is applied post inoculation to secure the applied spawn, seal in the moisture required for mushroom cultivation, and prevent undesired growth at the inoculation site (Kimmons, 2006). The use of microcrystalline cheesewax has been approved by the NOP at 7 CFR §205.601(o).

Organic Foods Production Act, USDA Final Rule:

Neither microcrystalline cheesewax, nor its components identified in this petition are listed in the Organic Foods Production Act of 1990.

Microcrystalline cheesewax is currently listed under the National Organic Program (NOP) regulations at 7 CFR §205.601(o) as a synthetic substance allowed as a "production aid," for "use in log grown mushroom production," with the exception that the wax "must be made without either ethylene-propylene co-polymer or synthetic colors."

International

Canadian General Standards Board Permitted Substances List

CAN/CGSB-32.311 "Table 6.5 Processing aids" prohibits the use of microcrystalline wax "either alone or in formulations with paraffin wax."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) -

Neither microcrystalline cheesewax, nor its components identified in this petition are listed in the CODEX (GL 32-1999).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

Neither microcrystalline cheesewax, nor its components identified in this petition are listed in EC No. 834-2007 nor EC No. 889/2008.

Japan Agricultural Standard (JAS) for Organic Production—

Neither microcrystalline cheesewax, nor its components identified in this petition are listed in the JAS for Organic Production.

International Federation of Organic Agriculture Movements (IFOAM) –

Neither microcrystalline cheesewax, nor its components identified in this petition are listed in IFOAM.

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

Evaluation Question #1: Indicate which category in OFPA that the substance falls under: (A) Does the substance contain an active ingredient in any of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180?

Microcrystalline cheesewax is categorized by the USDA NOP as a production aid at 7 CFR §205.601(o) "for use in log grown mushroom production," with the exception that it "must be made without either ethylene-propylene co-cpolymer or synthetic colors." Microcrystalline cheesewax does not contain an active ingredient in: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps, insect traps, sticky barriers, row covers, and equipment cleansers. However, microcrystalline cheesewax may be considered as a seal; it is used in the cultivation of shitake mushrooms as a sealant to keep the inoculated spawn in place, while also sealing in the required moisture (NOSB, 2008).

Microcrystalline cheesewax is listed on EPA List 4 under "petroleum wax," and petrolatum is also listed on List 4.

Evaluation Question #2: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Microcrystalline cheesewax is obtained by refining crude oil feed stocks. Petroleum waxes, including the components of microcrystalline cheesewax, are removed from the bulk of the crude oil by fractional distillation (CRC, 1999; EFSA, 2013). Upon completion of the distillation process, the crude waxes undergo further de-asphalting, de-waxing, and refining (i.e., solvent extraction) processes to yield petrolatum. The petrolatum undergoes further treatment by fractional crystallization (which also acts as a de-oiling measure), to provide specific waxes, including microcrystalline wax (McKetta, Weismantel, 1999; EFSA 2013).

Alternatively, after isolation of the petrolatum from the crude oil feedstock by fractional distillation, the petrolatum may be hydrotreated prior to fractional crystallization. In this process, the petrolatum undergoes a chemical change, in which the sites of unsaturation (multiple bonds) within the wax are hydrogenated to yield a saturated hydrocarbon (SCF, 1995; Kimmons, 2006; EFSA, 2013).

The substances may also be derived synthetically through the Fischer-Tropsch process. In this synthetic process, carbon monoxide (CO) gas is combined with hydrogen (H_2) gas at a range of temperatures in the presence of several possible metal catalysts (Schulz, 1999). The resulting hydrocarbon that is formed (via the Fischer-Tropsch process) is dependent upon both the temperature and catalyst employed, with lower temperatures favoring longer hydrocarbon chains (Schulz, 1999). In the synthetic process of wax production, the synthetic petroleum waxes have a reduced percentage of branched chains, although

synthetic microcrystalline waxes maintain a higher prevalence of branched chains than both 'natural' and synthetic paraffin waxes (SCF, 1995).

Evaluation Question #3: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).

Microcrystalline cheesewax and its components are isolated from mineral sources (crude oil) via industrial processes (i.e., distillation, crystallization, etc., see **Evaluation Question #2**). Also, as discussed in **Question #2**, the petrolatum derived from the mineral feed stock may undergo a chemical change by hydrotreatment, during which non-hydrocarbon atoms (e.g., sulfur, nitrogen) are removed and the wax increases in chemical saturation (hydrogenation) (McKetta, Weismantel, 1999; EFSA, 2013).

Evaluation Question #4: Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)).

Microcrystalline cheesewax, and its components, have not been subject to ecotoxicity studies. However, due to the long length of the hydrocarbons (>12), there is little to no solubility in water. This results in the lack of any expected impact to aquatic life and ecosystems (Kimmons, 2006; Baker Hughes, 2010; Sigma-Aldrich, 2017a, b).

A series of assessments done by Bareco Products, REPSO PETROLEO, S.A., and CONCAWE (Conservation of Clean Air and Water in Europe), found that the substance breaks down into a variety of smaller hydrocarbons (alkanes) in soil (Kimmons, 2006). These processes were found to be carried out by microfauna and microflora, with microflora as the more active means of degradation. Following the completions of these studies, the respective firms labeled the substance as "readily biodegradable" in soil, indicating no expected persistence of the petroleum waxes, or their by-products in the environment (Kimmons, 2006). A literature search on the bioaccumulation of microcrystalline cheesewax gave no results, other than the studies cited in the initial petition for the substance delivered to the NOSB.

Evaluation Question #5: Describe the toxicity and mode of action of the substance and of its breakdown products and any contaminants. Describe the persistence and areas of concentration in the environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).

There have been no ecotoxicity studies on the impacts of microcrystalline cheesewax; however, several assessments of the product are described in **Evaluation Question #4**, through which the substance was labeled as "readily biodegradable" (SCF, 1995; Kimmons, 2006). There have been no reports that indicate the likelihood of the bioaccumulation of either microcrystalline cheesewax or its breakdown products, nor any reports of associated ecotoxicity.

Evaluation Question #6: Describe any environmental contamination that could result from the petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).

Due to the labeling of microcrystalline wax as "readily biodegradable" in the environment, environmental contamination due to use, misuse, or disposal of the substance are not anticipated (SCF, 1995; EFSA, 2013).

Since the substance is isolated from refining crude oil, the manufacture and handling of the crude oil are the most likely means for environmental contamination. However, if good manufacturing practices are followed, incidents of contamination will be minimal.

Evaluation Question #7: Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).

There is no published literature that indicates the likelihood of chemical reactions between the substance and other substances allowed in organic crop or livestock production or handling. Due to the chemical

stability of microcrystalline cheesewax and its components, chemical reactions with the substance during handling, or in the environment are not anticipated.

Evaluation Question #8: Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt index and solubility of the soil), crops, and livestock (7 U.S.C. § 6518 (m) (5)).

As stated in **Evaluation Question #7**, microcrystalline cheesewax, as well as its components, are chemically stable, and are not anticipated to undergo chemical reactions in the environment. There have been no formal ecological studies on the impact of the substance; however, the substance has been widely reported to have no environmental impact (Kimmons, 2006; Baker Huges, 2010; Sigma-Aldrich, 2017a, b). Assessments of microcrystalline cheesewax were found to be "readily biodegradable," and were broken down by microflora and fauna, although the impact of the substance and its degradation products on the microflora and fauna was not reported (Kimmons, 2006).

A series of studies on the uptake of petroleum oils and waxes have been conducted, which indicate that the consumption of hydrocarbon waxes is unlikely to result in the absorption and metabolism of the waxes (WHO, 1993). Shubik et al. carried out a two-year study on the impact of consumption of a range of mineral products by rats, and reported no significant differences in weight, incidence of tumors, or survival rate due to toxic wax-associated effects (Shubik et al., 1962). Several other reports on the consumption of mineral substances have reported increased organ weights, increased counts of monocytes and neurtrophils, a reduction in red blood cell counts, as well as accumulation of hydrocarbon material in tissues. However, these studies also reported that these same effects were absent in the case of microcrystalline waxes, likely due to the higher molecular weight and longer carbon chain length (SCF, 1995; EFSA, 2012).

Evaluation Question #9: Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

As stated in **Evaluation Question #4**, there have been no ecotoxicity studies of the substance. Assessments conducted by several organizations all concluded that the substance was degraded into a variety of smaller alkanes by microorganisms, and labeled the petroleum waxes in question as "readily biodegradable" in soil, indicating no expected persistence of the petroleum waxes, or their by-products in the environment (Kimmons, 2006). Moreover, due to their long hydrocarbon chains (>12), these waxes have little to no water solubility, resulting in no impact to aquatic environments.

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

As discussed in **Evaluation Questions #4-8**, microcrystalline cheesewax, its components and its breakdown products, are chemically stable, and are not known to be health risks. There has been only minimal study as to the impact of mineral substances on humans, although those performed indicate similar outcomes to animal studies, while others report no accumulation of hydrocarbons in human tissue (JECFA, 1995). Due to the lack of reported health concerns linked to microcrystalline cheesewax, along with its absence of reported carcinogenicity and genotoxicity, and its unlikelihood of absorption due to the predominance of long carbon chains in microcrystalline waxes, it is widely regarded as having low health risks (Subik et al., 1962; WHO, 1993; SCF, 1995; JECFA, 1995; Kimmons, 2006; EFSA, 2012; EFSA, 2013).

The substance is known as a respiratory irritant in vapor form (Kimmons, 2006). Due to the low vapor pressure of the substance under normal conditions, this hazard is limited to the initial application of the wax, and is unlikely to be a concern following the application to the inoculation sites. However, as the substance is heated to provide for easier and more efficient application, the vapor pressure will increase compared to that of ambient conditions, making the initial application of the substance a concern for workers.

Evaluation Question #11: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

Beeswax is a natural wax that may be used as a sealant for mushroom cultivation in place of microcrystalline cheesewax. Beeswax is naturally produced by bees for beehive construction. This natural wax is readily available for use in mushroom cultivation, without the potential environmental hazards of the handling and processing of crude oil, as required for microcrystalline cheesewax. However, the seal formed by beeswax is inferior to that which is produced by the application of microcrystalline cheesewax. This is due to several considerations. Beeswax has a relatively low melting point (62 to 64 °C) compared to the substance (>80 °C), resulting in the softening and lower viscosity under environmental conditions (Kimmons, 2006). Furthermore, beeswax has a greater concentration of aromatic molecules, which act to attract insects that remove the sealant from the inoculation site (Kimmons, 2006).

Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

An alternative practice for mushroom cultivation is the use of plastic bags, which are more efficient as a means of sealing in moisture to allow for mushroom cultivation. However, plastic bags are unable to help to secure the mushroom spawn, which may fall out of the inoculation site (Kimmons, 2006). Furthermore, this practice also relies on the use of plastic bags derived from crude oil sources, which may not be biodegradable. These bags are also not FDA approved for use in and around food products, and are likewise not approved for use under NOP regulations.

There are no other alternative methods for 'log grown' mushroom cultivation.

Report Authorship

The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:

- Philip Shivokevich, Assistant Professor of Chemistry, Lander University
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All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

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