

Petition for Manganese Sulfate Monohydrate

NOP Petition for Inclusion of Manganese Sulfate Monohydrate to the
National List of Substances Allowed

Morse Enterprises, Ltd. Contact: Gerald O'Connor, President

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Item A: Morse Enterprises, Ltd. is amending their original petition to have manganese sulfate monohydrate for inclusion in the National List within the following category: Synthetic substances allowed for use in organic crop production, § 205.601. Specifically, this is a request to allow manganese sulfate monohydrate to be used as an inert substance in a pesticide elicitor formulation for 601(i), plant disease control.

Item B:

1. *Substance's chemical or material common name*—Manganese sulfate monohydrate. Synonyms—Manganous sulfate, monohydrate; sulfuric acid, manganese (2+) salt (1:1), monohydrate; Manganese (II) sulfate, monohydrate
2. *Manufacturer's or Producer's name, address and telephone number and other contact information of the manufacturer/producer of the substance listed in the petition.*

Mallinckrodt Baker, Inc.
222 Red School Lane
Phillipsburg, NJ 08865
Tel. No. 800-582-2537

3. *The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant. If the substance is an agricultural ingredient, the petition must provide a list of the types of product(s) (e.g., cereals, salad dressings) for which the substance will be used and a description of the substance's function in the product(s) (e.g., ingredient, flavoring agent, emulsifier, processing aid).*

Substance (i.e., manganese sulfate monohydrate) will be used as an inert ingredient in a biopesticide formulation that uses an elicitor of plant disease defenses for plant disease control.

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

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Product will be used in combination with other micronutrient chemicals on a number of horticultural crops. Example crops would include, but not limited to, solanaceous vegetables (e.g., tomatoes), legumes (e.g., common bean, soybeans, lentils, kidney beans, peanuts, etc.), corn, cole crops (cabbage, broccoli, Brussel sprouts, kale, collards, etc.), cucurbits (cucumbers, squash, melons, watermelons, etc.), citrus (e.g., oranges, pummelos, grapefruit, etc.), grapes, papaya, etc. Total manganese in product would be 0.75%. Rate of application would range from 1/400 to 1/100 dilution (i.e., 1 quart to 4 quarts per 100 gallons tank mixture of parent product) sprayed on foliage or applied to the soil in irrigation systems.

5. *The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information may follow the guidelines in the Instructions for Submitting CBI listed in #13.*

Typically manganese ores are purified by their conversion to manganese sulfate. Treatment of aqueous solutions of the sulfate with sodium carbonate leads to precipitation of manganese carbonate, which can be calcined to give the oxides MnO_x. Manganese dioxide reacts with sulfur dioxide to produce manganese sulfate. Manganese sulfate forms a variety of hydrates: monohydrate, tetrahydrate, pentahydrate, heptahydrate. The monohydrate is most common form.

6. *A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance. If this information is not available, the petitioner should state so in the petition.*

Not available.

The anhydrous form of manganese sulfate (CAS 7785-87-7) is on the August 2004 EPA list 4B.

7. *Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers. If this information does not exist, the petitioner should state so in the petition.*

The anhydrous form of manganese sulfate (CAS 7785-87-7) is on the August 2004 EPA list 4B. Information specifically for manganese sulfate monohydrate (CAS 10034-96-5) does not exist.

8. *The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance. If the substance does not have an assigned product number, the petitioner should state so in the petition.*

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CAS 10034-96-5

9. *The substance's physical properties and chemical mode of action including (a) Chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; 9c) environmental impacts from its use and/or manufacture; (d) effects on human health; and , (e) effects on soil organisms, crops, or livestock.*

a.) $\text{MnSO}_4 \cdot \text{H}_2\text{O}$ has a molecular weight of 169.01, pure form is pale pink monoclinic crystals with a density of 2.95. Solubility ranges from 98.47 (cold water) to 79.8 (hot water) g/100mL water. Compatible with substances used for organic farming.

b.) See EPA Notice "Inert Ingredients in Pesticide Products; Reclassification of Certain List 3 Inert Ingredients to List 4B" [Federal Register: July 7, 1995 (Volume 60, Number 130)] [Notices] [Page 35396-35399]. With regard to anhydrous manganese sulfate EPA stated the following. "As a part of its initial review of the inert ingredients originally categorized as List 3, EPA has identified 146 inert ingredients that merit reclassification to List 4B. The basis for this reclassification is as follows:

1. On behalf of the Office of Pesticide Programs, these substances were reviewed by the Structure Activity Team of EPA's Office of Pollution Prevention and Toxics with each judged to be of low concern for potential human health and/or environmental effects.

2. Each of these substances is either approved for use by the U.S. Food and Drug Administration as (a) a direct food additive under 40 CFR part 172 or (b) a polymer considered to not present an unreasonable risk on the basis of its conformance with the criteria given in the polymer exemption rule at 40 CFR 723.250. The polymer exemption rule exempts selected low-risk polymers from part or all of the premanufacture notification provisions of section 5 of the Toxic Substances Control Act (TSCA).

3. These inert ingredients were evaluated by the Office of Pesticide Program's Inert Review Group and determined to be of minimal risk.

The same should hold for manganese sulfate monohydrate.

c.) See 9b.

d.) See 9b.

e.) See 9b.

10. *Safety information about the substance including a Material Safety Data Sheet 9MSDS) and a substance report from the National Institute of Environmental*

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Health Studies. If this information does not exist, the petitioner should state so in the petition.

See Attachment #1.

11. *Research information about the substance which includes comprehensive substance research reviews and research bibliographies including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List. For petitions to include non-organic agricultural substances onto the National List. This information item should include research concerning why the substance should be permitted in the production or handling of an organic product, including the availability of organic alternatives. Commercial availability does not depend upon geographic location or local market conditions. If research information does not exist for the petitioned substance, the petitioner should state so in the petition.*

See 9b. Research for monohydrate form of manganese sulfate (CAS 10034-96-5) should be interchangeable with that of the anhydrous form (CAS 7785-87-7).

12.A "Petition Justification Statement" which provides justification for any of the following actions requested in the petition.

A. Inclusion of a Synthetic on the National List, §§ 205.601, 205.603, 205.605(b)

- Explain why the synthetic substance is necessary for the production or handling of an organic product.
- Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.
- Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support its use instead of the use of a non-synthetic substance or alternative cultural methods.

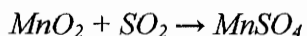
The product we wish to market, KP350 OR, is a biopesticide that involves the use of an "elicitor" of plant defense responses. The active ingredient causing this response is yeast hydrolysate which activates plant defenses. This product is not a classical contact biopesticide. We recommend application of KP350 OR prior to pathogen/pest infection/infestation to stimulate plant defense systems so that plants have the best opportunities to resist pathogens and insect pests. Yeast hydrolysate is composed of peptides and oligosaccharides resulting from the breakdown of yeast cells. These components pose no environmental hazard as they easily decomposed in the environment. Activation of plant defenses is an effective means to combat pathogen infections and insect pest infestations. However, marshaling defense systems is expensive from a nutrient resource standpoint. Plant nutrients are redirected from growth, fruit production, etc., to building plant defenses. Most often crop production is significantly reduced resulting in lower grower profits.

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Manganese sulfate is often a component that can be exhausted during the process of plant defense activation. KP350 OR is formulated to provide additional nutrients to the plant to negate nutrient deficits resulting from activation of plant defenses; manganese sulfate is one of the nutrients required for optimal responses. In most cases where KP350 OR has been applied correctly, disease severity is lowered and/or no or minimal production losses are observed. In fact, most growers see an increase in production with correct use of this product.

Manganese sulfate anhydrous (which is allowed as an inert in a pesticide formulation; EPA List 4B CAS#7785-87-7) is a synthetic material. The information below is from Wikipedia ([http://en.wikipedia.org/wiki/Manganese\(II\)_sulfate](http://en.wikipedia.org/wiki/Manganese(II)_sulfate)) which cites Arno H. Reidies "Manganese Compounds" Ullmann's Encyclopedia of Chemical Technology 2007; John Wiley.

Typically manganese ores are purified by their conversion to manganese sulfate. Treatment of aqueous solutions of the sulfate with sodium carbonate leads to precipitation of manganese carbonate, which can be calcined to give the oxides MnO_x. Manganese dioxide reacts with sulfur dioxide to produce manganese sulfate,



Like many metal sulfates, manganese sulfate forms a variety of hydrates: monohydrate, tetrahydrate, pentahydrate, heptahydrate. The monohydrate is most common.

The anhydrous is prepared by driving off the waters of crystallization by heating, so consequently, the anhydrous may be more of a synthetic than the monohydrate. What we are proposing to do is to replace manganese sulfate anhydrous (CAS#7785-87-7) that is an acceptable inert in pesticide formulations with manganese sulfate monohydrate (CAS#10034-96-5) that is not on the EPA List 4B. There is not a commercial source for naturally occurring anhydrous manganese sulfate that will meet EPA requirements. In trying to re-register the KP350 OR through the EPA we listed J.T. Baker Chemical Co. as the source of manganese sulfate anhydrous but ran into a problem as they would not provide a certificate of analysis for the material that EPA required. J.T. Baker was the only source known to us who could supply this material. We checked many sources worldwide but could not find another source even though website information indicated anhydrous manganese sulfate availability. Consequently, we petitioned to use the monohydrate form which is widely available at a higher purity and lower cost.

In addition, there are two points worthy of consideration. First, according to the NOSB Meeting Notes dated November 5, 2009, pp 72-73, manganese sulfate monohydrate is allowed for use by the "Synthetic Substances Allowed for Crop Production, 206.601(j)(6)(ii)." However, this does not extend to use in pesticide formulations according to USDA NOP. Second, is the fact that KP350 OR is ca. 40% water content as sold and is further diluted with water (1/200 or greater) for application to crops.

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Anhydrous manganese sulfate would immediately become hydrated upon KP350 OR formulation.

B. Removal of a Synthetic From the National List, §§ 205.601, 205.603, 205.605(b)

N/A

C. Inclusion of a Prohibition of a Non-Synthetic, §§ 205.602 and 205.604

N/A

D. Removal of a Prohibited Non-Synthetic From the National List, §§ 205.602 and 205.604

N/A

E. Inclusion of a Non-Synthetic, Non-Agricultural Substance Onto the National List, § 205.605(a)

N/A

F. Removal of a Non-Synthetic, Non-Agricultural Substance From the National List, § 205.605(a)

N/A

G. Inclusion of a Non-Organically Produced Agricultural Substance Onto the National List, § 205.606

N/A

H. Removal of a Non-Organically Produced Agricultural Substance From the National List, § 205.606

N/A

13. A Confidential Business Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Final determination regarding whether to afford CBI treatment to submitted petitions will be made by USDA pursuant to 7 CFR 1.27(d). Instructions for submitting CBI to the National List Petition process are presented in the instructions below:

No information within this petition is considered Confidential Business Information.

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Attachment #1 MSDS for Manganese Sulfate Monohydrate

MSDS Number: **M0793** * * * * * *Effective Date: 08/17/06* * * * * *
Supercedes: 12/05/03

MSDS <i>Material Safety Data Sheet</i>	24 Hour Emergency Telephone: 008-850-2151 CHEMTREC: 1-800-424-9300
	National Response in Canada CANUTEC: 619-996-6666
From: Mallinckrodt Baker, Inc. 222 Red School Lane Phillipsburg, NJ 08865	Outside U.S. and Canada Chemtrec: 703-527-3887
	NOTE: CHEMTREC, CANUTEC and National Response Center emergency numbers to be used only in the event of chemical emergencies involving a spill, leak, fire, exposure or accident involving chemicals

All non-emergency questions should be directed to Customer Service (1-800-582-2537) for assistance.

MANGANESE SULFATE

1. Product Identification

Synonyms: Manganous sulfate, monohydrate; sulfuric acid, manganese (2+) salt (1:1), monohydrate; Manganese (II) sulfate, monohydrate **CAS No.:** 7785-87-7 (Anhydrous) 10034-96-5 (Monohydrate)
Molecular Weight: 169.02
Chemical Formula: MnSO4 H2O
Product Codes: J.T. Baker: 2550, 2552 Mallinckrodt: 2147, 6097, 6192, 6200, 7780

2. Composition/Information on Ingredients

Ingredient	CAS No	Percent	Hazardous
Manganese(II) Sulfate (1:1)	7785-87-7	98 - 100%	Yes

3. Hazards Identification

Emergency Overview

WARNING! HARMFUL IF SWALLOWED OR INHALED. AFFECTS LUNGS, CENTRAL NERVOUS SYSTEM, BLOOD AND KIDNEYS. MAY CAUSE IRRITATION TO SKIN, EYES, AND RESPIRATORY TRACT. SAF-T-DATA^(tm)
Ratings (Provided here for your convenience)

Health Rating: 3 - Severe (Life)

Flammability Rating: 0 - None

Reactivity Rating: 1 - Slight

Contact Rating: 2 - Moderate

Lab Protective Equip: GOGGLES & SHIELD; LAB COAT & APRON; VENT HOOD;
PROPER GLOVES

Storage Color Code: Green (General Storage)

Potential Health Effects

Inhalation:

Inhalation can cause a flu-like illness (metal fume fever). This 24- to 48-hour illness is characterized by chills, fever, aching muscles, dryness in the mouth and throat and headache. May irritate the respiratory tract. May increase the incidence of upper respiratory infections (pneumonia). Absorption of inorganic manganese salts through the lungs is poor but may occur in chronic poisoning.

Ingestion:

May cause abdominal pain and nausea. Although they are poorly absorbed through the intestines, inorganic manganese salts may produce hypoglycemia and decreased calcium blood levels should absorption occur.

Skin Contact:

May cause irritation with redness and pain.

Eye Contact:

May cause irritation, redness and pain.

Chronic Exposure:

Chronic manganese poisoning can result from excessive inhalation and ingestion exposure and involves impairment of the central nervous system. Early symptoms include sluggishness, sleepiness, and weakness in the legs. Advanced cases have shown fixed facial expression, emotional disturbances, spastic gait, and falling. Illness closely resembles Parkinson's Disease. Kidney effects, blood changes and manganese psychosis also may occur as a result of chronic exposure. Chronic inhalation exposure can cause lung damage.

Aggravation of Pre-existing Conditions:

Persons with impaired respiratory function, psychiatric or neurological disturbances, and nutritional deficiencies may be more susceptible to the effect of this substance.

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4. First Aid Measures

Inhalation:

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion:

Induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.

Skin Contact:

Immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention if irritation develops.

Eye Contact:

Immediately flush eyes with plenty of water for at least 15 minutes, lifting upper and lower eyelids occasionally. Get medical attention if irritation persists.

5. Fire Fighting Measures

Fire:

Not considered to be a fire hazard.

Explosion:

Not considered to be an explosion hazard.

Fire Extinguishing Media:

Use any means suitable for extinguishing surrounding fire.

Special Information:

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

6. Accidental Release Measures

Ventilate area of leak or spill. Keep unnecessary and unprotected people away from area of spill. Wear appropriate personal protective equipment as specified in Section 8. Spills: Pick up and place in a suitable container for reclamation or disposal, using a method that does not generate dust. US Regulations (CERCLA) require reporting spills and releases to soil, water and air in excess of reportable quantities. The toll free number for the US Coast Guard National Response Center is (800) 424-8802.

7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Containers of this material may be hazardous when empty since they

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retain product residues (dust, solids); observe all warnings and precautions listed for the product.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:

- OSHA Permissible Exposure Limit (PEL): 5 mg/m³ Ceiling for manganese compounds as Mn

- ACGIH Threshold Limit Value (TLV): 0.2 mg/m³ (TWA) for manganese, elemental and inorganic compounds as Mn

Ventilation System: A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.

Personal Respirators (NIOSH Approved): If the exposure limit is exceeded and engineering controls are not feasible, a half facepiece particulate respirator (NIOSH type N95 or better filters) may be worn for up to ten times the exposure limit or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest.. A full-face piece particulate respirator (NIOSH type N100 filters) may be worn up to 50 times the exposure limit, or the maximum use concentration specified by the appropriate regulatory agency, or respirator supplier, whichever is lowest. If oil particles (e.g. lubricants, cutting fluids, glycerine, etc.) are present, use a NIOSH type R or P filter. For emergencies or instances where the exposure levels are not known, use a full-facepiece positive-pressure, air-supplied respirator. **WARNING:** Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.

Skin Protection: Wear protective gloves and clean body-covering clothing.

Eye Protection: Safety glasses. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Appearance:

Pale pink granular powder.

Odor:

Odorless.

Solubility:

Soluble in 1 part water.

Density:

2.95

pH:

No information found.

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% Volatiles by volume @ 21C (70F):

0

Boiling Point:

850C (1562F) Decomposes.

Melting Point:

700C (1292F) Loses all water @ 400-500C

Vapor Density (Air=1):

No information found.

Vapor Pressure (mm Hg):

No information found.

Evaporation Rate (BuAc=1):

No information found.

10. Stability and Reactivity

Stability:

Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products:

Oxides of sulfur and the contained metal.

Hazardous Polymerization:

Will not occur.

Incompatibilities:

Powdered metals, strong oxidizers.

Conditions to Avoid:

Incompatibles.

11. Toxicological Information

Toxicological Data:

Oral rat LD50: 2150 mg/kg. Investigated as a tumorigen, mutagen, reproductive effector.

Reproductive Toxicity:

For manganese metal: May damage the reproductive system. Has shown teratogenic effects in laboratory animals.

-----\Cancer Lists\-----

Ingredient Category	Known	---NTP Carcinogen---		IARC
		Anticipated		
Manganese(II) Sulfate (1:1) (7785-87-7)	No	No		None

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12. Ecological Information

Environmental Fate:

No information found.

Environmental Toxicity:

No information found.

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

Not regulated.

15. Regulatory Information

-----\Chemical Inventory Status - Part 1\-----

Ingredient	TSCA	EC	Japan	Australia
Manganese(II) Sulfate (1:1) (7785-87-7)	Yes	Yes	Yes	Yes

-----\Chemical Inventory Status - Part 2\-----

Ingredient	---Canada---	Korea	DSL	NDSL	Phil.
Manganese(II) Sulfate (1:1) (7785-87-7)		Yes	Yes	No	Yes

-----\Federal, State & International Regulations - Part 1\-----

-----SARA 302- -----SARA 313-----

Ingredient	RQ	TPQ	List
Manganese(II) Sulfate (1:1) (7785-87-7)	No	No	No

Manganese co

Ingredient	-RCRA-	-TSCA-	
	CERCLA	261.33	8(d)
Manganese(II) Sulfate (1:1) (7785-87-7)	1	No	No
Chemical Weapons Convention:	No	TSCA 12(b): No	CDTA: No
SARA 311/312: Acute:	Yes	Chronic: Yes	Fire: No Pressure: No
Reactivity: No (Pure / Solid)			

Australian Hazchem Code:

None allocated.

Poison Schedule:

None allocated.

WHMIS:

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. Other Information

NFPA Ratings: Health: 2 Flammability: 0 Reactivity: 0

Label Hazard Warning:

WARNING! HARMFUL IF SWALLOWED OR INHALED. AFFECTS LUNGS, CENTRAL NERVOUS SYSTEM, BLOOD AND KIDNEYS. MAY CAUSE IRRITATION TO SKIN, EYES, AND RESPIRATORY TRACT.

Label Precautions: Wash thoroughly after handling. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Keep container closed. Use only with adequate ventilation.

Label First Aid: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If swallowed, induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. In all cases, get medical attention.

Product Use: Laboratory Reagent.

Revision Information: MSDS Section(s) changed since last revision of document include: 11.

Disclaimer:

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***** **Prepared by:** Environmental Health & Safety Phone Number:
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