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

Morse Enterprises, Ltd. Contact: Gerald O'Connor, President Address: 200 West Welborne Ave. Suite 7 Winter Park FL 32789 Telephone No.: 407-682-6500

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<u>Item A</u>: Morse Enterprises, Ltd. is petitioning 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.

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 will be used as a crop micronutrient (in combination with other micronutrient components) to promote plant growth and plant health.

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.

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 components(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. 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.

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.) $MnSO_4.H_20$ 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

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 he 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.

Manganese sulfate monohydrate is the most common form of manganese sulfate; many other hydrated forms exist. The anhydrous for of manganese sulfate is already approved for use as an inert ingredient by the EPA (See 9b). Our petition is simply to allow use of the most common form of manganese sulfate and the least expensive form. Our goal is to provide an excellent nutritional product for organic farming needs for the smallest cost to the grower. To be in compliance our product (KeyPlex 350 OR) would have to use the anhydrous form of manganese sulfate(CAS 7785-87-7) at a cost of \$15,290/ton vs. the monohydrate (CAS 10034-96-5) at \$1,870/ton.

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:

(a) Financial or commercial information the petitioner does not want disclosed for competitive reasons may be claimed as CBI. Applicants must submit a written justification to support each claim.

(b) "Trade secrets" (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be (1) commercially valuable, (2) used in the applicant's business, and (3) maintained in secrecy.

(c) Each page containing CBI material must have "CBI Copy" marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and "CBI."

(d) The CBI-deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text where CBI has been deleted. Be sure that the CBI deleted copy is paginated the same as the CBI copy (The CBIdeleted copy of the application should be made from the same copy of the application which originally contained CBI). Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBI-deleted copy. (e) Each page with CBI-deletions should be marked "CBI-deleted" at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and "CBI-deleted."

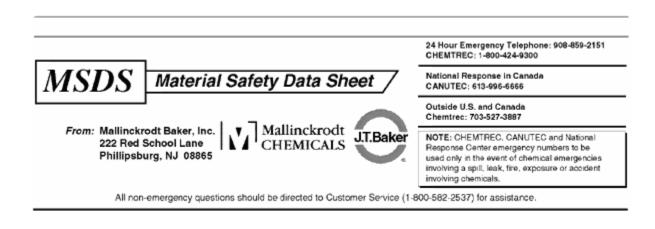
(f) If several pages are CBI-deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, "pages 7 through 10 have been CBI-deleted.")

(g) All published references that appear in the CBI copy should be included in the reference list of the CBI deleted copy. Published information cannot be claimed as confidential.

(h) Final determination regarding whether to afford CBI treatment to submitted petitions will be made by USDA pursuant to 7 CFR 1.27(d). If a determination is made to deny CBI treatment, the petitioner will be afforded an opportunity to withdraw the submission. No additional collection or recordkeeping requirements are imposed on the public by this rule. Accordingly, OMB clearance is not required by § 305(h) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*, or OMB's implementation regulation at 5 CFR, part 1320.

Attachment #1 MSDS for Manganese Sulfate Monohydrate

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



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

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.

Eve 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.

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

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: Petition for Manganese Sulfate Monohydrate

No information found. % 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\-----_____ ---NTP Carcinogen---Known Anticipated Ingredient IARC Category _____ ____ _____ ____ _____ No Manganese(II) Sulfate (1:1) No None (7785-87-7)

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

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-----\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\-----
_____
                                        --Canada--
 Ingredient
                                   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
Chemical Catq.
 _____
                                   _____ ____
 Manganese(II) Sulfate (1:1) (7785-87-7) No No
                                        No
Manganese co
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\Federal, State & International Re	gulations -	- Part 2\	
		-RCRA-	_
TSCA-			
Ingredient	CERCLA	261.33	8(d)
Manganese(II) Sulfate (1:1) (7785-87-7)	1	No	No
Chemical Weapons Convention: No TSCA 12 SARA 311/312: Acute: Yes Chronic: Yes 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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