MSDS Number: **PHONE** * * * * * *Effective Date:* ***04/07/06*** * * * * * *Supercedes:* ***04/15/02***

MSDS Material Safety Data Sheet

From: Mallinckrodt Inc.
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St. Louis, MO 63042

MALLINCKRODT

24 Hour Emergency Telephone: 314-654-1600
CHEMTREC: 1-800-424-9300
National Response in Canada
CANUTEC: 613-996-6666
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.

OXYMORPHONE

1. Product Identification

Synonyms: Dihydrohydroxymorphinone; 4,5-epoxy-3,14-dihydroxy-17-methylmorphinan-6-one; Oxymorphone Base ARS-(FOR R&D USE ONLY)
CAS No.: 76-41-5
Molecular Weight: 301.34
Chemical Formula: C17H19NO4
Product Codes: 3433, 5275, 5276

2. Composition/Information on Ingredients

Ingredient	CAS No	Percent	Hazardous
Oxymorphone	76-41-5	100%	Yes

3. Hazards Identification

Emergency Overview

DANGER! MAY BE FATAL IF SWALLOWED. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN. ALLERGEN. EXPOSURE MAY PRODUCE ALLERGIC RESPONSE. NARCOTIC.

Potential Health Effects

Inhalation:
No information found.
Ingestion:
Narcotic. May cause (in order of increasing dose) lightheadedness, nausea, vomiting, sedation, constipation, constricted pupils (miosis), sweating, respiratory depression, and circulatory collapse.
Skin Contact:
Not expected to cause health effects, although the possibility of absorption exists under conditions of skin breakage or inflammation.
Eye Contact:
Mild irritant but will also have a strong narcotic effect (pupil constriction) and the eye may serve as an absorption route to the body in general.
Chronic Exposure:
Caution, may be habit forming. Chronic exposure may lead to tolerance, dependence, and unpleasant withdrawal symptoms upon abrupt discontinuation of use (e.g., sweating, restlessness, irritability, hallucinations).
Aggravation of Pre-existing Conditions:
Some individuals may become sensitized from exposure and develop skin rashes, coughs, stuffy nose, asthma, and other allergic complaints. Sensitivity may develop soon after immediate contact or after years of exposure. Note: While there are no reports directly linking this material to allergic reactions, several other compounds form this chemical category have been associated with skin and respiratory allergic reactions associated with occupational exposure.

4. First Aid Measures

Inhalation:
Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
Ingestion:
Induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person.
Skin Contact:
Immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Call a physician, immediately. Wash clothing before reuse.
Eye Contact:
Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.

5. Fire Fighting Measures

Fire:
As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source.
Explosion:
Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Fire Extinguishing Media:
Water spray, dry chemical, alcohol foam, or carbon dioxide.
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. Follow handling guidance appropriate for OEB-3 potent compounds, (see Section 7).

6. Accidental Release Measures

Ventilate area of leak or spill. Remove all sources of ignition. Wear appropriate personal protective equipment as specified in Section 8, and follow handling guidance appropriate for OEB-3 potent compounds, (see Section 7). Isolate hazard area. Keep unnecessary and unprotected personnel from entering. All clean-up operations should be witnessed by more than one individual.
Spills: Carefully sweep up material into an appropriate container and save for reclamation or disposal. Use non-sparking tools and equipment. Do not flush to sewer! The amount of material collected should be assessed and documented.

7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect from physical damage and direct sunlight. CONTROLLED SUBSTANCE. Location of storage area must comply with all Drug Enforcement Agency regulations. 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.
Oxymorphone has potent pharmacological activity and is classified as an OEB-3* material. Handling practices for OEB-3 substances are described below:

Laboratory

* Wear appropriate gloves, lab coat, and safety glasses. Use good lab practices.
* A designated area is required for handling compounds.
* Work surfaces are to be cleaned daily. If lab bench absorbent paper is used, it is to be changed at least daily.
* High-energy operations such as milling, particle sizing, spraying or fluidizing should be done within an approved emission control or containment system.
* Develop cleaning procedures and techniques that limit potential exposure.
* Powders Handling:
To prevent contamination and overexposure, no open handling of powder should be allowed. Powder handling operations are to be done in a powders weighing hood, a glove box, or other equivalent ventilated containment system. In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used. Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs. An air-purifying respirator (P95 or other type providing a higher level of protection) should be worn by all personnel in the immediate area in cases where non-ventilated

containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.). Powder should be put into solution or a closed or covered container after handling. If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.

* Solutions Handling:
- Solutions can be handled outside a containment system or without local exhaust ventilation during procedures with no potential for aerosolization. If the procedures have a potential for aerosolization, an air-purifying respirator (P95 or other type providing a higher level of protection) is to be worn by all personnel in the immediate area.
- Solutions used for procedures where aerosolization may occur (e.g., vortexing, pumping) are to be handled within a containment system or with local exhaust ventilation. In situations where this is not feasible (may include animal dosing), an air-purifying respirator (P95 or other type providing a higher level of protection) is to be worn by all personnel in the immediate area.
- If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.
-Ensure gloves are protective against solvents in use.

Pilot Plant and Production

* Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties. Use good manufacturing practices (i.e., cGMPs).
* Protective garment (coveralls, Tyvek, lab coat) is not to be worn outside the work area.
* Clean/dirty/decontamination areas are to be established.
* Negative/positive air pressure relationships and buffer zones required (i.e., ante-room/degowning room/airlock).
* Area access is to be restricted.
* High-energy operations such as milling, particle sizing, spraying or fluidizing should be done within an approved emission control or containment system.
* Develop cleaning procedures and techniques that limit potential exposure.

* Powders Handling
- Emphasis is to be placed on closed material transfer systems and process containment, with no open handling of powders. Use enclosures and containment measures to reduce potential exposures.
- Use a powered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR) until processes have been monitored to show that respiratory protection is not required.

* Solutions Handling
- Enclose systems where possible. Processing tanks are to be kept covered. Process samples should be taken from sample ports if feasible.
- Wear a P95 Dust/Mist respirator or a respirator supplying a higher level of protection until processes have been monitored to show that respiratory protection is not required.
- Ensure gloves are protective against solvents in use.

*OEB - Mallinckrodt's Occupational Exposure Band: The classification of a compound or pharmaceutical ingredient into one of four ordinal categories of increasing potency and toxicity. This rating assigns a set of pre-determined handling and containment practices to a compound until a quantitative OEL is established.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:
For Oxymorphone:
Mallinckrodt Occupational Exposure Guideline (OEG): 7 ug/m3, as 8-hour time-weighted average
Short-term Exposure Guidelines (STEG): 30 ug/m3, as 15-minute average.
Ventilation System:
To prevent contamination and overexposure, no open handling of powder should be allowed. Powder handling operations are to be done in a powders weighing hood, a glove box, or other equivalent ventilated containment system. In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used. Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs.
Personal Respirators (NIOSH Approved):
See Section 7 for information on proper handling and specific respirator recommendations for potent compounds.
Skin Protection:
Wear protective gloves and clean body-covering clothing.
Eye Protection:
Use chemical safety goggles. Maintain eye wash fountain and quick-drench facilities in work

area.
Other Control Measures:
Allergic responses in sensitive individuals will disappear if removed from exposure.

9. Physical and Chemical Properties

Appearance:
Yellowish-tan powder.
Odor:
Odorless.
Solubility:
Insoluble in water.
Density:
ca. 1.3
pH:
No information found.
% Volatiles by volume @ 21C (70F):
No information found.
Boiling Point:
Not applicable.
Melting Point:
248 - 249C (478 - 480F)
Vapor Density (Air=1):
Not applicable.
Vapor Pressure (mm Hg):
Not applicable.
Evaporation Rate (BuAc=1):
Not applicable.

10. Stability and Reactivity

Stability:
Discolors on exposure to light.
Hazardous Decomposition Products:
Burning may produce carbon monoxide, carbon dioxide, nitrogen oxides.
Hazardous Polymerization:
Will not occur.
Incompatibilities:
Alkalis, tannin, strong oxidizing agents, borax, ferric chloride, iodides, lead acetate, mercuric chloride, gold salts.
Conditions to Avoid:
No information found.

11. Toxicological Information

No LD50/LC50 information found relating to normal routes of occupational exposure.
Intravenous mouse LD 50: 172 mg/kg

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

Ingredient	---NTP Carcinogen--- Known	Anticipated	IARC Category
Oxymorphone (76-41-5)	No	No	None

12. Ecological Information

Environmental Fate:
No information found.
Environmental Toxicity:
No information found.

13. Disposal Considerations

Notify site Drug Enforcement Agency compliance officer and local DEA office for appropriate disposal procedures. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Follow handling guidance appropriate for OEB-3 potent compounds, (see Section 7). 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
----------------------------------------------  ----  ---  -----  ---------
Oxymorphone (76-41-5)                        Exempt Yes   NE*      No

--------\Chemical Inventory Status - Part 2\---------------------------------
                                                      --Canada--
Ingredient                                    Korea  DSL   NDSL  Phil.
----------------------------------------------  -----  ---   ----  -----
Oxymorphone (76-41-5)                          No    No    No     No

--------\Federal, State & International Regulations - Part 1\----------------
                                        -SARA 302-    ------SARA 313------
Ingredient                              RQ    TPQ     List  Chemical Catg.
--------------------------------------  ---   -----   ----  --------------
Oxymorphone (76-41-5)                   No    No      No         No

--------\Federal, State & International Regulations - Part 2\----------------
                                                      -RCRA-    -TSCA-
Ingredient                              CERCLA     261.33     8(d)
--------------------------------------  ------     ------    ------
Oxymorphone (76-41-5)                   No         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)
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Australian Hazchem Code: None allocated.
Poison Schedule: S8
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: **3** Flammability: **1** Reactivity: **1**
Label Hazard Warning:
DANGER! MAY BE FATAL IF SWALLOWED. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN. ALLERGEN. EXPOSURE MAY PRODUCE ALLERGIC RESPONSE. NARCOTIC.
Label Precautions:
Avoid breathing dust.
Avoid contact with eyes, skin and clothing.
Keep container closed.
Wash thoroughly after handling.
Use with adequate ventilation.
Label First Aid:
In all cases call a physician immediately. If swallowed, induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes.
Product Use:
Medication: Analgesic; for relief of moderate to moderately severe pain.
Revision Information:
MSDS Section(s) changed since last revision of document include: 3, 5, 6, 7, 8, 13, 16.
Disclaimer:
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