

1. Product and Company Identification

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| Material name | OXYCODONE BASE | | |
| Version # | 03 | | |
| Issue date | 04-02-2012 | | |
| Revision date | 12-05-2014 | | |
| Supersedes date | 12-04-2014 | | |
| CAS # | 76-42-6 | | |
| Synonym(s) | 10-Ketooxycodone ARS (FOR R&D USE ONLY) * Oxycodone Base ARS * Dihydrohydroxycodone | | |
| Manufacturer information | Mallinckrodt 675 McDonnell Blvd. Hazelwood, MO 63042 Customer Service 888-744-1414 24 Hour Emergency 314-654-1600 Chemtrec 800-424-9300 | | |
| Item code | 1876, 3079, 3551, 3553, 3590, 3591, 3592, 3593, 3594, 3596, 4355, 4537, 6113, 6189, 6460, 6523, 6685, 7003, 8180, 8862 | | |

2. Hazards Identification

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| Emergency overview | DANGER |
| OSHA regulatory status | Narcotic. May be fatal if swallowed. Harmful if inhaled or absorbed through skin. Allergic reactions are possible. Causes central nervous system effects. Dust may form explosive mixture with air. This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication). |
| Potential health effects | |
| Routes of exposure | Inhalation. Ingestion. Skin contact. Eye contact. |
| Eyes | Dust or powder may irritate eye tissue. May have a strong narcotic effect (pupil constriction) and the eye may serve as an absorption route into the body. |
| Skin | May be harmful if absorbed through skin. May produce narcotic effects if absorbed through skin. May cause skin irritation. This product may cause an allergic skin reaction. May cause sensitization. Rash. |
| Inhalation | Harmful if inhaled. Narcotic effect. May cause typical symptoms of narcosis (see Ingestion.) Dust irritates the respiratory system, and may cause coughing and difficulties in breathing. Dizziness. May cause allergic respiratory reaction. May cause an asthma-like shortness of breath. Inhalation of powder/dust may cause lung edema. May cause sensitization by inhalation. |
| Ingestion | May be fatal if swallowed. Narcotic effect. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. Dizziness. May cause central nervous system depression. Large doses can lead to respiratory or cardiac arrest and death. |
| Chronic effects | May lead to habituation or addiction. Chronic exposure may lead to tolerance, dependence, and unpleasant withdrawal symptoms upon abrupt discontinuation of use (e.g., sweating, restlessness, irritability, hallucinations). |
| Potential environmental effects | Ecological injuries are not known or expected under normal use. |

3. Composition / Information on Ingredients

| Components | CAS # | Percent |
|----------------|---------|---------|
| OXYCODONE BASE | 76-42-6 | 100 |

4. First Aid Measures

First aid procedures

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| Eye contact | Immediately flush eyes with plenty of water for at least 15 minutes. If a contact lens is present, DO NOT delay irrigation or attempt to remove the lens. Get medical attention immediately. |
| Skin contact | Immediately flush skin with plenty of water. Remove and isolate contaminated clothing and shoes. Get medical attention if irritation develops and persists. Wash clothing separately before reuse. |
| Inhalation | If gas/fume/vapor/dust/mist from the material is inhaled, remove the affected person immediately to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Get medical attention immediately. |
| Ingestion | IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. |
| General advice | If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. |

5. Fire Fighting Measures

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| Flammable properties | As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source. Dusts at sufficient concentrations can form explosive mixtures with air. |
| Extinguishing media | |
| Suitable extinguishing media | Water. Foam. Dry chemical powder. Carbon dioxide (CO ₂). |
| Fire fighting equipment/instructions | In the event of fire, cool tanks with water spray. Move containers from fire area if you can do so without risk. As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. |
| Specific methods | Cool containers exposed to flames with water until well after the fire is out. Follow handling guidance appropriate for OEB-2 potent compounds, (see section 7). |

6. Accidental Release Measures

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| Personal precautions | Ensure adequate ventilation. Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear appropriate protective equipment and clothing during clean-up. Avoid contact with spilled material. Avoid inhalation of dust from the spilled material. Ventilate closed spaces before entering them. |
| Environmental precautions | Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. |
| Methods for containment | ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Collect spillage. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Prevent entry into waterways, sewer, basements or confined areas. |
| Methods for cleaning up | Do not flush to sewer. Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation. Collect dust using a vacuum cleaner equipped with HEPA filter. Use only non-sparking tools. Clean surface thoroughly to remove residual contamination. All clean-up operations should be witnessed by more than one individual. The amount of material collected should be assessed and documented. For waste disposal, see section 13 of the MSDS. |

7. Handling and Storage

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| Handling | Do not use in areas without adequate ventilation. DO NOT handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Dust may form explosive mixture with air. Keep formation of airborne dusts to a minimum. Provide appropriate exhaust ventilation at places where dust is formed. Material can accumulate static charges which may cause an electrical spark (ignition source). Use proper bonding and/or grounding procedures. Take precautionary measures against static discharges. Ground and bond containers when transferring material. All equipment used when handling the product must be grounded. Use non-sparking tools and explosion-proof equipment. Do not breathe dust. Avoid contact with eyes. Avoid contact with skin. Use personal protective equipment as required. Do not ingest. Wash thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment. Handle and open container with care. |
| Storage | Store locked up. Keep container tightly closed. Store in a cool, dry place. Store in a well-ventilated place. Guard against dust accumulation of this material. Keep away from heat, sparks and open flame. This material can accumulate static charge which may cause spark and become an ignition source. Prevent electrostatic charge build-up by using common bonding and grounding techniques. Ground container and transfer equipment to eliminate static electric sparks. Use care in handling/storage. Store in accordance with local/regional/national/international regulation. |
| Further information | CONTROLLED SUBSTANCE: Location of storage area must comply with all Drug Enforcement Agency regulations. |

Oxycodone base has potent pharmacological activity and is classified as an OEB-2* material. Handling practices for OEB-2 substances are described below.

LABORATORY:

- *Wear appropriate gloves, lab coat, and safety glasses. Use good lab practices.
- *No local exhaust ventilation required for transfer/handling of quantities of powder less than 100 g (total weight transferred or handled). However, if the source container contains 2 kg or more, pilot plant practices apply.
- *No local exhaust ventilation required for solutions of these compounds.
- *Quantities of solid above 100 g require use of a powders weighing hood or other approved containment/ventilation system.
- *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.

PILOT PLANT PRODUCTION:

- *Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses and safety shoes. Use good manufacturing practices (i.e., cGMPs).
- *Use local exhaust and/or enclosure at dust-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling of powders.
- *Where open handling of powders occurs, use a powered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR), unless air-monitoring data has shown that a lower level of respiratory protection is adequate.
- *Protective garments (coveralls, Tyveks, lab coat) are not to be worn in common areas (e.g., cafeterias) or out-of-doors.
- *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.

*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

Occupational exposure limits

Mallinckrodt

Material

Type

Value

Form

OXYCODONE BASE (CAS
76-42-6)

OEB

2 N/A

OEL

25 µg/m³

8-hour time-weighted
average

STEL

75 µg/m³

15-minute average

Biological limit values

No biological exposure limits noted for the ingredient(s).

Engineering controls

Explosion-proof general and local exhaust ventilation. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Ventilation should be sufficient to effectively remove and prevent buildup of any dusts or fumes that may be generated during handling or thermal processing. If engineering measures are not sufficient to maintain concentrations of dust particulates below the OEL, suitable respiratory protection must be worn. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits. Ensure adequate ventilation, especially in confined areas.

Personal protective equipment

Eye / face protection

Chemical goggles are recommended. Provide eyewash station and safety shower.

Skin protection

Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties.

Respiratory protection

Where open handling of powders occurs, use a powered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR), unless air-monitoring data has shown that a lower level of respiratory protection is adequate.

General hygiene
considerations

When using, do not eat, drink or smoke. Do not breathe dust. Avoid contact with eyes. Avoid contact with skin. Wash hands after handling and before eating. Contaminated work clothing should not be allowed out of the workplace. Handle in accordance with good industrial hygiene and safety practice. See Section 7 for additional information on occupational control measures appropriate for OEB-2 potent compounds.

9. Physical & Chemical Properties

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| Appearance | Powder. |
| Physical state | Solid. |
| Form | Powder. |
| Color | White. |
| Odor | Odorless. |
| Odor threshold | Not available. |
| pH | Not available. |
| Vapor pressure | < 0.0000001 kPa at 25 °C |
| Vapor density | Not available. |
| Boiling point | Not available. |
| Melting point/Freezing point | 424.4 - 428 °F (218 - 220 °C) |
| Solubility (water) | Insoluble |
| Specific gravity | Not available. |
| Relative density | Not available. |
| Flash point | Not available. |

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| Flammability limits in air, upper, % by volume | Not available. |
| Flammability limits in air, lower, % by volume | Not available. |
| Auto-ignition temperature | Not available. |
| Molecular weight | 315.36 g/mol |
| Molecular formula | C18-H21-N-O4 |
| Dust Electrostatic Properties | |
| Minimum Ignition Energy (Cloud) | < 3 mJ |
| Dust Explosion Properties | |
| dP/dT | 1482 bar/s |
| Kst | 402 bar.m/s |
| Limiting Oxygen Concentration | 9 - 10 % |
| Minimum Explosible Concentration | 20 - 30 g/m ³ |
| Minimum Ignition Temperature-Cloud | 788 - 824 °F (420 - 440 °C) |
| Minimum Ignition Temperature-Layer | > 752 °F (> 400 °C) |
| Pmax | 9.4 bar |

10. Chemical Stability & Reactivity Information

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| Chemical stability | Discoloration upon exposure to light. |
| Conditions to avoid | Exposure to light. Heat, flames and sparks. |
| Incompatible materials | Alkalies. Strong oxidizing agents. Iodides. Chlorides. |
| Hazardous decomposition products | Nitrogen oxides (NO _x). Toxic gas. |

11. Toxicological Information

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| Sensitization | May cause sensitization by inhalation and skin contact. |
| Acute effects | May be fatal if swallowed. Harmful if inhaled. |
| Local effects | Narcotic effect. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. Allergic reactions are possible. Inhalation of dusts may cause respiratory irritation. |
| Chronic effects | Chronic exposure may lead to tolerance, dependence, and unpleasant withdrawal symptoms upon abrupt discontinuation of use (e.g., sweating, restlessness, irritability, hallucinations). |
| Carcinogenicity | This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. |
| OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050) | |
| | Not listed. |
| Skin corrosion/irritation | Not available. |
| Epidemiology | Not available. |
| Neurological effects | Not available. |

12. Ecological Information

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|-------------------------------|---|
| Ecotoxicity | This product has no known eco-toxicological effects. |
| Environmental effects | An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. |
| Aquatic toxicity | Not available. |
| Persistence and degradability | No data is available on the degradability of this product. |

13. Disposal Considerations

Disposal instructions 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-2 potent compounds, (see Section 7). Dispose of contents/container in accordance with local/regional/national/international regulations.

14. Transport Information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
CERCLA/SARA Hazardous Substances - Not applicable.
TSCA exempt status.

Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2) and Chemical Code Number

Not listed.

Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))

Not regulated.

DEA Exempt Chemical Mixtures Code Number

Not regulated.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA (Superfund) reportable quantity

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

Section 302 extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Drug Enforcement Administration (DEA) (21 CFR 1308.11-15) Schedule II - 9143

International Inventories

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|----------------------|--|------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | Yes |
| Canada | Domestic Substances List (DSL) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | No |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | Yes |

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|---|------------------------|
| Europe | European List of Notified Chemical Substances (ELINCS) | No |
| Japan | Inventory of Existing and New Chemical Substances (ENCS) | No |
| Korea | Existing Chemicals List (ECL) | No |
| New Zealand | New Zealand Inventory | No |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No |

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

US state regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

16. Labeling Info

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| Label Hazard Warning | DANGER Narcotic. May be fatal if swallowed. Harmful if inhaled or absorbed through skin. Allergic reactions are possible. Causes central nervous system effects. Dust may form explosive mixture with air. |
| Label Precautions | Do not breathe dust. Do not get in eyes, on skin, or on clothing. Keep container closed. Wash thoroughly after handling. Use only with adequate ventilation. |
| Label First Aid | Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention immediately. Immediately flush skin with plenty of water. Get medical attention if irritation develops or persists. If gas/fume/vapor/dust/mist from the material is inhaled, remove the affected person immediately to fresh air. Do not use mouth-to-mouth method if victim inhaled the substance. Get medical attention immediately. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Rinse mouth thoroughly. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. |

17. Other Information

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| NFPA ratings | Health: 3 Flammability: 1 Instability: 0 |
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Disclaimer

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This data sheet contains changes from the previous version in section(s):

Handling and Storage: Further information
Physical & Chemical Properties: Multiple Properties
Toxicological Information: Toxicological Data
Other Information: Disclaimer