

1. Identification

Product identifier	ROXICODONE®	
CAS #	Mixture	
Other means of identification		
SDS number	RXCDN	
Synonyms	Dihydrohydroxycodone hydrochloride * 4,5 α -epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride	
Recommended use	Finished Pharmaceutical	
Recommended restrictions	None known.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	Mallinckrodt	
Address	675 McDonnell Blvd. Hazelwood, MO 63042	
Telephone	Not available.	
E-mail	Not available.	
Emergency phone number	Customer Service	888-744-1414
	24 Hour Emergency	314-654-1600
	Chemtec	800-424-9300
Item code	23635-581-10, 23635-582-10	

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 3
	Sensitization, respiratory	Category 1
	Sensitization, skin	Category 1
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Labeling

Contains OXYCODONE HYDROCHLORIDE

Label elements

Signal word Danger

Hazard statement Narcotic. Toxic if swallowed. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. May cause drowsiness or dizziness.

Precautionary statement**Prevention**

Avoid breathing dust/fume. Use only outdoors or in a well-ventilated area. In case of inadequate ventilation wear respiratory protection. Do not eat, drink or smoke when using this product. Wear protective gloves. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace.

Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell. If experiencing respiratory symptoms: Call a poison center/doctor. Wash contaminated clothing before reuse.
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	<p>The hazard warnings associated with this product are based on the individual ingredients included in the finished dosage form of the pharmaceutical product. The supplied package insert (approved labeling) provides the necessary drug safety information.</p> <p>As per 29 CFR 1910.1200(b)(5)(iii), any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (e.g. flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and regulations issued under that Act, when they are subject to the labeling requirements under that Act by the Food and Drug Administration are exempted from the requirements of the Hazard Communication Standard.</p> <p>All Mallinckrodt finished products are labeled in compliance with the requirements of the Food and Drug Administration (FDA) and must be used in the prescribed manner. Each package of the finished pharmaceutical product is supplied with a package insert (approved labeling) which provides necessary drug safety information.</p>

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
LACTOSE		63-42-3	30 - 60
OXYCODONE HYDROCHLORIDE		124-90-3	15 - 30
MICROCRYSTALLINE CELLULOSE		9004-34-6	10 - 20
STARCH		9005-25-8	10 - 20
SODIUM STARCH GLYCOLATE		9063-38-1	2.5 - 10
Other components below reportable levels			0.1 - 1

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

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.
Skin contact	Immediately flush skin with plenty of water. For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing and shoes. If skin irritation or rash occurs: Get medical advice/attention. Wash clothing separately before reuse.
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.
Ingestion	If swallowed: Immediately call a poison center/doctor. 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.

Most important symptoms/effects, acute and delayed	Narcosis. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. Decrease in motor functions. Respiratory disorder. May cause allergic respiratory and skin reactions. Dusts may irritate the respiratory tract, skin and eyes.
Indication of immediate medical attention and special treatment needed	In case of shortness of breath, give oxygen. Keep victim warm. Keep victim under observation. Symptoms may be delayed.
General information	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

Flammable properties	The product is not flammable.
Suitable extinguishing media	Use any media suitable for the surrounding fires.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.
Fire-fighting equipment/instructions	In case of fire and/or explosion do not breathe fumes. In the event of fire, cool tanks with water spray. Use water spray to cool unopened containers. Move containers from fire area if you can do so without risk.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	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.
Methods and materials for containment and cleaning up	ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Prevent entry into waterways, sewer, basements or confined areas. Do not flush to sewer. Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation. 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. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Do not handle until all safety precautions have been read and understood. 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. Protect from moisture. Do not breathe dust. Keep formation of airborne dusts to a minimum. Provide appropriate exhaust ventilation at places where dust is formed. Use personal protective equipment as required. Do not ingest. Do not get this material in contact with eyes. Do not get this material in contact with skin. Do not get this material on clothing. Wash thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment. Handle and open container with care.
Conditions for safe storage, including any incompatibilities	Store locked up. Keep container tightly closed. Store in a cool, dry place. Store in a well-ventilated place. Store at controlled room temperature 20-25°C (68-77°F). Guard against dust accumulation of this material. Keep away from heat and sources of ignition. Keep away from moisture. Keep away from food, drink and animal feedingstuffs. 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 or competent authority regulations.

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m ³	Respirable fraction.
STARCH (CAS 9005-25-8)	PEL	15 mg/m ³	Total dust.
		5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m ³
STARCH (CAS 9005-25-8)	TWA	10 mg/m ³
STEARIC ACID (CAS 57-11-4)	TWA	10 mg/m ³

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	5 mg/m ³	Respirable.
		10 mg/m ³	Total
STARCH (CAS 9005-25-8)	TWA	5 mg/m ³	Respirable.
		10 mg/m ³	Total

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Components	Type	Value	Form
OXYCODONE HYDROCHLORIDE (CAS 124-90-3)	OEB	2 OEB	
	OEG	25 µg/m ³	8-hour time-weighted average
	STEG	75 µg/m ³	15-minute average

Biological limit values

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

Exposure guidelines

No exposure standards allocated.

Appropriate engineering controls

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. Ensure adequate ventilation, especially in confined areas.

Individual protection measures, such as personal protective equipment

Eye/face protection

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

Skin protection

Hand protection

Chemical resistant gloves.

Other

Wear appropriate chemical resistant clothing.

Respiratory protection

Wear respirator with dust filter. Use a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations 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.

9. Physical and chemical properties

Appearance	Tablet.
Physical state	Solid.
Form	Solid.
Color	Various.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials. Exposure to light. Moisture.
Incompatible materials	Acids. Strong oxidizing agents.
Hazardous decomposition products	Carbon dioxide. Carbon monoxide. Nitrogen oxides (NOx). Hydrogen chloride.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Toxic 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.
Inhalation	Not relevant, due to the form of the product. Inhalation of dust from crushed tablets may be: Dust irritates the respiratory system, and may cause coughing and difficulties in breathing. Narcotic effect. May cause typical symptoms of narcosis (see Ingestion.) 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.
Skin contact	Contact with dust or powder generated by damaged tablets may cause skin irritation. May produce narcotic effects if absorbed through skin. May cause an allergic skin reaction. May cause sensitization by skin contact. Rash. Symptoms may parallel ingestion.
Eye contact	Not relevant, due to the form of the product. Contact with dust or powder generated by damaged tablets may irritate eye tissue. May have a strong narcotic effect (pupil constriction) and the eye may serve as an absorption route into the body.

Symptoms related to the physical, chemical and toxicological characteristics

Narcosis. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. Decrease in motor functions. Respiratory disorder. May cause allergic respiratory and skin reactions. Dusts may irritate the respiratory tract, skin and eyes.

Information on toxicological effects

Acute toxicity	Toxic if swallowed.
Chronic effects	May lead to habituation or addiction. May cause central nervous system disorder (e.g., narcosis involving a loss of coordination, weakness, fatigue, mental confusion and blurred vision) and/or damage.

Product	Species	Test Results
ROXICODONE® (CAS Mixture)		
Acute		
<i>Inhalation</i>		
LC50	Rat	32222.2227 mg/m3, 4 hours estimated
Components		
LACTOSE (CAS 63-42-3)		
Acute		
<i>Oral</i>		
LD50	Rat	> 10 g/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	>= 2000 mg/kg
<i>Inhalation</i>		
LC50	Rat	>= 5800 mg/m3, 4 hours
<i>Oral</i>		
LD50	Rat	>= 5000 mg/kg

Components	Species	Test Results
STEARIC ACID (CAS 57-11-4)		
Acute		
<i>Oral</i>		
LD50	Rat	4.6 g/kg
Skin corrosion/irritation	Contact with dust or powder generated by damaged tablets may cause skin irritation.	
Serious eye damage/eye irritation	Contact with dust or powder generated by damaged tablets may irritate eye tissue.	
Respiratory or skin sensitization		
Respiratory sensitization	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
Skin sensitization	May cause an allergic skin reaction.	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
ACGIH Carcinogens		
STARCH (CAS 9005-25-8)	A4 Not classifiable as a human carcinogen.	
STEARIC ACID (CAS 57-11-4)	A4 Not classifiable as a human carcinogen.	
Reproductive toxicity	Due to lack of data the classification is not possible.	
Specific target organ toxicity - single exposure	Narcotic effects.	
Specific target organ toxicity - repeated exposure	Due to lack of data the classification is not possible.	
Aspiration hazard	Due to lack of data the classification is not possible.	
12. Ecological information		
Ecotoxicity	This product has no known eco-toxicological effects.	
Persistence and degradability	No data is available on the degradability of this product.	
Bioaccumulative potential		
Partition coefficient n-octanol / water (log Kow)		
STEARIC ACID	8.23	
Mobility in soil	No data available.	
Other adverse effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.	
13. Disposal considerations		
Disposal instructions	Notify site Controlled Substances Compliance officer and local DEA office or competent authority 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. Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazardous waste code	Waste codes should be assigned by the user based on the application for which the product was used. The waste code should be assigned in discussion between the user, the producer and the waste disposal company.	
Waste from residues / unused products	Dispose of in accordance with local regulations.	
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.	
14. Transport information		
DOT		
Not regulated as dangerous goods.		

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

15. Regulatory information

US federal regulations TSCA exempt status.
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA (Superfund) reportable quantity

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

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

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

US. Massachusetts RTK - Substance List

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
STARCH (CAS 9005-25-8)

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

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

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

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

STARCH (CAS 9005-25-8)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

Not Listed.

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)	Yes
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)	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).

16. Other information, including date of preparation or last revision**Issue date** 05-31-2015**Version #** 01**Disclaimer**

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Revision Information

Product and Company Identification: Synonyms
 Composition / Information on Ingredients: Undisclosed Ingredient Statement
 Physical & Chemical Properties: Multiple Properties
 Toxicological Information: Toxicological Data
 Regulatory Information: United States
 HazReg Data: North America
 GHS: Classification