

Version 3.0 Revision Date: 2015/06/05 SDS Number: 100000004206 Date of last issue: 2015/04/23
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SECTION 1. IDENTIFICATION

Substance name : OXYCODONE HYDROCHLORIDE
oxycodone hydrochloride
Substance No. : 124-90-3
Reference number : JNJ-359203-AAC
R001174

Manufacturer or supplier's details

Company name of supplier : NORAMCO, Inc
Address : 500 Swedes Landing Road
Wilmington, DE 19801-4417
US
Telephone : (302) 761-2909

Emergency telephone number : **+32 14 60 24 44**
E-mail address Responsible/issuing person : SDSJanssen@its.jnj.com

Recommended use of the chemical and restrictions on use


Recommended use : Active Pharmaceutical Ingredient

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Oral) : Category 4
Acute toxicity : Category 4
Respiratory sensitisation : Category 1
Skin sensitisation : Category 1
Specific target organ toxicity - single exposure : Category 3

GHS Label element

Hazard pictograms : 

Signal word : Danger

Hazard statements : H302 Harmful if swallowed.
H332 Harmful if inhaled.
H334 May cause allergy or asthma symptoms or breathing diffi-

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culties if inhaled.
H317 May cause an allergic skin reaction.
H336 May cause drowsiness or dizziness.

Precautionary statements : **Prevention:**
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P314 Get medical advice/ attention if you feel unwell.
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
Storage:
P405 Store locked up.

Other hazards

Warning! May form combustible dust concentrations in air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Substance

Chemical nature : Solid

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
OXYCODONE HYDROCHLORIDE	124-90-3	>= 90 - <= 100

SECTION 4. FIRST AID MEASURES

If inhaled : If breathed in, move person into fresh air.
If unconscious place in recovery position and seek medical advice.
Artificial respiration and/or oxygen may be necessary.
Call a physician immediately.

In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off immediately with soap and plenty of water.
If symptoms persist, call a physician.
Wash contaminated clothing before re-use.

In case of eye contact : Rinse thoroughly with plenty of water, also under the eyelids.
Remove contact lenses.
If eye irritation persists, consult a specialist.

If swallowed : Call a physician immediately.
If swallowed, rinse mouth with water (only if the person is conscious).
Induce vomiting, but only if victim is fully conscious.

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Most important symptoms and effects, both acute and delayed : constriction of pupils
Sweating
Lowered blood pressure
slow pulse
unconsciousness
relaxation of the muscles
respiratory depression
Coma
Fatality
Watch victim for several hours because of possible delayed signs of poisoning.

Notes to physician : Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water mist
Aqueous film forming foam (AFFF).
Dry powder
Carbon dioxide (CO₂)
Sand

Unsuitable extinguishing media : Do NOT use water jet.

Specific hazards during fire-fighting : Dust may form explosive mixture in air.
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Hazardous combustion products : No hazardous combustion products are known

Further information : Avoid dust formation.
Cool containers/tanks with water spray.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Firefighters must wear fire resistant personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Avoid dust formation.
Ensure adequate ventilation.
Evacuate personnel to safe areas.
Keep away from open flames, hot surfaces and sources of ignition.
Refer to protective measures listed in sections 7 and 8.

Environmental precautions : Should not be released into the environment.

Methods and materials for : Sweep up and shovel into suitable containers for disposal.

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containment and cleaning up : Avoid dust formation.
Keep in suitable, closed containers for disposal.
Keep in properly labelled containers.
Treat recovered material as described in the section "Disposal considerations".

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Avoid formation of dust and aerosols. Keep away from open flames, hot surfaces and sources of ignition. No smoking.

Advice on safe handling : To avoid thermal decomposition, do not overheat.
Keep away from heat and sources of ignition.
Avoid formation of dust and aerosols.
For personal protection see section 8.

Conditions for safe storage : Store at room temperature.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Store in original container.
To avoid thermal decomposition, do not overheat.
To maintain product quality, do not store in heat or direct sunlight.
Keep away from fire, sparks and heated surfaces.
Keep locked up.

Recommended storage temperature : 15 - 25 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
OXYCODONE HYDROCHLORIDE	124-90-3	PBOEL-HHC	2	J&J OEL/PBOEL HHC
Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 2. This means that the OEL is estimated to be from 20 to 100 µg/m ³				
		TWA	0.020 mg/m ³	J&J OEL/PBOEL HHC
		STEL	0.130 mg/m ³	J&J OEL/PBOEL HHC

Engineering measures : Engineering controls should be used as the primary means to control possible exposures. Use process enclosures, local exhaust ventilation or other engineering controls to keep ex-

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posure levels below recommended exposure limits.

Personal protective equipment

- Respiratory protection : Respirator with a full face mask
Respirator with a particle filter (EN 143)
Engineering controls should always be the primary method of controlling exposures.
If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.
- Filter type : P2
- Eye protection : Respirator with a full face mask
Tightly fitting safety goggles
- Skin and body protection : closed work clothing
Long sleeved clothing
- Protective measures : The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.
When using do not eat, drink or smoke.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : crystalline, powder
- Colour : white
- Odour : odourless
- Odour Threshold : No data available
- pH : No data available
- Melting point/range : 218 - 223 °C
- Boiling point/boiling range : No data available
- Flash point : No data available
- Evaporation rate : No data available
- Flammability (solid, gas) : No information available.

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Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	380 °C Method: M.I.T. Dust Cloud BAM METHOD
Decomposition temperature	:	245 °C Relevant T 225 °C Minimum T
Explosive properties	:	No data available
Oxidizing properties	:	No data available
Molecular weight	:	351.82 g/mol

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under recommended storage conditions.
Possibility of hazardous reactions	:	No data available
Conditions to avoid	:	To avoid thermal decomposition, do not overheat. Avoid dust formation. Heat, flames and sparks.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	Carbon monoxide Nitrogen oxides (NO _x)

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SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity****Product:**

Acute oral toxicity : Remarks: Harmful if swallowed.

Acute inhalation toxicity : Remarks: Harmful by inhalation.

Acute toxicity (other routes of administration) : LD50 (Mouse): 320 mg/kg
Application Route: intraperitoneal; injection made in the abdominal area
Remarks: No data available

LD50 (Mouse): 426 mg/kg
Application Route: Subcutaneous; injection made in the back or neck of animal

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitisation**Product:**

Remarks: May cause sensitisation by inhalation and skin contact.

Germ cell mutagenicity**Product:**Genotoxicity in vitro : Test Type: Ames test
Result: negative**Carcinogenicity****Product:**

Remarks: No data available

IARC

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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Reproductive toxicity**Product:**

Effects on fertility

: Species: Rat
NOAEL: 10 mg/kg,
Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

Species: Rabbit
NOAEL: 125 mg/kg,
Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

Effects on foetal development

: Remarks: No data available

STOT - single exposure**Product:**

Remarks: No data available

STOT - repeated exposure**Repeated dose toxicity****Product:**

Species: Mouse
NOAEL: 1,320 mg/kg
Application Route: Dermal
Exposure time: 28 d

Species: Rat
LOAEL: 1 mg/kg
Application Route: Oral
Exposure time: 91 d

Species: Dog
NOAEL: 40 mg/kg
Application Route: Oral
Exposure time: 4 Weeks

Aspiration toxicity

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Product:**

Toxicity to fish

: LC50 (Danio rerio (zebra fish)): > 96 mg/l
Exposure time: 96 h
Test Type: LC50
Method: OECD Test Guideline 203

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NOEC (Danio rerio (zebra fish)): 96 mg/l Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h
Method: OECD Test Guideline 202

NOEC (Daphnia magna (Water flea)): 50 mg/l Method: OECD Test Guideline 202

Toxicity to algae : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201

NOECr (Pseudokirchneriella subcapitata (green algae)): 24 mg/l Test Type: Growth inhibition
Method: OECD Test Guideline 201

EbC50 (Pseudokirchneriella subcapitata (green algae)): 84 mg/l Exposure time: 72 h
Test Type: Cell multiplication inhibition test
Method: OECD Test Guideline 201

NOECb (Pseudokirchneriella subcapitata (green algae)): 24 mg/l Test Type: Cell multiplication inhibition test
Method: OECD Test Guideline 201

Toxicity to bacteria : EC50 (activated sludge): > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Persistence and degradability

Product:

Biodegradability : Remarks: Expected to be biodegradable

Bioaccumulative potential

Product:

Bioaccumulation : Remarks: Does not bioaccumulate.

Mobility in soil

Product:

Distribution among environmental compartments : Adsorption/Soil
log Koc: 2.25
Method: OECD Test Guideline 121

Other adverse effects

Product:

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Results of PBT and vPvB assessment	: This substance is not considered to be persistent, bioaccumulating and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulating (vPvB).
Ozone-Depletion Potential	: : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
Additional ecological information	: No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	: Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities. Uncontrolled disposal or recycling of this packaging is not permitted and can be dangerous. In accordance with National, Federal, State and Local regulations.
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SECTION 14. TRANSPORT INFORMATION

International transport regulations

ADR

Not dangerous goods

RID

Not dangerous goods

DOT

Not dangerous goods

IATA

Not dangerous goods

IMDG

Not dangerous goods

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SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

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New Jersey Right To Know

OXYCODONE HYDROCHLORIDE	124-90-3	90 - 100 %
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California Prop 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

Other regulations

: Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

The components of this product are reported in the following inventories:

REACH : Not in compliance with the inventory

: OXYCODONE HYDROCHLORIDE

CH INV : Not in compliance with the inventory

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	: OXYCODONE HYDROCHLORIDE
TSCA	: Not On TSCA Inventory
	: OXYCODONE HYDROCHLORIDE
NZIoC	: Not in compliance with the inventory
	: OXYCODONE HYDROCHLORIDE
ENCS	: Not in compliance with the inventory
	: OXYCODONE HYDROCHLORIDE
ISHL	: Not in compliance with the inventory
	: OXYCODONE HYDROCHLORIDE
KECI	: Not in compliance with the inventory
	: OXYCODONE HYDROCHLORIDE
PICCS	: Not in compliance with the inventory
	: OXYCODONE HYDROCHLORIDE
IECSC	: Not in compliance with the inventory
	: OXYCODONE HYDROCHLORIDE

Inventories

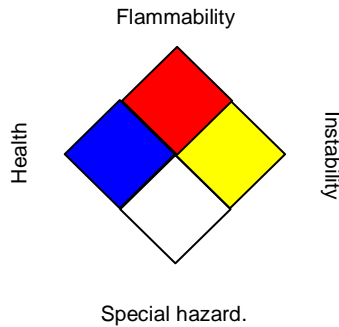
AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

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SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

HEALTH	
FLAMMABILITY	
PHYSICAL HAZARD	

0 = not significant, 1 =Slight,
 2 = Moderate, 3 = High
 4 = Extreme, * = Chronic

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Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date: Dec 31th, 2012 as 2012/12/31
Numbers: 123456,78 as 123,456.78

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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