

RISPERDAL

Version	Revision Date:	SDS Number:	Date of last issue:
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			Date of first issue: 2014/02/21

SECTION 1. IDENTIFICATION

Product name : RISPERDAL
Substance name : RISPERDAL 2 mg coated tablets (orange)
risperidone

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560

USA

Telephone : +16097302000

E-mail address of person responsible for the SDS : SDSJanssen@its.jnj.com

Emergency telephone number : **CHEMTREC US: 1-800-424-9300**
CHEMTREC International: +1 703-741-5970

Recommended use of the chemical and restrictions on use

Recommended use : Finished Pharmaceutical Product
Pharmacotherapeutic group: Psycholeptics
This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.
This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

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Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity:
9.66 %

Other hazards

This Finished Pharmaceutical Product is non-hazardous based on chemical classification rules. Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate the possible workplace hazards when this Finished Pharmaceutical Product is accidentally leaking, broken or crushed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

Components

Chemical name	CAS-No.	Concentration (% w/w)
Starch	9005-25-8	>= 20 - < 30
Cellulose	9004-34-6	>= 5 - < 10
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	>= 1 - < 5
RISPERIDONE	106266-06-2	>= 0.1 - < 1
TITANDIOXIDE	13463-67-7	>= 0.1 - < 1
Talc (Mg ₃ H ₂ (SiO ₃) ₄)	14807-96-6	>= 0.1 - < 1
Octadecanoic acid, magnesium salt	557-04-0	>= 0.1 - < 1
PROPYLENE GLYCOL	57-55-6	>= 0.1 - < 1
COLLOIDAL ANHYDROUS SILICA	112945-52-5	>= 0.1 - < 1
DODECYL SODIUM SULPHATE	151-21-3	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

If inhaled	: If breathed in, move person into fresh air. Consult a physician.
In case of skin contact	: Take off contaminated clothing and shoes immediately. Wash off with soap and water. If symptoms persist, call a physician.
In case of eye contact	: Remove contact lenses. Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes. If eye irritation persists, consult a specialist.
If swallowed	: If swallowed, rinse mouth with water (only if the person is conscious). Call a physician immediately.
Most important symptoms	: Consult the patient packaging insert for more information

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and effects, both acute and delayed

about this Finished Pharmaceutical Product.

Abdominal pain
Cough
Dizziness
Drowsiness
Fatigue
Fever
hypertension
Headache
muscle pain
Pain
Sleep
Tremors
Vomiting
Respiratory disorder

Notes to physician

: Treat symptomatically.
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Hazardous combustion products : No information available.
- Further information : No information available.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Avoid dust formation.
Avoid breathing dust.
Evacuate personnel to safe areas.
In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.
- Environmental precautions : Should not be released into the environment.
- Methods and materials for containment and cleaning up : Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".
Large spills: Sweep up (intact) or vacuum with HEPA filter (broken or crushed) or via wet cleaning into suitable containers for disposal. Pick up and arrange without creating dust. Keep in properly labelled containers.
Small spills: Moisten a towel, cover the spill, pick up the spill

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or use HEPA vacuum.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : None known.
- Advice on safe handling : Avoid inhalation, ingestion and contact with skin and eyes.
Keep away from heat and sources of ignition.
To avoid thermal decomposition, do not overheat.
Do not break, crush or spill this Finished Pharmaceutical Product.
Use personal protective equipment as required.
- Conditions for safe storage : Keep away from heat and sources of ignition.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep locked up.
Store in original container.
To maintain product quality, do not store in heat or direct sunlight.
- Recommended storage temperature : 59 - 77 °F / 15 - 25 °C
- Further information on storage stability : Do not store in the refrigerator or freezer.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Starch	9005-25-8	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH

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		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	TWA	10 mg/m3	ACGIH
RISPERIDONE	106266-06-2	TWA	0.0045 mg/m3	J&J OEL/PBOEL HHC
		PBOEL-HHC	3 B	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 3B.				
TITANDIOXIDE	13463-67-7	TWA	2.4 mg/m3	J&J OEL/PBOEL HHC
		TWA	10 mg/m3	ACGIH
Talc (Mg3H2(SiO3)4)	14807-96-6		2 mg/m3	ACGIH
		TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA (respirable dust fraction)	2 mg/m3	OSHA P0
		TWA (Respirable)	2 mg/m3	NIOSH REL
		TWA	0.1 fibres per cubic centimeter	ACGIH
		TWA (Respirable particulate matter)	2 mg/m3	ACGIH
		PEL (respirable)	0.05 mg/m3	OSHA CARC
Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate)	3 mg/m3	ACGIH

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		matter)		
PROPYLENE GLYCOL	57-55-6	TWA	10 mg/m3	US WEEL
COLLOIDAL ANHYDROUS SILICA	112945-52-5	TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3
		TWA (Dust)	80 mg/m3 / %SiO2 (Silica)	OSHA Z-3
		TWA	6 mg/m3 (Silica)	NIOSH REL
DODECYL SODIUM SULPHATE	151-21-3	TWA	0.5 mg/m3	J&J OEL/PBOEL HHC
		PBOEL-HHC	1 B	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 1B., Notation DSEN: has the potential to cause delayed allergic skin reaction (sensitization), such as wheals and rashes, Notation RSEN: has the potential to cause delayed allergic reactions (sensitization), such as shortness of breath, asthma and anaphylaxis.				

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.
If this product is processed not in accordance with the prescribed use, contact the Industrial Hygiene / Environment Health Safety Expert to assess the situation.
Validated Industrial Hygiene Analytical methods are developed to monitor and quantify inhalable exposure to the Active Pharmaceutical Ingredient. For more information contact Bureau Veritas Laboratories - Lake Zurich (BV_LZLab@bureauveritas.com) or the Laboratory of Occupational and Environmental Hygiene (lamh.be).

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection : Disposable gloves

Remarks : Disposable gloves

Eye protection : No special precautions required.

Skin and body protection : closed work clothing

Protective measures : The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if

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necessary.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: tablet
Colour	: orange
Odour	: No data available
pH	: No data available
Melting point/ range	: No data available
Boiling point/boiling range	: No data available
Flash point	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: Not applicable
Relative vapour density	: Not applicable
Relative density	: No data available
Density	: No data available
Solubility(ies)	
<u>Water solubility</u>	: No data available
Partition coefficient: n-octanol/water	: No data available
Decomposition temperature	: No data available
Viscosity	
<u>Viscosity, dynamic</u>	: Not applicable
<u>Viscosity, kinematic</u>	: Not applicable
Explosive properties	: No data available

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SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under recommended storage conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	Heat, flames and sparks. To avoid thermal decomposition, do not overheat.
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

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

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 10 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method

Components:**Cellulose:**

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
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RISPERIDONE:

Acute oral toxicity	:	LD50 (Rat, female): 63 mg/kg LD50 (Rat, male): 113 mg/kg LD50 (Mouse): 63 mg/kg LD50 (Dog): 18.3 mg/kg
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Acute inhalation toxicity	:	Remarks: No data available
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Acute dermal toxicity	:	Remarks: No data available
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Talc (Mg₃H₂(SiO₃)₄):

Acute oral toxicity	:	Remarks: No data available
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PROPYLENE GLYCOL:

Acute oral toxicity : LD50 (Rat): > 10,400 mg/kg

Acute inhalation toxicity : LC50 (Rabbit): > 317,042 mg/l
Exposure time: 2 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): 20,800 mg/kg

COLLOIDAL ANHYDROUS SILICA:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

DODECYL SODIUM SULPHATE:

Acute oral toxicity : LD50 Oral (Rat): 1,200 mg/kg
Method: OECD Test Guideline 401
Assessment: The component/mixture is moderately toxic after single ingestion.

Acute inhalation toxicity : Assessment: The component/mixture is moderately toxic after short term inhalation.

Acute dermal toxicity : LD50 Dermal (Rabbit): > 2,000 mg/kg

Skin corrosion/irritation**Components:****Cellulose:**

Species : Rabbit

Remarks : No skin irritation

RISPERIDONE:

Species : Rabbit

Result : No skin irritation

Talc (Mg₃H₂(SiO₃)₄):

Remarks : slight irritation

COLLOIDAL ANHYDROUS SILICA:

Species : Rabbit

Result : No skin irritation

DODECYL SODIUM SULPHATE:

Species : Rabbit

Method : OECD Test Guideline 404

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Result : Skin irritation

Serious eye damage/eye irritation**Components:****Cellulose:**

Species : Rabbit
Remarks : No eye irritation

RISPERIDONE:

Species : Rabbit
Result : No eye irritation
Method : ex vivo REET (Rabbit Enucleated Eye Test) assay

Talc (Mg₃H₂(SiO₃)₄):

Remarks : Mild eye irritation

COLLOIDAL ANHYDROUS SILICA:

Species : Rabbit
Result : No eye irritation

DODECYL SODIUM SULPHATE:

Species : Rabbit
Result : Corrosive to eyes
Method : OECD Test Guideline 405

Respiratory or skin sensitisation**Components:****Cellulose:**

Species : Guinea pig
Remarks : Did not cause sensitisation on laboratory animals.

RISPERIDONE:

Remarks : No data available

DODECYL SODIUM SULPHATE:

Result : Not a sensitizer

Germ cell mutagenicity**Components:****RISPERIDONE:**

Genotoxicity in vitro : Remarks: No data available

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Germ cell mutagenicity - Assessment : Animal testing did not show any mutagenic effects.

Talc (Mg₃H₂(SiO₃)₄):

Genotoxicity in vitro : Test Type: Ames test
Result: negative

DODECYL SODIUM SULPHATE:

Genotoxicity in vitro : Method: OECD Test Guideline 471
Result: negative

Carcinogenicity**Components:****RISPERIDONE:**

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

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.

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 on OSHA's list of regulated carcinogens.

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

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.

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.

Reproductive toxicity**Components:****RISPERIDONE:**

Reproductive toxicity - Assessment : Animal testing did not show any effects on fertility.

Teratogenicity - Assessment : Ingestion of excessive amounts by pregnant animals resulted in maternal and foetal toxicity.

DODECYL SODIUM SULPHATE:

Effects on fertility : Remarks: negative

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STOT - single exposure

Components:

RISPERIDONE:

Assessment : The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with narcotic effects.

DODECYL SODIUM SULPHATE:

Exposure routes : Inhalation

Assessment : The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.

STOT - repeated exposure

No data available

Repeated dose toxicity

Components:

RISPERIDONE:

Remarks : No data available

Aspiration toxicity

No data available

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

Neurological effects

No data available

Further information

No data available

Other health hazards

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:

Toxicity to fish : Remarks: No data available

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HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Toxicity to fish : Remarks: No data available

RISPERIDONE:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 5.8 mg/l
Exposure time: 96 h
Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 6 mg/l
Exposure time: 48 h
Method: FDA 4.08

Toxicity to algae/aquatic plants : EC50 (Scenedesmus capricornutum (fresh water algae)): 26 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (microcystis aeruginosa (blue green algae)): > 100 mg/l
Exposure time: 10 d
Method: FDA 4.01

Toxicity to microorganisms : NOEC (activated sludge): 47 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

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

Talc (Mg₃H₂(SiO₃)₄):

Toxicity to fish : (Danio rerio (zebra fish)): > 100,000 mg/l
Exposure time: 24 h
Test Type: LC50

PROPYLENE GLYCOL:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 51,600 mg/l
Exposure time: 96 h
Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 43,500 mg/l
Exposure time: 48 h

Toxicity to fish (Chronic toxicity) : NOEC: > 100 mg/l

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : (Daphnia sp. (water flea)): 13,020 mg/l
Exposure time: 7 d

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COLLOIDAL ANHYDROUS SILICA:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
aquatic invertebrates Exposure time: 24 h

DODECYL SODIUM SULPHATE:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 29 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other : LC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l
aquatic invertebrates Exposure time: 48 h
Test Type: flow-through test

Toxicity to algae/aquatic : EC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l
plants Exposure time: 72 h

Toxicity to fish (Chronic :
toxicity)

Toxicity to daphnia and other : NOEC: 1 mg/l
aquatic invertebrates
(Chronic toxicity)

Persistence and degradability**Components:****HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**

Biodegradability : Remarks: No data available

RISPERIDONE:

Biodegradability : Inoculum: activated sludge
Result: Not readily biodegradable.
Exposure time: 28 d
Method: FDA 3.11

PROPYLENE GLYCOL:

Biodegradability : Biodegradation: 81 %
Exposure time: 28 d

COLLOIDAL ANHYDROUS SILICA:

Biodegradability : Remarks: No data available

DODECYL SODIUM SULPHATE:

Biodegradability : Result: Readily biodegradable.

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Biochemical Oxygen Demand (BOD) : > 60 %(m)

Dissolved organic carbon (DOC) : > 70 %(m)

Bioaccumulative potential**Components:****Starch:**

Partition coefficient: n-octanol/water : Remarks: No data available

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Bioaccumulation : Remarks: No data available

RISPERIDONE:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Pow: 3.04

TITANDIOXIDE:

Partition coefficient: n-octanol/water : Remarks: No data available

Octadecanoic acid, magnesium salt:

Partition coefficient: n-octanol/water : Remarks: No data available

PROPYLENE GLYCOL:

Bioaccumulation : Bioconcentration factor (BCF): < 100
Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: -0.92

COLLOIDAL ANHYDROUS SILICA:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

DODECYL SODIUM SULPHATE:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: 0.83 (68 °F / 20 °C)

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octanol/water

Mobility in soil**Components:****HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**Distribution among : Remarks: No data available
environmental compartments**RISPERIDONE:**

Mobility : Remarks: No data available

PROPYLENE GLYCOL:Distribution among : Remarks: No data available
environmental compartments**COLLOIDAL ANHYDROUS SILICA:**Distribution among : Remarks: No data available
environmental compartments**DODECYL SODIUM SULPHATE:**

Mobility : Remarks: No data available

Distribution among : Remarks: No data available
environmental compartments**Other adverse effects****Components:****HYDROXYPROPYLMETHYLCELLULOSE (HPMC):**Results of PBT and vPvB : No information available.
assessmentAdditional ecological : No data available
information**PROPYLENE GLYCOL:**Results of PBT and vPvB : No information available.
assessmentAdditional ecological : No data available
information**COLLOIDAL ANHYDROUS SILICA:**Results of PBT and vPvB : No information available.
assessment

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Additional ecological information : No data available

DODECYL SODIUM SULPHATE:

Environmental fate and pathways : No data available

Results of PBT and vPvB assessment : Substance is not persistent, bioaccumulative, and toxic (PBT).

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : In accordance with National, Federal, State and Local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

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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.

US State Regulations**Massachusetts Right To Know**

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

Massachusetts Right To Know

Starch	9005-25-8
microcrystalline cellulose	9004-34-6

Pennsylvania Right To Know

alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1)	5989-81-1
Starch	9005-25-8
Cellulose	9004-34-6

Pennsylvania Right To Know

alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1)	5989-81-1
Starch	9005-25-8
microcrystalline cellulose	9004-34-6

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

New Jersey Right To Know

alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1)	5989-81-1
Starch	9005-25-8
Cellulose	9004-34-6
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3

California Permissible Exposure Limits for Chemical Contaminants

Starch	9005-25-8
microcrystalline cellulose	9004-34-6

Other regulations

Restricted to professional users.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

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SECTION 16. OTHER INFORMATION**Full text of other abbreviations**

ACGIH	: US. ACGIH Threshold Limit Values
ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
J&J OEL/PBOEL HHC	: J&J OEL/PBOEL HHC
NIOSH REL	: USA. NIOSH Recommended Exposure Limits
OSHA CARC	: OSHA Specifically Regulated Chemicals/Carcinogens
OSHA P0	: USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3	: USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
US WEEL	: USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA	: Time weighted average
ACGIH / TWA	: 8-hour, time-weighted average
J&J OEL/PBOEL HHC / TWA	: Time weighted average
J&J OEL/PBOEL HHC / PBOEL-HHC	: PBOEL-HHC
NIOSH REL / TWA	: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA CARC / PEL	: Permissible exposure limit (PEL)
OSHA P0 / TWA	: 8-hour time weighted average
OSHA Z-1 / TWA	: 8-hour time weighted average
OSHA Z-3 / TWA	: 8-hour time weighted average
US WEEL / TWA	: 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS

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- Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 2025/02/23

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

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