

SAFETY DATA SHEET



RISPERDAL

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/03
6.0	2024/11/06	100000000607	Date of first issue: 2013/12/17

SECTION 1. IDENTIFICATION

Product name : RISPERDAL
Substance name : RISPERDAL oral solution (1 mg/ml)
risperidone

Reference number : R064766

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 not 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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Other hazards

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

Components

Chemical name	CAS-No.	Concentration (% w/w)
benzoic acid	65-85-0	>= 0.1 - < 1
RISPERIDONE	106266-06-2	>= 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 and effects, both acute and delayed : Ingestion may provoke the following symptoms:
calming
Consult the patient packaging insert for more information
about this Finished Pharmaceutical Product.
- 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 hazardous combustion products are known

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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 : 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. Evacuate personnel to safe areas.

Environmental precautions : Should not be released into the environment.

Methods and materials for containment and cleaning up : Large spills: Dam up. Soak up with inert absorbent material. Keep in properly labelled containers.
Small spills: Gently cover the spill with an absorbent towel or pad.
Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : No data available

Advice on safe handling : To avoid thermal decomposition, do not overheat. Avoid inhalation, ingestion and contact with skin and eyes. 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. To maintain product quality, do not store in heat or direct sunlight. Store in original container.

Materials to avoid : Do not freeze.

Recommended storage temperature : 59 - 77 °F / 15 - 25 °C

Further information on storage stability : Do not store in the refrigerator or freezer.

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
benzoic acid	65-85-0	TWA (Inhalable fraction and vapor)	0.5 mg/m ³	ACGIH
RISPERIDONE	106266-06-2	TWA	0.0045 mg/m ³	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.				

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
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 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.

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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Aqueous solution
Colour	:	colourless
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/ range	:	No data available
Boiling point/boiling range	:	Not applicable
Flash point	:	Not applicable
Evaporation rate	:	No data available
Upper explosion limit / Upper flammability limit	:	Not applicable
Lower explosion limit / Lower flammability limit	:	Not applicable
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
<u>Water solubility</u>	:	> 500 g/l
Partition coefficient: n-octanol/water	:	No data available
Decomposition temperature	:	No data available
Viscosity		
<u>Viscosity, dynamic</u>	:	No data available
<u>Viscosity, kinematic</u>	:	No data available
Conductivity	:	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 : 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

Components:**benzoic acid:**

Acute oral toxicity : LD50 (Rat): > 2,001 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 12.2 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 10,000 mg/kg

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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

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

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Skin corrosion/irritation**Components:****benzoic acid:**

Species : Rabbit
Exposure time : 24 h
Method : Draize Test
Result : Mild skin irritation

Result : Skin irritation
Remarks : Classification according to Regulation 1272/2008 Annex VI

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Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation**Components:****benzoic acid:**

Species : Rabbit
Result : Corrosive to eyes
Method : Draize Test

RISPERIDONE:

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

Respiratory or skin sensitisation**Components:****RISPERIDONE:**

Remarks : No data available

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

Genotoxicity in vitro : Remarks: No data available

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

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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.

OSHA 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.

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.

STOT - single exposure**Components:****RISPERIDONE:**

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

STOT - repeated exposure**Components:****benzoic acid:**

Assessment : The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 1.

Repeated dose toxicity**Components:****RISPERIDONE:**

Remarks : No data available

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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:****benzoic acid:**

Toxicity to fish : LC50 (*Gambusia affinis* (Mosquito fish)): 180 mg/l
Exposure time: 96 h

Toxicity to algae/aquatic plants : EC50 (*Scenedesmus quadricauda* (Green algae)): > 10 mg/l
Exposure time: 14 d
Test Type: Growth inhibition

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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

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Method: OECD Test Guideline 209

EC50 (activated sludge): > 1,000 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Persistence and degradability**Components:****benzoic acid:**

Biodegradability : Remarks: No data available

RISPERIDONE:Biodegradability : Inoculum: activated sludge
Result: Not readily biodegradable.
Exposure time: 28 d
Method: FDA 3.11**Bioaccumulative potential****Components:****benzoic acid:**Bioaccumulation : Species: Leuciscus idus (Golden orfe)
Exposure time: 3 d
Concentration: 0.05 mg/l

Bioconcentration factor (BCF): 5.3

Partition coefficient: n-octanol/water : log Pow: 1.9

RISPERIDONE:

Bioaccumulation : Remarks: No data available

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

Mobility in soil**Components:****benzoic acid:**

Distribution among environmental compartments : Remarks: No data available

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Mobility : Remarks: No data available

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Other adverse effects

Components:

benzoic acid:

Results of PBT and vPvB assessment : No information available.

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

US State Regulations

Massachusetts Right To Know

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

Pennsylvania Right To Know

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water	7732-18-5
benzoic acid	65-85-0

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 York City Hazardous Substances

benzoic acid	65-85-0
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Other regulations

Restricted to professional users.

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

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

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
J&J OEL/PBOEL HHC	:	J&J OEL/PBOEL HHC
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	:	

AIIIC - 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

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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 - 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 : 2024/11/06

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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