

RISPERDAL CONSTA powder

Version	Revision Date:	SDS Number:	Date of last issue: 2023/12/29
3.5	2024/09/03	100000010193	Date of first issue: 2014/06/10

SECTION 1. IDENTIFICATION

Product name : RISPERDAL CONSTA powder
Substance name : RISPERDAL CONSTA powder (12.5 - 25 - 37.5 - 50 mg
Prolonged Release Suspension for Intramuscular Injection)
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)**

Acute toxicity (Oral) : Category 3
Specific target organ toxicity : Category 3 (Central nervous system)
- single exposure
Short-term (acute) aquatic : Category 2

RISPERDAL CONSTA powder

Version 3.5	Revision Date: 2024/09/03	SDS Number: 100000010193	Date of last issue: 2023/12/29 Date of first issue: 2014/06/10
----------------	------------------------------	-----------------------------	---

hazard

Long-term (chronic) aquatic hazard : Category 2

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H301 Toxic if swallowed.
H336 May cause drowsiness or dizziness.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P273 Avoid release to the environment.

Response:

P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER/ doctor. Rinse mouth.
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
P391 Collect spillage.

Storage:

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.
P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

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

SAFETY DATA SHEET



RISPERDAL CONSTA powder

Version 3.5 Revision Date: 2024/09/03 SDS Number: 100000010193 Date of last issue: 2023/12/29
Date of first issue: 2014/06/10

Chemical nature : Solid

Components

Chemical name	CAS-No.	Concentration (% w/w)
RISPERIDONE	106266-06-2	>= 30 - < 50

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

- If inhaled : Artificial respiration and/or oxygen may be necessary.
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 : Consult the patient packaging insert for more information
about this Finished Pharmaceutical Product.
Respiratory disorder
Fever
insomnia
drowsiness
headache
Dizziness
Tremors
Sleep
Cough
Pain
Vomiting
Abdominal pain
Diarrhoea
muscle pain
Fatigue
hypertension
- Notes to physician : Treat symptomatically.
Consult the patient packaging insert for more information
about this Finished Pharmaceutical Product.

SECTION 5. FIREFIGHTING MEASURES

RISPERDAL CONSTA powder

Version 3.5	Revision Date: 2024/09/03	SDS Number: 100000010193	Date of last issue: 2023/12/29 Date of first issue: 2014/06/10
----------------	------------------------------	-----------------------------	---

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Hazardous combustion products : No information available.
- Further information : Avoid dust formation.
- 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 or use HEPA vacuum.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Avoid dust formation.
- Advice on safe handling : Avoid inhalation, ingestion and contact with skin and eyes.
Ensure all equipment is electrically grounded before beginning transfer operations.
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 refrigerated.
Store in original container.
To maintain product quality, do not store in heat or direct

RISPERDAL CONSTA powder

Version 3.5	Revision Date: 2024/09/03	SDS Number: 100000010193	Date of last issue: 2023/12/29 Date of first issue: 2014/06/10
----------------	------------------------------	-----------------------------	---

sunlight.

Recommended storage temperature : 36 - 46 °F / 2 - 8 °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
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 based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if

RISPERDAL CONSTA powder

Version	Revision Date:	SDS Number:	Date of last issue: 2023/12/29
3.5	2024/09/03	100000010193	Date of first issue: 2014/06/10

necessary.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.
Wash hands before breaks and at the end of workday.
When using do not eat, drink or smoke.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	white, off-white
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

RISPERDAL CONSTA powder

Version	Revision Date:	SDS Number:	Date of last issue: 2023/12/29
3.5	2024/09/03	100000010193	Date of first issue: 2014/06/10

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: 165.35 mg/kg
Method: Calculation method

Components:**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

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation**Components:****RISPERIDONE:**

Species : Rabbit
Result : No skin irritation

RISPERDAL CONSTA powder

Version 3.5	Revision Date: 2024/09/03	SDS Number: 100000010193	Date of last issue: 2023/12/29 Date of first issue: 2014/06/10
----------------	------------------------------	-----------------------------	---

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

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

RISPERDAL CONSTA powder

Version 3.5	Revision Date: 2024/09/03	SDS Number: 100000010193	Date of last issue: 2023/12/29 Date of first issue: 2014/06/10
----------------	------------------------------	-----------------------------	---

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

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:

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

SAFETY DATA SHEET



RISPERDAL CONSTA powder

Version	Revision Date:	SDS Number:	Date of last issue: 2023/12/29
3.5	2024/09/03	100000010193	Date of first issue: 2014/06/10

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

Persistence and degradability

Components:

RISPERIDONE:

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

Bioaccumulative potential

Components:

RISPERIDONE:

Bioaccumulation : Remarks: No data available

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

Mobility in soil

Components:

RISPERIDONE:

Mobility : Remarks: No data available

Other adverse effects

No data available

RISPERDAL CONSTA powder

Version 3.5	Revision Date: 2024/09/03	SDS Number: 100000010193	Date of last issue: 2023/12/29 Date of first issue: 2014/06/10
----------------	------------------------------	-----------------------------	---

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**

UN number : UN 3249

Proper shipping name : MEDICINE, SOLID, TOXIC, N.O.S.
(risperidone)

Class : 6.1

Packing group : III

Labels : 6.1

IATA-DGR

UN/ID No. : UN 3249

Proper shipping name : Medicine, solid, toxic, n.o.s.
(risperidone)

Class : 6.1

Packing group : III

Labels : 6.1

Packing instruction (cargo aircraft) : 677

Packing instruction (LQ) : Y645

Packing instruction (EQ) : E1

Packing instruction (passenger aircraft) : 670

Packing instruction (LQ) : Y645

Remarks : This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package \leq 1mL for liquids or \leq 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of IATA DGR §2.6.10 are met.

IMDG-Code

UN number : UN 3249

Proper shipping name : MEDICINE, SOLID, TOXIC, N.O.S.
(risperidone)

Class : 6.1

Packing group : III

Labels : 6.1

EmS Code : F-A, S-A

Marine pollutant : yes

Remarks : This substance can be shipped under 'de minimi's quantities'

SAFETY DATA SHEET



RISPERDAL CONSTA powder

Version	Revision Date:	SDS Number:	Date of last issue: 2023/12/29
3.5	2024/09/03	100000010193	Date of first issue: 2014/06/10

provisions if the net quantity per inner package \leq 1mL for liquids or \leq 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of ADR/RID/ADN/IMDG §3.5.1.4 are met.

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

UN/ID/NA number	: UN 3249
Proper shipping name	: Medicine, solid, toxic, n.o.s. (risperidone)
Class	: 6.1
Packing group	: III
Labels	: 6.1
ERG Code	: 151
Marine pollutant	: yes
Remarks	: This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package \leq 1mL for liquids or \leq 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of 49 CFR 173.4b are met.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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.

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.

Pennsylvania Right To Know

poly-d,l-lactide-co-glycolide (7525 DL JN1)	26780-50-7
RISPERIDONE	106266-06-2

New Jersey Right To Know

poly-d,l-lactide-co-glycolide (7525 DL JN1)	26780-50-7
RISPERIDONE	106266-06-2

SAFETY DATA SHEET



RISPERDAL CONSTA powder

Version	Revision Date:	SDS Number:	Date of last issue: 2023/12/29
3.5	2024/09/03	100000010193	Date of first issue: 2014/06/10

New York City Hazardous Substances

No components listed on the New York City Hazardous Substances List

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.

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

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

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.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

J&J OEL/PBOEL HHC : J&J OEL/PBOEL HHC
J&J OEL/PBOEL HHC / TWA : Time weighted average
J&J OEL/PBOEL HHC / : PBOEL-HHC
PBOEL-HHC

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

RISPERDAL CONSTA powder

Version	Revision Date:	SDS Number:	Date of last issue: 2023/12/29
3.5	2024/09/03	100000010193	Date of first issue: 2014/06/10

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 : 2024/09/03

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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