

**RISPERDAL CONSTA diluent in pre-filled syringe**

Version	Revision Date:	SDS Number:	Date of last issue:
1.62	2018/06/20	100000010036	2018/05/19
			Date of first issue: 2014/07/17

**SECTION 1. IDENTIFICATION**

Product name : RISPERDAL CONSTA diluent in pre-filled syringe  
Substance name : RISPERDAL CONSTA diluent in pre-filled syringe (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  
US

Telephone : (609) 730-2000  
E-mail address Responsible/issuing person : SDSJanssen@its.jnj.com

**Emergency telephone number** : **CHEMTREC US: 1-800-424-9300**  
**CHEMTREC International: +1 703-527-3887**

**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**

Not a hazardous substance or mixture.

**GHS label elements**

Not a hazardous substance or mixture., Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

**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.

**RISPERDAL CONSTA diluent in pre-filled syringe**

Version 1.62	Revision Date: 2018/06/20	SDS Number: 100000010036	Date of last issue: 2018/05/19 Date of first issue: 2014/07/17
-----------------	------------------------------	-----------------------------	---

The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity:  
2.25 %

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

Chemical nature : Liquid

**Hazardous components**

Chemical name	CAS-No.	Concentration (%)
sodium hydroxide	1310-73-2	< 0.1

**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 : 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

Further information : No information available.

**RISPERDAL CONSTA diluent in pre-filled syringe**

Version	Revision Date:	SDS Number:	Date of last issue:
1.62	2018/06/20	100000010036	2018/05/19
			Date of first issue: 2014/07/17

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 + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".  
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.

**SECTION 7. HANDLING AND STORAGE**

Advice on protection against fire and explosion : No data available

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

Recommended storage temperature : > 2 °C  
< 8 °C

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

**RISPERDAL CONSTA diluent in pre-filled syringe**

Version 1.62      Revision Date: 2018/06/20      SDS Number: 100000010036      Date of last issue: 2018/05/19  
 Date of first issue: 2014/07/17

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
sodium hydroxide	1310-73-2	C	2 mg/m <sup>3</sup>	ACGIH
		TWA	2 mg/m <sup>3</sup>	ACGIH
		C	2 mg/m <sup>3</sup>	NIOSH REL
		TWA	2 mg/m <sup>3</sup>	OSHA Z-1
		C	2 mg/m <sup>3</sup>	OSHA P0
		C	2 mg/m <sup>3</sup>	CAL PEL

**Engineering measures** : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

**Personal protective equipment**

**Respiratory protection** : No personal respiratory protective equipment normally required.  
 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.

**Hand protection**

**Remarks** : No special precautions required.

**Eye protection** : No special precautions required.

**Skin and body protection** : No special precautions required.

**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 necessary.

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

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance** : Prefilled syringe

**Colour** : clear, colourless

**Odour** : No data available

**Odour Threshold** : No data available

**pH** : No data available

**RISPERDAL CONSTA diluent in pre-filled syringe**

Version 1.62	Revision Date: 2018/06/20	SDS Number: 100000010036	Date of last issue: 2018/05/19 Date of first issue: 2014/07/17
-----------------	------------------------------	-----------------------------	---

Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
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	: No data available
Solubility in other solvents	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: No data available
Viscosity, kinematic	: No data available
Explosive properties	: No data available

**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.

**RISPERDAL CONSTA diluent in pre-filled syringe**

Version 1.62	Revision Date: 2018/06/20	SDS Number: 100000010036	Date of last issue: 2018/05/19 Date of first issue: 2014/07/17
-----------------	------------------------------	-----------------------------	---

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:****sodium hydroxide**

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : Remarks: No data available

**Skin corrosion/irritation****Components:****sodium hydroxide**

Species: Rabbit

Result: Corrosive to skin

Remarks: Classification according to Regulation 1272/2008 Annex VI

**Serious eye damage/eye irritation****Components:****sodium hydroxide**

Species: Rabbit

Result: Corrosive

**Respiratory or skin sensitisation****Components:****sodium hydroxide**

Species: human

Result: Does not cause skin sensitisation.

**Germ cell mutagenicity****Components:****sodium hydroxide**

**RISPERDAL CONSTA diluent in pre-filled syringe**

Version 1.62	Revision Date: 2018/06/20	SDS Number: 100000010036	Date of last issue: 2018/05/19 Date of first issue: 2014/07/17
-----------------	------------------------------	-----------------------------	---

Germ cell mutagenicity - Assessment : No information available.

**Carcinogenicity****Components:****sodium hydroxide**

Carcinogenicity - Assessment : No information 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 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:****sodium hydroxide**

Reproductive toxicity - Assessment : No information available.

Teratogenicity - Assessment : No information available.

**STOT - single exposure**

No data available

**STOT - repeated exposure**

No data available

**Repeated dose toxicity**

No data available

**Aspiration toxicity**

No data available

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****sodium hydroxide**

Toxicity to fish : LC50 (Gambusia affinis (Mosquito fish)): 125 mg/l  
Exposure time: 96 h

**RISPERDAL CONSTA diluent in pre-filled syringe**

Version 1.62	Revision Date: 2018/06/20	SDS Number: 100000010036	Date of last issue: 2018/05/19 Date of first issue: 2014/07/17
-----------------	------------------------------	-----------------------------	---

Test Type: LC50

LC50 (*Poecilia reticulata* (guppy)): 145 mg/l  
Exposure time: 24 h  
Test Type: LC50

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 76 mg/l  
Exposure time: 24 h

Toxicity to bacteria : EC50 (*Photobacterium phosphoreum*): 22 mg/l  
Exposure time: 15 min

**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

**Other adverse effects****Product:**

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).

**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

# RISPERDAL CONSTA diluent in pre-filled syringe

Version 1.62	Revision Date: 2018/06/20	SDS Number: 100000010036	Date of last issue: 2018/05/19 Date of first issue: 2014/07/17
-----------------	------------------------------	-----------------------------	---

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

sodium hydroxide	1310-73-2	1000
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**SARA 302** : 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.

**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 112 (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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

Cellulose, carboxymethyl ether, sodium salt	9004-32-4	2.25 %
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**Clean Water Act**

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

	Not Assigned	0.13 %
sodium hydroxide	1310-73-2	0.05 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

	Not Assigned	0.13 %
sodium hydroxide	1310-73-2	0.05 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

**US State Regulations****Massachusetts Right To Know**

**RISPERDAL CONSTA diluent in pre-filled syringe**

Version 1.62	Revision Date: 2018/06/20	SDS Number: 100000010036	Date of last issue: 2018/05/19 Date of first issue: 2014/07/17
-----------------	------------------------------	-----------------------------	---

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

**Pennsylvania Right To Know**

water	7732-18-5	90 - 100 %
	Not Assigned	0.1 - 1 %
sodium hydroxide	1310-73-2	0 - 0.1 %

**New Jersey Right To Know**

water	7732-18-5	90 - 100 %
Cellulose, carboxymethyl ether, sodium salt	9004-32-4	1 - 5 %

**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**

: 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.

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

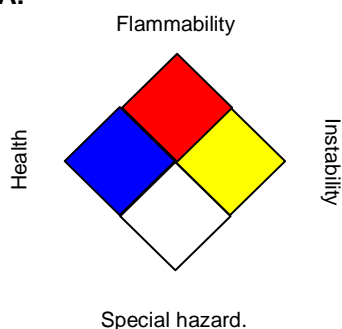
: This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

**Inventories**

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

**RISPERDAL CONSTA diluent in pre-filled syringe**

Version 1.62	Revision Date: 2018/06/20	SDS Number: 100000010036	Date of last issue: 2018/05/19 Date of first issue: 2014/07/17
-----------------	------------------------------	-----------------------------	---

**SECTION 16. OTHER INFORMATION****Further information****NFPA:****HMIS III:**

<b>HEALTH</b>	
<b>FLAMMABILITY</b>	
<b>PHYSICAL HAZARD</b>	

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

Revision Date : 2018/06/20

**Date and Number Formats**

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

<b>Date:</b>	Dec 31th, 2012	as	2012/12/31
<b>Numbers:</b>	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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