



SAFETY DATA SHEET

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006

Product code: JANBER064766
Issuing date: 09-Sep-2010
Revision Date: 09-Sep-2010

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Supplier:

J&J Pharmaceutical Research & Development
A division of Janssen Pharmaceutica NV
Turnhoutseweg 30
2340 Beerse
Belgium
+32 14 602111

Importer:

No information available

Product name:

Risperidone

Product code:

JANBER064766

Pure substance/preparation

Substance***

Chemical Name:

3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one

Synonyms:

R64766
JNJ-410397-AAA

Risperdal Active Ingredient

Identified use:

Pharmacologically active compound. Nervous System - Antipsychotic

Contact person:

Responsible/issuing person:

E-mail address

RA-JANBE-SAFETYDA@JANBE.JNJ.COM

Emergency telephone number:

(908) 218-7325 [USA]; +32 14 602444 [EU]

2. HAZARDS IDENTIFICATION

Classification and labelling

Classification and labelling according to Directive 67/548/EEC***

Classification:

T, N, R25 - R51/53

Indication of danger: T - Toxic

N - Dangerous for the environment.



Most important hazards

Risk Phrase R25 - Toxic if swallowed.

R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

General hazard information: May be harmful by inhalation.
Toxic if swallowed.
Toxic to aquatic organisms.
May cause long-term adverse effects in the aquatic environment.

Carcinogenicity rating:
Johnson & Johnson: None.
European Union: None.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical nature of the preparation:
Not applicable.***

| Components | CAS Number | Weight % | REACH No. | EINECS-No. | Synonyms | Classification |
|-------------|-------------|----------|-----------|------------|----------|------------------------|
| Risperidone | 106266-06-2 | 100 | | | | T; R25 N; R51/53*** |

4. FIRST AID MEASURES

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical attention.

Skin contact: After contact with skin, wash immediately with plenty of water. Immediately remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Seek medical attention if symptoms appear.

Ingestion: If ingested, seek medical attention immediately and show the label.

Inhalation: Move to fresh air immediately. If experiencing difficulty breathing, seek medical attention.

Notes to physician: Observed symptoms by overdose (oral and inhalation) are extrapyramidal disturbances (shaking, hypersalivation, abnormal features in a expressionless, rigid, mask-like face), sedation (tranquillization) to sleep, akathisia (inability to sit still), catalepsy (sudden muscle rigidity) and hypertonia (increased muscle tone).

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water fog or mist. Carbon dioxide (CO₂). Dry powder. Dry sand. foam.

Extinguishing media which must not be used for safety reasons: None.

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases: None.

Combustion products or resulting gases: Nitrogen oxides (NO_x) Hydrogen fluoride
Fluorine Carbon monoxide Carbon dioxide (CO₂) Water

Special protective equipment for firefighters: Wear a self-contained breathing apparatus and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

| | |
|-----------------------------------|--|
| Personal precautions: | Wear appropriate eye, skin, respiratory protection, disposable dust impervious suit and shoe covers. Avoid dust formation. |
| Environmental precautions: | Do not allow material to contaminate ground water system. Prevent product from entering drains. |
| Methods for cleaning up: | Evacuate area. Next, use disposable towels moistened with an appropriate cleaning agent (i.e. solvent, detergent and water, etc.) to complete cleaning process. A designated HEPA vacuum can be used as an alternative cleaning method for large spills of powder. All waste must be placed in a sealable, properly labeled waste disposal bag. Over bag into a sealable, properly labeled waste disposal bag. Material must be disposed of as hazardous drug waste. |

7. HANDLING AND STORAGE

Handling:

| | |
|--|--|
| Technical measures/precautions: | Use only in an area that has proper containment or provided with appropriate exhaust ventilation. Handle and store according to labeled instructions. |
| Safe handling advice: | Wear safety glasses with side-shields and nitrile gloves when handling powders or chemically resistant gloves when handling solutions (be sure to wear appropriate chemically resistant glove depending on type of solvents used). Clean work surfaces at the end of each day. |

Storage:

| | |
|---|---|
| Technical measures/storage conditions: | Store and transport in sealed bags contained within rigid drums or appropriate closed containers in a manner that minimizes the potential for spillage or container damage. |
| Incompatible products: | No special restrictions on storage with other products. |

Specific use(s):

None under normal use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limits:

| Components | J&J - OEL (TWA - 8 hr) | J&J - OEL (STEL) | J&J - OEL (Ceiling) | J&J - PBOEL | ASL |
|-----------------------------------|---------------------------|------------------|---------------------|-------------|-----|
| Risperidone (100%) 106266-06-2 | 2.5 µg/m ³ *** | | | Category 3B | |

| Components | European Union | France | Germany | Switzerland | The Netherlands | The United Kingdom |
|--------------------------------|----------------|--------|---------|-------------|-----------------|--------------------|
| Risperidone (100%) 106266-06-2 | N/A | N/A | N/A | N/A | N/A | N/A |

| Components | Spain | Italy | Portugal | Finland | Denmark | Austria |
|--------------------------------|-------|-------|----------|---------|---------|---------|
| Risperidone (100%) 106266-06-2 | N/A | N/A | N/A | N/A | N/A | N/A |

| Components | Norway | Poland | Ireland | Belgium | Bulgaria | Czech Republic |
|--------------------------------|--------|--------|---------|---------|----------|----------------|
| Risperidone (100%) 106266-06-2 | N/A | N/A | N/A | N/A | N/A | N/A |

| Components | Estonia | Greece | Hungary | Latvia | Lithuania | Luxembourg |
|--------------------------------|---------|--------|---------|--------|-----------|------------|
| Risperidone (100%) 106266-06-2 | N/A | N/A | N/A | N/A | N/A | N/A |

| Components | Slovenia | Slovakia | Sweden | Cyprus | Malta | Romania |
|--------------------------------|----------|----------|--------|--------|-------|---------|
| Risperidone (100%) 106266-06-2 | N/A | N/A | N/A | N/A | N/A | N/A |

| Components | Argentina | Brazil | Chile | Venezuela | Chile Prohibited Substances List |
|--------------------------------|-----------|--------|-------|-----------|----------------------------------|
| Risperidone (100%) 106266-06-2 | N/A | N/A | N/A | N/A | N/A |

Exposure controls / personal protection

| | |
|---------------------------------|--|
| Engineering controls: | Ensure adequate ventilation. Use vented enclosures or fume hoods when weighing, handling, or transferring small quantities (<500mg) of powders. For large scale activities (greater than 500 mg), use glove boxes or contained processes supplemented with local exhaust at contaminant release points. |
| Respiratory protection: | When handling small quantities (between 200mg and 500mg) use a particulate respirator (HEPA/N100 or in EU: ABEK-P3). When handling large quantities or performing higher exposure risk activities, use powered air-purifying respirators equipped with HEPA filters or air-supplied hood, helmet or hardcap. Supplied air respirators with HEPA filters may be required in the absence of effective local exhaust ventilation for control of airborne dusts. |
| Hand protection: | Double gloving is recommended for high exposure risk activities.. Wear nitrile gloves when handling as a solid or liquid formulation. When handling solutions, wear chemical-resistant gloves appropriate for the solvent(s) making up the solution.. |
| Eye protection: | Wear eye and face protection. Safety glasses with side-shields recommended. Goggles recommended if potential exists for direct exposure to dust or splashes. |
| Skin and body protection | Disposable dust impervious protective suit and shoe covers are recommended for larger scale and high exposure risk activities. Tape gloves and boots to dust impervious suit for added protection. |

Environmental exposure controls No information available

9. PHYSICAL AND CHEMICAL PROPERTIES

General Information

| | |
|------------------------|----------------------|
| Physical state: | solid |
| Appearance: | powder |
| Colour: | White to pale beige. |
| Odour: | Odorless |

Important Health Safety and Environmental Information

| | | | |
|-----------------------------------|-----------------|-----------------------------|---------------------------|
| Flash point: | Not determined. | Boiling point/range: | No information available. |
| Decomposition temperature: | 356 °F 180 °C | | |

| | |
|---|--|
| pH: | No information available. |
| Flammability (solid, gas): | No information available |
| Explosive properties: | No information available |
| Oxidising properties: | No information available |
| Vapor pressure: | No information available |
| Specific Gravity: | No information available |
| Density (20/4): | No information available |
| Water solubility: | 0.064 g/l (pH = 8.7) |
| Solubility in other solvents: | Methanol: 41 g/l Dichloromethane: 330 g/l Acetone: 11 g/l Ethanol: 14 g/l 2-Propanol: 6.0 g/l N,N-Dimethylformamide: 23 g/l |
| Partition coefficient (n-octanol/water): | 3.04 |
| Viscosity: | No information available |
| Vapor density: | No information available |

Evaporation rate: No information available

Other information

Autoignition temperature: No information available

Melting point/range: 338 - 342 °F 170 - 172 °C

Molecularweight: 410.49

Miscibility No information available

Fat solubility (g/l) 2.7

Volume resistivity or conductivity: > 1.0E+15 Ohm.m

Gas Group No information available

Risk of dust explosion: Dust explosion class 2

Dust cloud ignition temperature: 460 °C

Thermal sensitivity: Qualitatively stable at 120 °C-15 hours (slight discoloration).

Mechanical sensitivity (shock): Not shock sensitive.

Flammable limits in air - lower (%): < 15 g/m³

10. STABILITY AND REACTIVITY

Chemical stability:

Exothermicity:Lowest Temperature-180°C
Gas Evolving (>10 liter gas/kg below 220°C)-No
Light stability: Stable (7 days 17000lux)

Materials to avoid:

Oxidising agents.

Conditions to avoid:

Heat, flames and sparks.

Hazardous polymerisation:

Hazardous polymerisation does not occur.

Possibility of hazardous reactions:

No information available

Hazardous decomposition products:

Will not occur

11. TOXICOLOGICAL INFORMATION

Acute toxicity

| | | | |
|---------------------|-----------------------------|---------------|--|
| Eye contact | Not irritating to the eyes. | Method | ex vivo REET (Rabbit Enucleated Eye Test) assay |
| Skin contact | Non-irritating to the skin. | Method | in vivo Primary Dermal Irritation assay (rabbit) |
| Ingestion | Toxic if swallowed. | | |
| Inhalation | May be harmful if inhaled. | | |

| | |
|-----------------------------------|------|
| LD50 Oral Rat (f) (mg/kg): | 63 |
| LD50 Oral Rat (m) (mg/kg): | 113 |
| LD50/Oral/Mouse (mg/kg) = | 63 |
| LD50 Oral Dog (mg/kg): | 18.3 |

Sub-Chronic/Chronic Toxicity

| Application Route | Species | Dosing | Result |
|------------------------------|--|---------------|--|
| Oral administration | rats | at high doses | No significant adverse effects were observed |
| Target Organ(s) | Central nervous system | | |
| Reproductive effects | Resulted in no direct effect on fertility. | | |
| Developmental effects | Studies in rats and rabbits showed no primary harmful effects on the unborn child. At maternally toxic doses, secondary effects were observed as a result of excessive pharmacodynamic mechanisms. | | |
| Carcinogenic effects | Not a genotoxic carcinogen. Resulted in prolactin-mediated tumorigenesis in rodents related to pharmacodynamic effects at toxic doses. | | |
| Genotoxic effects | Not mutagenic. Not genotoxic. | | |
| Method | Microbial (Ames) mutagenicity assay in vivo rodent micronucleus bone marrow assay sex-specific, recessive lethal assay (fruit fly drosophila melanogaster) | | |
| General Information | The most common adverse effects of risperidone observed in greater than 10% of patients treated in clinical trials include: somnolence, increased appetite, fatigue, rhinitis, upper respiratory tract infection, vomiting, coughing, urinary incontinence, increased saliva, constipation, fever, dystonia, abdominal pain, anxiety, nausea, dizziness, dry mouth, tremor, rash akathisia and dyspepsia. Risperidone has the potential to impair judgment, thinking or motor skills.***** | | |

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects:

12. ECOLOGICAL INFORMATION

Aquatic toxicity effects: Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.
EC50/48h/Daphnia magna = 6 mg/l
LC50/96h/Bluegill sunfish (Lepomis macrochirus) = 5.8 mg/l
EC50/3h/activated sludge = >1000 mg/l
EC50/72h/Selenastrum capricornutum = 26 mg/l

Mobility: Not known
Persistence / degradability: Not readily biodegradable.
Bioaccumulation: Not known
Degradation: No information available

General notes

Elimination Data:
Abiotic (COD): not known
Aerbiotic: <60%

Distribution over environmental compartments:

Water: 66.23%
Soil: 15.77%
Air: 0.19%
Sediment: 17.52%
Biota: 0%
Groundwater: 0.3%

13. DISPOSAL CONSIDERATIONS

Waste from residues / unused products: In accordance with local and national regulations.
Should not be released into the environment.

Contaminated packaging: Empty packing materials should be handled according to local current procedures or according to local by-laws or national laws.

14. TRANSPORT INFORMATION

IATA/ICAO

ID/UN No.: UN 2811
Proper shipping name UN 2811, Toxic solid, organic, n.o.s. (Risperidone), 6.1, III
Hazard class: 6.1
Packing group: PG III
IATA - label: 6.1
ERG # 154

IMO/IMDG

UN/Id No.: UN 2811
Proper shipping name UN 2811, Toxic solid, organic, n.o.s. (Risperidone), 6.1, III
Hazard class: 6.1
Packing group: PG III
IMDG-labels: 6.1

ADR/RID

ADR/RID UN/Id No.: UN 2811
Proper shipping name UN 2811, Toxic solid, organic, n.o.s. (Risperidone), 6.1, III
Hazard class/item No. letter: 6.1, PG III
ADR/RID-labels: Toxic (6.1)
TREM-card: 61GT2-III

15. REGULATORY INFORMATION

Classification and labelling according to Directive 67/548/EEC***

Indication of danger: T - Toxic
N - Dangerous for the environment.



R -phrase(s)

R25 - Toxic if swallowed.
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S -phrase(s)

S22 - Do not breathe dust.
S35 - This material and its container must be disposed of in a safe way.
S38 - In case of insufficient ventilation, wear suitable respiratory equipment.
S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
S61 - Avoid release to the environment. Refer to special instructions/safety data sheets.
S36/37 - Wear suitable protective clothing and gloves.

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):
Complete update.

Restrictions on use: No information available
Additional advice: Consult your supplier if the material is to be used for special applications such as in the food industry or for hygiene, medical or surgical end-use.

Full text of R-phrases referred to under sections 2 and 3

R25 - Toxic if swallowed.
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Literary reference:

1. List of active Janssen R-Compounds.
2. VTL summary.
3. Toxicology department Janssen Pharmaceutica.
4. Environmental department.
5. Medical service department.
6. ADR 2007
7. PBOEL/OEL Monograph Summary
8. PBOEL/OEL global list
9. PC-CHAR, 86-17

MSDS Format: European Format***
Regulation This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006

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End of Safety Data Sheet