SAFETY DATA SHEET

1. Identification

Product identifier
ZOFRAN ODT ORALLY DISINTEGRATING TABLETS

Other means of identification

Synonyms
ZOFRAN ORALLY DISINTEGRATING TABLETS 4 MG * ZOFRAN ORALLY DISINTEGRATING TABLETS 8 MG * ZOFRAN MELT 4 MG * ZOFRAN ZYDIS * ZOFRAN ZYDIS WAFER * IZOFRAN ZYDIS TABLETS * ZOPHREN ZYDIS TABLETS * ONDANSETRON BASE TABLETS * ONDANSETRON BASE, FORMULATED PRODUCT

Recommended use of the chemical and restrictions on use

Recommended use
Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Restrictions on use
No other uses are advised.

Details of manufacturer or importer

Manufacturer
GlaxoSmithKline Australia
1061 Mountain Highway
Melbourne, Victoria 3155
Australia
Australia General Information (Normal Business Hours): (03) 9721 6000

TRANSPORTATION EMERGENCY NUMBERS
(available 24hrs/7days: multi-language response)
Australia Toll Free +(61) 2 9037 2994
International Toll Call +(1) 703 527 3887

2. Hazard(s) identification

Classification of the hazardous chemical
Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements, including precautionary statements
Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Other hazards which do not result in classification
Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixture
### Identity of chemical ingredients

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS Number</th>
<th>Concentration of Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>MANNITOL</td>
<td>69-65-8</td>
<td>20 - &lt; 30</td>
</tr>
<tr>
<td>D-MANNITOL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1,2,3,4,5,6-HEXANEHEXOL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MANNA SUGAR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MANNITE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OSMITROL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BP-686</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MANNITOL, D-DIOSMOL</td>
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<td></td>
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<tr>
<td>MANITON-S</td>
<td></td>
<td></td>
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<tr>
<td>MANNINDEX</td>
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<tr>
<td>MANNIGEN</td>
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<td>MANNISTOL</td>
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<tr>
<td>OSMOSOL</td>
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<td></td>
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<tr>
<td>D-MANNITE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CORDYCEPIC ACID</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D-(-)-MANNITOL</td>
<td></td>
<td></td>
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<tr>
<td>MANNITOLUM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OSMOSAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISOTOL</td>
<td>69-65-8</td>
<td></td>
</tr>
<tr>
<td>C6H14O6</td>
<td>99614-02-5</td>
<td>20 - &lt; 30</td>
</tr>
<tr>
<td>ONDANSETRON</td>
<td>22839-47-0</td>
<td>3 - &lt; 5</td>
</tr>
<tr>
<td>GR 38032X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>113 (GW ACN)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1,2,3,9-TETRAHYDRO-3-((2-METHYLIMIDAZOL-1-YL)METHYL)-9-METHYL-4H-CARBAZOL-4-ONETETRAHYDRO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASPARTAME</td>
<td>5026-62-0</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>ASPARTYLPHENYLALANINE METHYL ESTER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NUTRASWEET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SODIUM METHYL PARABEN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SODIUM METHYL PARA-HYDROXYBENZOATE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BENZOIC ACID, 4-HYDROXY-, METHYL ESTER, SODIUM SALT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SODIUM METHYL P-HYDROXYBENZOATE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BENZOIC ACID, P-HYDROXY-, METHYL ESTER, SODIUM SALT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SODIUM, (P-CARBOXYPHENOXY), METHYL ESTER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SODIUM 4-CARBOMETHOXYPHENOLATE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SOLPAROL</td>
<td></td>
<td></td>
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<tr>
<td>SODIUM METHYL HYDROXYBENZOATE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SODIUM METHYL 4-HYDROXYBENZOATE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>METHYLPARABEN SODIUM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>METHYL P-HYDROXYBENZOATE, SODIUM SALT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4-HYDROXYBENZOIC ACID, METHYL ESTER, SODIUM SALT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P-HYDROXYBENZOIC ACID, METHYL ESTER, SODIUM SALT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PARA-HYDROXYBENZOIC ACID, METHYL ESTER, SODIUM SALT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NIPAGIN(R) M SODIUM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SODIUM METHYLPARABEN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>METHYL (P-CARBOXYPHENOXY)SODIUM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NATRIUM-4-(METHOXYCARBONYL)PHENOLAT</td>
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</tr>
<tr>
<td>GR30517A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other components below reportable levels 40 - < 50

### 4. First-aid measures

**Description of necessary first aid measures**

- **Inhalation**
  - Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

- **Skin contact**
  - Get medical attention if symptoms occur. Take off contaminated clothing and wash before reuse.

- **Eye contact**
  - Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Ingestion
If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately.

Personal protection for first-aid responders
Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

Symptoms caused by exposure
The following adverse effects have been noted with therapeutic use of this material: headache; flushing; constipation; abnormal nervous system sensations; burning; symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing).

Medical attention and special treatment
No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

5. Fire-fighting measures
Extinguishing media
Suitable extinguishing media
Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions
Move containers from fire area if you can do so without risk.

Hazchem Code
Not available.

General fire hazards
No unusual fire or explosion hazards noted.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures
Personal precautions, protective equipment and emergency procedures
For non-emergency personnel
Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8.

For emergency responders
Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

Environmental precautions
Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up
Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13.

7. Handling and storage
Precautions for safe handling
Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities
Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls and personal protection
Control parameters
Follow standard monitoring procedures.

Occupational exposure limits

<table>
<thead>
<tr>
<th>GSK Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASPARTAME (CAS 22839-47-0)</td>
<td>8 HR TWA</td>
<td>5000 mcg/m3</td>
</tr>
<tr>
<td>MANNITOL (CAS 69-65-8)</td>
<td>OHC</td>
<td>1</td>
</tr>
<tr>
<td>ONDANSETRON BASE (CAS 99614-02-5)</td>
<td>8 HR TWA</td>
<td>30 mcg/m3</td>
</tr>
<tr>
<td></td>
<td>OHC</td>
<td>3</td>
</tr>
<tr>
<td>GSK Components</td>
<td>Type</td>
<td>Value</td>
</tr>
<tr>
<td>----------------</td>
<td>----------</td>
<td>------------</td>
</tr>
<tr>
<td>SODIUM METHYL PARABEN (CAS 5026-62-0)</td>
<td>8 HR TWA</td>
<td>5000 mcg/m3</td>
</tr>
</tbody>
</table>

**Biological limit values**
No biological exposure limits noted for the ingredient(s).

**Exposure guidelines**
No exposure standards allocated.

**Appropriate engineering controls**
An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

**Individual protection measures, for example personal protective equipment (PPE)**

**Eye/face protection**
If contact is likely, safety glasses with side shields are recommended.

**Skin protection**

**Hand protection**
The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

**Other**
Wear suitable protective clothing.

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

**Thermal hazards**
Wear appropriate thermal protective clothing, when necessary.

**Hygiene measures**
An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

### 9. Physical and chemical properties

**Appearance**

**Physical state**
Solid.

**Form**
Tablet.

**Colour**
Not available.

**Odour**
Not available.

**Odour threshold**
Not available.

**pH**
Not available.

**Melting point/freezing point**
Not available.

**Initial boiling point and boiling range**
Not available.

**Flash point**
Not available.

**Evaporation rate**
Not available.

**Flammability (solid, gas)**
Not available.

**Upper/lower flammability or explosive limits**

**Flammability limit - lower (%)**
Not available.

**Flammability limit - upper (%)**
Not available.

**Explosive limit - lower (%)**
Not available.

**Explosive limit – upper (%)**
Not available.

**Vapour pressure**
Not available.

**Vapour density**
Not available.

**Relative density**
Not available.

**Solubility(ies)**

**Solubility (water)**
Not available.

**Partition coefficient (n-octanol/water)**
Not available.
Auto-ignition temperature Not available.
Decomposition temperature Not available.
Viscosity Not available.

10. Stability and reactivity
Reactivity Not available.
Chemical stability Material is stable under normal conditions.
Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.
Conditions to avoid Contact with incompatible materials.
Incompatible materials Strong oxidising agents.
Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information
Information on possible routes of exposure
Ingestion Harmful if swallowed.
Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact Health injuries are not known or expected under normal use.
Eye contact Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Symptoms related to exposure The following adverse effects have been noted with therapeutic use of this material: headache; constipation; abnormal nervous system sensations; burning; flushing; symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing).

Acute toxicity Harmful if swallowed.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MANNITOL (CAS 69-65-8)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>13.5 g/kg</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ONDANSETRON BASE (CAS 99614-02-5)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>100 - 150 mg/kg Results from ondansetron HCl.</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>&gt; 36 mg/kg/day Results from ondansetron HCl.</td>
</tr>
<tr>
<td>LD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOEL</td>
<td>Dog</td>
<td>1 mg/kg/day, 52 weeks Results from ondansetron HCl.</td>
</tr>
<tr>
<td>NOAEL</td>
<td>Rat</td>
<td>1 mg/kg/day, 18 months Results from ondansetron HCl.</td>
</tr>
<tr>
<td><strong>SODIUM METHYL PARABEN (CAS 5026-62-0)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Mouse</td>
<td>2 g/kg</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Health injuries are not known or expected under normal use.
Corrosivity ONDANSETRON BASE 50 %, Results from ondansetron HCl. Formulated in soft paraffin. Result: Non-irritant Species: Guinea pig.

Material name: ZOFRAN ODT ORALLY DISINTEGRATING TABLETS
110604
Serious eye damage/irritation
Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Eye
ONDANSETRON BASE
OECD 405, Results from ondansetron HCl.
Result: Severe Irritant
Species: Rabbit

Respiratory or skin sensitisation

Respiratory sensitisation
Due to partial or complete lack of data the classification is not possible.

Skin sensitisation
This product is not expected to cause skin sensitisation.

Maximisation assay (Magnusson and Kligman)
ZOFRAN ODT ORALLY DISINTEGRATING TABLETS

Sensitisation
ONDANSETRON BASE
Split adjuvant assay, Results from ondansetron HCl.
Result: negative
Species: Guinea pig

Germ cell mutagenicity
No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity
ONDANSETRON BASE
Ames, Results from ondansetron HCl.
Result: negative
Chromosomal Aberration Assay In Vitro, Results from ondansetron HCl.
Result: positive
HPRT gene mutation in human lymphocytes, Results from ondansetron HCl.
Result: negative
Micronucleus test, Results from ondansetron HCl.
Result: negative
Species: Mouse
V79 Cell Mutagenicity Assay, Results from ondansetron HCl.
Result: negative

Carcinogenicity
ONDANSETRON BASE
Not classifiable as to carcinogenicity to humans.
ICH S1B, Results from ondansetron HCl.
Result: negative
Species: Mouse
ICH S1B, Results from ondansetron HCl.
Result: negative
Species: Rat

Reproductive toxicity
Contains no ingredient listed as toxic to reproduction

Specific target organ toxicity - single exposure
Central nervous system.

Specific target organ toxicity - repeated exposure
None known.

Aspiration hazard
Not likely, due to the form of the product.

Other information
Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity
Contains a substance which causes risk of hazardous effects to the environment. Very toxic to aquatic life with long lasting effects.

Components

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONDANSETRON BASE (CAS 99614-02-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aquatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activated Sludge Respiration</td>
<td>IC50 Residential sludge</td>
<td>&gt; 802 mg/l, 3 hours OECD 209</td>
</tr>
<tr>
<td>Algae</td>
<td>EC50 Green algae (Selenastrum capricornutum)</td>
<td>0.7 mg/l, 72 hours Static , OECD 201</td>
</tr>
<tr>
<td>Components</td>
<td>Species</td>
<td>Test results</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>NOEC</td>
<td>Green algae (Selenastrum capricornutum)</td>
<td>0.25 mg/l, 72 hours Measured</td>
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<tr>
<td>Crustacea</td>
<td>EC50 Water flea (Daphnia pulex)</td>
<td>22 mg/l, 48 hours Static, TAD 4.08</td>
</tr>
<tr>
<td>NOEC</td>
<td>Water flea (Daphnia pulex)</td>
<td>13 mg/l, 48 hours Measured</td>
</tr>
<tr>
<td>Fish</td>
<td>EC50 Rainbow trout (Adult Oncorhyncus mykiss)</td>
<td>5.2 mg/l, 96 hours Static, OECD 203</td>
</tr>
<tr>
<td>NOEC</td>
<td>Rainbow trout (Adult Oncorhyncus mykiss)</td>
<td>2.1 mg/l, 96 hours Measured</td>
</tr>
<tr>
<td>Chronic</td>
<td>Crustacea EC50 Water flea (Ceriodaphnia dubia)</td>
<td>1 mg/l, 8 days Static renewal, EPA 1002</td>
</tr>
<tr>
<td>LOEC</td>
<td>Water flea (Ceriodaphnia dubia)</td>
<td>0.8 mg/l, 8 days</td>
</tr>
<tr>
<td>NOEC</td>
<td>Water flea (Ceriodaphnia dubia)</td>
<td>0.3 mg/l, 8 days</td>
</tr>
</tbody>
</table>

* Estimates for product may be based on additional component data not shown.

**Persistence and degradability** No data is available on the degradability of this product.

**Photolysis**
- **UV/visible spectrum wavelength**
  - ONDANSETRON BASE 310 nm Measured, pH 5-9

**Hydrolysis**
- **Half-life (Hydrolysis-basic)**
  - ASPARTAME < 1 Days Measured
- **Half-life (Hydrolysis-neutral)**
  - ONDANSETRON BASE > 1 years

**Biodegradability**
- **Percent degradation (Aerobic biodegradation-ready)**
  - ASPARTAME 60 - 90 %, 5 days
  - ONDANSETRON BASE 18.9 %, 28 days Semi-continuous activated sludge (SCAS), Activated sludge
- **Percent degradation (Aerobic biodegradation-soil)**
  - ONDANSETRON BASE 20.3 - 99.9 %, 64 days, Soil

**Bioaccumulative potential** No data available.

**Partition coefficient**
- **n-octanol / water (log Kow)**
  - MANNITOL -3.1
  - ONDANSETRON BASE 0.8

**Bioconcentration factor** *(BCF)*
- ASPARTAME 1 Estimated
- MANNITOL 1 Estimated

**Mobility in soil** No data available for this product.

**Adsorption**
- **Sludge/biomass distribution coefficient - log Kd**
  - ONDANSETRON BASE 3.95 - 4.23 Calculated

**Soil/sediment sorption - log Koc**
- ASPARTAME 1.78 Estimated
- MANNITOL 0.7 Estimated
- ONDANSETRON BASE 4.22 - 4.51 Measured

**Volatility**
- **Henry’s law**
  - ASPARTAME < 0 atm m^3/mol Estimated
  - MANNITOL 0 atm m3/mol

**Distribution**
- **Octanol/water distribution coefficient log DOW**
  - ONDANSETRON BASE 0.23, pH 5
  - 0.99, pH 7
Distribution
Octanol/water distribution coefficient log DOW
ONDANSETRON BASE
1.26, pH 9

Other adverse effects
Not available.

13. Disposal considerations

Disposal methods
Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.

Residual waste
Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

IATA

UN number
3077

UN proper shipping name
Environmentally hazardous substance, solid, n.o.s. (ONDANSETRON BASE TABLETS)

Transport hazard class(es)
Class
9
Subsidiary risk
-
Label(s)
9

Packing group
III

Environmental hazards
No.

ERG Code
9L

Special precautions for user
Not available.

Other information
Passenger and cargo aircraft
Allowed.

Cargo aircraft only
Allowed.

IMDG

UN number
3077

UN proper shipping name
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ONDANSETRON BASE TABLETS)

Transport hazard class(es)
Class
9
Subsidiary risk
-
Label(s)
9

Packing group
III

Environmental hazards

Marine pollutant
Yes

EmS
F-A, S-F

Special precautions for user
Not available.

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

IATA; IMDG
15. Regulatory information

Safety, health and environmental regulations

National regulations

This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

Australia Medicines & Poisons Appendix A
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J
Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8
Poisons schedule number not allocated.
Australia Medicines & Poisons Schedule 9
Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)
Not listed.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)
Not listed.

National Pollutant Inventory (NPI) substance reporting list
Not listed.

Prohibited Carcinogenic Substances
Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)
Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)
Not listed.

Restricted Carcinogenic Substances
Not regulated.

International regulations

Stockholm Convention
Not applicable.

Rotterdam Convention
Not applicable.

Kyoto protocol
Not applicable.

Montreal Protocol
Not applicable.

Basel Convention
Not applicable.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
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<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
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</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
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<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
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<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
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<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*“Yes” indicates that all components of this product comply with the inventory requirements administered by the governing country(s) and “No” indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date
11-August-2014

Revision date
11-August-2014

References
GSK Hazard Determination

Disclaimer
The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.