# SAFETY DATA SHEET

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

**1.1. Product identifier**

| | |
|---|---|
| **Trade name or designation of the mixture** | ZOFRAN TABLETS |
| **Registration number** | - |
| **Synonyms** | ZOFRAN TABLETS 4 MG * ZOFRAN TABLETS 8 MG * ONDANSETRON HYDROCHLORIDE TABLETS * ONDANSETRON HYDROCHLORIDE DIHYDRATE, FORMULATED PRODUCT |
| **Issue date** | 11-August-2014 |
| **Version number** | 11 |
| **Revision date** | 11-August-2014 |

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

| | |
|---|---|
| **Identified uses** | Medicinal Product<br><br>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. |
| **Uses advised against** | No other uses are advised. |

**1.3. Details of the supplier of the safety data sheet**

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

**1.4. Emergency telephone number**

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

## SECTION 2: Hazards identification

**2.1. Classification of the substance or mixture**

**Classification according to Directive 67/548/EEC or 1999/45/EC as amended**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**Classification according to Regulation (EC) No 1272/2008 as amended**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**2.2. Label elements**

**Label according to Regulation (EC) No. 1272/2008 as amended**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**Supplemental label information** None.

**2.3. Other hazards** Caution - Pharmaceutical agent.
See section 11 for additional information on health hazards.

## SECTION 3: Composition/information on ingredients

**3.2. Mixtures**

**General information**

| Chemical name | % | CAS-No. / EC No. | REACH Registration No. | INDEX No. | Notes |
|---|---|---|---|---|---|
| MICROCRYSTALLINE CELLULOSE | 20 - < 30 | 9004-34-6<br>232-674-9 | - | - | |
| **Classification:** **DSD:** - | | | | | |
| **CLP:** - | | | | | |
| OPASPRAY M-1-8429 | 5 - < 10 | Unassigned<br>- | - | - | |
| **Classification:** **DSD:** R10, Xn;R68/20/21/22 | | | | | |
| **CLP:** Flam. Liq. 2;H225, STOT SE 2;H371 | | | | | |
| HYDROXYPROPYL METHYL CELLULOSE | 3 - < 5 | 9004-65-3<br>- | - | - | |
| **Classification:** **DSD:** - | | | | | |
| **CLP:** - | | | | | |
| ONDANSETRON HYDROCHLORIDE DIHYDRATE | 3 - < 5 | 103639-04-9<br>- | - | - | |
| **Classification:** **DSD:** T;R25, Xi;R41, N;R50/53 | | | | | |
| **CLP:** Acute Tox. 3;H301, Eye Dam. 1;H318, Aquatic Acute 1;H400, Aquatic Chronic 2;H411 | | | | | |
| Starch | 3 - < 5 | 9005-25-8<br>232-679-6 | - | - | |
| **Classification:** **DSD:** - | | | | | |
| **CLP:** - | | | | | |
| MAGNESIUM STEARATE | < 1 | 557-04-0<br>209-150-3 | - | - | |
| **Classification:** **DSD:** - | | | | | |
| **CLP:** - | | | | | |
| Other components below reportable levels | 50 - < 60 | | | | |

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

**Composition comments** The full text for all R- and H-phrases is displayed in section 16.

## SECTION 4: First aid measures

**General information** In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

**4.1. Description of first aid measures**

**Inhalation** If breathing is difficult, trained personnel should give oxygen.

**Skin contact** Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

**Eye contact** Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

**Ingestion** If swallowed, rinse mouth with water (only if the person is conscious). Do not induce vomiting without medical advice. If ingestion of a large amount does occur, call a poison control centre immediately.

**4.2. Most important symptoms and effects, both acute and delayed** Direct contact with eyes may cause temporary irritation. Exposed may experience eye tearing, redness, and discomfort.

**4.3. Indication of any immediate medical attention and special treatment needed** 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.

## SECTION 5: Firefighting measures

**General fire hazards** No unusual fire or explosion hazards noted.

**5.1. Extinguishing media**

**Suitable extinguishing media** Water. Foam. Dry chemical powder. Carbon dioxide ($CO_2$).

**Unsuitable extinguishing media** None known.

**5.2. Special hazards arising from the substance or mixture** During fire, gases hazardous to health may be formed.

**5.3. Advice for firefighters**

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

**Special fire fighting procedures** Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers.

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

## SECTION 6: Accidental release measures

**6.1. Personal precautions, protective equipment and emergency procedures**

**For non-emergency personnel** Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate personal protective equipment. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.

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

**6.2. Environmental precautions** Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

**6.3. Methods and material for containment and cleaning up** Stop the flow of material, if this is without risk. Collect spillage. Prevent product from entering drains. Following product recovery, flush area with water.

**6.4. Reference to other sections** For personal protection, see section 8. For waste disposal, see section 13.

## SECTION 7: Handling and storage

**7.1. Precautions for safe handling** Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

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

**7.3. Specific end use(s)** Medicinal Product

## SECTION 8: Exposure controls/personal protection

**8.1. Control parameters**

**Occupational exposure limits**

**GSK**

| Components | Type | Value |
|---|---|---|
| HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3) | OHC | 1 |
| MAGNESIUM STEARATE (CAS 557-04-0) | OHC | 1 |
| MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) | OHC | 1 |
| ONDANSETRON HYDROCHLORIDE DIHYDRATE (CAS 103639-04-9) | 8 HR TWA | 30 mcg/m3 |
| | OHC | 3 |

**Ireland. Occupational Exposure Limits**

| Components | Type | Value | Form |
|---|---|---|---|
| MAGNESIUM STEARATE (CAS 557-04-0) | TWA | 10 mg/m3 | |

**Ireland. Occupational Exposure Limits**

| Components | Type | Value | Form |
|---|---|---|---|
| MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) | STEL | 20 mg/m3 | Total inhalable dust. |
| | TWA | 4 mg/m3 | Respirable dust. |
| | | 10 mg/m3 | Total inhalable dust. |
| Starch (CAS 9005-25-8) | TWA | 4 mg/m3 | Respirable dust. |
| | | 10 mg/m3 | Total inhalable dust. |

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

**Recommended monitoring procedures** Follow standard monitoring procedures.

**Derived no-effect level (DNEL)** Not available.

**Predicted no effect concentrations (PNECs)** Not available.

**8.2. Exposure controls**

**Appropriate engineering controls** Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

**Individual protection measures, such as personal protective equipment**

**General information** Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

**Eye/face protection** If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

**Skin protection**

**- Hand protection** For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

**- Other** Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust)

**Respiratory protection** Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387). When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

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

**Hygiene measures** Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

**Environmental exposure controls**

**Hazard guidance and control recommendations** Contain spills and prevent releases and observe national regulations on emissions. Environmental manager must be informed of all major releases.

## SECTION 9: Physical and chemical properties

**9.1. Information on basic 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. |
| **Vapour pressure** | Not available. |
| **Vapour density** | Not available. |
| **Relative density** | Not available. |
| **Solubility(ies)** | |
| **Solubility (water)** | Not available. |
| **Solubility (other)** | Not available. |
| **Partition coefficient (n-octanol/water)** | Not available. |
| **Auto-ignition temperature** | Not available. |
| **Decomposition temperature** | Not available. |
| **Viscosity** | Not available. |
| **Explosive properties** | Not available. |
| **Oxidizing properties** | Not available. |
| **9.2. Other information** | No relevant additional information available. |

## SECTION 10: Stability and reactivity

| | |
|---|---|
| **10.1. Reactivity** | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| **10.2. Chemical stability** | Material is stable under normal conditions. |
| **10.3. Possibility of hazardous reactions** | No dangerous reaction known under conditions of normal use. |
| **10.4. Conditions to avoid** | Contact with incompatible materials. |
| **10.5. Incompatible materials** | Strong oxidising agents. Fluorine. |
| **10.6. Hazardous decomposition products** | Irritating and/or toxic fumes and gases may be emitted upon the products decomposition. |

## SECTION 11: Toxicological information

**General information** Occupational exposure to the substance or mixture may cause adverse effects.

**Information on likely routes of exposure**

| | |
|---|---|
| **Ingestion** | Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure. |
| **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. |
| **Symptoms** | Exposure may cause temporary irritation, redness, or discomfort. |

**11.1. Information on toxicological effects**

**Acute toxicity** Health injuries are not known or expected under normal use.

| Components | Species | Test results |
|---|---|---|
| HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3) | | |
| **Acute** | | |
| *Oral* | | |
| LD50 | Rat | > 2000 mg/kg |
| MAGNESIUM STEARATE (CAS 557-04-0) | | |
| **Acute** | | |
| *Oral* | | |
| LD50 | Rat | > 2000 mg/kg |
| MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) | | |
| **Acute** | | |
| *Dermal* | | |
| LD50 | Rabbit | > 2000 mg/kg |
| *Oral* | | |
| LD50 | Rat | > 2000 mg/kg |

| Components | Species | Test results |
|---|---|---|
| ONDANSETRON HYDROCHLORIDE DIHYDRATE (CAS 103639-04-9) | | |
| **Acute** | | |
| *Oral* | | |
| LD50 | Rat | 100 - 150 mg/kg |
| **Chronic** | | |
| *Oral* | | |
| LD | Rat | > 36 mg/kg/day |
| LOEL | Dog | 1 mg/kg/day, 52 weeks |
| NOAEL | Rat | 1 mg/kg/day, 18 months |

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

**Skin corrosion/irritation** Based on available data, the classification criteria are not met.

**Corrosivity**
ONDANSETRON HYDROCHLORIDE DIHYDRATE — 50 %, formulated in soft paraffin.
Result: Non-irritant
Species: Guinea pig

**Irritation Corrosion - Skin: P.I.I. value**
MAGNESIUM STEARATE — 0

**Serious eye damage/eye irritation** Based on available data, the classification criteria are not met.

**Eye**
ONDANSETRON HYDROCHLORIDE DIHYDRATE — OECD 405
Result: Severe Irritant
Species: Rabbit

**Eye / Kay and Calandra class - Intact**
MAGNESIUM STEARATE — 4
Recovery Period: 2 days

**Respiratory sensitisation** Not available.

**Skin sensitisation** Based on available data, the classification criteria are not met.

**Maximisation assay (Magnusson and Kligman)**
HYDROXYPROPYL METHYL CELLULOSE — Result: negative
Species: Guinea pig

**Sensitisation**
ONDANSETRON HYDROCHLORIDE DIHYDRATE — Split adjuvant assay
Result: negative
Species: Guinea pig

**Germ cell mutagenicity** Based on available data, the classification criteria are not met.

**Mutagenicity**
ONDANSETRON HYDROCHLORIDE DIHYDRATE — Ames
Result: negative
Chromosomal Aberration Assay In Vitro
Result: positive
HPRT gene mutation in human lymphocytes
Result: negative
Micronucleus test
Result: negative
Species: Mouse
V79 Cell Mutagenicity Assay
Result: negative

**Carcinogenicity** Due to partial or complete lack of data the classification is not possible.
ONDANSETRON HYDROCHLORIDE DIHYDRATE — ICH S1B
Result: negative
Species: Mouse
ICH S1B
Result: negative
Species: Rat

**Reproductive toxicity** Based on available data, the classification criteria are not met.

**Reproductivity**
ONDANSETRON HYDROCHLORIDE DIHYDRATE — Embryofetal Development
Result: No effect
Species: Rabbit
Embryofetal Development
Result: No effect
Species: Rat

**Reproductivity**

| | |
|---|---|
| ONDANSETRON HYDROCHLORIDE DIHYDRATE | Fertility<br>Result: No effect<br>Species: Rat<br>Pre- and Post-natal development<br>Result: negative<br>Species: Rat |

**Specific target organ toxicity - single exposure** None known.

**Specific target organ toxicity - repeated exposure** None known.

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

**Mixture versus substance information** No information available.

**Other information** Not available.

## SECTION 12: Ecological information

**12.1. Toxicity** Contains a substance which causes risk of hazardous effects to the environment.

| Components | | Species | Test results |
|---|---|---|---|
| HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3) | | | |
| **Aquatic** | | | |
| *Acute* | | | |
| Fish | EC50 | Fish | > 100 mg/l, 96 hours |
| MAGNESIUM STEARATE (CAS 557-04-0) | | | |
| **Aquatic** | | | |
| *Acute* | | | |
| Fish | EC50 | Orange-red killfish (Adult Oryzias latipes) | 130 mg/l, 96 hours |
| Microtox | EC50 | Microtox | 12.5 mg/l, 15 minutes |
| ONDANSETRON HYDROCHLORIDE DIHYDRATE (CAS 103639-04-9) | | | |
| **Aquatic** | | | |
| *Acute* | | | |
| Activated Sludge Respiration | IC50 | Residential sludge | > 1000 mg/l, 3 hours OECD 209 |
| Algae | EC50 | Green algae (Selenastrum capricornutum) | 0.87 mg/l, 72 hours Measured, OECD 201 |
| | NOEC | Green algae (Selenastrum capricornutum) | 0.31 mg/l, 72 hours Static test |
| Crustacea | EC50 | Water flea (Daphnia pulex) | 28 mg/l, 48 hours Static test, TAD 4.08 |
| | NOEC | Water flea (Daphnia pulex) | 16 mg/l, 48 hours Static test |
| Fish | EC50 | Rainbow trout (Adult Oncorhyncus mykiss) | 6.5 mg/l, 96 hours Static test, OECD 203 |
| | NOEC | Rainbow trout (Adult Oncorhyncus mykiss) | 2.6 mg/l, 96 hours Measured |
| *Chronic* | | | |
| Crustacea | EC50 | Water flea (Ceriodaphnia dubia) | 1.4 mg/l, 8 days Static renewal test, EPA 1002 |
| | LOEC | Water flea (Ceriodaphnia dubia) | 1 mg/l, 8 days |
| | NOEC | Water flea (Ceriodaphnia dubia) | 0.32 mg/l, 8 days |

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

**Photolysis**

**Half-life (Photolysis-atmospheric)**

| | |
|---|---|
| MAGNESIUM STEARATE | 17 Hours Estimated |

**UV/visible spectrum wavelength**

| | |
|---|---|
| MAGNESIUM STEARATE | 210 nm |
| ONDANSETRON HYDROCHLORIDE DIHYDRATE | 305 nm, pH 5-9 |

**Hydrolysis**

**Half-life (Hydrolysis-neutral)**

| | |
|---|---|
| ONDANSETRON HYDROCHLORIDE DIHYDRATE | > 1 years |

**Biodegradability**

**Percent degradation (Aerobic biodegradation-inherent)**

| | |
|---|---|
| MAGNESIUM STEARATE | 77 %, 28 days BOD |
| ONDANSETRON HYDROCHLORIDE DIHYDRATE | 18.9 %, 28 days Semi-continuous activated sludge (SCAS), Activated sludge |

**Percent degradation (Aerobic biodegradation-ready)**

| | |
|---|---|
| MAGNESIUM STEARATE | 95 %, 22 days Sturm test |

**Percent degradation (Aerobic biodegradation-soil)**

| | |
|---|---|
| MAGNESIUM STEARATE | 50 %, 13 days |
| ONDANSETRON HYDROCHLORIDE DIHYDRATE | 20.3 - 99.9 %, 64 days, Soil |

**12.3. Bioaccumulative potential** No data available for this product.

**Partition coefficient n-octanol/water (log Kow)**

| | |
|---|---|
| HYDROXYPROPYL METHYL CELLULOSE | -5 |
| ONDANSETRON HYDROCHLORIDE DIHYDRATE | 0.995 |

**Bioconcentration factor (BCF)**

| | |
|---|---|
| HYDROXYPROPYL METHYL CELLULOSE | 3.2 Estimated |
| MAGNESIUM STEARATE | > 9999 Estimated |

**12.4. Mobility in soil** No data available.

**Adsorption**

**Sludge/biomass distribution coefficient - log Kd**

| | |
|---|---|
| ONDANSETRON HYDROCHLORIDE DIHYDRATE | 3.95 - 4.23 Calculated |

**Soil/sediment sorption - log Koc**

| | |
|---|---|
| MAGNESIUM STEARATE | 5.86 Estimated |
| ONDANSETRON HYDROCHLORIDE DIHYDRATE | 4.22 - 4.51 Measured |

**Mobility in general** Not available.

**Volatility**

**Henry's law**

| | |
|---|---|
| HYDROXYPROPYL METHYL CELLULOSE | 0 atm m3/mol Estimated |

**Distribution**

**Octanol/water distribution coefficient log DOW**

| | |
|---|---|
| ONDANSETRON HYDROCHLORIDE DIHYDRATE | 0.23, pH 5<br>0.99, pH 7<br>1.26, pH 9 |

**12.5. Results of PBT and vPvB assessment** Not available.

**12.6. Other adverse effects** Not available.

## SECTION 13: Disposal considerations

**13.1. Waste treatment methods**

**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.

**EU waste code** The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Disposal methods/information** Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

**Special precautions** Dispose in accordance with all applicable regulations.

## SECTION 14: Transport information

**General** Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

**ADR**

| | |
|---|---|
| **14.1. UN number** | UN3077 |
| **14.2. UN proper shipping name** | Environmentally hazardous substances, solid, n.o.s. (ONDANSETRON HYDROCHLORIDE TABLETS) |
| **14.3. Transport hazard class(es)** | |
| **Class** | 9 |
| **Subsidiary risk** | - |
| **Label(s)** | 9 |
| **Hazard No. (ADR)** | Not available. |
| **Tunnel code** | Not available. |
| **14.4. Packing group** | III |
| **14.5. Environmental hazards** | No. |
| **14.6. Special precautions for user** | Not available. |

**IATA**

| | |
|---|---|
| **14.1. UN number** | UN3077 |
| **14.2. UN proper shipping name** | Environmentally hazardous substance, solid, n.o.s. (ONDANSETRON HYDROCHLORIDE TABLETS) |
| **14.3. Transport hazard class(es)** | 9 |
| **Subsidiary class(es)** | - |
| **14.4. Packing group** | III |
| **Labels required** | 9 |
| **14.5. Environmental hazards** | No. |
| **ERG Code** | 9L |
| **14.6. Special precautions for user** | Not available. |
| **Other information** | |
| **Cargo aircraft only** | Allowed. |
| **Additional Information:** | |
| **Passenger & cargo** | Allowed. |

**IMDG**

| | |
|---|---|
| **14.1. UN number** | UN3077 |
| **14.2. UN proper shipping name** | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ONDANSETRON HYDROCHLORIDE TABLETS) |
| **14.3. Transport hazard class(es)** | |
| **Class** | 9 |
| **Subsidiary risk** | - |
| **Label(s)** | 9 |
| **14.4. Packing group** | III |
| **14.5. Environmental hazards** | |
| **Marine pollutant** | Yes |
| **EmS** | F-A, S-F |
| **14.6. Special precautions for user** | Not available. |

| | |
|---|---|
| **14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** | MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk. |

**ADR; IATA; IMDG**

**Marine pollutant**

**General information** Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

## SECTION 15: Regulatory information

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

**EU regulations**

**Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I**

Not listed.

**Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II**

Not listed.

**Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended**

Not listed.

**Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry**

Not listed.

**Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA**

Not listed.

**Authorisations**

**Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended**

Not listed.

**Restrictions on use**

**Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended**

Not listed.

**Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work**

Not listed.

**Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding**

Not listed.

**Other EU regulations**

**Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances**

Not listed.

**Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work**

Not listed.

**Directive 94/33/EC on the protection of young people at work**

Not listed.

**Other regulations** The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

**National regulations** Follow national regulation for work with chemical agents.

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| **15.2. Chemical safety assessment** | No Chemical Safety Assessment has been carried out. |

## SECTION 16: Other information

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| **List of abbreviations** | Not available. |
| **References** | GSK Hazard Determination |
| **Information on evaluation method leading to the classification of mixture** | The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available. |
| **Full text of any statements or R-phrases and H-statements under Sections 2 to 15** | R10 Flammable.<br>R22 Harmful if swallowed.<br>R25 Toxic if swallowed.<br>R41 Risk of serious damage to eyes.<br>R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.<br>R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.<br>R68/20/21/22 Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed.<br>H225 Highly flammable liquid and vapour.<br>H301 Toxic if swallowed.<br>H318 Causes serious eye damage.<br>H371 May cause damage to organs.<br>H400 Very toxic to aquatic life.<br>H411 Toxic to aquatic life with long lasting effects.<br>May form combustible dust concentrations in air. |
| **Revision information** | Product and Company Identification: Product and Company Identification<br>Composition / Information on Ingredients: Ingredients<br>Physical & Chemical Properties:<br>Toxicological Information: Toxicological Property Data<br>Ecological Information: Ecotoxicity<br>Transport Information: Material Transportation Information<br>Regulatory Information: United States<br>Material Attributes & Uses; Experimental Data: Material Uses<br>GHS: Classification<br>Consumer Products: CPSC Hazard Categories |
| **Training information** | Follow training instructions when handling this material. |
| **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. |