



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** ZOFRAN TABLETS

### Other means of identification

**Synonyms**

ZOFRAN TABLETS 4 MG \* ZOFRAN TABLETS 8 MG \* ONDANSETRON HYDROCHLORIDE TABLETS \* ONDANSETRON HYDROCHLORIDE DIHYDRATE, 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

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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	CAS number and other unique identifiers	Concentration of ingredients
MICROCRYSTALLINE CELLULOSE AVICEL PH MICROCRYSTALLINE CELLULOSE ABICEL ALPHA-CELLULOSE ARBOCEL ARBOCELL B 600/30 ARBOCELL BC 200 AVICEL PH101 AVICEL PH102 AVICEL PH103 AVICEL PH105 AVICEL PH112 AVICEL PH200 BETA-AMYLOSE CELLEX MX CELLULOSE (8CI9CI) CELLULOSE 248 CELLULOSE CRYSTALLINE CELLULOSE, FOOD GRADE CELUFI CRYSTALLINE CELLULOSE EMOCEL MCC MICROCRYSTALLINE CELLULOSE POWDERED CELLULOSE RTECS FJ5691460 SOLKA FLOC BW200 CELLULOSA (FIBRA PAPEL) CELLULOSE (PAPER FIBRES) CELLULOSE-PAPER FIBER CELULOSA (FIBRA PAPEL) TSELLULOOS	9004-34-6	20 - < 30
OPASPRAY M-1-8429	Unassigned	5 - < 10
HYDROXYPROPYL METHYL CELLULOSE METHOCEL K4M GONIOSOL ISOPRO ALKALINE METHOCEL E,F,K METHOCEL HG METHYL CELLULOSE PROPYLENE GLYCOL ETHER HYPROMELLOSE CELLULOSE, 2-HYDROXYPROPYL METHYL ESTER METHYLHYDROXYPROPYLCELLULOSE PHARMACOAT 603	9004-65-3	3 - < 5
ONDANSETRON HYDROCHLORIDE DIHYDRATE GR 38032F 1,2,3,9-TETRAHYDRO-3-((2-METHYLIMIDAZOL-1-YL)METHYL)-9-METHYL-4H-CARBAZOL-4 -ONE, HYDROCHLORIDE, DIHYDRATE 59 (GW ACN)	103639-04-9	3 - < 5
Starch ARROWROOT STARCH CORN STARCH POTATO STARCH RICE STARCH	9005-25-8	3 - < 5
MAGNESIUM STEARATE STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE	557-04-0	< 1
Other components below reportable levels		50 - < 60

## 4. First-aid measures

### Description of necessary first aid measures

<b>Inhalation</b>	If breathing is difficult, trained personnel should give oxygen.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	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.
<b>Personal protection for first-aid responders</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.
<b>Symptoms caused by exposure</b>	Direct contact with eyes may cause temporary irritation. Exposed may experience eye tearing, redness, and discomfort.
<b>Medical attention and special treatment</b>	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

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for fire fighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers.
<b>Hazchem Code</b>	Not available.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

<b>For non-emergency personnel</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.
<b>For emergency responders</b>	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
<b>Environmental precautions</b>	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.
<b>Methods and materials for containment and cleaning up</b>	Stop the flow of material, if this is without risk. Collect spillage. 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

<b>Precautions for safe handling</b>	Do not taste or swallow. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Avoid release to the environment. Do not empty into drains.
<b>Conditions for safe storage, including any incompatibilities</b>	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

#### 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

#### Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	Inhalable dust.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	Inhalable fibers.
Starch (CAS 9005-25-8)	TWA	10 mg/m3	Inhalable dust.

#### Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	Inspirable dust.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	Inspirable dust.
Starch (CAS 9005-25-8)	TWA	10 mg/m3	Inspirable dust.

#### US. ACGIH Threshold Limit Values

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3
Starch (CAS 9005-25-8)	TWA	10 mg/m3

#### UK. EH40 Workplace Exposure Limits (WELs)

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

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

**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, for example personal protective equipment (PPE)

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

<b>Skin protection</b>	
<b>Hand protection</b>	For prolonged or repeated skin contact use suitable protective gloves.
<b>Other</b>	Wear suitable protective clothing as protection against splashing or contamination.
<b>Respiratory protection</b>	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>Hygiene measures</b>	When using, do not eat, drink or smoke. 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.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.

### Upper/lower flammability or explosive limits

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit – upper (%)</b>	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 established.

**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. Fluorine.

**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

<b>Ingestion</b>	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.
<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use.

**Symptoms related to exposure** Direct contact with eyes may cause temporary irritation.

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

Components	Species	Test results
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	> 2000 mg/kg
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
ONDANSETRON HYDROCHLORIDE DIHYDRATE (CAS 103639-04-9)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	100 - 150 mg/kg
<b>Chronic</b>		
<i>Oral</i>		
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** Prolonged skin contact may cause temporary irritation.

### 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/irritation** Direct contact with eyes may cause temporary irritation.

### 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 or skin sensitisation

**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**

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

**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**

ONDANSETRON HYDROCHLORIDE DIHYDRATE

ICH S1B  
Result: negative  
Species: Mouse  
ICH S1B  
Result: negative  
Species: Rat**ACGIH Carcinogens**

MAGNESIUM STEARATE (CAS 557-04-0)

A4 Not classifiable as a human carcinogen.

STARCH (CAS 9005-25-8)

A4 Not classifiable as a human carcinogen.

**Reproductive toxicity**

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

**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.

**Chronic effects**

Prolonged inhalation may be harmful. Prolonged exposure may cause chronic effects.

**12. Ecological information****Ecotoxicity**

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 &gt; 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 &gt; 1000 mg/l, 3 hours OECD 209

Components		Species	Test results
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 Oncorhynchus mykiss)	6.5 mg/l, 96 hours Static test, OECD 203
	NOEC	Rainbow trout (Adult Oncorhynchus mykiss)	2.6 mg/l, 96 hours Measured
<i>Chronic</i> 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

**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

**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

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

#### 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  
0.99, pH 7  
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. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable 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 HYDROCHLORIDE 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 HYDROCHLORIDE 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** Not available.

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.

## 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**

HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3) in preparations for injection

**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**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)  
A "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

<b>Issue date</b>	11-August-2014
<b>Revision date</b>	11-August-2014
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	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.
<b>Revision Information</b>	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Toxicological Information: Toxicological Property Data Ecological Information: Ecotoxicity Transport Information: Proper Shipping Name/Packing Group Regulatory Information: United States Material Attributes & Uses; Experimental Data: Product Uses GHS: Classification Consumer Products: CPSC Hazard Categories