



SAFETY DATA SHEET

1. Identification

Product identifier ZOFRAN ORAL SOLUTION

Other means of identification

Synonyms

ZOFRAN ORAL SOLUTION 4 MG/5 ML * ZOFRAN SYRUP 4 MG/5 ML * ZOFRAN JARABE * ZOFRAN LOSUNG * ZOFRAN MIKSTUR * ZOFRAN MIXTUR * ZOFRAN SCIROPPPO * ZOFRAN SIROP * ZOFRAN SIRUP * ZOFRAN STROOP * ZOFRAN SYROP * ZOFRAN XAROPE * NDC NO 0173-0489-00 * 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

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
D-SORBITOL Sorbitol L-GULITOL 1,2,3,4,5,6-HEXANEHEXOL D-SORBOL	50-70-4	< 45
CITRIC ACID ANHYDROUS BETA-HYDROXYTRICARBALLYLIC ACID ANHYDROUS CITRIC ACID 2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID CITIRIC ACID	77-92-9	< 1

ONDANSETRON HYDROCHLORIDE DIHYDRATE

103639-04-9

< = 0.10

GR 38032F

1,2,3,9-TETRAHYDRO-3-((2-METHYLIMIDAZOL-1-YL)METHYL)-9-METHYL-4H-CARBAZOL-4 -ONE, HYDROCHLORIDE, DIHYDRATE
59 (GW ACN)

Other components below reportable levels

> 57

4. First-aid measures

Description of necessary first aid measures

Inhalation	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
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). If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center.

Personal protection for first-aid responders 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.

Symptoms caused by exposure Direct contact with eyes may cause temporary irritation.

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. 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 fire fighters 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. 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 Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

7. Handling and storage

Precautions for safe handling Avoid prolonged exposure. 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

GSK

Components

Components	Type	Value
CITRIC ACID ANHYDROUS (CAS 77-92-9)	8 HR TWA	5000 mcg/m ³
	OHC	1
D-SORBITOL (CAS 50-70-4)	OHC	1
ONDANSETRON HYDROCHLORIDE DIHYDRATE (CAS 103639-04-9)	8 HR TWA	30 mcg/m ³
	OHC	3

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

Exposure guidelines

Appropriate engineering controls General ventilation normally adequate.

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

For prolonged or repeated skin contact use suitable protective gloves.

Other

Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection

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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Liquid.

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	The product is stable and non-reactive under normal conditions of use, storage and transport.
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	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on possible routes of 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.
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.

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

Components	Species	Test results
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Acute		
<i>Oral</i>		
LD50	Rat	3000 mg/kg
D-SORBITOL (CAS 50-70-4)		
Acute		
<i>Oral</i>		
LD50	Rat	15.9 g/kg
ONDANSETRON HYDROCHLORIDE DIHYDRATE (CAS 103639-04-9)		
Acute		
<i>Oral</i>		
LD50	Rat	100 - 150 mg/kg

Components	Species	Test results
Chronic		
<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		
CITRIC ACID ANHYDROUS		OECD 404 Result: Mild to moderate irritant. Species: Rabbit
Serious eye damage/irritation	Direct contact with eyes may cause temporary irritation.	
Eye		
CITRIC ACID ANHYDROUS		Acute ocular irritation; OECD 405 Result: Severe Irritant Species: Rabbit
ONDANSETRON HYDROCHLORIDE DIHYDRATE		OECD 405 Result: Severe Irritant Species: Rabbit
Respiratory or skin sensitisation		
Skin sensitisation	This product is not expected to cause skin sensitisation.	
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	Carcinogenic effects are not expected as a result of occupational exposure.	
ONDANSETRON HYDROCHLORIDE DIHYDRATE		ICH S1B Result: negative Species: Mouse ICH S1B Result: negative Species: Rat
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.	
Specific target organ toxicity - single exposure	Not classified.	
Specific target organ toxicity - repeated exposure	Not classified.	
Aspiration hazard	Not available.	
Chronic effects	Prolonged inhalation may be harmful.	

Other information

Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity Not expected to be harmful to aquatic organisms.

Components		Species	Test results
CITRIC ACID ANHYDROUS (CAS 77-92-9)			
Aquatic			
<i>Acute</i>			
Algae	NOEC	Green algae (Scenedesmus quadricauda)	425 mg/l, 8 days Static Test
Crustacea	EC50	Water flea (Daphnia magna)	120 mg/l, 72 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	1516 mg/l, 96 hours Static test
		Golden ide/orfe (Adult Leuciscus idus)	440 - 760 mg/l, 96 hours Static test
ONDANSETRON HYDROCHLORIDE DIHYDRATE (CAS 103639-04-9)			
Aquatic			
<i>Acute</i>			
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 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

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

Persistence and degradability**Photolysis****UV/visible spectrum wavelength**

ONDANSETRON HYDROCHLORIDE DIHYDRATE 305 nm, pH 5-9

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

ONDANSETRON HYDROCHLORIDE DIHYDRATE > 1 years

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

CITRIC ACID ANHYDROUS 98 %, 2 days Modified Zahn-Wellens, Activated sludge
 ONDANSETRON HYDROCHLORIDE DIHYDRATE 18.9 %, 28 days Semi-continuous activated sludge (SCAS), Activated sludge

Percent degradation (Aerobic biodegradation-soil)

ONDANSETRON HYDROCHLORIDE DIHYDRATE 20.3 - 99.9 %, 64 days, Soil

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

D-SORBITOL -2.2

ONDANSETRON HYDROCHLORIDE DIHYDRATE 0.995

Bioconcentration factor (BCF)

D-SORBITOL 1 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

D-SORBITOL 0.3 Estimated

ONDANSETRON HYDROCHLORIDE DIHYDRATE 4.22 - 4.51 Measured

Mobility in general

Volatility

Henry's law

CITRIC ACID ANHYDROUS < 0 atm m³/mol Calculated, 25 °C

D-SORBITOL 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). Avoid discharge into water courses or onto the ground.

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

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

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)

CITRIC ACID ANHYDROUS (CAS 77-92-9)

1000 - 9999 TONNES See the regulation for additional information.

D-SORBITOL (CAS 50-70-4)

1000 - 9999 TONNES See the regulation for additional information.

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
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

Issue date 22-October-2014

Revision date 22-October-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.

Revision Information Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Undisclosed Ingredient Statement
Physical & Chemical Properties:
Ecological Information: Ecotoxicity
Transport Information: Agency Name, Packaging Type, and Transport Mode Selection
Regulatory Information: United States
Material Attributes & Uses; Experimental Data: Product Uses