SAFETY DATA SHEET

1. Identification

Product identifier **ZOFRAN INJECTION**

Other means of identification

Synonyms ZOFRAN INJECTION 2 MG/ML * ZOFRAN FLEXI-AMP 2 MG/ML * IZOFRAN FLEXI-AMP INJECTION * ZOFRON FLEXI-AMP INJECTION * ZOPHREN INJECTION * ZOFRAN I.M./I.V * 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
Sodium chloride COMMON SALT ROCK SALT SODIUM MONOCHLORIDE Salt SEA SALT TABLE SALT SALT, WHITE CRYSTALS, SOLAR	7647-14-5	< 1
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	< 0.3

HYDROUS CITRIC ACID 2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID, MONOHYDRATE CITRIC ACID MONOHYDRATE	5949-29-1	< 0.1
METHYL PARABEN GR30517X METHYL P-HYDROXYBENZOATE P-HYDROXYBENZOIC ACID, METHYL ESTER 4-HYDROXYBENZOIC ACID, METHYL ESTER METHYL P-OXYBENZOATE METHYL PARAHYDROXYBENZOATE	99-76-3	< = 0.1
MONOBASIC SODIUM CITRATE 2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID, DISODIUM SALT CITRIC ACID, DISODIUM SALT DISODIUM CITRATE DISODIUM HYDROGEN CITRATE DISODIUM MONOHYDROGEN CITRATE SODIUM CITRATE	144-33-2	< 0.1
PROPYL PARABEN PROPYL P-HYDROXYBENZOATE PROTABEN 4-HYDROXYBENZOIC ACID, PROPYL ESTER P-HYDROXYBENZOIC ACID, PROPYL ESTER PASEPTOL PARASEPT PROPYL ASEPTOFORM PROPYL P-OXYBENZOATE	94-13-3	< = 0.01
Other components below reportable levels		90 - 100

4. First-aid measures

Description of necessary first aid measures

Inhalation	Move to fresh air. If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. 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 medical advice.
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	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).
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 (CO_2).
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	This product is non-flammable.
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. Wear appropriate protective equipment and clothing during clean-up. 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.
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.
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. Prevent product from entering drains. 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.

7. Handling and storage

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.
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	Type	Value
HYDROUS CITRIC ACID (CAS 5949-29-1)	8 HR TWA	5000 mcg/m3
	OHC	1
MONOBASIC SODIUM CITRATE (CAS 144-33-2)	8 HR TWA	5000 mcg/m3
	OHC	1
ONDANSETRON HYDROCHLORIDE DIHYDRATE (CAS 103639-04-9)	8 HR TWA	30 mcg/m3
	OHC	3
PROPYL PARABEN (CAS 94-13-3)	8 HR TWA	5000 mcg/m3
	OHC	1

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure standards allocated.
Appropriate engineering controls	General ventilation normally adequate. 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	Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection	
Hand protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.
Other	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
Respiratory protection	No personal respiratory protective equipment normally required.
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. An occupational/industrial hygiene monitoring method has been developed for this material.

9. Physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Liquid.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	3.4 - 3.6
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 products decomposition.

11. Toxicological information

Information on possible 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 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	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test results
METHYL PARABEN (CAS 99-76-3)		
Acute		
Oral		
LD50	Mouse	> 8 g/kg
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
PROPYL PARABEN (CAS 94-13-3)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
Sodium chloride (CAS 7647-14-5)		
Acute		
Oral		
LD50	Rat	3000 mg/kg

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

Serious eye damage/irritation Health injuries are not known or expected under normal use.

Eye

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.

Maximisation assay (Magnusson and Kligman)

ZOFRAN INJECTION	Result:

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 Not classifiable as to carcinogenicity to humans.

ONDANSETRON HYDROCHLORIDE DIHYDRATE	ICH S1B Result: negative Species: Mouse ICH S1B 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 Not assigned.

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

Other information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity The product contains a substance which may cause long-term adverse effects in the environment. Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test results
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
Sodium chloride (CAS 7647-14-5)			
Aquatic			
Acute			
Algae	EC50	Algae (Nitscheria linearis)	2430 mg/l, 5 days

Components		Species	Test results
Crustacea	EC50	Water flea (Daphnia magna)	3310 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Juvenile Lepomis macrochirus)	1295 mg/l, 96 hours Static test
		Fathead minnow (Juvenile Pimephales promelas)	6390 mg/l, 96 hours Static test
		Goldfish (Adult Carassius auratus)	7000 mg/l, 96 hours
		Mosquito fish (Adult Gambusia affinis)	17550 mg/l, 96 hours Static test

* 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)

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)

METHYL PARABEN 1.96

ONDANSETRON HYDROCHLORIDE DIHYDRATE 0.995

PROPYL PARABEN 3.04

Mobility in soil Not available.

Adsorption

Sludge/biomass distribution coefficient - log Kd

ONDANSETRON HYDROCHLORIDE DIHYDRATE 3.95 - 4.23 Calculated

Soil/sediment sorption - log Koc

ONDANSETRON HYDROCHLORIDE DIHYDRATE 4.22 - 4.51 Measured

Distribution

Octanol/water distribution coefficient log DOW

ONDANSETRON HYDROCHLORIDE DIHYDRATE 0.23, pH 5
0.99, pH 7
1.26, pH 9

PROPYL PARABEN 3.04

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

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

METHYL PARABEN (CAS 99-76-3) Low toxicity. General: Preservative

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.

Australia National Pollutant Inventory (NPI): Threshold quantity

SODIUM CHLORIDE (CAS 7647-14-5) 10 TONNES/YR Threshold Category: 1

High Volume Industrial Chemicals (HVIC)

HYDROUS CITRIC ACID (CAS 5949-29-1) 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.

Resricted 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	11-July-2014
Revision date	11-July-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: Ingredients Physical & Chemical Properties: Toxicological Information: Genetic Tox and Carcinogen Ecological Information: Reports Transport Information: Material Transportation Information Regulatory Information: United States GHS: Classification