SAFETY DATA SHEET

1. Identification

Product identifier **ZOFRAN ODT ORALLY DISINTEGRATING TABLETS**

Other means of identification

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

Recommended use of the chemical and restrictions on use

Recommended use Medicinal Product

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

Restrictions on use No other uses are advised.

Details of manufacturer or importer

Manufacturer

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

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

2. Hazard(s) identification

Classification of the hazardous chemical

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

Label elements, including precautionary statements

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

Other hazards which do not result in classification

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

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
MANNITOL D-MANNITOL 1,2,3,4,5,6-HEXANEHEXOL MANNA SUGAR MANNITE OSMITROL BP-686 MANNITOL, D- DIOSMOL MANITON-S MANNIDEX MANNIGEN MANNISTOL OSMOSOL D-MANNITE CORDYCEPIC ACID D-(-)-MANNITOL MANNITOLUM OSMOSAL ISOTOL C6H14O6 OHS13660 RTECS OP2060000	69-65-8	20 - < 30
ONDANSETRON BASE ONDANSETRON GR 38032X 113 (GW ACN) 1,2,3,9-TETRAHYDRO-3-((2-METHYLIMIDAZOL-1-YL)METHYL)-9-METHYL-4H-CARBAZOL-4-ONETETRAHYDRO	99614-02-5	20 - < 30
ASPARTAME ASPARTYLPHENYLALANINE METHYL ESTER NUTRASWEET	22839-47-0	3 - < 5
SODIUM METHYL PARABEN SODIUM METHYL PARA-HYDROXYBENZOATE BENZOIC ACID, 4-HYDROXY-, METHYL ESTER, SODIUM SALT SODIUM METHYL P-HYDROXYBENZOATE BENZOIC ACID, P-HYDROXY-, METHYL ESTER, SODIUM SALT SODIUM, (P-CARBOXYPHENOXY)-, METHYL ESTER SODIUM 4-CARBOMETHOXYPHENOLATE SOLPAROL SODIUM METHYL HYDROXYBENZOATE SODIUM METHYL 4-HYDROXYBENZOATE METHYLPARABEN SODIUM METHYL P-HYDROXYBENZOATE, SODIUM SALT 4-HYDROXYBENZOIC ACID, METHYL ESTER, SODIUM SALT P-HYDROXYBENZOIC ACID, METHYL ESTER, SODIUM SALT PARA-HYDROXYBENZOIC ACID, METHYL ESTER, SODIUM SALT NIPAGIN(R) M SODIUM SODIUM METHYLPARABEN METHYL (P-CARBOXYPHENOXY)SODIUM NATRIUM-4-(METHOXYCARBONYL)PHENOLAT GR30517A	5026-62-0	< 1
Other components below reportable levels		40 - < 50

4. First-aid measures

Description of necessary first aid measures

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Get medical attention if symptoms occur. Take off contaminated clothing and wash before reuse.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately.
Personal protection for first-aid responders	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.
Symptoms caused by exposure	The following adverse effects have been noted with therapeutic use of this material: headache; flushing; constipation; abnormal nervous system sensations; burning; symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing).
Medical attention and special treatment	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for 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. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13.

7. Handling and storage

Precautions for safe handling	Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

GSK

Components	Type	Value
ASPARTAME (CAS 22839-47-0)	8 HR TWA	5000 mcg/m3
	OHC	1
MANNITOL (CAS 69-65-8)	OHC	1
ONDANSETRON BASE (CAS 99614-02-5)	8 HR TWA	30 mcg/m3
	OHC	3

GSK Components	Type	Value
SODIUM METHYL PARABEN (CAS 5026-62-0)	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 An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

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

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

Skin protection

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

Other Wear suitable protective clothing.

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

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

9. Physical and chemical properties

Appearance

Physical state Solid.

Form Tablet.

Colour Not available.

Odour Not available.

Odour threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit – upper (%) Not available.

Vapour pressure Not available.

Vapour density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

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

11. Toxicological information

Information on possible routes of exposure

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

Components	Species	Test results
MANNITOL (CAS 69-65-8)		
Acute		
Oral		
LD50	Rat	13.5 g/kg
ONDANSETRON BASE (CAS 99614-02-5)		
Acute		
Oral		
LD50	Rat	100 - 150 mg/kg Results from ondansetron HCl.
Chronic		
Oral		
LD	Rat	> 36 mg/kg/day Results from ondansetron HCl.
LOEL	Dog	1 mg/kg/day, 52 weeks Results from ondansetron HCl.
NOAEL	Rat	1 mg/kg/day, 18 months Results from ondansetron HCl.
SODIUM METHYL PARABEN (CAS 5026-62-0)		
Acute		
Oral		
LD50	Mouse	2 g/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 BASE	50 %, Results from ondansetron HCl. Formulated in soft paraffin. Result: Non-irritant Species: Guinea pig

Serious eye damage/irritation Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Eye

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

Respiratory or skin sensitisation

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

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

Maximisation assay (Magnusson and Kligman)

ZOFRAN ODT ORALLY DISINTEGRATING TABLETS — Result:

Sensitisation

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

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

Mutagenicity

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

Carcinogenicity Not classifiable as to carcinogenicity to humans.

ONDANSETRON BASE — ICH S1B, Results from ondansetron HCl.
Result: negative
Species: Mouse
ICH S1B, Results from ondansetron HCl.
Result: negative
Species: Rat

Reproductive toxicity Contains no ingredient listed as toxic to reproduction

Specific target organ toxicity - single exposure Central nervous system.

Specific target organ toxicity - repeated exposure None known.

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

Other information Caution - Pharmaceutical agent.

12. Ecological information

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

Components		Species	Test results
ONDANSETRON BASE (CAS 99614-02-5)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 802 mg/l, 3 hours OECD 209
Algae	EC50	Green algae (Selenastrum capricornutum)	0.7 mg/l, 72 hours Static ., OECD 201

Components		Species	Test results
	NOEC	Green algae (Selenastrum capricornutum)	0.25 mg/l, 72 hours Measured
Crustacea	EC50	Water flea (Daphnia pulex)	22 mg/l, 48 hours Static ., TAD 4.08
	NOEC	Water flea (Daphnia pulex)	13 mg/l, 48 hours Measured
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	5.2 mg/l, 96 hours Static ., OECD 203
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	2.1 mg/l, 96 hours Measured
Chronic			
Crustacea	EC50	Water flea (Ceriodaphnia dubia)	1 mg/l, 8 days Static renewal ., EPA 1002
	LOEC	Water flea (Ceriodaphnia dubia)	0.8 mg/l, 8 days
	NOEC	Water flea (Ceriodaphnia dubia)	0.3 mg/l, 8 days

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

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

Photolysis

UV/visible spectrum wavelength

ONDANSETRON BASE 310 nm Measured, pH 5-9

Hydrolysis

Half-life (Hydrolysis-basic)

ASPARTAME < 1 Days Measured

Half-life (Hydrolysis-neutral)

ONDANSETRON BASE > 1 years

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

ASPARTAME 60 - 90 %, 5 days

ONDANSETRON BASE 18.9 %, 28 days Semi-continuous activated sludge (SCAS), Activated sludge

Percent degradation (Aerobic biodegradation-soil)

ONDANSETRON BASE 20.3 - 99.9 %, 64 days, Soil

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

MANNITOL -3.1

ONDANSETRON BASE 0.8

Bioconcentration factor (BCF)

ASPARTAME 1 Estimated

MANNITOL 1 Estimated

Mobility in soil No data available for this product.

Adsorption

Sludge/biomass distribution coefficient - log Kd

ONDANSETRON BASE 3.95 - 4.23 Calculated

Soil/sediment sorption - log Koc

ASPARTAME 1.78 Estimated

MANNITOL 0.7 Estimated

ONDANSETRON BASE 4.22 - 4.51 Measured

Volatility

Henry's law

ASPARTAME < 0 atm m^3/mol Estimated

MANNITOL 0 atm m3/mol

Distribution

Octanol/water distribution coefficient log DOW

ONDANSETRON BASE 0.23, pH 5

0.99, pH 7

Distribution

Octanol/water distribution coefficient log DOW

ONDANSETRON BASE	1.26, pH 9

Other adverse effects Not available.

13. Disposal considerations

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

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

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

14. Transport information

IATA

UN number	3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (ONDANSETRON BASE TABLETS)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
Packing group	III
Environmental hazards	No.
ERG Code	9L
Special precautions for user	Not available.
Other information	
Passenger and cargo aircraft	Allowed.
Cargo aircraft only	Allowed.

IMDG

UN number	3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ONDANSETRON BASE TABLETS)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
Packing group	III
Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
Special precautions for user	Not available.

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

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

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-August-2014
Revision date	11-August-2014
References	GSK Hazard Determination
Disclaimer	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Revision Information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: Ecological Information: Mobility Regulatory Information: Risk Phrases - Class. GHS: Classification