



# 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**

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.

**Recommended restrictions**

No other uses are advised.

**Manufacturer/Importer/Supplier/Distributor information**

**Manufacturer**

GlaxoSmithKline US  
5 Moore Drive  
Research Triangle Park, NC 27709 USA  
US General Information (normal business hours): +1-888-825-5249  
Email Address: [msds@gsk.com](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://www.gsk.com)  
EMERGENCY PHONE NUMBERS -  
TRANSPORT EMERGENCIES::  
US / International toll call +1 703 527 3887  
available 24 hrs/7 days; multi-language response

## 2. Hazard(s) identification

**Classified hazards**

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

**Label elements**

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

**Hazard(s) not otherwise classified (HNOC)**

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

## 3. Composition/information on ingredients

**Mixtures**

Chemical name	Common name and synonyms	CAS number	%
SODIUM CHLORIDE	COMMON SALT * ROCK SALT * SODIUM MONOCHLORIDE * SALT * SEA SALT * TABLE SALT * SALT, WHITE CRYSTALS, SOLAR	7647-14-5	0.9
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	0.25
HYDROUS CITRIC ACID	2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID, MONOHYDRATE * CITRIC ACID MONOHYDRATE	5949-29-1	0.05

Chemical name	Common name and synonyms	CAS number	%
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	0.02
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			98.78

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

#### 4. First-aid measures

<b>Inhalation</b>	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.
<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). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
<b>Most important symptoms/effects, acute and delayed</b>	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).
<b>Indication of immediate medical attention and special treatment needed</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 center.
<b>General information</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.

#### 5. Fire-fighting measures

<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 firefighters</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.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	This product is non-flammable.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	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 of the SDS.
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**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 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.

**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/personal protection****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).

**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, such as personal protective equipment****Eye/face protection**

Not normally needed. If contact is likely, safety glasses with side shields are recommended.

**Hand protection**

Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

**Skin protection****Other**

Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

**Respiratory protection**

No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

**Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**

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.

<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	3.4 - 3.6
<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.
<b>Upper/lower flammability or explosive limits</b>	
<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.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	None known. Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

## 11. Toxicological information

### Information on likely 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 the physical, chemical and toxicological characteristics** 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).

### Information on toxicological effects

**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)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Mouse	> 8 g/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
PROPYL PARABEN (CAS 94-13-3)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
SODIUM CHLORIDE (CAS 7647-14-5)		
<b>Acute</b>		
<i>Oral</i>		
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/eye 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 sensitization**

**Respiratory sensitization** Not available.

**Skin sensitization** This product is not expected to cause skin sensitization.

**Maximisation assay (Magnusson and Kligman)**

ZOFRAN INJECTION Result:

**Sensitization**

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

**Mutagenicity**

ONDANSETRON HYDROCHLORIDE DIHYDRATE 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

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Reproductive toxicity**

Contains no ingredient listed as toxic to reproduction

**Reproductivity**

ONDANSETRON HYDROCHLORIDE DIHYDRATE

Embryofetal Development  
Result: No effect  
Species: Rabbit  
Embryofetal Development  
Result: No effect  
Species: Rat  
Fertility  
Result: No effect  
Species: Rat  
Pre- and Post-natal development  
Result: Negative  
Species: Rat

**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.

**Further 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)		
<b>Aquatic</b>		
<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

Components	Species	Test Results
SODIUM CHLORIDE (CAS 7647-14-5)		
<b>Aquatic</b>		
<i>Acute</i>		
Algae	EC50	Algae ( <i>Nitscheria linearis</i> ) 2430 mg/l, 5 days
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> ) 3310 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Juvenile <i>Lepomis macrochirus</i> ) 1295 mg/l, 96 hours Static test
		Fathead minnow (Juvenile <i>Pimephales promelas</i> ) 6390 mg/l, 96 hours Static test
		Goldfish (Adult <i>Carassius auratus</i> ) 7000 mg/l, 96 hours
		Mosquito fish (Adult <i>Gambusia affinis</i> ) 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

##### 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

#### Mobility in general

##### 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 instructions** 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.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

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

**Waste from residues / unused products** 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****DOT**

Not regulated as a dangerous good.

**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**

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.

**15. Regulatory information****US federal regulations****TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)****Hazard categories**

Immediate Hazard - Yes  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical**

No

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)**

Not regulated.

**US state regulations****US. Massachusetts RTK - Substance List**

Not regulated.

**US. New Jersey Worker and Community Right-to-Know Act**

Not listed.

**US. Pennsylvania Worker and Community Right-to-Know Law**

Not listed.

**US. Rhode Island RTK**

Not regulated.

**US. California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.



## 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, including date of preparation or last revision

<b>Issue date</b>	07-11-2014
<b>Revision date</b>	07-11-2014
<b>Version #</b>	09
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 2 Flammability: 0 Physical hazard: 0
<b>NFPA ratings</b>	Health: 2 Flammability: 0 Instability: 0
<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: Business Units 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