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
Website: 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

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 center immediately. Do not induce vomiting without advice from poison control center.

Most important symptoms/effects, acute and delayed 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).

Indication of immediate medical attention and special treatment needed 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.

General information 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

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 firefighters 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.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards This product is non-flammable.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures 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.

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.

Color	Not available.
Odor	Not available.
Odor 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.
Vapor pressure	Not available.
Vapor 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 oxidizing 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 likely 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 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)		
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/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)			
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

Components		Species	Test Results
SODIUM CHLORIDE (CAS 7647-14-5)			
Aquatic			
Acute			
Algae	EC50	Algae (Nitscheria linearis)	2430 mg/l, 5 days
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

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

Issue date 07-11-2014

Revision date 07-11-2014

Version # 09

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 2
Flammability: 0
Physical hazard: 0

NFPA ratings
Health: 2
Flammability: 0
Instability: 0

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: 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