SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material **ZOFRAN INJECTION**

Synonym(s) 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 * NDC NO 0173-0442-00 * NDC NO 0173-0442-02 * ONDANSETRON HYDROCHLORIDE DIHYDRATE, FORMULATED PRODUCT

Company Name

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Multi-language response

* 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
NON-HAZARDOUS INGREDIENTS	Unassigned	99.75	
ONDANSETRON HYDROCHLORIDE DIHYDRATE	103639-04-9	0.25	

3. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

Health Caution - Potent pharmaceutical agent. Health effects information is based on hazards of components.
Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); headache; constipation; flushing; abnormal nervous system sensations.

Environment Harmful to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

4. FIRST-AID MEASURES

Ingestion Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre. Medical treatment in cases of overexposure should be treated as an overdose of antagonist of 5-hydroxytryptamine. In allergic individuals, exposure to this material may require treatment for initial or delayed allergic symptoms and signs. This may include immediate and/or delayed treatment of anaphylactic reactions.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
Health Surveillance Procedures	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.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
Clean-up Methods	Spread an inert absorbent on the spill and place in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

HANDLING

General Requirements	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
STORAGE	No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	ONDANSETRON HYDROCHLORIDE DIHYDRATE
GSK Occupational Hazard Category	3
GSK Occupational Exposure Limit	30 mcg/m3 (8 HR TWA)

ENGINEERING CONTROLS

Exposure Controls	An internal GSK Occupational Exposure Level (OEL) of 30 mcg/m3 (8 hr TWA) has been set for Ondansetron, the active substance in this product. 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. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them.
Other Equipment or Procedures	Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form	Aqueous solution.
pH of Aqueous Solutions	3.4 to 3.6

10. STABILITY AND REACTIVITY

Stability	This product is expected to be stable.
Conditions to Avoid	None for normal handling of this product.

11. TOXICOLOGY INFORMATION

Pharmacological Effects	This material is a 5-hydroxytryptamine antagonist. It is an agent intended for the treatment of nausea.
Target Organ Effects	Adverse effects might occur in the following organ(s) following overexposure: central nervous system.

Routes of Exposure

Oral Toxicity	Not expected to be toxic following ingestion.
Skin Effects	Irritation is not expected following direct contact.
Eye Effects	Minor irritation might occur following direct contact with eyes.
Sensitisation	Sensitisation (allergic skin reaction) is not expected.
Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions.
Carcinogenicity	Not expected to produce cancer in humans under occupational exposure conditions.
Reproductive Effects	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
Other Adverse Effects	Overexposure in the workplace might have the following effects: symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing); headache; constipation; flushing; activity in the nervous system.

12. ECOLOGICAL INFORMATION

Summary	This product contains an active ingredient that has been tested and which may be harmful if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted prior to environmental release. Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

Activated Sludge Respiration

This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.

IC50:	> 1000 mg/l, 3 Hours, Activated sludge

Algal

This material contains an active pharmaceutical ingredient that is very toxic to algae.

IC50:	0.87 mg/l, 72 Hours, Selenastrum capricornutum, green algae, Measured
NOEC:	0.31 mg/l, 72 Hours, , Static test

Daphnid

This material contains an active pharmaceutical ingredient that is toxic to daphnids in chronic toxicity studies.

EC50:	28 mg/l, 48 Hours, Daphnia pulex, Static test
NOEC:	16 mg/l, 48 Hours, Daphnia pulex, Static test
Chronic EC50:	1.4 mg/l, 8 Days, Ceriodaphnia dubia, Static renewal test
Chronic LOEC:	1 mg/l, 8 Days, Ceriodaphnia dubia
Chronic NOEC:	0.32 mg/l, 8 Days, Ceriodaphnia dubia

Fish

This material contains an active pharmaceutical ingredient that is toxic to fish.

Adult Oncorhyncus mykiss, rainbow trout

EC50:	6.5 mg/l, 96 Hours, Static test
NOEC:	2.6 mg/l, 96 Hours, Measured

MOBILITY

Solubility

This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.

Adsorption

This material contains an active pharmaceutical ingredient that is likely to adsorb to soil or sediment. This material contains an active pharmaceutical ingredient that is likely to adsorb to sludges and other biomass.

Soil Sediment Sorption (log Koc):	4.22 to 4.51, Measured
Sludge Biomass Distribution Coefficient (log Kd):	3.95 to 4.23 Calculated

Partitioning

This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION

Hydrolysis

This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism.

Half-Life, Neutral:	> 1 Years

Photolysis

This material contains an active pharmaceutical ingredient that is likely to undergo photodegradation.

UV/Visible Spectrum:	305 nm at pH 5 to 9

Biodegradation

This material contains an active pharmaceutical ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines).

Aerobic - Inherent

Percent Degradation:	18.9 %, 28 days, Semi-continuous activated sludge (SCAS), Activated sludge

Aerobic - Soil

Percent Degradation:	20.3 to 99.9 %, 64 days, , Soil

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Transport Information Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification This product is classified as hazardous according to the OSHA Hazard Communication Standard.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

SDS Version Number 8

SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	

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.