

## 1. Identification

<b>Product identifier</b>	<b>ZOFRAN SUPPOSITORIES</b>
<b>Other means of identification</b>	Not available.
<b>Synonym(s)</b>	ZOFRAN SUPPOSITORIES 16MG * ZOFRAN CZOPKI * ZOFRAN KUP * ZOFRAN PERAPUIKKO * ZOFRAN STIKKPILLER * ZOFRAN SUPOSITORIOS * ZOPHRAN SUPPOSITOIRE * ZOFRAN SUPPOSITORIEN * ZOFRAN SUPPOSITORIER * ZOFRAN SUPPOSTE * FORMULA CODE P042 * ONDANSETRON BASE, FORMULATED PRODUCT
<b>Recommended use</b>	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

#### Hazardous components

Chemical name	Common name and synonyms	CAS number	%
ONDANSETRON BASE	ONDANSETRON GR 38032X 113 (GW ACN) 1,2,3,9-TETRAHYDRO-3-((2-METHYLIMIDA	99614-02-5	1.6

Other components below reportable levels 98.4

\*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>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse immediately with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth thoroughly. Get medical advice/attention if you feel unwell. Do not induce vomiting.

<b>Most important symptoms/effects, acute and delayed</b>	The following adverse effects have been noted with therapeutic use of this material: headache; constipation; changes in clinical chemistry parameters; changes in heart rate or pulse.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. 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.
<b>General information</b>	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.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. 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>	In the event of fire, cool tanks with water spray.
<b>Specific methods</b>	Cool containers exposed to flames with water until well after the fire is out.

## 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. Keep out of low areas. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the MSDS.
<b>Methods and materials for containment and cleaning up</b>	Stop the flow of material, if this is without risk. Collect spillage. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the MSDS.
<b>Environmental precautions</b>	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

<b>Precautions for safe handling</b>	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.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### GSK

#### Components

	Type	Value
ONDANSETRON BASE (CAS 99614-02-5)	8 HR TWA	30 mcg/m <sup>3</sup>
	OHC	3

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	No particular ventilation requirements. 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.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Not normally needed.
<b>Hand protection</b>	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.
<b>Other</b>	Wear suitable protective clothing.
<b>Respiratory protection</b>	Respiratory protective equipment (RPE) is not required for normal handling of this product. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
<b>Thermal hazards</b>	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. 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**

<b>Physical state</b>	Solid.
<b>Form</b>	Suppository.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<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>	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>	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>	May be harmful if swallowed.
<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>	Direct contact with eyes may cause temporary irritation.
<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	The following adverse effects have been noted with therapeutic use of this material: headache; constipation; changes in clinical chemistry parameters; changes in heart rate or pulse.

**Information on toxicological effects****Acute toxicity** May be harmful if swallowed.

Components	Species	Test Results
ONDANSETRON BASE (CAS 99614-02-5)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	100 - 150 mg/kg, Results from ondansetron HCl.
<b>Chronic</b>		
<i>Oral</i>		
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.

\* 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/eye 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 sensitization** Due to partial or complete lack of data the classification is not possible.**Skin sensitization** Health injuries are not known or expected under normal use.**Maximisation assay (Magnusson and Kligman)**

ZOFTRAN SUPPOSITORIES Result:

**Sensitization**

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.

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

ONDANSETRON BASE Embryofetal Development, Results from ondansetron HCl.  
Result: No effect  
Species: Rabbit

Embryofetal Development, Results from ondansetron HCl.  
 Result: No effect  
 Species: Rat  
 Fertility, Results from ondansetron HCl.  
 Result: No effect  
 Species: Rat  
 Pre- and Post-natal development, Results from ondansetron HCl.  
 Result: Negative  
 Species: Rat

<b>Specific target organ toxicity - single exposure</b>	Not assigned.
<b>Specific target organ toxicity - repeated exposure</b>	Not assigned.
<b>Aspiration hazard</b>	Not likely, due to the form of the product.
<b>Further information</b>	Caution - Pharmaceutical agent.

## 12. Ecological information

**Ecotoxicity** No information is available about the potential of this product to produce adverse environmental effects. Contains a substance which causes risk of hazardous effects to the environment. The product contains a substance which may cause long-term adverse effects in the environment.

Components	Species	Test Results
ONDANSETRON BASE (CAS 99614-02-5)		
<b>Aquatic</b>		
<i>Acute</i>		
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
	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 Oncorhynchus mykiss)	5.2 mg/l, 96 hours, Static ., OECD 203
	NOEC Rainbow trout (Adult Oncorhynchus mykiss)	2.1 mg/l, 96 hours, Measured
<i>Chronic</i>		
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

#### Photolysis

##### UV/visible spectrum wavelength

ONDANSETRON BASE 310 nm Measured, pH 5-9

#### Hydrolysis

##### Half-life (Hydrolysis-neutral)

ONDANSETRON BASE > 1 Years

#### Biodegradability

##### Percent degradation (Aerobic biodegradation-soil)

ONDANSETRON BASE 20.3 - 99.9 %, 64 days, Soil

**Bioaccumulative potential** Not available.

##### Partition coefficient n-octanol / water (log Kow)

ONDANSETRON BASE 0.8

### Mobility in soil

#### Adsorption

##### Sludge/biomass distribution coefficient - log Kd

ONDANSETRON BASE 3.95 - 4.23 Calculated

## Adsorption

### Soil/sediment sorption - log Koc

ONDANSETRON BASE

4.22 - 4.51 Measured

## Mobility in general

### Distribution

#### Octanol/water distribution coefficient log DOW

ONDANSETRON BASE

0.23, pH 5

0.99, pH 7

1.26, pH 9

### 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 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.

### 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 a dangerous good.

### IMDG

Not regulated as a dangerous good.

### 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.

#### US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

#### SARA 304 Emergency release notification

Not regulated.

### 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

No

#### SARA 311/312 Hazardous chemical

No

### NFPA ratings

Health: 2  
Flammability: 1  
Instability: 0

### HMIS® ratings

Health: 2  
Flammability: 1  
Physical hazard: 0

## 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.

**Food and Drug Administration (FDA)** Not regulated.

## US state regulations

### US. Massachusetts RTK - Substance List

Not regulated.

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

Not regulated.

### US. Pennsylvania RTK - Hazardous Substances

Not regulated.

### 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>	02-24-2014
<b>Revision date</b>	02-24-2014
<b>Version #</b>	06
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 2 Flammability: 1 Physical hazard: 0
<b>NFPA ratings</b>	Health: 2 Flammability: 1 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: Product and Company Identification Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Transport Information: Material Transportation Information GHS: Classification