

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078914243

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078914401

## SAFETY DATA SHEET



GlaxoSmithKline

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

<b>Material</b>	<b>ZANTAC INJECTION</b>	
<b>Synonyms</b>	ZANTAC INJECTION 25MG/ML * ZANTAC 2 INYECTABLE * ZANTAC AMPOLLA * ZANTAC AMPULLE * ZANTAC INFUSIONKONCENTRAT * ZANTAC INJECTIEVLOEISTOF * ZANTAC INJEKCIJAS * ZANTAC INJEKCIO * ZANTAC INJEKSJONSVAESKE * ZANTAC INJEKTIONESTE * ZANTAC INJEKTIJONSVATSKA * ZANTAC INYECTABLE * ZANTAC SOLUCAO INJECTAVEL * ZANTAC SOLUCION INYECTABLE * ZANTAC ZAWIESINA DO INIEKJIE * NDC NO 0173-0362-38 * NDC NO 0173-0363-00 * NDC NO 0173-0363-01 * RANITIDINE HYDROCHLORIDE, FORMULATED PRODUCT	
<b>Company Name</b>	GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response  GlaxoSmithKline, Corporate Environment, Health & Safety 2200 Renaissance Blvd, Suite 105 King of Prussia, PA 19406 US US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response	

### 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
RANITIDINE HYDROCHLORIDE	66357-59-3	3
NON-HAZARDOUS INGREDIENTS	Unassigned	97

### 3. HAZARDS IDENTIFICATION

<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>Health</b>	Handling this product in its final form presents minimal risk from occupational exposure. Caution - Pharmaceutical agent. Health effects information is based on hazards of components. Respiratory allergen. May produce allergic skin reactions.

<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.
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#### 4. FIRST-AID MEASURES

<b>Ingestion</b>	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.
<b>Inhalation</b>	Physical form suggests that risk of inhalation exposure is negligible.
<b>Skin Contact</b>	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.
<b>Eye Contact</b>	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

#### NOTES TO HEALTH PROFESSIONALS

<b>Medical Treatment</b>	Medical treatment in cases of overexposure should be treated as an overdose of a histamine antagonist (H2-type). Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
<b>Medical Conditions Caused or Aggravated by Exposure</b>	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
<b>Antidotes</b>	No specific antidotes are recommended.

#### 5. FIRE-FIGHTING MEASURES

<b>Fire and Explosion Hazards</b>	This product is non-combustible, although the packaging is combustible.
<b>Extinguishing Media</b>	Water is recommended for fires involving packaging.
<b>Special Firefighting Procedures</b>	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.
<b>Hazardous Combustion Products</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

#### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental Precautions</b>	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
<b>Clean-up Methods</b>	Spread an inert absorbent on the spill and place in a suitable, properly labelled container for recovery or disposal.
<b>Decontamination Procedures</b>	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

<b>INGREDIENT</b>	RANITIDINE HYDROCHLORIDE
<b>GSK Occupational Hazard Category</b>	3
<b>GSK Occupational Exposure Limit</b>	50 mcg/m <sup>3</sup> (15 MIN STEL) SKIN SENSITISER, RESPIRATORY SENSITISER

### ENGINEERING CONTROLS

**Exposure 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. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them.

### PERSONAL PROTECTIVE EQUIPMENT

**Eye Protection** Wear approved safety glasses with side shields if eye contact is possible.

**Other Equipment or Procedures** An eye wash station should be available. Wash hands and arms thoroughly after handling. Wear appropriate clothing to avoid skin contact.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Appearance

**Physical Form** Solution.

**pH of Aqueous Solutions** 6.8 to 7.1

## 10. STABILITY AND REACTIVITY

**Stability** DO NOT FREEZE - dispose of properly if frozen.

**Conditions to Avoid** None for normal handling of this product.

## 11. TOXICOLOGICAL INFORMATION

**Oral Toxicity** Not expected to be toxic following ingestion.

**Skin Effects** Irritation is not expected following direct contact.

**Eye Effects** Irritation is not expected following direct contact with eyes.

**Target Organ Effects** No specific target organ effects have been identified.

**Sensitisation** Assessment based upon effects of structurally similar substances. Allergic skin reactions might occur following dermal exposure. Assessment based upon information from human exposure.

**Genetic Toxicity** Not expected to be genotoxic under occupational exposure conditions.

**Carcinogenicity** No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

**Reproductive Effects** Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

<b>Pharmacological Effects</b>	This product contains active ingredient(s) with the following activity: a histamine antagonist (H2 sub-type). It is an agent intended for the treatment of gastric ulcers. Adverse effects of overexposure might include: altered heart rate and pulse; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); temporary decrease in white blood cell counts; coughing; headache; increased mucous secretion.
<b>Other Adverse Effects</b>	None known for occupational exposure.

## 12. ECOLOGICAL INFORMATION

<b>* Summary</b>	This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.
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Specific information on the active pharmaceutical ingredient is provided below.

### ECOTOXICITY

#### Aquatic

<b>* Activated Sludge Respiration</b>	This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.
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IC50: > 1000 mg/l, 3 Hours, Activated sludge

<b>* Algal</b>	This material contains an active pharmaceutical ingredient that is not toxic to algae.
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IC50: 167 mg/l, 72 Hours, Selenastrum capricornutum, green algae

NOEL: 56 mg/l, 72 Hours, Selenastrum capricornutum, green algae

<b>* Daphnid</b>	This material contains an active pharmaceutical ingredient that is not toxic to daphids.
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EC50: 730 mg/l, 48 Hours, Daphnia magna, Static test

NOEL: 347 mg/l, 48 Hours, Daphnia magna, Static test

<b>* Fish</b>	This material contains an active pharmaceutical ingredient that is not toxic to fish.
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Juvenile Oncorhyncus mykiss, rainbow trout

EC50: > 112 mg/l, 14 Days, Flow-through test

Juvenile Oncorhyncus mykiss, rainbow trout

NOEL: 112 mg/l, 14 Days, Flow-through test

### MOBILITY

<b>* Solubility</b>	This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.
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<b>* Volatility</b>	This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance.
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Henry's Law Constant 2.30E-11 atm m<sup>3</sup>/mol, Estimated at 24 C

<b>* Adsorption</b>	This material contains an active pharmaceutical ingredient that is likely to adsorb to soil or sediment. It may persist in soil or sediment if released directly to the environment.
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Soil Sediment Sorption 2.51 to 4.49 at pH 5 to 7  
(log Koc):

- \* 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, Measured
- \* Photolysis** This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water when exposed to light. Aqueous photolysis may be a significant depletion mechanism.  
Half-Life, Aqueous: 70 Minutes, Measured, Lake water  
UV/Visible Spectrum: 313 nm at pH 7, Measured
- \* Biodegradation** This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment.  
Aerobic - Ready  
Percent Degradation: < 1 %, 28 days, Modified Sturm test.  
Aerobic - Inherent  
Percent Degradation: 43 %, 28 days, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge  
Percent Degradation: 2 %, 28 days, Modified Zahn-Wellens, DOC removal., Activated sludge  
Anaerobic  
Percent Degradation: 12 %, 35 days  
Aerobic - Soil  
Percent Degradation: 3 to 10 %, 67 days
- \* BIOACCUMULATION** This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.  
Bioconcentration Factor: 1

### 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 product.

### 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.

For waste disposal purpose, this product should be classified in line with the European Waste Catalogue criteria.

### 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

**Date Approved/Revised** 18-Nov-2004

**SDS Version Number** 8

### SDS Sections Updated

#### Sections

ECOLOGICAL INFORMATION

#### Subsections

Activated Sludge Respiration  
Adsorption  
Algal  
Algal Degradation  
Bioaccumulation  
Biodegradation  
Daphnid  
Distribution  
Earthworm  
Ecotoxicity  
Fish  
Hydrolysis  
Microbial Growth Inhibition  
Microtox  
Mobility  
Other Adverse Effects  
Other Species - Aquatic  
Other Species - Terrestrial  
Partitioning  
Persistence/Degradation  
Photolysis  
Solubility  
Summary  
Volatility

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.

## SAFETY DATA SHEET



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

<b>Material</b>	<b>ZANTAC INJECTION</b>
<b>Synonym(s)</b>	ZANTAC INJECTION 25 MG/ML * ANTAK INJECTION * AZANTAC INJECTION * SOSTRIL INJECTION * ZANTIC INJECTION * ZINETAC INJECTION * NDC NO 0173-0362-38 * NDC NO 0173-0363-00 * NDC NO 0173-0363-01 * RANITIDINE HYDROCHLORIDE, FORMULATED PRODUCT
<b>Company Name</b>	GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK  UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response  GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US  US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response

### 2. HAZARDS IDENTIFICATION

<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>Health</b>	Handling this product in its final form presents minimal risk from occupational exposure. Caution - Pharmaceutical agent. Health effects information is based on hazards of components. Respiratory allergen. May produce allergic skin reactions.
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
NON-HAZARDOUS INGREDIENTS	Unassigned	97	
RANITIDINE HYDROCHLORIDE	66357-59-3	3	266-333-0

### 4. FIRST-AID MEASURES

<b>Ingestion</b>	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.
<b>Inhalation</b>	Physical form suggests that risk of inhalation exposure is negligible.



**Material** ZANTAC INJECTION

<b>Skin Contact</b>	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.
<b>Eye Contact</b>	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

**NOTES TO HEALTH PROFESSIONALS**

<b>Medical Treatment</b>	Medical treatment in cases of overexposure should be treated as an overdose of a histamine antagonist (H2-type). Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
<b>Medical Conditions Caused or Aggravated by Exposure</b>	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
<b>Antidotes</b>	No specific antidotes are recommended.

**5. FIRE-FIGHTING MEASURES**

<b>Fire and Explosion Hazards</b>	This product is non-combustible, although the packaging is combustible.
<b>Extinguishing Media</b>	Water is recommended for fires involving packaging.
<b>Special Firefighting Procedures</b>	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.
<b>Hazardous Combustion Products</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

**6. ACCIDENTAL RELEASE MEASURES**

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

**7. HANDLING AND STORAGE****HANDLING**

<b>General Requirements</b>	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.
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**STORAGE**

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

<b>INGREDIENT</b>	RANITIDINE HYDROCHLORIDE	
<b>GSK Occupational Hazard Category</b>	3	
<b>GSK Occupational Exposure Limit</b>	50 mcg/m3 (15 MIN STEL)	SKIN SENSITISER, RESPIRATORY SENSITISER
<b>ENGINEERING CONTROLS</b>		
<b>Exposure Controls</b>	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.	

**PERSONAL PROTECTIVE EQUIPMENT**

<b>Eye Protection</b>	Wear approved safety glasses with side shields if eye contact is possible.
<b>Other Equipment or Procedures</b>	Follow all local regulations if personal protective equipment (PPE) is used in the workplace. An eye wash station should be available. Wash hands and arms thoroughly after handling. Wear appropriate clothing to avoid skin contact.

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>
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**Appearance**

<b>Physical Form</b>	Solution.
<b>pH of Aqueous Solutions</b>	6.8 to 7.1

<b>10. STABILITY AND REACTIVITY</b>
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<b>Stability</b>	DO NOT FREEZE - dispose of properly if frozen.
<b>Conditions to Avoid</b>	None for normal handling of this product.

<b>11. TOXICOLOGY INFORMATION</b>
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<b>Pharmacological Effects</b>	This product contains active ingredient(s) with the following activity: a histamine antagonist (H2 sub-type). It is an agent intended for the treatment of gastric ulcers. Adverse effects of overexposure might include: altered heart rate and pulse; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); temporary decrease in white blood cell counts; coughing; headache; increased mucous secretion.
<b>Target Organ Effects</b>	No specific target organ effects have been identified.
<b>Routes of Exposure</b>	
<b>Oral Toxicity</b>	Not expected to be toxic following ingestion.
<b>Skin Effects</b>	Irritation is not expected following direct contact.
<b>Eye Effects</b>	Irritation is not expected following direct contact with eyes.
<b>Sensitisation</b>	Assessment based upon effects of structurally similar substances. Allergic skin reactions might occur following dermal exposure. Assessment based upon information from human exposure.
<b>Genetic Toxicity</b>	Not expected to be genotoxic under occupational exposure conditions.
<b>Carcinogenicity</b>	No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
<b>Reproductive Effects</b>	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
<b>Other Adverse Effects</b>	None known for occupational exposure.

<b>* 12. ECOLOGICAL INFORMATION</b>
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<b>* Summary</b>	This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.
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Specific information on the active pharmaceutical ingredient is provided below.

**ECOTOXICITY****Aquatic**

<b>* Activated Sludge Respiration</b>	This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms. IC50: > 1000 mg/l, 3 Hours, Activated sludge
<b>* Algal</b>	This material contains an active pharmaceutical ingredient that is not toxic to algae. IC50: 167 mg/l, 72 Hours, Selenastrum capricornutum, green algae

**Material** ZANTAC INJECTION

NOEC: 56 mg/l, 72 Hours, Selenastrum capricornutum, green algae

**\* Daphnid**

This material contains an active pharmaceutical ingredient that is not toxic to daphnids. This material contains an active pharmaceutical ingredient that is not toxic to daphnids in chronic toxicity studies.

EC50: 730 mg/l, 48 Hours, Daphnia magna, Static test

NOEC: 347 mg/l, 48 Hours, Daphnia magna, Static test

Chronic LOEC: 100 mg/l, 8 Days, Ceriodaphnia dubia, Static renewal test

Chronic NOEC: 32 mg/l, 8 Days

**\* Fish**

This material contains an active pharmaceutical ingredient that is not toxic to fish.

Juvenile Oncorhynchus mykiss, rainbow trout

EC50: > 112 mg/l, 14 Days, Flow-through test

Juvenile Oncorhynchus mykiss, rainbow trout

NOEC: 112 mg/l, 14 Days, Flow-through test

**MOBILITY****\* Solubility**

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

**\* Volatility**

This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance.

Henry's Law Constant 2.30E-11 atm m<sup>3</sup>/mol, Estimated at 24 C

**\* Adsorption**

This material contains an active pharmaceutical ingredient that is likely to adsorb to soil or sediment. It may persist in soil or sediment if released directly to the environment.

Soil Sediment Sorption 2.51 to 4.49 at pH 5 to 7  
(log K<sub>oc</sub>):

**\* 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, Measured

**\* Photolysis**

This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water when exposed to light. Aqueous photolysis may be a significant depletion mechanism.

Half-Life, Aqueous: 70 Minutes, Measured, Lake water

UV/Visible Spectrum: 313 nm at pH 7, Measured

**\* Biodegradation**

This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment.

Aerobic - Ready

Percent Degradation: < 1 %, 28 days, Modified Sturm test.

Aerobic - Inherent

Percent Degradation: 43 %, 28 days, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Aerobic - Inherent

Percent Degradation: 2 %, 28 days, Modified Zahn-Wellens, DOC removal., Activated sludge

Anaerobic

Percent Degradation: 12 %, 35 days

Aerobic - Soil

Percent Degradation: 3 to 10 %, 67 days

**\* Bioaccumulation**

This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.

Bioconcentration Factor: 1

**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 product.

**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**

11

**SDS Sections Updated****Sections**

ECOLOGICAL INFORMATION

**Subsections**

Activated Sludge Respiration  
Adsorption  
Algal  
Algal Degradation  
Bioaccumulation  
Biodegradation  
Crustacea  
Daphnid  
Desorption  
Distribution  
Earthworm  
Ecotoxicity  
EHAC Notation  
Fish  
GSK Environmental Hazard Category  
Hydrolysis  
Microbial Growth Inhibition  
Microtox  
Mobility  
Other Adverse Effects  
Other Species - Aquatic  
Other Species - Terrestrial  
Partitioning  
PBT Assessment  
Persistence/Degradation  
Photolysis  
Solubility  
Summary  
Very bioaccumulative  
Very persistent  
Volatility

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.