SAFETY DATA SHEETS

This SDS packet was issued with item:

078914401

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

078914243

SAFETY DATA SHEET

1. Identification

Product identifier **ZANTAC INJECTION**

Other means of identification

Synonyms ZANTAC INJECTION 25 MG/ML * ZANTAC INJECTION 50 MG/2ML * ANTAK INJECTION * AZANTAC INJECTION * SOSTRIL INJECTION * ZANTIC INJECTION * ZINETAC INJECTION * RANITIDINE HYDROCHLORIDE, 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

COMPANY NAME GlaxoSmithKline US

Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA

Telephone: +1-888-825-5249 (General Inquiries)

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

CHEMTREC EMERGENCY NUMBERS

Telephone: +(1) 703 527 3887 (International)
24/7; multi-language response

Contract Number: CCN9484

VERISK 3E GLOBAL INCIDENT RESPONSE

Telephone: +(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 334878

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	%
RANITIDINE HYDROCHLORIDE	AH 19065AB N,N-DIMETHYL-5-(2-(1-METHYLAMINO-2-NITROVINYLAMINO)ETHYLTHIOMETHYL)FURFURYL AMINE HYDROCHLORIDE	66357-59-3	2.5
SODIUM PHOSPHATE, DIBASIC	PHOSPHORIC ACID, DISODIUM SALT, HYDRATE	10140-65-5	0.24

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	0.2
POTASSIUM PHOSPHATE MONOBASIC	POTASSIUM ACID PHOSPHATE POTASSIUM DIPHOSPHATE POTASSIUM BIPHOSPHATE POTASSIUM ORTHOPHOSPHATE MONOPOTASSIUM PHOSPHATE POTASSIUM DIHYDROGEN PHOSPHAT E POTASSIUM DIHYDROGEN ORTHOPHOSPHATE POTASSIUM PHOSPHATE, MONOBASIC	7778-77-0	< 0.1
Other components below reportable levels			90 - 100

*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, trained personnel should give oxygen. 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 Sensitization. The following adverse effects have been noted with therapeutic use of this material:; decrease in heart rate; decrease in blood pressure; temporary decrease in white blood cell counts; increased mucous secretion. Headache. Coughing.

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 In case of fire and/or explosion do not breathe fumes. 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. Avoid breathing mist or vapor. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. 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. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Following product recovery, flush area with water.

Small Spills: Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. 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 discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Avoid prolonged exposure. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing.

Conditions for safe storage, including any incompatibilities Store in a cool, dry place out of direct sunlight. Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
POTASSIUM PHOSPHATE MONOBASIC (CAS 7778-77-0)	OHC	1	>1000 - </=5000 mcg/m3
RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)	15 MIN STEL	50 mcg/m3	SKIN SENSITISER
		50 mcg/m3	RESPIRATORY SENSITISER
	OHC	3	RESPIRATORY SENSITISER, SKIN SENSITISER
SODIUM CHLORIDE (CAS 7647-14-5)	OHC	1	
SODIUM PHOSPHATE, DIBASIC (CAS 10140-65-5)	OHC	1	>1000 - </=5000 mcg/m3

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Appropriate engineering controls General ventilation normally adequate.

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.

Skin protection

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

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.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Ampoule orVial.

Color Not available.

Odor Not available.

Odor threshold	Not available.
pH	6.8 - 7.1
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 applicable.
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.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

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	Hazardous polymerization does not occur.
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 product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact	May cause an allergic skin reaction.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Ingestion	May be harmful if swallowed. 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.
Symptoms related to the physical, chemical and toxicological characteristics	Sensitization. The following adverse effects have been noted with therapeutic use of this material: decrease in heart rate; decrease in blood pressure; temporary decrease in white blood cell counts; increased mucous secretion. Coughing.; Headache.

Information on toxicological effects

Acute toxicity	May be harmful if swallowed.

Components	Species	Test Results
RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)		
Acute		
Oral		
LD50	Rat	> 4190 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.

Irritation Corrosion - Skin

RANITIDINE HYDROCHLORIDE

Acute dermal irritation; OECD 404, Primary dermal irritation index = 0
Result: Negative
Species: Rabbit

Serious eye damage/eye irritation Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Eye

RANITIDINE HYDROCHLORIDE

Acute ocular irritation; OECD 405, Kay and Calandra score = 3
Result: Minimal Irritant
Species: Rabbit
IRE Assay
Result: Negative; not likely to be a severe irritant
Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled.

RANITIDINE HYDROCHLORIDE

Occupational exposure
Result: Positive
Species: Human

Skin sensitization May cause an allergic skin reaction.

Sensitization

RANITIDINE HYDROCHLORIDE

Occupational exposure
Result: Positive
Species: Human
Optimisation Test
Result: Weak sensitiser
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

RANITIDINE HYDROCHLORIDE

Ames Assay, GLP assay
Result: Negative
Chromosomal Aberration Assay In Vitro, human lymphocytes, Ranitidine bismuth citrate tested
Result: Positive
Chromosomal Aberration Assay In Vivo; germ cells, Maximum dose = 1000 mg/kg
Result: Negative
Species: Mouse
GreenScreen Assay
Result: Negative
Micronucleus Test
Result: Negative
Species: Rat
Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay
Result: Negative
SOS/umu Assay
Result: Negative

Mutagenicity

RANITIDINE HYDROCHLORIDE

Unscheduled DNA Synthesis in vivo, Maximum dose = 200 mg/kg
Result: Negative
Species: Rat
Organ: Stomach
Yeast Mutation Assay
Result: Negative

Carcinogenicity Carcinogenic effects are not expected as a result of occupational exposure. Not classifiable as to carcinogenicity to humans.

RANITIDINE HYDROCHLORIDE

2 year bioassay, Maximum dose = 2000 mg/kg/day
Result: Negative
Species: Mouse
2 year bioassay, Maximum dose = 2000 mg/kg/day
Result: Negative
Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Reproductivity

RANITIDINE HYDROCHLORIDE

Embryo-foetal development - Oral
Result: Foetal NOAEL = 100 mg/kg/day (maximum dose); Maternal NOAEL = 25 mg/kg/day (decreased weight gain at 50 and 100 mg/kg/day)
Species: Rat
Embryo-foetal development - Oral
Result: NOAEL = 100 mg/kg/day (maximum dose)
Species: Rabbit
Fertility
Result: NOAEL / fertility = 100 mg/kg/day (male) and 200 mg/kg/day (female) (maximum doses)
Species: Rat

Specific target organ toxicity - single exposure Not assigned.

Specific target organ toxicity - repeated exposure Not assigned.

Aspiration hazard Not established.

Further information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components		Species	Test Results
RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 1000 mg/l, 3 hours OECD 209
Algae	EC50	Green algae (Selenastrum capricornutum)	167 mg/l, 72 hours OECD 201
	NOEC	Green algae (Selenastrum capricornutum)	56 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	730 mg/l, 48 hours Static test, OECD 202
	NOEC	Water flea (Daphnia magna)	347 mg/l, 48 hours Static test

Components		Species	Test Results
Fish	EC50	Rainbow trout (Juvenile Oncorhyncus mykiss)	> 112 mg/l, 14 days Flow-through test, OECD 203
	NOEC	Rainbow trout (Juvenile Oncorhyncus mykiss)	112 mg/l, 14 days Flow-through test
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	100 mg/l, 8 days Static renewal test, EPA 1002
	NOEC	Water flea (Ceriodaphnia dubia)	32 mg/l, 8 days
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

Half-life (Photolysis-aqueous)

RANITIDINE HYDROCHLORIDE — 70 Minutes Measured, Lake water

UV/visible spectrum wavelength

RANITIDINE HYDROCHLORIDE — 313 nm Measured, pH 7

Hydrolysis

Half-life (Hydrolysis-neutral)

RANITIDINE HYDROCHLORIDE — > 1 Years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

RANITIDINE HYDROCHLORIDE — 2 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge
43 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Percent degradation (Aerobic biodegradation-ready)

RANITIDINE HYDROCHLORIDE — < 1 %, 28 days Modified Sturm test.

Percent degradation (Aerobic biodegradation-soil)

RANITIDINE HYDROCHLORIDE — 3 - 10 %, 67 days

Percent degradation (Anaerobic biodegradation)

RANITIDINE HYDROCHLORIDE — 12 %, 35 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

RANITIDINE HYDROCHLORIDE — 0.0815

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

RANITIDINE HYDROCHLORIDE — 2.51 - 4.49, pH 5-7

Mobility in general

Volatility

Henry's law

RANITIDINE HYDROCHLORIDE — 0 atm m^3/mol, 24 C Estimated

Distribution

Octanol/water distribution coefficient log DOW

RANITIDINE HYDROCHLORIDE	0.14, pH 9 -1.09, pH 7 -2.5, pH 5

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). Avoid discharge into water courses or onto the ground.

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

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 Not established.

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)

SODIUM PHOSPHATE, DIBASIC (CAS 10140-65-5) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

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

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.

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)	Yes
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	Yes
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 05-23-2018

Revision date 05-23-2018

Version # 14

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

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 This document has undergone significant changes and should be reviewed in its entirety.

SAFETY DATA SHEET

1. Identification

Product identifier **ZANTAC INJECTION**

Other means of identification

Synonyms ZANTAC INJECTION 25 MG/ML * ZANTAC INJECTION 50 MG/2ML * ANTAK INJECTION * AZANTAC INJECTION * SOSTRIL INJECTION * ZANTIC INJECTION * ZINETAC INJECTION * RANITIDINE HYDROCHLORIDE, 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

CHEMTREC EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES:
Customer Number: CCN9484
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	%
RANITIDINE HYDROCHLORIDE	AH 19065AB N,N-DIMETHYL-5-(2-(1-METHYLAMINO-2-NITROVINYLAMINO)ETHYLTHIOMETHYL) FURFURYL AMINE HYDROCHLORIDE	66357-59-3	2.5
SODIUM PHOSPHATE, DIBASIC	PHOSPHORIC ACID, DISODIUM SALT, HYDRATE	10140-65-5	0.24

Chemical name	Common name and synonyms	CAS number	%
POTASSIUM PHOSPHATE MONOBASIC	POTASSIUM ACID PHOSPHATE POTASSIUM DIPHOSPHATE POTASSIUM BIPHOSPHATE POTASSIUM ORTHOPHOSPHATE MONOPOTASSIUM PHOSPHATE POTASSIUM DIHYDROGEN PHOSPHATE POTASSIUM DIHYDROGEN ORTHOPHOSPHATE POTASSIUM PHOSPHATE, MONOBASIC	7778-77-0	< 0.1
Other components below reportable levels			90 - 100

*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, trained personnel should give oxygen. 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 Sensitization. The following adverse effects have been noted with therapeutic use of this material:; decrease in heart rate; decrease in blood pressure; temporary decrease in white blood cell counts; increased mucous secretion. Headache. Coughing.

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 In case of fire and/or explosion do not breathe fumes. 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. Avoid breathing mist or vapor. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. 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. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Following product recovery, flush area with water.

Small Spills: Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. 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 discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Avoid prolonged exposure. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing.

Conditions for safe storage, including any incompatibilities Store in a cool, dry place out of direct sunlight. Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Form
POTASSIUM PHOSPHATE MONOBASIC (CAS 7778-77-0)	OHC	1	>1000 - </=5000 mcg/m3
RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)	OHC	3	RESPIRATORY SENSITISER, SKIN SENSITISER
		50 mcg/m3	RESPIRATORY SENSITISER
		50 mcg/m3	SKIN SENSITISER
SODIUM PHOSPHATE, DIBASIC (CAS 10140-65-5)	OHC	1	>1000 - </=5000 mcg/m3

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Appropriate engineering controls General ventilation normally adequate.

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.

Skin protection

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

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.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Ampoule or Vial.

Color Not available.

Odor Not available.

Odor threshold Not available.

pH 6.8 - 7.1

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 applicable.

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.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

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	Hazardous polymerization does not occur.
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 product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact	May cause an allergic skin reaction.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Ingestion	May be harmful if swallowed. 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.
Symptoms related to the physical, chemical and toxicological characteristics	Sensitization. The following adverse effects have been noted with therapeutic use of this material: decrease in heart rate; decrease in blood pressure; temporary decrease in white blood cell counts; increased mucous secretion. Coughing.; Headache.

Information on toxicological effects

Acute toxicity May be harmful if swallowed.

Components	Species	Test Results
RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)		
Acute		
Oral		
LD50	Rat	> 4190 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.

Irritation Corrosion - Skin

RANITIDINE HYDROCHLORIDE	Acute dermal irritation; OECD 404, Primary dermal irritation index = 0 Result: Negative Species: Rabbit

Serious eye damage/eye irritation Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Eye

RANITIDINE HYDROCHLORIDE	Acute ocular irritation; OECD 405, Kay and Calandra score = 3 Result: Minimal Irritant Species: Rabbit IRE Assay Result: Negative; not likely to be a severe irritant Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled.

RANITIDINE HYDROCHLORIDE	Occupational exposure Result: Positive Species: Human

Skin sensitization May cause an allergic skin reaction.

Sensitization

RANITIDINE HYDROCHLORIDE	Occupational exposure Result: Positive Species: Human Optimisation Test Result: Weak sensitiser 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

RANITIDINE HYDROCHLORIDE	Ames Assay, GLP assay Result: Negative Chromosomal Aberration Assay In Vitro, human lymphocytes, Ranitidine bismuth citrate tested Result: Positive Chromosomal Aberration Assay In Vivo; germ cells, Maximum dose = 1000 mg/kg Result: Negative Species: Mouse GreenScreen Assay Result: Negative Micronucleus Test Result: Negative Species: Rat Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay Result: Negative SOS/umu Assay Result: Negative Unscheduled DNA Synthesis in vivo, Maximum dose = 200 mg/kg Result: Negative Species: Rat Organ: Stomach Yeast Mutation Assay Result: Negative

Carcinogenicity Carcinogenic effects are not expected as a result of occupational exposure. Not classifiable as to carcinogenicity to humans.

RANITIDINE HYDROCHLORIDE	2 year bioassay, Maximum dose = 2000 mg/kg/day Result: Negative Species: Mouse 2 year bioassay, Maximum dose = 2000 mg/kg/day Result: Negative Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Reproductivity

RANITIDINE HYDROCHLORIDE	Embryo-foetal development - Oral Result: Foetal NOAEL = 100 mg/kg/day (maximum dose); Maternal NOAEL = 25 mg/kg/day (decreased weight gain at 50 and 100 mg/kg/day) Species: Rat Embryo-foetal development - Oral Result: NOAEL = 100 mg/kg/day (maximum dose) Species: Rabbit Fertility Result: NOAEL / fertility = 100 mg/kg/day (male) and 200 mg/kg/day (female) (maximum doses) Species: Rat

Specific target organ toxicity - single exposure Not assigned.

Specific target organ toxicity - repeated exposure Not assigned.

Aspiration hazard Not established.

Further information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components		Species	Test Results
RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 1000 mg/l, 3 hours OECD 209
Algae	EC50	Green algae (Selenastrum capricornutum)	167 mg/l, 72 hours OECD 201
	NOEC	Green algae (Selenastrum capricornutum)	56 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	730 mg/l, 48 hours Static test, OECD 202
	NOEC	Water flea (Daphnia magna)	347 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Juvenile Oncorhyncus mykiss)	> 112 mg/l, 14 days Flow-through test, OECD 203
	NOEC	Rainbow trout (Juvenile Oncorhyncus mykiss)	112 mg/l, 14 days Flow-through test
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	100 mg/l, 8 days Static renewal test, EPA 1002
	NOEC	Water flea (Ceriodaphnia dubia)	32 mg/l, 8 days

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

RANITIDINE HYDROCHLORIDE	70 Minutes Measured, Lake water

UV/visible spectrum wavelength

RANITIDINE HYDROCHLORIDE	313 nm Measured, pH 7

Hydrolysis

Half-life (Hydrolysis-neutral)

RANITIDINE HYDROCHLORIDE	> 1 Years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

RANITIDINE HYDROCHLORIDE	2 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge 43 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Percent degradation (Aerobic biodegradation-ready)

RANITIDINE HYDROCHLORIDE	< 1 %, 28 days Modified Sturm test.

Percent degradation (Aerobic biodegradation-soil)

RANITIDINE HYDROCHLORIDE	3 - 10 %, 67 days

Percent degradation (Anaerobic biodegradation)

RANITIDINE HYDROCHLORIDE	12 %, 35 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

RANITIDINE HYDROCHLORIDE	0.0815

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

RANITIDINE HYDROCHLORIDE	2.51 - 4.49, pH 5-7

Mobility in general

Volatility

Henry's law

RANITIDINE HYDROCHLORIDE	0 atm m^3/mol, 24 C Estimated

Distribution

Octanol/water distribution coefficient log DOW

RANITIDINE HYDROCHLORIDE	-1.09, pH 7 -2.5, pH 5 0.14, 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 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). Avoid discharge into water courses or onto the ground.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

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 Not established.

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)

SODIUM PHOSPHATE, DIBASIC (CAS 10140-65-5) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

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

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. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

SODIUM PHOSPHATE, DIBASIC (CAS 10140-65-5)

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

SODIUM PHOSPHATE, DIBASIC (CAS 10140-65-5)

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

SODIUM PHOSPHATE, DIBASIC (CAS 10140-65-5)

US. Rhode Island RTK

SODIUM PHOSPHATE, DIBASIC (CAS 10140-65-5)

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

Country(s) or region	Inventory name	On inventory (yes/no)*
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
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	Yes
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 08-14-2013

Revision date 09-12-2016

Version # 14

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

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 This document has undergone significant changes and should be reviewed in its entirety.