

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

1. Identification

Product identifier

ZANTAC INJECTION

Other means of identification

Synonyms

ZANTAC INJECTION 25 MG/ML * ZANTAC INJECTION 50 MG/2ML * ANATK 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.
Environmental precautions	Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. 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.
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Components	Species	Test Results
RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)		
<u>Acute</u>		
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.
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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 Oncorhynchus mykiss)	> 112 mg/l, 14 days Flow-through test, OECD 203
	NOEC	Rainbow trout (Juvenile Oncorhynchus 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 m³/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.

1. Identification

Product identifier

ZANTAC INJECTION

Other means of identification

Synonyms

ZANTAC INJECTION 25 MG/ML * ZANTAC INJECTION 50 MG/2ML * ANATK INJECTION * AZANTAC INJECTION * SOSTRIL INJECTION * ZANTIC INJECTION * ZINETAC INJECTION * RANITIDINE HYDROCHLORIDE, FORMULATED PRODUCT

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2. Hazard(s) identification

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SODIUM PHOSPHATE, DIBASIC	PHOSPHORIC ACID, DISODIUM SALT, HYDRATE	10140-65-5	0.24

Chemical name	Common name and synonyms	CAS number	%
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90 - 100

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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.
Environmental precautions	Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. 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

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>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.
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Components	Species	Test Results
RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)		
<u>Acute</u>		
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.
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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 Oncorhynchus mykiss)	> 112 mg/l, 14 days Flow-through test, OECD 203
	NOEC	Rainbow trout (Juvenile Oncorhynchus 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 m³/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.