



SAFETY DATA SHEET

1. Identification

Product identifier ZANTAC INJECTION
Other means of identification Not available.
Synonym(s) ZANTAC INJECTION 25 MG/ML * 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
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
RANITIDINE HYDROCHLORIDE	AH 19065AB N,N-DIMETHYL-5-(2-(1-METHYLAMINO-2-N AMINE HYDROCHLORIDE 54 (GW ACN)	66357-59-3	3

Other components below reportable levels 97.0

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. If not breathing, give artificial respiration. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Get medical attention immediately.

Skin contact

Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately. For minor skin contact, avoid spreading material on unaffected skin.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion	Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
Most important symptoms/effects, acute and delayed	May cause allergic skin reaction. May cause allergic respiratory reaction. Sensitization. Direct contact with eyes may cause temporary irritation. 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; coughing; headache; increased mucous secretion.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Symptoms may be delayed. No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse. The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed individuals should receive health surveillance focused on detecting respiratory symptoms and including respiratory function testing. In the event of overexposure, individuals should receive post exposure health surveillance focused on detecting respiratory conditions and other allergy symptoms.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. 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	Move containers from fire area if you can do so without risk.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of vapors or mists. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the MSDS.
Methods and materials for containment and cleaning up	<p>Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.</p> <p>Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.</p> <p>Never return spills in original containers for re-use. For waste disposal, see section 13 of the MSDS.</p>
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid breathing mist or vapor. Avoid contact with skin. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK Components	Type	Value	Note
RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)	15 MIN STEL	50 mcg/m3	SKIN SENSITISER
		50 mcg/m3	RESPIRATORY SENSITISER
	OHC	3	
Biological limit values	No biological exposure limits noted for the ingredient(s).		

Appropriate engineering 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. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection Avoid contact with eyes. Face-shield. Wear a full-face respirator, if needed. Eye wash fountain is recommended.

Hand protection The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

Other Wear suitable protective clothing.

Respiratory protection Do not breathe dust/fume/gas/mist/vapors/spray. Wear positive pressure self-contained breathing apparatus (SCBA).

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. 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. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Solution.

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 available.

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) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

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	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	May be harmful if swallowed.
Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact	May cause an allergic skin reaction.
Eye contact	Direct contact with eyes may cause temporary irritation.

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; coughing; headache; increased mucous secretion.

Information on toxicological effects

Acute toxicity May cause allergic skin reaction.

Components	Species	Test Results
RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)		
Acute		
<i>Oral</i>		
LD50	Rat	> 1000 mg/kg

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

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Irritation Corrosion - Skin

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

Serious eye damage/eye irritation Avoid contact with eyes.

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 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.

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 RANITIDINE HYDROCHLORIDE This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. 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

Reproductive toxicity RANITIDINE HYDROCHLORIDE This product is not expected to cause reproductive or developmental effects.
 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 None known.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Not available.

Chronic effects Prolonged inhalation may be harmful.

Further information Caution - Pharmaceutical agent.

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		
<i>Acute</i>		
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

Components	Species		Test Results
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-soil)

RANITIDINE HYDROCHLORIDE 3 - 10 %, 67 days

Percent degradation (Anaerobic biodegradation)

RANITIDINE HYDROCHLORIDE 12 %, 35 days

Bioaccumulative potential Not available.

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. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

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

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as a dangerous good.

Read safety instructions, SDS and emergency procedures before handling.

IMDG

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

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

Not listed.

SARA 304 Emergency release notification

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

No

SARA 311/312 Hazardous chemical

No

NFPA ratings

Health: 2
Flammability: 0
Instability: 0

HMIS® ratings

Health: 2
Flammability: 0
Physical hazard: 0

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

Food and Drug Administration (FDA)

Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No

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	11-29-2013
Revision date	11-29-2013
Version #	13
Further information	HMIS® is a registered trade and service mark of the NPCA.
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	Other information, including date of preparation or last revision: Further information