SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	ZANTAC INJECTION
Registration number	-
Synonyms	ZANTAC INJECTION 25 MG/ML * ANTAK INJECTION * AZANTAC INJECTION * SOSTRIL INJECTION * ZANTIC INJECTION * ZINETAC INJECTION * RANITIDINE HYDROCHLORIDE, FORMULATED PRODUCT
Issue date	29-November-2013
Version number	13
Revision date	29-November-2013
Supersedes date	14-August-2013

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	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.
Uses advised against	No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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

Supplemental label information Not applicable.

2.3. Other hazards Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
RANITIDINE HYDROCHLORIDE	3	66357-59-3 266-333-0	-	-	

Classification: **DSD:** Xn;R22, R42/43

CLP: Acute Tox. 4;H302, Skin Sens. 1;H317, Resp. Sens. 1;H334

Other components below reportable levels 97.0

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

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.

4.1. Description of 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 centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person.

4.2. Most important symptoms and effects, both acute and delayed May cause allergic skin reaction. May cause allergic respiratory reaction. Sensitisation. 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.

4.3. Indication of any 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.

SECTION 5: Firefighting measures

General fire hazards Expected to be non-combustible.

5.1. Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO_2).

Unsuitable extinguishing media None known.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures Move containers from fire area if you can do so without risk.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch or walk through spilled material. Avoid inhalation of vapours or mists. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.
6.2. Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material 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. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills in original containers for re-use.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid breathing mist or vapour. Avoid contact with skin. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
7.2. 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).
7.3. Specific end use(s)	Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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).
Recommended monitoring procedures	Follow standard monitoring procedures.
Derived No Effect Level (DNEL)	Not available.
Predicted no effect concentrations (PNECs)	Not available.

8.2. Exposure controls

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

General information	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.
Eye/face protection	Avoid contact with eyes. Face-shield. (eg. EN 166) Wear a full-face respirator, if needed. Eye wash fountain is recommended.
Skin protection	

- 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. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Wear suitable protective clothing. (EN 14605 for splashes, EN ISO 13982 for dust)
Respiratory protection	Do not breathe dust/fume/gas/mist/vapors/spray. Wear positive pressure self-contained breathing apparatus (SCBA). Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	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.
Environmental exposure controls	
Hazard guidance and control recommendations	Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Solution.
Colour	Not available.
Odour	Not available.
Odour 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.
Vapour pressure	Not available.
Vapour 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.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.

10.4. Conditions to avoid Contact with incompatible materials.

10.5. Incompatible materials Strong oxidising agents.

10.6. Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

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 Sensitisation. 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.

11.1. Information on toxicological effects

Acute toxicity May cause allergic skin reaction.

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

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

Skin corrosion/irritation Due to partial or complete lack of data the classification is not possible.

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 sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled.

RANITIDINE HYDROCHLORIDE

Occupational exposure
Result: positive
Species: Human

Skin sensitisation May cause an allergic skin reaction.

Sensitisation

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.

Germ cell mutagenicity

Mutagenicity

RANITIDINE HYDROCHLORIDE

Ames Assay, GLP assay
Result: negative
Chromosomal Aberration Assay In Vitro, human lymphocytes, Ranitidine bismuth citrate tested
Result: positive

Mutagenicity

RANITIDINE HYDROCHLORIDE

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 Due to partial or complete lack of data the classification is not possible.

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

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

Reproductive toxicity

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 None known.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Due to partial or complete lack of data the classification is not possible.

Mixture versus substance information No information available.

Other information Caution - Pharmaceutical agent.

SECTION 12: Ecological information

12.1. Toxicity 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

Components		Species	Test results
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.

12.2. Persistence and degradability

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

12.3. Bioaccumulative potential Not available.

Partition coefficient n-octanol/water (log Kow)

RANITIDINE HYDROCHLORIDE — 0.0815

12.4. 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

12.5. Results of PBT and vPvB assessment Not a PBT or vPvB substance or mixture.

12.6. Other adverse effects Not available.

12.7. Additional information Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	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.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	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.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Read safety instructions, SDS and emergency procedures before handling.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 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.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed.

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations	The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.
National regulations	Young people under 18 years old are not allow to work with this product according to the EU Directive 94/33/EC on the protection of young people at work. Follow national regulation for work with chemical agents.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R22 Harmful if swallowed. R42/43 May cause sensitization by inhalation and skin contact. H302 Harmful if swallowed. H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Revision information	None.
Training information	Follow training instructions when handling this material.
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.