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 SYRUP
Registration number	-
Synonyms	ZANTAC SYRUP 15 MG/ML * ANTAK ORAL SOLUTION * AZANTAC ORAL SOLUTION * ZANTAC SIROP * RANITIDINE HYDROCHLORIDE, FORMULATED PRODUCT
Issue date	11-November-2013
Version number	11
Revision date	11-November-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 This product is flammable.
Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.
No information is available about the potential of this product to produce adverse environmental effects.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
ETHANOL	5 - < 10	64-17-5 200-578-6	-	603-002-00-5	
Classification: **DSD:** F;R11, Xi;R36 **CLP:** Flam. Liq. 2;H225, Eye Irrit. 2;H319					
RANITIDINE HYDROCHLORIDE	1 - < 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					
MINT FLAVOUR	< 1	Unassigned -	-	-	
Classification: **DSD:** Xn;R22-65, Xi;R38, R43, N;R51/53 **CLP:** Acute Tox. 4;H302, Asp. Tox. 1;H304, Skin Irrit. 2;H315, Skin Sens. 1;H317, Aquatic Chronic 2;H411					
BUTYL PARABEN	< 0.1	94-26-8 202-318-7	-	-	
Classification: **DSD:** - **CLP:** -					
PROPYL PARABEN	< 0.1	94-13-3 202-307-7	-	-	
Classification: **DSD:** Xi;R36 **CLP:** Eye Irrit. 2;H319					

Other components below reportable levels >85.0

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 Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

4.1. Description of first aid measures

Inhalation 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 Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

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 centre immediately.

4.2. Most important symptoms and effects, both acute and delayed Accidental exposure or contact might produce: 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.

4.3. Indication of any 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 centre.

SECTION 5: Firefighting measures

General fire hazards This product is flammable.

5.1. Extinguishing media

Suitable extinguishing media	Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Water jets may intensify the fire or be ineffective. Do not use water extinguishers.
5.2. Special hazards arising from the substance or mixture	Fire may produce irritating, corrosive and/or toxic gases.

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	In the event of fire, cool tanks with water spray. For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal. Move containers from the fire area if possible without increased personal risk.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Fence or cordon the affected area and do not allow individuals to touch or walk through the spilled material unless wearing appropriate protective clothing. Keep unnecessary personnel away. Wear protective clothing and equipment consistent with the degree of hazard. Stop leak and eliminate all sources of ignition (no smoking, sparks or flames). Vapour-suppressing foam or water spray may be used to control vapours as appropriate. 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	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
6.3. Methods and material for containment and cleaning up	Spread an inert absorbent on the spill and place in a suitable, properly labelled container for recovery or disposal. Stop the flow of material, if this is without risk. Equipment used for clean-up should be earthed (grounded) and non-sparking. Dike far ahead of spill for later disposal. Following product recovery, flush area with water. Never return spills in original containers for re-use. No specific decontamination or detoxification procedures have been identified for this product. Water can be used for clean-up and decontamination operations.
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	This material contains flammable components. Ensure that any area in which this material is handled has sufficient ventilation to avoid the build up of vapour and to control employee potential exposure to volatiles below National Occupational Exposure Limits. Avoid contact with ignition sources. This liquid might ignite in contact with some types of ignition source.
7.2. Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the MSDS). Keep in tightly sealed containers or packages in a well-ventilated area. No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy. Keep away from sources of ignition.
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
PROPYL PARABEN (CAS 94-13-3)	8 HR TWA	5000 mcg/m3	
	OHC	1	
RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)	15 MIN STEL	50 mcg/m3	RESPIRATORY SENSITISER
		50 mcg/m3	SKIN SENSITISER
	OHC	3	

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
ETHANOL (CAS 64-17-5)	TWA	1920 mg/m3

UK. EH40 Workplace Exposure Limits (WELs)		
Components	**Type**	**Value**
		1000 ppm

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	Follow all local regulations if personal protective equipment (PPE) is used in the workplace.
Eye/face protection	Wear safety glasses with side shields (or goggles). (eg. EN 166) 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	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	Follow all local regulations if personal protective equipment (PPE) is used in the workplace. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

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	Syrup.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	49 - 50 °C (120.2 - 122 °F) Closed cup . (Does not support sustained combustion)
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	This product is expected to be stable.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Avoid temperatures exceeding the flash point. Contact with incompatible materials. Avoid direct sunlight, conditions that might generate heat and sources of ignition.
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 Caution - Pharmaceutical agent.

Information on likely routes of exposure

Ingestion	May be harmful if swallowed.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Direct contact with eyes may cause temporary irritation.

Symptoms Accidental exposure or contact might produce: 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; increased mucous secretion.

11.1. Information on toxicological effects

Acute toxicity May be harmful if swallowed.

Components	Species	Test results
BUTYL PARABEN (CAS 94-26-8)		
Acute		
Oral		
LD50	Mouse	> 5000 mg/kg
ETHANOL (CAS 64-17-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
Chronic		
Oral		
LOAEL	Monkey	40 %, 48 months, % ingested calories
Subacute		
Oral		
LOEL	Rat	16.9 g/kg, 4 weeks, Dietary - Dose given as g/kg/day
		6 %, 4 weeks, percent in diet - continuous
Subchronic		
Inhalation		
LOEL	Rat	2 ml, 36 weeks, haematological parameters

Components	Species	Test results
NOAEL	Guinea pig	3000 ppm, No adverse effects
	Rat	86 mg/m3, 90 Day, Daily dosing
Oral		
LOAEL	Rat	5000 mg/kg/day, 10 weeks, Liver toxicity
		80 ml/kg, 85 Day, Daily dose - Liver toxicity
		10.2 g/kg, 12 weeks, Dosed in drinking water - Continuous
		7.7 g/kg, 12 weeks, Dosed in drinking water - continuous
PROPYL PARABEN (CAS 94-13-3)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
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 Health injuries are not known or expected under normal use.

Corrosivity

ETHANOL
OECD 404
Result: Negative; not considered a significant irritant
Species: Rabbit

Irritation Corrosion - Skin

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

Serious eye damage/eye irritation 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

ETHANOL
OECD 405
Result: Severe
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

ETHANOL
OECD 406
Result: negative
Species: Guinea pig

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

ETHANOL
Ames
Result: negative

Mutagenicity

RANITIDINE HYDROCHLORIDE	Ames Assay, GLP assay Result: negative
ETHANOL	Chromosomal Aberration Assay In Vitro, CHO cells Result: negative
RANITIDINE HYDROCHLORIDE	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
ETHANOL	Dominant lethal assay Result: positive Species: Mouse Dominant lethal assay Result: positive Species: Rat Gene mutation and repair Result: negative Species: Bacteria Gene mutation and repair Result: positive Species: Bacteria
RANITIDINE HYDROCHLORIDE	GreenScreen Assay Result: negative
ETHANOL	In vitro cytogenetics assay Result: positive In vitro cytogenetics assay Result: positive Species: Aspergillus niger L5178Y mouse lymphoma thymidine kinase locus assay Result: Weakly positive
RANITIDINE HYDROCHLORIDE	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
ETHANOL	Yeast mutation Result: negative Yeast mutation Result: positive in vitro micronucleus assay Result: negative in vivo cytogenetics assay Result: negative Species: Hamster in vivo cytogenetics assay Result: negative Species: Rat in vivo cytogenetics assay Result: positive Species: Mouse sister chromatid exchange Result: positive

Carcinogenicity Health injuries are not known or expected under normal use.

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

Carcinogenicity

ETHANOL	Epidemiology, causation linked to excessive consumption. Species: Human Organ: oral cavity, larynx, pharynx, oesophagus, liver Neonatal, inadequate study Result: negative Species: Rat inadequate study Result: Increase in liver sarcomas Species: Mouse inadequate study Result: Time to tumour reduced Species: Mouse Test Duration: 80 weeks inadequate study Result: negative Species: Hamster Test Duration: 807 Day inadequate study Result: negative Species: Mouse Test Duration: 1020 Day inadequate study Result: negative Species: Rat inadequate study Result: negative Species: Rat Test Duration: 78 weeks

Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

Reproductive toxicity

Reproductivity

ETHANOL	0.3 - 4.1 g/kg Embryo-foetal development - Oral, daily dose Species: Monkey Organ: facial anomolies, nervous system dysfunction 1 - 2 g/kg Embryo-foetal development - Oral, daily dose Result: embryolethality Species: Rat 1.8 g/kg Embryo-foetal development - Oral, daily dose Result: Increased abortion Species: Monkey 5 g/kg Embryo-foetal development - Oral, daily dose - intravenous Result: reduced foetal body weight; no malformations or other variations Species: Monkey 7 - 17 g/kg Embryo-foetal development - Oral, daily dose - gavage Species: Rat Organ: skeletal malformations, dilated renal pelves
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
ETHANOL	Embryo-foetal development - Oral, 15-30% in diet Result: resorptions, neural defects, cardiac malformations Species: Mouse Embryo-foetal development - Oral, Causation is linked to excessive consumption. Species: Human Organ: growth deficiency, CNS dysfunction, facial defects, major organ malformation Embryofetal Development, in utero - 36% total calories Species: Rat Organ: gonadal growth and development

Reproductivity

RANITIDINE HYDROCHLORIDE	Fertility Result: NOAEL / fertility = 100 mg/kg/day (male) and 200 mg/kg/day (female) (maximum doses) Species: Rat
ETHANOL	Fertility, Female, 10% in drinking water Result: negative Species: Rat Fertility, Female, 20-25% total calories Result: negative Species: Rat Fertility, Male, 5-6% v/v liquid diet Species: Mouse Organ: significant effects on testes and seminal vesicles Test Duration: 70 Day

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Not available.

Mixture versus substance information No information available.

Other information Caution - Pharmaceutical agent.

SECTION 12: Ecological information

12.1. Toxicity The product contains a substance which may cause long-term adverse effects in the environment. No information is available about the potential of this product to produce adverse environmental effects.

Components		Species	Test results
ETHANOL (CAS 64-17-5)			
Aquatic			
Acute			
Algae	EC50	Blue-green algae (Microcystis aeruginosa)	1450 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	9190 mg/l, 48 hours, Static test
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	14200 mg/l, 96 hours, Flow-through test
		Rainbow trout (Adult Salmo gairdneri)	13000 mg/l, 96 hours, Static test
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.

12.2. Persistence and degradability

Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

ETHANOL	1 - 36.6 years Measured
RANITIDINE HYDROCHLORIDE	70 Minutes Measured, Lake water

Half-life (Photolysis-atmospheric)

ETHANOL	4 - 5.9 Days Estimated

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)

ETHANOL	37 - 86 %, 5 days BOD5, Activated sludge
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

Partition coefficient n-octanol/water (log Kow)

BUTYL PARABEN	3.57
ETHANOL	-0.31
PROPYL PARABEN	3.04
RANITIDINE HYDROCHLORIDE	0.0815

Bioconcentration factor (BCF)

BUTYL PARABEN	302 Calculated

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

BUTYL PARABEN	2.9 Calculated
ETHANOL	1.2 Calculated
RANITIDINE HYDROCHLORIDE	2.51 - 4.49, pH 5-7

Mobility in general

Volatility

Henry's law

BUTYL PARABEN	0 atm m3/mol Calculated
ETHANOL	0.000005 atm m3/mol Measured
RANITIDINE HYDROCHLORIDE	0 atm m^3/mol, 24 C Estimated

Distribution

Octanol/water distribution coefficient log DOW

PROPYL PARABEN	3.04
RANITIDINE HYDROCHLORIDE	-1.09, pH 7 -2.5, pH 5 0.14, pH 9

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects 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. Observe all local and national regulations when disposing of this product. Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.
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.

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

ETHANOL (CAS 64-17-5)

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

ETHANOL (CAS 64-17-5)

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 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

R11 Highly flammable.
R22 Harmful if swallowed.
R36 Irritating to eyes.
R38 Irritating to skin.
R42/43 May cause sensitization by inhalation and skin contact.
R43 May cause sensitization by skin contact.
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R65 Harmful: may cause lung damage if swallowed.
H225 Highly flammable liquid and vapour.
H302 Harmful if swallowed.
H304 May be fatal if swallowed and enters airways.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H411 Toxic to aquatic life with long lasting effects.

Revision information

Product and Company Identification: Business Units
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
Transport Information: Agency Name and Packaging Type/Transport Mode Selection
Regulatory Information: United States
GHS: Classification

Training information Follow training instructions when handling this material.

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