



SAFETY DATA SHEET

1. Identification

Product identifier ZANTAC SYRUP
Other means of identification Not available.
Synonym(s) ZANTAC SYRUP 15 MG/ML * ANTAK ORAL SOLUTION * AZANTAC ORAL SOLUTION *
ZANTAC SIROP * 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	%
ETHANOL	243 (GW ACN) ALCOHOL ALCOHOL ANHYDROUS ANHYDROUS ETHANOL ANHYDROUS ETHYL ALCOHOL ETHANOL 200 PROOF ETHYL ALCOHOL ETHYL ALCOHOL USP 200 PROOF (USI) ETHYL ALCOHOL, 100% ETHYL HYDRATE ETHYL HYDROXIDE ETHYLIC ALCOHOL GRAIN ALCOHOL METHYL CARBINOL RTECS KQ6300000 UN 1170 ALCOHOL ETILICO (ETANOL) ALCOOL ETILICO ALCOOL ÉTHYLIQUE ETANOL ETANOLI ETANOLO ETANOOL ETHANOL ETHYLALCOHOL ETHYLALKOHOL ÁLCOOL ETÍLICO ÉTHANOL ÉTHANOL (ALCOOL ÉTHYLIQUE) OU ÉTHANOL EN SOLUTION (ALCOOL ÉTHYLIQUE EN SOLUTION)	64-17-5	5 - < 10
RANITIDINE HYDROCHLORIDE	AH 19065AB N,N-DIMETHYL-5-(2-(1-METHYLAMINO-2-N AMINE HYDROCHLORIDE 54 (GW ACN)	66357-59-3	1 - < 3
MINT FLAVOUR		Unassigned	< 1
PROPYL PARABEN	PROPYL P-HYDROXYBENZOATE NIPASOL TEGOSEPT P PROTABEN 4-HYDROXYBENZOIC ACID, PROPYL ESTER P-HYDROXYBENZOIC ACID, PROPYL ESTER PASEPTOL PARASEPT ASEPTOFORM P BETACIDE P BONOMOLD OP PROPYL ASEPTOFORM PROPYL P-OXYBENZOATE PROPYL CHEMOSEPT PRESERVAL P CHEMOCIDE PK SOLBROL P PROPYL PARASEPT C10H12O3 OHS19941 RTECS DH2800000	94-13-3	< 0.1

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
BUTYL PARABEN	BENZOIC ACID, 4-HYDROXY-, BUTYL ESTER BENZOIC ACID, P-HYDROXY-, BUTYL ESTER 4-(BUTOXYCARBONYL)PHENOL BUTYL P-HYDROXYBENZOATE BUTYL 4-HYDROXYBENZOATE P-HYDROXYBENZOIC ACID BUTYL ESTER 4-HYDROXYBENZOIC ACID BUTYL ESTER BUTOBEN BUTYL CHEMOSEPT BUTYL PARASEPT TEGOSEPT B BUTYL TEGOSEPT SOLBROL B N-BUTYL PARAHYDROXYBENZOATE BUTYL PARABEN	94-26-8	0.008
Other components below reportable levels			>85.0

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

4. 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 center immediately.
Most important symptoms/effects, acute and delayed	Accidental exposure or contact might produce: 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.
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 centre.
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.

5. Fire-fighting measures

Suitable extinguishing media	Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Water jets may intensify the fire or be ineffective. Do not use water extinguishers.
Specific hazards arising from the chemical	Fire may produce irritating, corrosive and/or toxic gases.
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 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.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	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 of the MSDS.
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Methods and materials 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. For waste disposal, see section 13 of the MSDS. No specific decontamination or detoxification procedures have been identified for this product. Water can be used for clean-up and decontamination operations.

Environmental precautions

Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.

7. Handling and storage**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.

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.

8. Exposure controls/personal protection**Occupational exposure limits****GSK****Components****Type****Value****Note**

PROPYL PARABEN (CAS 94-13-3)

8 HR TWA

5000 mcg/m³

RANITIDINE HYDROCHLORIDE (CAS 66357-59-3)

OHC
15 MIN STEL

1
50 mcg/m³

RESPIRATORY SENSITISER

OHC

50 mcg/m³
3

SKIN SENSITISER

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**Components****Type****Value**

ETHANOL (CAS 64-17-5)

PEL

1900 mg/m³
1000 ppm

US. ACGIH Threshold Limit Values**Components****Type****Value**

ETHANOL (CAS 64-17-5)

STEL

1000 ppm

US. NIOSH: Pocket Guide to Chemical Hazards**Components****Type****Value**

ETHANOL (CAS 64-17-5)

TWA

1900 mg/m³
1000 ppm

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**

Wear safety glasses with side shields (or goggles). 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

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

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.

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Syrup.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	120.2 - 122 °F (49 - 50 °C) 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.
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	This product is expected to be stable.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
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.
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	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 related to the physical, chemical and toxicological characteristics	Accidental exposure or contact might produce: 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; increased mucous secretion.

Information on toxicological effects

Acute toxicity	May be harmful if swallowed.
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Components	Species	Test Results
BUTYL PARABEN (CAS 94-26-8)		
Acute		
<i>Oral</i>		
LD50	Mouse	> 5000 mg/kg
ETHANOL (CAS 64-17-5)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
Chronic		
<i>Oral</i>		
LOAEL	Monkey	40 %, 48 months, % ingested calories
Subacute		
<i>Oral</i>		
LOEL	Rat	16.9 g/kg, 4 weeks, Dietary - Dose given as g/kg/day 6 %, 4 weeks, percent in diet - continuous
Subchronic		
<i>Inhalation</i>		
LOEL	Rat	2 ml, 36 weeks, haematological parameters
NOAEL	Guinea pig	3000 ppm, No adverse effects
	Rat	86 mg/m3, 90 Day, Daily dosing
<i>Oral</i>		
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		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
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	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

Eye		
	ETHANOL	OECD 405 Result: Severe 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		
	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.	
	ETHANOL	Ames Result: Negative
	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

ETHANOL

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

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: 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
inadequate study
Result: Time to tumour reduced
Species: Mouse
Test Duration: 80 weeks

US. National Toxicology Program (NTP) Report on Carcinogens

ETHANOL (CAS 64-17-5)

Known To Be Human Carcinogen.

Reproductive toxicity

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

ETHANOL

0.3 - 4.1 g/kg Embryo-foetal development - Oral, daily dose
Species: Monkey
Organ: facial anomalies, nervous system dysfunction
1 - 2 g/kg Embryo-foetal development - Oral, daily dose
Result: embryoletality
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

ETHANOL	7 - 17 g/kg Embryo-foetal development - Oral, daily dose - gavage Species: Rat
RANITIDINE HYDROCHLORIDE	Organ: skeletal malformations, dilated renal pelves 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
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.
Further information	Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity 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		
<i>Acute</i>		
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		
<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

Components		Species	Test Results
	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
<i>Chronic</i>			
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)

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-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)

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

Bioconcentration factor (BCF)

BUTYL PARABEN 302 Calculated

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 m³/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

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions	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.
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.
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

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

ETHANOL (CAS 64-17-5) 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 - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

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

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

US. Massachusetts RTK - Substance List

ETHANOL (CAS 64-17-5)

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

ETHANOL (CAS 64-17-5)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

ETHANOL (CAS 64-17-5)

Listed: April 29, 2011

Listed: July 1, 1988

US - California Proposition 65 - CRT: Listed date/Developmental toxin

ETHANOL (CAS 64-17-5)

Listed: October 1, 1987

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
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	No
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** 11-11-2013**Revision date** 11-11-2013**Version #** 11**Further information** This material has not been assessed for HMIS or NFPA ratings.**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** Product and Company Identification: Business Units
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
Transport Information: Agency Name, Packaging Type, and Transport Mode Selection
Regulatory Information: United States
GHS: Classification