

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

### 1.1. Product identifier

Trade name or designation of the mixture	BEECHAMS ALL-IN-ONE LIQUID
Registration number	-
Synonyms	BEECHAMS ALL-IN-ONE LIQUID (UK) * R&D CODE 50/56 * PARACETAMOL, GUAIPHENESIN AND PHENYLEPHRINE HYDROCHLORIDE, FORMULATED PRODUCT
Issue date	01-August-2014
Version number	12
Revision date	01-August-2014

### 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 None.

### 2.3. Other hazards

Flammable liquid and vapour.  
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
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D-SORBITOL	< 25	50-70-4 200-061-5	-	-	
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**Classification:** **DSD:** -  
**CLP:** -

ETHANOL	< 20	64-17-5 200-578-6	-	603-002-00-5	
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**Classification:** **DSD:** F;R11, Xi;R36  
**CLP:** Flam. Liq. 2;H225, Eye Irrit. 2;H319

PARACETAMOL	< 3	103-90-2 203-157-5	-	-	
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**Classification:** **DSD:** Xn;R22, R52/53  
**CLP:** Acute Tox. 4;H302, Aquatic Chronic 3;H412

GUAIPHENESIN	< = 1	93-14-1 202-222-5	-	-	
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**Classification:** **DSD:** Xn;R22  
**CLP:** Acute Tox. 4;H302

SODIUM CYCLAMATE	< 1	139-05-9 205-348-9	-	-	
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**Classification:** **DSD:** Xn;R22  
**CLP:** Acute Tox. 4;H302

CITRIC ACID ANHYDROUS	< 0.5	77-92-9 201-069-1	-	-	
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**Classification:** **DSD:** Xi;R36  
**CLP:** Skin Corr. 1;H314, Eye Irrit. 2;H319

PHENYLEPHRINE HYDROCHLORIDE	< 0.1	61-76-7 200-517-3	-	-	
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**Classification:** **DSD:** Repr. Cat. 3;R62-63, T;R24, Xn;R22, Xi;R37, N;R50/53  
**CLP:** Acute Tox. 4;H302, Acute Tox. 3;H311, Acute Tox. 4;H312, STOT SE 3;H335, Repr. 2;H361, Aquatic Acute 1;H400, Aquatic Chronic 1;H410

Other components below reportable levels < 61

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** In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

**4.1. Description of first aid measures**

**Inhalation** Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

**Skin contact** Immediately flush skin with plenty of water. Get medical attention if symptoms occur. Take off contaminated clothing and wash before reuse.

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

<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). Do not induce vomiting without medical advice. If ingestion of a large amount does occur, call a poison control centre immediately.
<b>4.2. Most important symptoms and effects, both acute and delayed</b>	None known.
<b>4.3. Indication of any immediate medical attention and special treatment needed</b>	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

<b>General fire hazards</b>	Flammable liquid and vapour.
<b>5.1. Extinguishing media</b>	
<b>Suitable extinguishing media</b>	Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Water.
<b>5.2. Special hazards arising from the substance or mixture</b>	Vapours may form explosive mixtures with air. Vapours may travel considerable distance to a source of ignition and flash back. During fire, gases hazardous to health may be formed.
<b>5.3. Advice for firefighters</b>	
<b>Special protective equipment for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Special fire fighting procedures</b>	In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

## SECTION 6: Accidental release measures

<b>6.1. Personal precautions, protective equipment and emergency procedures</b>	
<b>For non-emergency personnel</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapour. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.
<b>For emergency responders</b>	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up.
<b>6.2. Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.
<b>6.3. Methods and material for containment and cleaning up</b>	Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Keep combustibles (wood, paper, oil etc) away from spilled material.  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. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Use water spray to reduce vapours or divert vapour cloud drift. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.  Small Spills: Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.  Never return spills to original containers for re-use.
<b>6.4. Reference to other sections</b>	For personal protection, see section 8. For waste disposal, see section 13.

## SECTION 7: Handling and storage

<b>7.1. Precautions for safe handling</b>	Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Do not breathe mist or vapour. Avoid prolonged exposure. When using, do not eat, drink or smoke. Provide adequate ventilation. Wash hands thoroughly after handling.
<b>7.2. Conditions for safe storage, including any incompatibilities</b>	Keep away from heat and sources of ignition. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store in a well-ventilated place.
<b>7.3. Specific end use(s)</b>	Medicinal Product

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Occupational exposure limits

##### GSK

Components	Type	Value
CITRIC ACID ANHYDROUS (CAS 77-92-9)	8 HR TWA	5000 mcg/m3
	OHC	1
D-SORBITOL (CAS 50-70-4)	OHC	1
GUAIPHENESIN (CAS 93-14-1)	8 HR TWA	600 mcg/m3
	OHC	2
PARACETAMOL (CAS 103-90-2)	8 HR TWA	4000 mcg/m3
	OHC	1
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)	15 MIN STEL	200 mcg/m3
	8 HR TWA	30 mcg/m3
	OHC	3

##### UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
ETHANOL (CAS 64-17-5)	TWA	1920 mg/m3 1000 ppm	
PARACETAMOL (CAS 103-90-2)	TWA	10 mg/m3	Inhalable dust.

#### 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

General ventilation normally adequate. 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.

#### Individual protection measures, such as personal protective equipment

##### General information

Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Use personal protective equipment as required. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

##### Eye/face protection

If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

##### Skin protection

###### - Hand protection

For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

###### - Other

Wear suitable protective clothing as protection against splashing or contamination. (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). If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.

##### 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.

## 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

<b>Physical state</b>	Liquid.
<b>Form</b>	Syrupy liquid.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	38 °C (100.4 °F) Closed cup (Estimation based on components).
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Solubility (other)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Explosive properties</b>	Not available.
<b>Oxidizing properties</b>	Not available.

### 9.2. Other information

**Percent volatile** 56.1 % estimated

## SECTION 10: Stability and reactivity

<b>10.1. Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>10.2. Chemical stability</b>	Material is stable under normal conditions.
<b>10.3. Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>10.4. Conditions to avoid</b>	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
<b>10.5. Incompatible materials</b>	Strong oxidising agents.
<b>10.6. Hazardous decomposition products</b>	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

<b>Ingestion</b>	May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
<b>Inhalation</b>	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** Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

**Symptoms** None known.

**11.1. Information on toxicological effects**

**Acute toxicity** May be harmful if swallowed. Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test results
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	3000 mg/kg
D-SORBITOL (CAS 50-70-4)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	15.9 g/kg
ETHANOL (CAS 64-17-5)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
<b>Chronic</b>		
<i>Oral</i>		
LOAEL	Monkey	40 %, 48 months % ingested calories
<b>Subacute</b>		
<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
<b>Subchronic</b>		
<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
GUAIPHENESIN (CAS 93-14-1)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	1510 mg/kg
PARACETAMOL (CAS 103-90-2)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	1944 mg/kg
TD	Human	>= 150 mg/kg
<b>Subacute</b>		
<i>Oral</i>		
NOAEL	Rat	12500 ppm, 14 Day dietary, continuous
<b>Subchronic</b>		
<i>Oral</i>		
NOAEL	Rat	6200 ppm, 13 weeks dietary, continuous

Components	Species	Test results
TD	Rat	>= 12500 ppm, 13 weeks dietary, continuous
<i>Other</i>		
LOAEL	Mouse	130 ppm, 61 weeks dietary, continuous
NOAEL	Mouse	3200 ppm, 13 weeks dietary, continuous 0.3 %, 41 weeks dietary, continuous
TD	Mouse	6100 ppm, 13 weeks dietary, continuous 1.25 %, 41 weeks dietary, continuous

PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)

**Acute**

*Oral*

LD50 Rat 350 mg/kg

**Subacute**

*Oral*

NOAEL Mouse 2000 ppm, 14 Day Dietary study, highest dose tested.

Rat 2000 ppm, 14 Day Dietary study, highest dose tested.

**Subchronic**

*Oral*

LD Mouse 5000 - 20000 ppm, 12 weeks dietary study

Rat 5000 - 20000 ppm, 12 weeks dietary study

LOAEL Mouse 1250 ppm, 12 weeks dietary study

Rat 1250 ppm, 12 weeks dietary study

SODIUM CYCLAMATE (CAS 139-05-9)

**Acute**

*Oral*

LD50 Rat 1280 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**

PHENYLEPHRINE HYDROCHLORIDE

Supplier SDS

Result: Non-irritant

Species: Rabbit

Notes: US Pharmacopeia

**Irritation Corrosion - Skin: P.I.I. value**

PARACETAMOL

OECD 404, Literature data

Result: Slight irritant

Species: Rabbit

**Serious eye damage/eye irritation** Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.

**Eye**

PHENYLEPHRINE HYDROCHLORIDE

Clinical use

Result: Pharmacological, cardiovascular effects.

Species: Human

ETHANOL

OECD 405

Result: Severe

Species: Rabbit

PARACETAMOL

OECD 405

Result: Slight irritant

Species: Rabbit

PHENYLEPHRINE HYDROCHLORIDE

Supplier SDS

Result: Irritant

**Eye / Initial pain reaction score**

PARACETAMOL

Literature data

<b>Respiratory sensitisation</b>	Not available.
<b>Skin sensitisation</b>	This product is not expected to cause skin sensitisation.
<b>Sensitisation</b>	
PHENYLEPHRINE HYDROCHLORIDE	Clinical use - Ophthalmology Result: Low incidence of contact hypersensitivity. Species: Human
ETHANOL	OECD 406 Result: negative Species: Guinea pig
GUAIPHENESIN	SAR / QSAR, DEREK, Lhasa, UK Result: negative
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
<b>Mutagenicity</b>	
ETHANOL	Ames Result: negative
PHENYLEPHRINE HYDROCHLORIDE	Ames Result: negative Notes: NTP Study report - Phenylephrine.
PARACETAMOL	Ames, Literature data Result: negative
ETHANOL	Chromosomal Aberration Assay In Vitro, CHO cells Result: negative
PHENYLEPHRINE HYDROCHLORIDE	Chromosomal Aberration Assay In Vitro, CHO cells Result: negative Notes: NTP Study report - Phenylephrine.
PARACETAMOL	Chromosomal Aberration Assay In Vitro, Literature data Result: positive
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
PARACETAMOL	HPRT gene mutation in human lymphocytes, Literature data Result: negative
ETHANOL	In vitro cytogenetics assay Result: positive In vitro cytogenetics assay Result: positive Species: Aspergillus niger
PARACETAMOL	In vivo Micronucleus, Literature data Result: negative Species: Mouse
PHENYLEPHRINE HYDROCHLORIDE	L5178Y mouse lymphoma thymidine kinase locus assay Result: Equivocal Notes: NTP Study report - Phenylephrine.
ETHANOL	L5178Y mouse lymphoma thymidine kinase locus assay Result: Weakly positive
GUAIPHENESIN	SAR / QSAR, DEREK, Lhasa, UK 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

**Mutagenicity**  
ETHANOL

in vivo cytogenetics assay  
Result: positive  
Species: Mouse  
sister chromatid exchange  
Result: positive  
sister chromatid exchange  
Result: positive  
Notes: NTP Study report - Phenylephrine.

PHENYLEPHRINE HYDROCHLORIDE

**Carcinogenicity**

Health injuries are not known or expected under normal use. Contains a material (ethanol) classified as a carcinogen by external agencies. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

PHENYLEPHRINE HYDROCHLORIDE

133 - 270 mg/kg/day  
Result: negative  
Species: Mouse  
Test Duration: 103 weeks  
Notes: NTP Report - Tox and carc studies with phenylephrine hydrochloride.  
24 - 50 mg/kg/day  
Result: negative  
Species: Rat  
Test Duration: 103 weeks  
Notes: NTP Report - Tox and carc studies with phenylephrine hydrochloride.

ETHANOL

Epidemiology, causation linked to excessive consumption.  
Species: Human  
Organ: oral cavity, larynx, pharynx, oesophagus, liver

PARACETAMOL

Literature data  
Result: Equivocal. Increase in adenomas at toxic dose.  
Species: Mouse  
Literature data  
Result: Equivocal. Liver and bladder neoplasms at toxic doses.  
Species: Rat  
Literature data  
Result: negative  
Species: Mouse  
Literature data  
Result: negative  
Species: Rat

ETHANOL

Neonatal, inadequate study  
Result: negative  
Species: Rat

GUAIPHENESIN

SAR / QSAR, DEREK, Lhasa, UK  
Result: negative

ETHANOL

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

**IARC Monographs. Overall Evaluation of Carcinogenicity**

PARACETAMOL (CAS 103-90-2)

3 Not classifiable as to carcinogenicity to humans.

SODIUM CYCLAMATE (CAS 139-05-9)

3 Not classifiable as to carcinogenicity to humans.

**Reproductive toxicity**

Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

**Reproductivity**

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: embryoethality Species: Rat 1.8 g/kg Embryo-foetal development - Oral, daily dose Result: Increased abortion Species: Monkey
PARACETAMOL	250 mg/kg/day Embryofetal Development, Literature data Result: Foetal NOAEL Species: Rat 387 mg/kg/day Embryofetal Development, Literature data Result: negative Species: Mouse
ETHANOL	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
PARACETAMOL	750 mg/kg/day Embryofetal Development, Literature data Result: decrease in foetal weight, minor skeletal abnormalities. Species: Rat <= 1400 mg/kg/day Pre- and Post-natal development, Literature data Result: reduced weight gain during nursing. Species: Rat
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
GUAIPHENESIN	Embryofetal Development, Epidemiology Result: No clear association with developmental effects. Species: Human
ETHANOL	Embryofetal Development, in utero - 36% total calories Species: Rat Organ: gonadal growth and development
PHENYLEPHRINE HYDROCHLORIDE	Epidemiology Result: Equivocal, evidence of malformations, or other adverse foetal effectw from clinical use. Other studies show no such association. Species: Human
PARACETAMOL	Epidemiology, Literature data Result: No clear association with therapeutic use. Species: Human
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
PHENYLEPHRINE HYDROCHLORIDE	Result: Foetal growth retardation and onset of early delivery at doses equivalent to clinical exposure. Species: Rabbit

**Specific target organ toxicity - single exposure**

PHENYLEPHRINE HYDROCHLORIDE	Clinical use Organ: Cardiovascular effects, some marked.
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**Specific target organ toxicity - single exposure**

PARACETAMOL

Species: Human

Organ: Liver

**Specific target organ toxicity - repeated exposure**

May cause damage to organs through prolonged or repeated exposure by ingestion.

**Aspiration hazard**

Not likely, due to the form of the product.

**Mixture versus substance information**

No information available.

**Other information**

Not available.

**SECTION 12: Ecological information****12.1. Toxicity**

Not expected to be harmful to aquatic organisms.

Components		Species	Test results
CITRIC ACID ANHYDROUS (CAS 77-92-9)			
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	120 mg/l, 72 hours Static test
Fish	EC50	Bluegill sunfish (Adult <i>Lepomis macrochirus</i> )	1516 mg/l, 96 hours Static test
		Golden ide/orfe (Adult <i>Leuciscus idus</i> )	440 - 760 mg/l, 96 hours Static test
Microtox	EC50	Microtox	14 mg/l, 15 minutes
ETHANOL (CAS 64-17-5)			
<b>Aquatic</b>			
<i>Acute</i>			
Algae	EC50	Blue-green algae ( <i>Microcystis aeruginosa</i> )	1450 mg/l, 72 hours
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	9190 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Adult <i>Pimephales promelas</i> )	14200 mg/l, 96 hours Flow-through test
		Rainbow trout (Adult <i>Salmo gairdneri</i> )	13000 mg/l, 96 hours Static test
GUAIPHENESIN (CAS 93-14-1)			
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	> 100 mg/l, 24 hours
PARACETAMOL (CAS 103-90-2)			
<b>Aquatic</b>			
<i>Acute</i>			
Algae	EC50	Green algae ( <i>Scenedesmus subspicatus</i> )	134 mg/l, 72 hours
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	50 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Juvenile <i>Pimephales promelas</i> )	814 mg/l, 96 hours Flow-through test
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)			
<b>Aquatic</b>			
<i>Acute</i>			
Algae	EC50	Green algae ( <i>Selenastrum capricornutum</i> )	> 124 mg/l, 72 hours Measured
	NOEC	Algae	31 mg/l, 72 hours
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	0.86 mg/l, 48 hours Measured
	NOEC	<i>Daphnia</i>	0.21 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult <i>Oncorhynchus mykiss</i> )	> 100 mg/l, 96 hours Measured
	NOEC	Rainbow trout (Adult <i>Oncorhynchus mykiss</i> )	100 mg/l, 96 hours

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

## 12.2. Persistence and degradability

### Photolysis

#### Half-life (Photolysis-aqueous)

ETHANOL 1 - 36.6 years Measured

#### Half-life (Photolysis-atmospheric)

ETHANOL 4 - 5.9 Days Estimated

### Biodegradability

#### Percent degradation (Aerobic biodegradation-inherent)

CITRIC ACID ANHYDROUS 98 %, 2 days Modified Zahn-Wellens, Activated sludge

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

PARACETAMOL 99 %, 5 days Modified Zahn-Wellens, Activated sludge

PHENYLEPHRINE HYDROCHLORIDE 81 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge

99 %, 7 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

## 12.3. Bioaccumulative potential

### Partition coefficient

#### n-octanol/water (log Kow)

D-SORBITOL -2.2

ETHANOL -0.31

GUAIPHENESIN -0.98

PARACETAMOL 0.36

PHENYLEPHRINE HYDROCHLORIDE 0.49 (Measured).

### Bioconcentration factor (BCF)

D-SORBITOL 1 Estimated

## 12.4. Mobility in soil

### Adsorption

#### Soil/sediment sorption - log Koc

D-SORBITOL 0.3 Estimated

ETHANOL 1.2 Calculated

### Mobility in general

#### Volatility

##### Henry's law

CITRIC ACID ANHYDROUS < 0 atm m<sup>3</sup>/mol Calculated, 25 °C

D-SORBITOL 0 atm m<sup>3</sup>/mol Estimated

ETHANOL 0.000005 atm m<sup>3</sup>/mol Measured

PARACETAMOL 0 atm m<sup>3</sup>/mol Estimated

12.5. Results of PBT Not available.

### and vPvB assessment

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. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

**Special precautions** Dispose in accordance with all applicable regulations.

## SECTION 14: Transport information

### ADR

Not regulated as dangerous goods.

Not subject to provisions of ADR, see SP 144.

## IATA

Not regulated as dangerous goods.  
Not subject to provisions of IATA, see SP A58.

## IMDG

Not regulated as dangerous goods.  
Not subject to provisions of IMDG, see SP 144.

**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**

R10 Flammable.  
R11 Highly flammable.  
R22 Harmful if swallowed.  
R24 Toxic in contact with skin.  
R36 Irritating to eyes.  
R37 Irritating to respiratory system.  
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
R62 Possible risk of impaired fertility.  
R63 Possible risk of harm to the unborn child.  
H225 Highly flammable liquid and vapour.  
H302 Harmful if swallowed.  
H311 Toxic in contact with skin.  
H312 Harmful in contact with skin.  
H314 Causes severe skin burns and eye damage.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.  
H361 Suspected of damaging fertility or the unborn child.  
H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.  
H412 Harmful to aquatic life with long lasting effects.

**Revision information**

Product and Company Identification: Product and Company Identification  
Composition / Information on Ingredients: Undisclosed Ingredient Statement  
Physical & Chemical Properties:  
TOXICOLOGICAL INFORMATION:  
Transport Information: Material Transportation Information  
Regulatory Information: United States  
GHS: Classification

**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.