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	BEECHAMS ALL-IN-ONE LIQUID POCKET PACK
Registration number	-
Synonyms	MFC 50/56 * PARACETAMOL, GUAIPHENESIN AND PHENYLEPHRINE HYDROCHLORIDE, FORMULATED PRODUCT
Issue date	06-August-2014
Version number	02
Revision date	06-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
D-SORBITOL	< 20	50-70-4 200-061-5	-	-	
Classification:	**DSD:** -				
	CLP: -				
ETHANOL	< 20	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				
GLYCERIN	< = 20	56-81-5 200-289-5	-	-	
Classification:	**DSD:** -				
	CLP: -				
Propylene glycol	< = 10	57-55-6 200-338-0	-	-	
Classification:	**DSD:** -				
	CLP: -				
PARACETAMOL	< 3	103-90-2 203-157-5	-	-	
Classification:	**DSD:** Xn;R22, R52/53				
	CLP: Acute Tox. 4;H302, Aquatic Chronic 3;H412				
GUAIPHENESIN	< = 1	93-14-1 202-222-5	-	-	
Classification:	**DSD:** Xn;R22				
	CLP: Acute Tox. 4;H302				
ACESULFAME K	< 0,5	55589-62-3 259-715-3	-	-	
Classification:	**DSD:** -				
	CLP: -				
CITRIC ACID ANHYDROUS	< 0,5	77-92-9 201-069-1	-	-	
Classification:	**DSD:** Xi;R36				
	CLP: Skin Corr. 1;H314, Eye Irrit. 2;H319				
SODIUM CITRATE, ANHYDROUS	< 0,5	68-04-2 200-675-3	-	-	
Classification:	**DSD:** -				
	CLP: -				
XANTHAN GUM	< 0,2	11138-66-2 234-394-2	-	-	
Classification:	**DSD:** -				
	CLP: -				

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
PHENYLEPHRINE HYDROCHLORIDE	< 0,1	61-76-7 200-517-3	-	-	

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 < 35

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. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

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

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. Do not induce vomiting without medical advice. Get medical attention if symptoms occur.

4.2. Most important symptoms and effects, both acute and delayed Not established.

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 Flammable liquid and vapour.

5.1. Extinguishing media

Suitable extinguishing media Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media Water.

5.2. Special hazards arising from the substance or mixture 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.

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 case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. 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.

For emergency responders	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up.
6.2. Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material for containment and cleaning up	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.
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	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.
7.2. Conditions for safe storage, including any incompatibilities	Keep away from heat, sparks and open flame. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).
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
ACESULFAME K (CAS 55589-62-3)	OHC	1
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
SODIUM CITRATE, ANHYDROUS (CAS 68-04-2)	8 HR TWA	5000 mcg/m3
	OHC	1
XANTHAN GUM (CAS 11138-66-2)	OHC	1

Biological limit values	No biological exposure limits noted for the ingredient(s).
Recommended monitoring procedures	Follow standard monitoring procedures.
Derived no-effect level (DNEL)	Not available.

Predicted no effect concentrations (PNECs)	Not available.

8.2. Exposure controls

Appropriate engineering controls	An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

General information	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. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.
Eye/face protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)
Skin protection	
- Hand protection	Not normally needed. 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	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust)
Respiratory protection	No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. 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	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. 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	Syrupy liquid.
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	37 - 40 °C (98,6 - 104 °F) Closed cup (Estimation based on components).
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)	
Solubility (water)	Not available.
Solubility (other)	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

Percent volatile	78,2 % estimated

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Keep away from heat, sparks and open flame. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Ingestion	May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Inhalation	Prolonged inhalation may be harmful. May cause damage to organs by 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	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Symptoms	Not established.

11.1. Information on toxicological effects

Acute toxicity	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test results
ACESULFAME K (CAS 55589-62-3)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Acute		
Oral		
LD50	Rat	3000 mg/kg
D-SORBITOL (CAS 50-70-4)		
Acute		
Oral		
LD50	Rat	15,9 g/kg
ETHANOL (CAS 64-17-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
Chronic		
Oral		
LOAEL	Monkey	40 %, 48 months % ingested calories

Components	Species	Test results
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
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
GLYCERIN (CAS 56-81-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
GUAIPHENESIN (CAS 93-14-1)		
Acute		
Oral		
LD50	Rat	1510 mg/kg
PARACETAMOL (CAS 103-90-2)		
Acute		
Oral		
LD50	Rat	1944 mg/kg
TD	Human	>= 150 mg/kg
Subacute		
Oral		
NOAEL	Rat	12500 ppm, 14 Day dietary, continuous
Subchronic		
Oral		
NOAEL	Rat	6200 ppm, 13 weeks dietary, continuous
TD	Rat	>= 12500 ppm, 13 weeks dietary, continuous
Other		
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.

Components	Species	Test results
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
XANTHAN GUM (CAS 11138-66-2)		
Acute		
Inhalation		
LC50	Rat	> 21 mg/l, 1 hour exposure
Oral		
LD50	Rat	> 5000 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 Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

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

Respiratory sensitisation Not available.

Skin sensitisation None known. This product is not expected to cause skin sensitisation.

Sensitisation

PHENYLEPHRINE HYDROCHLORIDE	Clinical use - Opthalmology Result: Low incidence of contact hypersensitivity. Species: Human
ETHANOL	OECD 406 Result: negative Species: Guinea pig
GUAIPHENESIN	SAR / QSAR, DEREK, Lhasa, UK Result: negative

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

ETHANOL	Ames Result: negative
PHENYLEPHRINE HYDROCHLORIDE	Ames Result: negative Notes: NTP Study report - Phenylephrine.

Mutagenicity

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

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.

Carcinogenicity

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 ademomas 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.

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 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
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

Reproductivity

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 weght, 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 May cause damage to organs.

PHENYLEPHRINE HYDROCHLORIDE	Clinical use Organ: Cardiovascular effects, some marked.
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
ACESULFAME K (CAS 55589-62-3)			
Aquatic			
Acute			
Crustacea	NOEC	Water flea (Daphnia magna)	> 1000 mg/l, 24 hours
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 1000 mg/l, 96 hours
Chronic			
Other	LC50	Bacteria	> 10000 mg/l
CITRIC ACID ANHYDROUS (CAS 77-92-9)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	120 mg/l, 72 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	1516 mg/l, 96 hours Static test
		Golden ide/orfe (Adult Leuciscus idus)	440 - 760 mg/l, 96 hours Static test
Microtox	EC50	Microtox	14 mg/l, 15 minutes
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
GUAIPHENESIN (CAS 93-14-1)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 100 mg/l, 24 hours
PARACETAMOL (CAS 103-90-2)			
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	134 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	50 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	814 mg/l, 96 hours Flow-through test
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	> 124 mg/l, 72 hours Measured
	NOEC	Algae	31 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	0,86 mg/l, 48 hours Measured
	NOEC	Daphnia	0,21 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	> 100 mg/l, 96 hours Measured
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	100 mg/l, 96 hours
Propylene glycol (CAS 57-55-6)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	19000 mg/l, 14 days

Components		Species	Test results
	NOEC	Green algae (Selenastrum capricornutum)	15000 mg/l, 14 days
Crustacea	EC50	Daphnia	43500 mg/l, 48 hours
	NOEC	Daphnia	28500 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	51400 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	51600 mg/l, 96 hours Static test
	NOEC	Fathead minnow (Adult Pimephales promelas)	41000 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	42000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	51400 mg/l, 30 minutes
SODIUM CITRATE, ANHYDROUS (CAS 68-04-2)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	161 mg/l, 72 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	2031 mg/l, 96 hours Static test
		Golden ide/orfe (Adult Leuciscus idus)	590 - 1018 mg/l, 96 hours Static test
Microtox	EC50	Microtox	18,8 mg/l, 15 minutes
XANTHAN GUM (CAS 11138-66-2)			
Aquatic			
Acute			
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	420 mg/l, 96 hours Static test

* 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
Propylene glycol	1,3 - 2,3 years Estimated

Half-life (Photolysis-atmospheric)

ETHANOL	4 - 5,9 Days Estimated
Propylene glycol	32 Hours Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ACESULFAME K	0 - 8 %, 25 days Batch activated sludge (BAS), Activated sludge
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
Propylene glycol	62 %, 5 days BOD5, Activated sludge
	79 %, 20 Days BOD20, Activated sludge
SODIUM CITRATE, ANHYDROUS	98 %, 2 days Modified Zahn-Wellens, Activated sludge

Percent degradation (Anaerobic biodegradation)

Propylene glycol	100 %, 9 days

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

D-SORBITOL	-2,2
ETHANOL	-0,31
GLYCERIN	-1,76
GUAIPHENESIN	-0.98
PARACETAMOL	0,36

PHENYLEPHRINE HYDROCHLORIDE	0,49 (Measured).
Propylene glycol	-0,92 -1,35

Bioconcentration factor (BCF)

D-SORBITOL	1 Estimated
Propylene glycol	< 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^3/mol Calculated, 25 °C
D-SORBITOL	0 atm m^3/mol Estimated
ETHANOL	0,000005 atm m3/mol Measured
PARACETAMOL	0 atm m^3/mol Estimated
Propylene glycol	0 atm m^3/mol Estimated

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. 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

General Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

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.

General information Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

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:
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.