

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

1.1. Product identifier

Trade name or designation of the mixture	DAY NURSE LIQUID
Registration number	-
Synonyms	DAY NURSE LIQUID (UK) * R&D CODE B19/69 * PARACETAMOL, PSEUDOEPHEDRINE HYDRCHLORIDE AND PHOLCODINE, FORMULATED PRODUCT
Issue date	08-September-2014
Version number	13
Revision date	08-September-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

This material will support combustion.
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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ETHANOL	5	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	3.3	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

PSEUDOEPHEDRINE HYDROCHLORIDE	0.2	345-78-8 206-462-1	-	-	
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Classification: **DSD:** Xn;R22
CLP: Acute Tox. 4;H302

PHOLCODINE	0.03	509-67-1 208-102-9	-	-	
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Classification: **DSD:** Xn;R22
CLP: Acute Tox. 4;H302

Other components below reportable levels 91.47

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 Take off all contaminated clothing immediately. 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. Wash contaminated clothing before reuse.

4.1. Description of first aid measures

Inhalation In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.

Skin contact Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Take off immediately all contaminated clothing. Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. If eye irritation persists: Get medical advice/attention.

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.

4.2. Most important symptoms and effects, both acute and delayed Direct contact with eyes may cause temporary irritation.

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 local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards Combustible liquid.

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.
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 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. Avoid prolonged exposure. Do not taste or swallow. 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
PARACETAMOL (CAS 103-90-2)	8 HR TWA	4000 mcg/m ³
PSEUDOEPHEDRINE HYDROCHLORIDE (CAS 345-78-8)	OHC	1
	8 HR TWA	200 mcg/m ³
	OHC	2

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
ETHANOL (CAS 64-17-5)	TWA	1920 mg/m ³	
		1000 ppm	

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Mist.
PARACETAMOL (CAS 103-90-2)	TWA	10 mg/m3	Inhalable dust.
Propylene glycol (CAS 57-55-6)	TWA	474 mg/m3	Total vapour and particulates.
		10 mg/m3	Particulate.
		150 ppm	Total vapour and particulates.
SUGAR SYRUP SUCROSE (67.5%) (CAS 57-50-1)	STEL	20 mg/m3	
	TWA	10 mg/m3	
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	Explosion-proof general and local exhaust ventilation. 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. 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	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	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. 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. 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. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).		
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.		
Hygiene measures	For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. When using do not smoke. Wash hands after handling and before eating. An occupational/industrial hygiene monitoring method has been developed for this material.		
Environmental exposure controls			
Hazard guidance and control recommendations	Contain spills and prevent releases and observe national regulations on emissions. Environmental manager must be informed of all major releases.		

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties****Appearance**

Physical state	Liquid.
Form	Solution.Bottle.
Colour	Orange.
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	70 °C (158 °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	No relevant additional information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
Information on likely routes of exposure	
Ingestion	Harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
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.
Symptoms	Possible effects of overexposure in the workplace include: constipation, nausea, vomiting, headache, insomnia.

11.1. Information on toxicological effects

Acute toxicity Harmful if swallowed. Health injuries are not known or expected under normal use.

Components	Species	Test results
ETHANOL (CAS 64-17-5)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg

Components	Species	Test results
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
PARACETAMOL (CAS 103-90-2)		
Acute		
<i>Oral</i>		
LD50	Rat	1944 mg/kg
TD	Human	>= 150 mg/kg
Subacute		
<i>Oral</i>		
NOAEL	Rat	12500 ppm, 14 Day dietary, continuous
Subchronic		
<i>Oral</i>		
NOAEL	Rat	6200 ppm, 13 weeks dietary, continuous
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
PHOLCODINE (CAS 509-67-1)		
Acute		
<i>Oral</i>		
LD50	Mouse	1000 RTECS Database
PSEUDOEPHEDRINE HYDROCHLORIDE (CAS 345-78-8)		
Acute		
<i>Oral</i>		
LD50	Mouse	371 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: P.I.I. valuePSEUDOEPHEDRINE HYDROCHLORIDE
PARACETAMOL0.2
OECD 404, Literature data
Result: Slight irritant
Species: Rabbit**Serious eye damage/eye irritation**

Health injuries are not known or expected under normal use.

Eye

ETHANOL

OECD 405
Result: Severe
Species: Rabbit

PARACETAMOL

OECD 405
Result: Slight irritant
Species: Rabbit**Eye / Initial pain reaction score**

PARACETAMOL

Literature data

Respiratory sensitisation

Health injuries are not known or expected under normal use.

Skin sensitisation

Health injuries are not known or expected under normal use.

Sensitisation

ETHANOL

OECD 406
Result: negative
Species: Guinea pig**Germ cell mutagenicity**

Health injuries are not known or expected under normal use.

Mutagenicity

ETHANOL

Ames
Result: negative

PARACETAMOL

Ames, Literature data
Result: negative

ETHANOL

Chromosomal Aberration Assay In Vitro, CHO cells
Result: negative

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

ETHANOL

L5178Y mouse lymphoma thymidine kinase locus assay

Result: Weakly positive

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

Carcinogenicity
ETHANOL

Health injuries are not known or expected under normal use.

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
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. Health injuries are not known or expected under normal use. 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: embryoletality
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 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

Embryofetal Development, in utero - 36% total calories

Species: Rat

Organ: gonadal growth and development

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

Specific target organ toxicity - single exposure

May cause damage to organs by ingestion.

PARACETAMOL

Species: Human

Organ: Liver

Specific target organ toxicity - repeated exposure

Causes 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

Caution - Pharmaceutical agent.

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

Not expected to be harmful to aquatic organisms.

Components**Species****Test results**

ETHANOL (CAS 64-17-5)

Aquatic*Acute*

Algae

EC50

Blue-green algae (Microcystis aeruginosa)

1450 mg/l, 72 hours

Crustacea

EC50

Water flea (Daphnia magna)

9190 mg/l, 48 hours Static test

Fish

EC50

Fathead minnow (Adult Pimephales promelas)

14200 mg/l, 96 hours Flow-through test

Rainbow trout (Adult Salmo gairdneri)

13000 mg/l, 96 hours Static test

Components	Species	Test results
PARACETAMOL (CAS 103-90-2)		
Aquatic		
<i>Acute</i>		
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
PSEUDOEPHEDRINE HYDROCHLORIDE (CAS 345-78-8)		
<i>Acute</i>		
	IC50	Activated sludge > 100 mg/l, 3 hours
	NOEC	Activated sludge 3.2 mg/l, 3 hours
Aquatic		
<i>Acute</i>		
Algae	EC50	Green algae (Selenastrum capricornutum) 82 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna) > 120 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna) 7.5 mg/l, 48 hours Static test
Fish	EC50	Golden ide/orfe (Juvenile Leuciscus idus) 460 - 1000 mg/l, 96 hours
<i>Chronic</i>		
Algae	NOEC	Green algae (Selenastrum capricornutum) > 7.5 mg/l, 72 hours
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
Hydrolysis		
Half-life (Hydrolysis-neutral)		
PSEUDOEPHEDRINE HYDROCHLORIDE		> 99 %, 14 days, Activated sludge
Biodegradability		
Percent degradation (Aerobic biodegradation-inherent)		
ETHANOL		37 - 86 %, 5 days BOD5, Activated sludge
PARACETAMOL		99 %, 5 days Modified Zahn-Wellens, Activated sludge
Percent degradation (Aerobic biodegradation-ready)		
PSEUDOEPHEDRINE HYDROCHLORIDE		60 % BOD20
12.3. Bioaccumulative potential		
Partition coefficient n-octanol/water (log Kow)		
ETHANOL		-0.31
PARACETAMOL		0.36
PSEUDOEPHEDRINE HYDROCHLORIDE		0.89
12.4. Mobility in soil		
Adsorption		
Sludge/biomass distribution coefficient - log Kd		
PSEUDOEPHEDRINE HYDROCHLORIDE		< -1.39 Measured
Soil/sediment sorption - log Koc		
ETHANOL		1.2 Calculated
Mobility in general		
Volatility		
Henry's law		
ETHANOL		0.000005 atm m ³ /mol Measured
PARACETAMOL		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

ADR	Not regulated as dangerous goods.
RID	Not regulated as dangerous goods.
ADN	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods. Read safety instructions, SDS and emergency procedures before handling.
IMDG	Not regulated as dangerous goods.
14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

SECTION 15: Regulatory information

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

EU regulations

- Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I**
Not listed.
- Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II**
Not listed.
- Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended**
Not listed.
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended**
Not listed.
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended**
Not listed.
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended**
Not listed.
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended**
Not listed.
- Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry**
Not listed.
- Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA**
Not listed.

Authorisations

- Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended**
Not listed.

Restrictions on use

- Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended**
ETHANOL (CAS 64-17-5)

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

Not listed.

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

Not listed.

Other EU regulations

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

Not listed.

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

ETHANOL (CAS 64-17-5)

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

Not listed.

Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

Not available.

References

GSK Hazard Determination

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R11 Highly flammable.
R22 Harmful if swallowed.
R36 Irritating to eyes.
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
H225 Highly flammable liquid and vapour.
H302 Harmful if swallowed.
H319 Causes serious eye irritation.
H412 Harmful to aquatic life with long lasting effects.

Revision information

Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
Ecological Information: Mobility
TRANSPORT INFORMATION:
Regulatory Information: Risk Phrases - Class.
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.