

1. Identification

Product identifier

DAY NURSE LIQUID

Other means of identification

Synonyms

DAY NURSE LIQUID (UK) * R&D CODE B19/69 * PARACETAMOL, PSEUDOEPHEDRINE HYDRCHLORIDE AND PHOLCODINE, FORMULATED PRODUCT

Recommended use

Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions

No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
GLYCERIN	GLYCEROL * GLYCERIN ANHYDROUS * GLYCERINE * GLYCERITOL * GLYCYL ALCOHOL * 1,2,3-PROPANETRIOL * PROPANETRIOL * GLYROL * GLYSANIN * TRIHYDROXYPROPANE * 1,2,3-TRIHYDROXYPROPANE * OSMOGLYN	56-81-5	33.3

Chemical name	Common name and synonyms	CAS number	%
PROPYLENE GLYCOL	1,2-PROPANEDIOL * 1,2-DIHYDROXYPROPANE * 2-HYDROXYPROPANOL * ISOPROPYLENE GLYCOL * METHYLETHYLENE GLYCOL * METHYLETHYL GLYCOL * MONOPROPYLENE GLYCOL * 2,3-PROPANEDIOL * ALPHA-PROPYLENE GLYCOL * 1,2-PROPYLENE GLYCOL * (RS)-1,2-PROPANEDIOL * 1,2-(RS)-PROPANEDIOL * 1,2-PROPANDIOL * DL-1,2-PROPANEDIOL * DL-PROPYLENE GLYCOL * PROPANE-1,2-DIOL (PROPYLENE GLYCOL) * PROPANE-1-2-DIOL * PROPANEDIOL, 1,2-	57-55-6	25.4876
SUGAR SYRUP SUCROSE (67.5%)		57-50-1	20
ETHANOL	ALCOHOL ANHYDROUS * ANHYDROUS ETHANOL * ANHYDROUS ETHYL ALCOHOL * ETHANOL 200 PROOF * ETHYL ALCOHOL * ETHYL ALCOHOL USP 200 PROOF (USI) * ETHYL ALCOHOL, 100% * ETHYL HYDROXIDE * GRAIN ALCOHOL * ETHANOL	64-17-5	5
PARACETAMOL	ACETAMIDE, N-(4-HYDROXYPHENYL)- * ACETANILIDE, 4'-HYDROXY- * 4'-HYDROXYACETANILIDE * PANADOL * PARACETAMOL * TYLENOL * PARA-ACETAMIDOPHENOL * 4-ACETAMINOPHENOL * PARA-HYDROXYACETANILIDE	103-90-2	3.3
CITRIC ACID ANHYDROUS	BETA-HYDROXYTRICARBALLYLIC ACID * ANHYDROUS CITRIC ACID * 2-HYDROXY-1,2,3-PROPANETRICARBOX YLIC ACID * CITIRIC ACID	77-92-9	0.34
SODIUM CITRATE, ANHYDROUS	CITREME	68-04-2	0.34
PSEUDOEPHEDRINE HYDROCHLORIDE	(S-(R*,R*))-ALPHA-(1-METHYLAMINO)ETH YL)BENZENEMETHANOL HYDROCHLORIDE * (+)-PSEUDOEPHEDRINE HYDROCHLORIDE * D-PSEUDOEPHEDRINE HYDROCHLORIDE * GR 95006B * 1803 (GW ACN) * RTECS UL5950000 * (+)-PSI-EPHEDRINE HYDROCHLORIDE * 71U51	345-78-8	0.2
SODIUM BENZOATE	BENZOIC ACID, SODIUM SALT * BENZOATE OF SODA * SODIUM BENZOIC ACID	532-32-1	0.1
ACESULFAME K	1,2,3-OXATHIAZIN-4(3H)-ONE, 6-METHYL-, 2,2-DIOXIDE, POTASSIUM SALT (9CI) * ACESULFAM	55589-62-3	0.06
MENTHOL	HEXAHYDROTHYMOL * MENTHACAMPHOR * MENTHOMENTHOL * PEPPERMINT CAMPHOR * NATURAL MENTHOL	89-78-1	0.05
PHOLCODINE	GR140220X	509-67-1	0.03
Other components below reportable levels			11.7924

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

4. 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 center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
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.

5. Fire-fighting measures

Suitable extinguishing media	Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Water.
Specific hazards arising from the chemical	Vapors may form explosive mixtures with air. Vapors may travel considerable distance to a source of ignition and flash back. During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	In case of fire and/or explosion do not breathe fumes.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	Combustible liquid.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	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 of the SDS.
Methods and materials for containment and cleaning up	<p>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.</p> <p>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 vapors or divert vapor cloud drift. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.</p> <p>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.</p>
Environmental precautions	Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

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.

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).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
ACESULFAME K (CAS 55589-62-3)	OHC	1	
CITRIC ACID ANHYDROUS (CAS 77-92-9)	8 HR TWA	5000 mcg/m3	
MENTHOL (CAS 89-78-1)	OHC	1	
	8 HR TWA	1000 mcg/m3	
PARACETAMOL (CAS 103-90-2)	OHC	1	SKIN SENSITISER
	8 HR TWA	4000 mcg/m3	
PSEUDOEPHEDRINE HYDROCHLORIDE (CAS 345-78-8)	OHC	1	
	8 HR TWA	200 mcg/m3	
SODIUM BENZOATE (CAS 532-32-1)	OHC	2	
	8 HR TWA	5000 mcg/m3	
SODIUM CITRATE, ANHYDROUS (CAS 68-04-2)	OHC	1	
	8 HR TWA	5000 mcg/m3	
	OHC	1	

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

Components	Type	Value	Form
ETHANOL (CAS 64-17-5)	PEL	1900 mg/m3 1000 ppm	
GLYCERIN (CAS 56-81-5)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
SUGAR SYRUP SUCROSE (67.5%) (CAS 57-50-1)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
ETHANOL (CAS 64-17-5)	STEL	1000 ppm
SUGAR SYRUP SUCROSE (67.5%) (CAS 57-50-1)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
ETHANOL (CAS 64-17-5)	TWA	1900 mg/m3 1000 ppm	
SUGAR SYRUP SUCROSE (67.5%) (CAS 57-50-1)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
PROPYLENE GLYCOL (CAS 57-55-6)	TWA	10 mg/m3	Aerosol.

Biological limit values	No biological exposure limits noted for the ingredient(s).
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	
Eye/face protection	Chemical goggles are recommended. If contact is likely, safety glasses with side shields are recommended.
Hand protection	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.
Skin protection	
Other	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
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.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	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.

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Solution.Bottle.
Color	Orange.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	158 °F (70 °C) 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.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.

Viscosity Not available.

10. Stability and reactivity

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

11. Toxicological information

Information on likely routes of exposure

Ingestion	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 related to the physical, chemical and toxicological characteristics
Possible effects of overexposure in the workplace include: constipation, nausea, vomiting, headache, insomnia.

Information on toxicological effects

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

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

Components	Species	Test Results
		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		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
MENTHOL (CAS 89-78-1)		
Acute		
<i>Oral</i>		
LD50	Rat	3200 mg/kg
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

MENTHOL

Literature data

Result: Irritating to skin

Species: Rabbit

Notes: IUCLID data

Irritation Corrosion - Skin: P.I.I. value	
PSEUDOEPHEDRINE HYDROCHLORIDE	0.2
CITRIC ACID ANHYDROUS	OECD 404
	Result: Mild to moderate irritant.
	Species: Rabbit
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.
Eye	
CITRIC ACID ANHYDROUS	Acute ocular irritation; OECD 405
	Result: Severe Irritant
	Species: Rabbit
MENTHOL	Literature data
	Result: Mild-moderate
	Species: Rabbit
ETHANOL	OECD 405
	Result: Severe
	Species: Rabbit
PARACETAMOL	OECD 405
	Result: Slight irritant
	Species: Rabbit
Eye / Initial pain reaction score	
PARACETAMOL	Literature data
Respiratory or skin sensitization	
Respiratory sensitization	Health injuries are not known or expected under normal use.
Skin sensitization	Health injuries are not known or expected under normal use.
Sensitization	
MENTHOL	Buehler assay, Literature data
	Result: Negative
	Species: Guinea pig
	Notes: IUCLID data
	Epidemiology, Literature data
	Result: Low incidence of contact hypersensitivity.
	Notes: IUCLID data
	Modified Draize, Literature data
	Result: Positive
	Species: Guinea pig
	Notes: IUCLID data
ETHANOL	OECD 406
	Result: Negative
	Species: Guinea pig
MENTHOL	Open repetitive dermal test, Literature data
	Result: Negative
	Species: Guinea pig
	Notes: IUCLID data
Germ cell mutagenicity	Health injuries are not known or expected under normal use.
Mutagenicity	
MENTHOL	725 mg/kg In vivo-In vitro Replicative DNA synthesis
	Result: Positive
	Species: Rat
	Alkaline Elution Assay In Vitro, Literature data
	Result: Negative
	Notes: IUCLID data
ETHANOL	Ames
	Result: Negative
PARACETAMOL	Ames, Literature data
	Result: Negative
MENTHOL	Ames, Literature dataLiterature data
	Result: Negative
	Notes: IUCLID data
	BlueScreen mammalian cell mutation assay, Literature data
	Result: Negative
	Notes: IUCLID data

Mutagenicity

ETHANOL	Chromosomal Aberration Assay In Vitro, CHO cells Result: Negative
MENTHOL	Chromosomal Aberration Assay In Vitro, CHO cells, Literature data Result: Negative Notes: IUCLID data
PARACETAMOL	Chromosomal Aberration Assay In Vitro, Literature data Result: Positive
MENTHOL	Chromosomal Aberration Assay In Vitro, human lymphocytes, Literature data Result: Negative Notes: IUCLID data
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
MENTHOL	GreenScreen mammalian cell mutation assay, Literature dat a Result: Negative Notes: IUCLID data
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
MENTHOL	L5178Y mouse lymphoma thymidine kinase locus assay, Literature data Result: Negative Notes: IUCLID data Micronucleus Test, Literature data Result: Negative Species: Mouse Notes: IUCLID data Mutation in Drosophila melanogaster, Literature data Result: Negative Notes: IUCLID data
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

Mutagenicity
MENTHOL

sister chromatid exchange, Literature data
Result: Negative
Notes: IUCLID data

Carcinogenicity
MENTHOL

Health injuries are not known or expected under normal use.

<= 1000 mg/kg/day, Literature data, dietary study.

Result: Negative

Species: Rat

Test Duration: 103 weeks

Notes: IUCLID data

<= 2143 mg/kg/day, Literature data, dietary study.

Result: Negative

Species: Mouse

Notes: IUCLID data

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

inadequate study

Result: Increase in liver sarcomas

Species: Mouse

inadequate study

Result: Negative

Species: Hamster

Test Duration: 807 Day

inadequate study

Result: Negative

Species: Mouse

Test Duration: 1020 Day

inadequate study

Result: Negative

Species: Rat

inadequate study

Result: Negative

Species: Rat

Test Duration: 78 weeks

inadequate study

Result: Time to tumour reduced

Species: Mouse

Test Duration: 80 weeks

IARC Monographs. Overall Evaluation of Carcinogenicity

PARACETAMOL (CAS 103-90-2)

3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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

Reproductivity

ETHANOL

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

MENTHOL

185 mg/kg/day Embryo-foetal development, Literature data

Result: NOAEL-Highest dose.

Species: Mouse

Notes: IUCLID data

218 mg/kg/day Embryo-foetal development - Oral, Literature data

Result: NOAEL-Highest dose.

Species: Rat

Notes: IUCLID data

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

MENTHOL

405 mg/kg/day Embryo-foetal development - Oral, Literature data

Result: NOAEL-Highest dose.

Species: Hamster

Notes: IUCLID data

475 mg/kg/day Embryo-foetal development - Oral, Literature data

Result: NOAEL-Highest dose.

Species: Rabbit

Notes: IUCLID data

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

Reproductivity
ETHANOL

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.

Chronic effects Prolonged inhalation may be harmful. Prolonged exposure may cause chronic effects.

Further information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity Not expected to be harmful to aquatic organisms.

Components		Species	Test Results
ACESULFAME K (CAS 55589-62-3)			
Aquatic			
<i>Acute</i>			
Crustacea	NOEC	Water flea (Daphnia magna)	> 1000 mg/l, 24 hours
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 1000 mg/l, 96 hours
<i>Chronic</i>			
Other	LC50	Bacteria	> 10000 mg/l
CITRIC ACID ANHYDROUS (CAS 77-92-9)			
Aquatic			
<i>Acute</i>			
Algae	NOEC	Green algae (Scenedesmus quadricauda)	425 mg/l, 8 days Static Test
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
ETHANOL (CAS 64-17-5)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Blue-green algae (Microcystis aeruginosa)	1450 mg/L, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	9190 mg/L, 48 hours Static test
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	14200 mg/L, 96 hours Flow-through test
		Rainbow trout (Adult Salmo gairdneri)	13000 mg/L, 96 hours Static test
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
PROPYLENE GLYCOL (CAS 57-55-6)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours

Components		Species	Test Results
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	19000 mg/l, 14 days
	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
PSEUDOEPHEDRINE HYDROCHLORIDE (CAS 345-78-8)			
Acute			
	IC50	Activated sludge	> 100 mg/l, 3 hours
	NOEC	Activated sludge	3.2 mg/l, 3 hours
Aquatic			
Acute			
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
Chronic			
Algae	NOEC	Green algae (Selenastrum capricornutum)	> 7.5 mg/l, 72 hours
SODIUM BENZOATE (CAS 532-32-1)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 100 mg/L, 96 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	484 mg/L, 96 hours Flow-through test
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
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	

Hydrolysis

Half-life (Hydrolysis-neutral)

PSEUDOEPHEDRINE HYDROCHLORIDE > 99 %, 14 days, Activated sludge

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
PROPYLENE GLYCOL 62 %, 5 days BOD5, Activated sludge
79 %, 20 Days BOD20, Activated sludge
98 %, 2 days Modified Zahn-Wellens, Activated sludge
SODIUM CITRATE, ANHYDROUS

Percent degradation (Anaerobic biodegradation)

PROPYLENE GLYCOL 100 %, 9 days
SODIUM BENZOATE 93 %, 7 days Other degradation test system, Mixed Residential/Industrial

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

ETHANOL -0.31
GLYCERIN -1.76
MENTHOL 3.4
PARACETAMOL 0.36
PROPYLENE GLYCOL -1.35
PSEUDOEPHEDRINE HYDROCHLORIDE 0.89
SODIUM BENZOATE 1.89
SUGAR SYRUP SUCROSE (67.5%) -3.7

Bioconcentration factor (BCF)

PROPYLENE GLYCOL < 1 Estimated

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

PSEUDOEPHEDRINE HYDROCHLORIDE < -1.39 Measured

Soil/sediment sorption - log Koc

ETHANOL 1.2 Calculated
SODIUM BENZOATE 1.16 Calculated

Mobility in general

Volatility

Henry's law

CITRIC ACID ANHYDROUS < 0 atm m³/mol Calculated, 25 °C
ETHANOL 0.000005 atm m³/mol Measured
MENTHOL 0.000015 atm m³/mol, 25 C Estimated
PARACETAMOL 0 atm m³/mol Estimated
PROPYLENE GLYCOL 0 atm m³/mol Estimated

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions 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.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a dangerous good.

Read safety instructions, SDS and emergency procedures before handling.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

15. Regulatory information

US federal regulations

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

ETHANOL (CAS 64-17-5) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))

PSEUDOEPHEDRINE HYDROCHLORIDE (CAS 345-78-8) 0 %WV

DEA Exempt Chemical Mixtures Code Number

PSEUDOEPHEDRINE HYDROCHLORIDE (CAS 345-78-8) 8112
8113

US state regulations

US. Massachusetts RTK - Substance List

ETHANOL (CAS 64-17-5)
GLYCERIN (CAS 56-81-5)
SUGAR SYRUP SUCROSE (67.5%) (CAS 57-50-1)

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

ETHANOL (CAS 64-17-5)
GLYCERIN (CAS 56-81-5)

PROPYLENE GLYCOL (CAS 57-55-6)

US. Pennsylvania Worker and Community Right-to-Know Law

ETHANOL (CAS 64-17-5)

GLYCERIN (CAS 56-81-5)

PROPYLENE GLYCOL (CAS 57-55-6)

SUGAR SYRUP SUCROSE (67.5%) (CAS 57-50-1)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

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

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

ETHANOL (CAS 64-17-5)

Listed: April 29, 2011

Listed: July 1, 1988

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

ETHANOL (CAS 64-17-5)

Listed: October 1, 1987

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	09-08-2014
Revision date	09-08-2014
Version #	13
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 2 Flammability: 2 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 2 Instability: 0
References	GSK Hazard Determination
Disclaimer	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.
Revision Information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Ecological Information: Mobility Transport Information: Regulatory Information: Risk Phrases - Class. GHS: Classification