# 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** | 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<br><br>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 |
|---|---|---|---|---|---|
| ETHANOL | 5 | 64-17-5<br>200-578-6 | - | 603-002-00-5 | |
| **Classification:** **DSD:** F;R11, Xi;R36<br>**CLP:** Flam. Liq. 2;H225, Eye Irrit. 2;H319 | | | | | |
| PARACETAMOL | 3.3 | 103-90-2<br>203-157-5 | - | - | |
| **Classification:** **DSD:** Xn;R22, R52/53<br>**CLP:** Acute Tox. 4;H302, Aquatic Chronic 3;H412 | | | | | |
| PSEUDOEPHEDRINE HYDROCHLORIDE | 0.2 | 345-78-8<br>206-462-1 | - | - | |
| **Classification:** **DSD:** Xn;R22<br>**CLP:** Acute Tox. 4;H302 | | | | | |
| PHOLCODINE | 0.03 | 509-67-1<br>208-102-9 | - | - | |
| **Classification:** **DSD:** Xn;R22<br>**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.<br><br>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.<br><br>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.<br><br>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/m3 |
| | OHC | 1 |
| PSEUDOEPHEDRINE HYDROCHLORIDE (CAS 345-78-8) | 8 HR TWA | 200 mcg/m3 |
| | OHC | 2 |

**Ireland. Occupational Exposure Limits**

| Components | Type | Value | Form |
|---|---|---|---|
| ETHANOL (CAS 64-17-5) | STEL | 1000 ppm | |
| GLYCERIN (CAS 56-81-5) | TWA | 10 mg/m3 | Mist. |

**Ireland. Occupational Exposure Limits**

| Components | Type | Value | Form |
|---|---|---|---|
| PARACETAMOL (CAS 103-90-2) | TWA | 10 mg/m3 | Total inhalable dust. |
| Propylene glycol (CAS 57-55-6) | TWA | 470 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** | | |
| *Oral* | | |
| LD50 | Rat | > 2000 mg/kg |

| Components | Species | Test results |
|---|---|---|
| **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 |
| | | 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** | | |
| *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 |
| PHOLCODINE (CAS 509-67-1) | | |
| **Acute** | | |
| *Oral* | | |
| LD50 | Mouse | 1000 RTECS Database |
| PSEUDOEPHEDRINE HYDROCHLORIDE (CAS 345-78-8) | | |
| **Acute** | | |
| *Oral* | | |
| 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. value**

| | |
|---|---|
| PSEUDOEPHEDRINE HYDROCHLORIDE | 0.2 |
| PARACETAMOL | OECD 404, Literature data<br>Result: Slight irritant<br>Species: Rabbit |

**Serious eye damage/eye irritation** Health injuries are not known or expected under normal use.

**Eye**

| | |
|---|---|
| ETHANOL | OECD 405<br>Result: Severe<br>Species: Rabbit |
| PARACETAMOL | OECD 405<br>Result: Slight irritant<br>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<br>Result: negative<br>Species: Guinea pig |

**Germ cell mutagenicity** Health injuries are not known or expected under normal use.

**Mutagenicity**

| | |
|---|---|
| ETHANOL | Ames<br>Result: negative |
| PARACETAMOL | Ames, Literature data<br>Result: negative |
| ETHANOL | Chromosomal Aberration Assay In Vitro, CHO cells<br>Result: negative |
| PARACETAMOL | Chromosomal Aberration Assay In Vitro, Literature data<br>Result: positive |
| ETHANOL | Dominant lethal assay<br>Result: positive<br>Species: Mouse<br>Dominant lethal assay<br>Result: positive<br>Species: Rat<br>Gene mutation and repair<br>Result: negative<br>Species: Bacteria<br>Gene mutation and repair<br>Result: positive<br>Species: Bacteria |
| PARACETAMOL | HPRT gene mutation in human lymphocytes, Literature data<br>Result: negative |
| ETHANOL | In vitro cytogenetics assay<br>Result: positive<br>In vitro cytogenetics assay<br>Result: positive<br>Species: Aspergillus niger |
| PARACETAMOL | In vivo Micronucleus, Literature data<br>Result: negative<br>Species: Mouse |
| ETHANOL | L5178Y mouse lymphoma thymidine kinase locus assay<br>Result: Weakly positive<br>Yeast mutation<br>Result: negative<br>Yeast mutation<br>Result: positive<br>in vitro micronucleus assay<br>Result: negative<br>in vivo cytogenetics assay<br>Result: negative<br>Species: Hamster<br>in vivo cytogenetics assay<br>Result: negative<br>Species: Rat |

**Mutagenicity**

| | |
|---|---|
| ETHANOL | in vivo cytogenetics assay<br>Result: positive<br>Species: Mouse<br>sister chromatid exchange<br>Result: positive |

**Carcinogenicity** Health injuries are not known or expected under normal use.

| | |
|---|---|
| ETHANOL | Epidemiology, causation linked to excessive consumption.<br>Species: Human<br>Organ: oral cavity, larynx, pharynx, oesophagus, liver |
| PARACETAMOL | Literature data<br>Result: Equivocal. Increase in ademomas at toxic dose.<br>Species: Mouse<br>Literature data<br>Result: Equivocal. Liver and bladder neoplasms at toxic doses.<br>Species: Rat<br>Literature data<br>Result: negative<br>Species: Mouse<br>Literature data<br>Result: negative<br>Species: Rat |
| ETHANOL | Neonatal, inadequate study<br>Result: negative<br>Species: Rat<br>inadequate study<br>Result: Increase in liver sarcomas<br>Species: Mouse<br>inadequate study<br>Result: Time to tumour reduced<br>Species: Mouse<br>Test Duration: 80 weeks<br>inadequate study<br>Result: negative<br>Species: Hamster<br>Test Duration: 807 Day<br>inadequate study<br>Result: negative<br>Species: Mouse<br>Test Duration: 1020 Day<br>inadequate study<br>Result: negative<br>Species: Rat<br>inadequate study<br>Result: negative<br>Species: Rat<br>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<br>Species: Monkey<br>Organ: facial anomolies, nervous system dysfunction<br>1 - 2 g/kg Embryo-foetal development - Oral, daily dose<br>Result: embryolethality<br>Species: Rat<br>1.8 g/kg Embryo-foetal development - Oral, daily dose<br>Result: Increased abortion<br>Species: Monkey |
| PARACETAMOL | 250 mg/kg/day Embryofetal Development, Literature data<br>Result: Foetal NOAEL<br>Species: Rat<br>387 mg/kg/day Embryofetal Development, Literature data<br>Result: negative<br>Species: Mouse |

**Reproductivity**

| | |
|---|---|
| ETHANOL | 5 g/kg Embryo-foetal development - Oral, daily dose - intravenous<br>Result: reduced foetal body weight; no malformations or other variations<br>Species: Monkey<br>7 - 17 g/kg Embryo-foetal development - Oral, daily dose - gavage<br>Species: Rat<br>Organ: skeletal malformations, dilated renal pelves |
| PARACETAMOL | 750 mg/kg/day Embryofetal Development, Literature data<br>Result: decrease in foetal weght, minor skeletal abnormalities.<br>Species: Rat<br><= 1400 mg/kg/day Pre- and Post-natal development, Literature data<br>Result: reduced weight gain during nursing.<br>Species: Rat |
| ETHANOL | Embryo-foetal development - Oral, 15-30% in diet<br>Result: resorptions, neural defects, cardiac malformations<br>Species: Mouse<br>Embryo-foetal development - Oral, Causation is linked to excessive consumption.<br>Species: Human<br>Organ: growth deficiency, CNS dysfunction, facial defects, major organ malformation<br>Embryofetal Development, in utero - 36% total calories<br>Species: Rat<br>Organ: gonadal growth and development |
| PARACETAMOL | Epidemiology, Literature data<br>Result: No clear association with therapeutic use.<br>Species: Human |
| ETHANOL | Fertility, Female, 10% in drinking water<br>Result: negative<br>Species: Rat<br>Fertility, Female, 20-25% total calories<br>Result: negative<br>Species: Rat<br>Fertility, Male, 5-6% v/v liquid diet<br>Species: Mouse<br>Organ: significant effects on testes and seminal vesicles<br>Test Duration: 70 Day |

**Specific target organ toxicity - single exposure** May cause damage to organs by ingestion.

| | |
|---|---|
| PARACETAMOL | Species: Human<br>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** | | | |
| *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 |
| 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 |

**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 m3/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**

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**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.<br>R22 Harmful if swallowed.<br>R36 Irritating to eyes.<br>R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.<br>H225 Highly flammable liquid and vapour.<br>H302 Harmful if swallowed.<br>H319 Causes serious eye irritation.<br>H412 Harmful to aquatic life with long lasting effects. |
| **Revision information** | Product and Company Identification: Product and Company Identification<br>Composition / Information on Ingredients: Ingredients<br>Physical & Chemical Properties:<br>Ecological Information: Mobility<br>TRANSPORT INFORMATION:<br>Regulatory Information: Risk Phrases - Class.<br>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. |