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 HYDROCHLORIDE 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

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>%</th>
<th>CAS-No. / EC No.</th>
<th>REACH Registration No.</th>
<th>INDEX No.</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHANOL</td>
<td>5</td>
<td>64-17-5 200-578-6</td>
<td>-</td>
<td>603-002-00-5</td>
<td></td>
</tr>
<tr>
<td><strong>Classification:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DSD:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F;R11, Xi;R36</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CLP:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flam. Liq. 2;H225, Eye Irrit. 2;H319</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| PARACETAMOL         | 3.3 | 103-90-2 203-157-5 | -                      | -         |       |
| **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 | -                      | -         |       |
| **Classification:**          |    |                 |                        |           |       |
| DSD:                         |    |                 |                        |           |       |
| Xn;R22                      |    |                 |                        |           |       |
| CLP:                         |    |                 |                        |           |       |
| Acute Tox. 4;H302            |    |                 |                        |           |       |

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

Other components below reportable levels 91.47

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

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

GSK exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PARACETAMOL (CAS 103-90-2)</td>
<td>8 HR TWA</td>
<td>4000 mcg/m3</td>
</tr>
<tr>
<td></td>
<td>OHC</td>
<td>1</td>
</tr>
<tr>
<td>PSEUDOEPHEDRINE HYDROCHLORIDE (CAS 345-78-8)</td>
<td>8 HR TWA</td>
<td>200 mcg/m3</td>
</tr>
<tr>
<td></td>
<td>OHC</td>
<td>2</td>
</tr>
</tbody>
</table>

UK EH40 Workplace Exposure Limits (WELs)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHANOL (CAS 64-17-5)</td>
<td>TWA</td>
<td>1920 mg/m3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1000 ppm</td>
<td></td>
</tr>
<tr>
<td>Components</td>
<td>Type</td>
<td>Value</td>
<td>Form</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>--------</td>
<td>-------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>GLYCOLIN (CAS 56-81-5)</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>Mist.</td>
</tr>
<tr>
<td>PARACETAMOL (CAS 103-90-2)</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>Inhalable dust.</td>
</tr>
<tr>
<td>Propylene glycol (CAS 57-55-6)</td>
<td>TWA</td>
<td>474 mg/m³</td>
<td>Total vapour and</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>particulates.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 mg/m³</td>
<td>Particulate.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>150 ppm</td>
<td>Total vapour and</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>particulates.</td>
</tr>
<tr>
<td>SUGAR SYRUP SUCROSE (67.5%) (CAS 57-50-1)</td>
<td>STEL</td>
<td>20 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

**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.
**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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHANOL (CAS 64-17-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Components</td>
<td>Species</td>
<td>Test results</td>
</tr>
<tr>
<td>---------------------</td>
<td>---------------</td>
<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Chronic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Monkey</td>
<td>40 %, 48 months % ingested calories</td>
</tr>
<tr>
<td>Subacute</td>
<td>Rat</td>
<td>16.9 g/kg, 4 weeks Dietary - Dose given as g/kg/day</td>
</tr>
<tr>
<td>LOEL</td>
<td></td>
<td>6 %, 4 weeks percent in diet - continuous</td>
</tr>
<tr>
<td>Subchronic</td>
<td>Rat</td>
<td>2 ml, 36 weeks haematological parameters</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Guinea pig</td>
<td>3000 ppm No adverse effects</td>
</tr>
<tr>
<td>LOEL</td>
<td>Rat</td>
<td>86 mg/m3, 90 Day Daily dosing</td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>5000 mg/kg/day, 10 weeks Liver toxicity</td>
</tr>
<tr>
<td>LOAEL</td>
<td>Rat</td>
<td>80 ml/kg, 85 Day Daily dose - Liver toxicity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10.2 g/kg, 12 weeks Dosed in drinking water - Continuous</td>
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<tr>
<td></td>
<td></td>
<td>7.7 g/kg, 12 weeks Dosed in drinking water - continuous</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PARACETAMOL (CAS 103-90-2)</td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>1944 mg/kg</td>
</tr>
<tr>
<td>TD</td>
<td>Human</td>
<td>&gt;= 150 mg/kg</td>
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<tr>
<td>Subacute</td>
<td>Rat</td>
<td>12500 ppm, 14 Day dietary, continuous</td>
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<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOAEL</td>
<td>Rat</td>
<td>6200 ppm, 13 weeks dietary, continuous</td>
</tr>
<tr>
<td>TD</td>
<td>Rat</td>
<td>&gt;= 12500 ppm, 13 weeks dietary, continuous</td>
</tr>
<tr>
<td>Other</td>
<td>Mouse</td>
<td>130 ppm, 61 weeks dietary, continuous</td>
</tr>
<tr>
<td>LOAEL</td>
<td>Mouse</td>
<td>3200 ppm, 13 weeks dietary, continuous</td>
</tr>
<tr>
<td>NOAEL</td>
<td>Mouse</td>
<td>0.3 %, 41 weeks dietary, continuous</td>
</tr>
<tr>
<td>TD</td>
<td>Mouse</td>
<td>6100 ppm, 13 weeks dietary, continuous</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.25 %, 41 weeks dietary, continuous</td>
</tr>
<tr>
<td>PHOLCODINE (CAS 509-67-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Mouse</td>
<td>1000 RTECS Database</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSEUDOEPHEDRINE HYDROCHLORIDE (CAS 345-78-8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Mouse</td>
<td>371 mg/kg</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Estimates for product may be based on additional component data not shown.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Health injuries are not known or expected under normal use.</td>
<td></td>
</tr>
<tr>
<td>Corrosivity</td>
<td>ETHANOL</td>
<td>OECD 404</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: Negative; not considered a significant irritant</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Species: Rabbit</td>
</tr>
</tbody>
</table>

Material name: DAY NURSE LIQUID

SDS UK

1374 Version No.: 13 Revision date: 08-September-2014 Issue date: 08-September-2014

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

<table>
<thead>
<tr>
<th>Pseudoephedrine Hydrochloride</th>
<th>0.2</th>
<th>OECD 404, Literature data</th>
<th>Result: Slight irritant</th>
<th>Species: Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paracetamol</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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

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

Species: Human

ORGAN: oral cavity, larynx, pharynx, oesophagus, liver

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: embryo lethality
Species: Rat
1.8 g/kg Embryo-foetal development - Oral, daily dose
Result: increased abortion
Species: Rat

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

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

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

Species: Human
Organ: skeletal malformations, dilated renal pelves

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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHANOL (CAS 64-17-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Aquatic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Algae</td>
<td>EC50</td>
<td>Blue-green algae (Microcystis aeruginosa)</td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>Water flea (Daphnia magna)</td>
</tr>
<tr>
<td>Fish</td>
<td>EC50</td>
<td>Fathead minnow (Adult Pimephales promelas)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rainbow trout (Adult Salmo gairdneri)</td>
</tr>
</tbody>
</table>

Material name: DAY NURSE LIQUID

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### Components Test results

#### PARACETAMOL (CAS 103-90-2)

<table>
<thead>
<tr>
<th>Aquatic</th>
<th>Species</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute</strong></td>
<td><strong>Algae</strong> EC50</td>
<td>Green algae (Scenedesmus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>subspicatus)</td>
</tr>
<tr>
<td></td>
<td><strong>Crustacea</strong> EC50</td>
<td>Water flea (Daphnia magna)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Static test</td>
</tr>
<tr>
<td></td>
<td><strong>Fish</strong> EC50</td>
<td>Fathead minnow (Juvenile</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pimephales promelas)</td>
</tr>
</tbody>
</table>

#### PSEUDOEPHEDRINE HYDROCHLORIDE (CAS 345-78-8)

<table>
<thead>
<tr>
<th>Acute</th>
<th>IC50 Activated sludge</th>
<th>&gt; 100 mg/l, 3 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC Activated</td>
<td>sludge</td>
<td>3.2 mg/l, 3 hours</td>
</tr>
</tbody>
</table>

| Aquatic Acute   | Algae EC50                        | Green algae (Selenastrum    |
|                 |                                  | capricornutum)             | 82 mg/l, 72 hours          |
|                 | Crustacea EC50                    | Water flea (Daphnia magna)  | > 120 mg/l, 48 hours       |
|                 | NOEC Water flea (Daphnia magna)  | Static test                | 7.5 mg/l, 48 hours        |
|                 | Fish EC50                         | Golden ide/orfe (Juvenile   | 460 - 1000 mg/l, 96 hours |
|                 |                                  | Leuciscus idus)            |                            |
| 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**
  - 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. 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. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA Not listed.

Authorisations

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)
   Not listed.
   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
   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.