

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

### 1.1. Product identifier

|                                          |                                                                                                                                                                                                                                |
|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Trade name or designation of the mixture | PANADOL NIGHT TABLETS                                                                                                                                                                                                          |
| Registration number                      | -                                                                                                                                                                                                                              |
| Synonyms                                 | PANADOL NIGHT CAPLETS * PANADOL NIGHT PAIN TABLETS * PANADOL NIGHT PAIN RELIEF TABLETS * PARACETAMOL 500 MG AND DIPHENHYDRAMINE HYDROCHLORIDE 25 MG TABLETS * PARACETAMOL AND DIPENHYDRAMINE HYDROCHLORIDE, FORMULATED PRODUCT |
| Issue date                               | 23-July-2014                                                                                                                                                                                                                   |
| Version number                           | 12                                                                                                                                                                                                                             |
| Revision date                            | 23-July-2014                                                                                                                                                                                                                   |

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

|                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Identified uses      | Medicinal Product<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](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://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 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 |
|---------------|---|------------------|------------------------|-----------|-------|
|---------------|---|------------------|------------------------|-----------|-------|

|                                  |                                                                                              |                         |   |   |  |
|----------------------------------|----------------------------------------------------------------------------------------------|-------------------------|---|---|--|
| PARACETAMOL                      | < 80                                                                                         | 103-90-2<br>203-157-5   | - | - |  |
| <b>Classification:</b>           | <b>DSD:</b> Xn;R22, R52/53                                                                   |                         |   |   |  |
|                                  | <b>CLP:</b> Acute Tox. 4;H302, Aquatic Chronic 3;H412                                        |                         |   |   |  |
| Starch                           | < 15                                                                                         | 9005-25-8<br>232-679-6  | - | - |  |
| <b>Classification:</b>           | <b>DSD:</b> -                                                                                |                         |   |   |  |
|                                  | <b>CLP:</b> -                                                                                |                         |   |   |  |
| DIPHENHYDRAMINE<br>HYDROCHLORIDE | < 5                                                                                          | 147-24-0<br>205-687-2   | - | - |  |
| <b>Classification:</b>           | <b>DSD:</b> Xn;R22, Xi;R41, N;R50/53                                                         |                         |   |   |  |
|                                  | <b>CLP:</b> Acute Tox. 4;H302, Eye Dam. 1;H318, Aquatic Acute 1;H400, Aquatic Chronic 1;H410 |                         |   |   |  |
| Talc                             | < 5                                                                                          | 14807-96-6<br>238-877-9 | - | - |  |
| <b>Classification:</b>           | <b>DSD:</b> -                                                                                |                         |   |   |  |
|                                  | <b>CLP:</b> -                                                                                |                         |   |   |  |
| Polyvinylpyrrolidone             | < 0.5                                                                                        | 9003-39-8<br>-          | - | - |  |
| <b>Classification:</b>           | <b>DSD:</b> R52/53                                                                           |                         |   |   |  |
|                                  | <b>CLP:</b> Aquatic Chronic 3;H412                                                           |                         |   |   |  |

Other components below reportable levels < 6

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

**Composition comments** The full text for all R- and H-phrases is displayed in section 16.

**SECTION 4: First aid measures**

**General information** In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

**4.1. Description of first aid measures**

|                     |                                                                                                                                                                                                                      |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Inhalation</b>   | If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard. |
| <b>Skin contact</b> | Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.                                                                          |
| <b>Eye contact</b>  | Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.                                                                                                                               |
| <b>Ingestion</b>    | 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** Not established.

**4.3. Indication of any immediate medical attention and special treatment needed** No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

**SECTION 5: Firefighting measures**

**General fire hazards** No unusual fire or explosion hazards noted.

### 5.1. Extinguishing media

**Suitable extinguishing media** Water. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

**Unsuitable extinguishing media** None known.

**5.2. Special hazards arising from the substance or mixture** 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** Use water spray to cool unopened containers.

**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. Wear appropriate protective equipment and clothing during clean-up. Do not breathe dust. Wear a dust mask if dust is generated above exposure limits. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.

**For emergency responders** Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

**6.2. Environmental precautions** Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

**6.3. Methods and material for containment and cleaning up** Stop the flow of material, if this is without risk. Collect spillage. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Collect dust using a vacuum cleaner equipped with HEPA filter. Minimise dust generation and accumulation. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Sweep up or vacuum up spillage and collect in suitable container for disposal.

**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** Provide appropriate exhaust ventilation at places where dust is formed. Minimise dust generation and accumulation. Do not breathe dust. Avoid contact with eyes. Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

**7.2. Conditions for safe storage, including any incompatibilities** Store locked up. Store in original tightly closed container. 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

DIPHENHYDRAMINE  
HYDROCHLORIDE (CAS  
147-24-0)

8 HTWA

200 mcg/m<sup>3</sup>

OHC

2

PARACETAMOL (CAS  
103-90-2)

8 HR TWA

4000 mcg/m<sup>3</sup>

OHC

1

##### UK. EH40 Workplace Exposure Limits (WELs)

##### Components

##### Type

##### Value

##### Form

PARACETAMOL (CAS  
103-90-2)

TWA

10 mg/m<sup>3</sup>

Inhalable dust.

Starch (CAS 9005-25-8)

TWA

4 mg/m<sup>3</sup>

Respirable.

**UK. EH40 Workplace Exposure Limits (WELs)**

| Components                                                            | Type                                                                                                                                                                                                                                                                                                                                         | Value               | Form                          |
|-----------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-------------------------------|
| Talc (CAS 14807-96-6)                                                 | TWA                                                                                                                                                                                                                                                                                                                                          | 10 mg/m3<br>1 mg/m3 | Inhalable<br>Respirable dust. |
| 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                                      | General ventilation normally adequate. 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                                                     | Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).                                                                                                                               |                     |                               |
| - Other                                                               | Wear suitable protective clothing as protection against splashing or contamination. Not normally needed. (EN 14605 for splashes, EN ISO 13982 for dust)                                                                                                                                                                                      |                     |                               |
| Respiratory protection                                                | No personal respiratory protective equipment normally required. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).                                                                                   |                     |                               |
| Thermal hazards                                                       | Wear appropriate thermal protective clothing, when necessary.                                                                                                                                                                                                                                                                                |                     |                               |
| Hygiene measures                                                      | Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. |                     |                               |
| Environmental exposure controls                                       |                                                                                                                                                                                                                                                                                                                                              |                     |                               |
| Hazard guidance and control recommendations                           | 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**

|                                                     |                |
|-----------------------------------------------------|----------------|
| <b>Physical state</b>                               | Solid.         |
| <b>Form</b>                                         | Tablet.        |
| <b>Colour</b>                                       | Not available. |
| <b>Odour</b>                                        | Not available. |
| <b>Odour threshold</b>                              | Not available. |
| <b>pH</b>                                           | Not available. |
| <b>Melting point/freezing point</b>                 | Not available. |
| <b>Initial boiling point and boiling range</b>      | Not available. |
| <b>Flash point</b>                                  | Not available. |
| <b>Evaporation rate</b>                             | Not available. |
| <b>Flammability (solid, gas)</b>                    | Not available. |
| <b>Upper/lower flammability or explosive limits</b> |                |
| <b>Flammability limit - lower (%)</b>               | Not available. |
| <b>Flammability limit - upper (%)</b>               | Not available. |
| <b>Vapour pressure</b>                              | Not available. |

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|                                         |                                               |
|-----------------------------------------|-----------------------------------------------|
| 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                | Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). |
| 10.5. Incompatible materials             | Acids. Alkali metals.                                                                                                       |
| 10.6. Hazardous decomposition products   | None known. Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.                         |

## SECTION 11: Toxicological information

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

### Information on likely routes of exposure

|              |                                                                                                                      |
|--------------|----------------------------------------------------------------------------------------------------------------------|
| Ingestion    | 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. Direct contact with eyes may cause temporary irritation. |

|          |                  |
|----------|------------------|
| Symptoms | Not established. |
|----------|------------------|

### 11.1. Information on toxicological effects

|                |                                                                                                                     |
|----------------|---------------------------------------------------------------------------------------------------------------------|
| Acute toxicity | Harmful if swallowed. Expected to be a low hazard for usual industrial or commercial handling by trained personnel. |
|----------------|---------------------------------------------------------------------------------------------------------------------|

| Components                                   | Species | Test results                               |
|----------------------------------------------|---------|--------------------------------------------|
| DIPHENHYDRAMINE HYDROCHLORIDE (CAS 147-24-0) |         |                                            |
| Acute                                        |         |                                            |
| Oral                                         |         |                                            |
| LD50                                         | Rat     | 500 mg/kg                                  |
| PARACETAMOL (CAS 103-90-2)                   |         |                                            |
| Acute                                        |         |                                            |
| Oral                                         |         |                                            |
| LD50                                         | Rat     | 1944 mg/kg                                 |
| TD                                           | Human   | >= 150 mg/kg                               |
| Subacute                                     |         |                                            |
| Oral                                         |         |                                            |
| NOAEL                                        | Rat     | 12500 ppm, 14 Day dietary, continuous      |
| Subchronic                                   |         |                                            |
| Oral                                         |         |                                            |
| NOAEL                                        | Rat     | 6200 ppm, 13 weeks dietary, continuous     |
| TD                                           | Rat     | >= 12500 ppm, 13 weeks dietary, continuous |

| Components                                                                   | Species                                                                                                              | Test results                                                                                                                                                                                                                              |
|------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <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                                                                                                                                                                                                      |
| Polyvinylpyrrolidone (CAS 9003-39-8)                                         |                                                                                                                      |                                                                                                                                                                                                                                           |
| <b>Acute</b>                                                                 |                                                                                                                      |                                                                                                                                                                                                                                           |
| <i>Oral</i>                                                                  |                                                                                                                      |                                                                                                                                                                                                                                           |
| LD50                                                                         | Rat                                                                                                                  | > 5000 mg/kg                                                                                                                                                                                                                              |
| * Estimates for product may be based on additional component data not shown. |                                                                                                                      |                                                                                                                                                                                                                                           |
| <b>Skin corrosion/irritation</b>                                             | Health injuries are not known or expected under normal use.                                                          |                                                                                                                                                                                                                                           |
| <b>Irritation Corrosion - Skin</b>                                           |                                                                                                                      |                                                                                                                                                                                                                                           |
| DIPHENHYDRAMINE HYDROCHLORIDE                                                |                                                                                                                      | Acute dermal irritation; OECD 404, Supplier SDS<br>Result: Non-irritant<br>Species: Rabbit<br>Notes: Pfizer SDS                                                                                                                           |
| <b>Irritation Corrosion - Skin: P.I.I. value</b>                             |                                                                                                                      |                                                                                                                                                                                                                                           |
| PARACETAMOL                                                                  |                                                                                                                      | OECD 404, Literature data<br>Result: Slight irritant<br>Species: Rabbit                                                                                                                                                                   |
| <b>Serious eye damage/eye irritation</b>                                     | Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation. |                                                                                                                                                                                                                                           |
| <b>Eye</b>                                                                   |                                                                                                                      |                                                                                                                                                                                                                                           |
| DIPHENHYDRAMINE HYDROCHLORIDE                                                |                                                                                                                      | Acute ocular irritation; OECD 405, Supplier SDS<br>Result: Non-Irritating<br>Species: Rabbit<br>Notes: Pfizer SDS                                                                                                                         |
| PARACETAMOL                                                                  |                                                                                                                      | OECD 405<br>Result: Slight irritant<br>Species: Rabbit                                                                                                                                                                                    |
| DIPHENHYDRAMINE HYDROCHLORIDE                                                |                                                                                                                      | REET<br>Result: positive                                                                                                                                                                                                                  |
| <b>Eye / Initial pain reaction score</b>                                     |                                                                                                                      |                                                                                                                                                                                                                                           |
| PARACETAMOL                                                                  |                                                                                                                      | Literature data                                                                                                                                                                                                                           |
| <b>Respiratory sensitisation</b>                                             | Not established.                                                                                                     |                                                                                                                                                                                                                                           |
| <b>Skin sensitisation</b>                                                    | This product is not expected to cause skin sensitisation.                                                            |                                                                                                                                                                                                                                           |
| <b>Germ cell mutagenicity</b>                                                | No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.     |                                                                                                                                                                                                                                           |
| <b>Mutagenicity</b>                                                          |                                                                                                                      |                                                                                                                                                                                                                                           |
| PARACETAMOL                                                                  |                                                                                                                      | Ames, Literature data<br>Result: negative                                                                                                                                                                                                 |
| DIPHENHYDRAMINE HYDROCHLORIDE                                                |                                                                                                                      | Ames, Literature data<br>Result: negative<br>Notes: NTP study<br>Chromosomal Aberration Assay In Vitro, CHO cells, Literature data<br>Result: Positive at concentration toxic to cells<br>Notes: CCRIS                                    |
| PARACETAMOL                                                                  |                                                                                                                      | Chromosomal Aberration Assay In Vitro, Literature data<br>Result: positive<br>HPRT gene mutation in human lymphocytes, Literature data<br>Result: negative<br>In vivo Micronucleus, Literature data<br>Result: negative<br>Species: Mouse |
| DIPHENHYDRAMINE HYDROCHLORIDE                                                |                                                                                                                      | L5178Y mouse lymphoma thymidine kinase locus assay, Literature data<br>Result: negative<br>Notes: NTP study<br>Sister Chromatid Exchange, Supplier SDS<br>Result: negative                                                                |

|                                                               |                                                                                                                                                                                                                                                                                                                                             |  |
|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| <b>Carcinogenicity</b>                                        | Health injuries are not known or expected under normal use. Contains a material (talc) classified as a carcinogen by external agencies. These effects are linked only to high doses of this substance; lower doses did not cause this adverse effect.                                                                                       |  |
| DIPHENHYDRAMINE HYDROCHLORIDE                                 | 156 - 313 ppm, Dietary study<br>Species: Mouse<br>Test Duration: 2 years<br>Notes: NTP study<br>313 - 635 ppm, Dietary study<br>Species: Rat<br>Test Duration: 2 years<br>Notes: NTP study                                                                                                                                                  |  |
| 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                            |  |
| <b>IARC Monographs. Overall Evaluation of Carcinogenicity</b> |                                                                                                                                                                                                                                                                                                                                             |  |
| PARACETAMOL (CAS 103-90-2)                                    | 3 Not classifiable as to carcinogenicity to humans.                                                                                                                                                                                                                                                                                         |  |
| POLYVINYLPIRROLIDONE (CAS 9003-39-8)                          | 3 Not classifiable as to carcinogenicity to humans.                                                                                                                                                                                                                                                                                         |  |
| TALC (CAS 14807-96-6)                                         | 2B Possibly carcinogenic to humans.<br>3 Not classifiable as to carcinogenicity to humans.                                                                                                                                                                                                                                                  |  |
| <b>Reproductive toxicity</b>                                  | Contains no ingredient listed as toxic to reproduction                                                                                                                                                                                                                                                                                      |  |
| <b>Reproductivity</b>                                         |                                                                                                                                                                                                                                                                                                                                             |  |
| DIPHENHYDRAMINE HYDROCHLORIDE                                 | 25 - 100 mg/kg/day Embryo-foetal development, Literature data<br>Result: Maternal toxicity; adverse foetal effects<br>Species: Rat<br>Notes: NTP study                                                                                                                                                                                      |  |
| 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<br>750 mg/kg/day Embryofetal Development, Literature data<br>Result: decrease in foetal weght, minor skeletal abnormalities.<br>Species: Rat |  |
| DIPHENHYDRAMINE HYDROCHLORIDE                                 | 80 - 200 Embryo-foetal development, Literature data<br>Result: Maternal toxicity, Foetotoxicity, some malformations.<br>Species: Mouse<br>Notes: NTP study                                                                                                                                                                                  |  |
| PARACETAMOL                                                   | <= 1400 mg/kg/day Pre- and Post-natal development, Literature data<br>Result: reduced weight gain during nursing.<br>Species: Rat<br>Epidemiology, Literature data<br>Result: No clear association with therapeutic use.<br>Species: Human                                                                                                  |  |
| <b>Specific target organ toxicity - single exposure</b>       | Causes damage to organs.                                                                                                                                                                                                                                                                                                                    |  |
| DIPHENHYDRAMINE HYDROCHLORIDE                                 | Organ: Central nervous system.                                                                                                                                                                                                                                                                                                              |  |
| PARACETAMOL                                                   | Species: Human<br>Organ: Liver                                                                                                                                                                                                                                                                                                              |  |
| <b>Specific target organ toxicity - repeated exposure</b>     | Causes damage to organs.                                                                                                                                                                                                                                                                                                                    |  |
| <b>Aspiration hazard</b>                                      | Not likely, due to the form of the product.                                                                                                                                                                                                                                                                                                 |  |
| <b>Mixture versus substance information</b>                   | No information available.                                                                                                                                                                                                                                                                                                                   |  |
| <b>Other information</b>                                      | Caution - Pharmaceutical agent.                                                                                                                                                                                                                                                                                                             |  |

## SECTION 12: Ecological information

**12.1. Toxicity** Contains a substance which causes risk of hazardous effects to the environment.

| Components                                   |      | Species                                       | Test results                            |
|----------------------------------------------|------|-----------------------------------------------|-----------------------------------------|
| DIPHENHYDRAMINE HYDROCHLORIDE (CAS 147-24-0) |      |                                               |                                         |
| <b>Aquatic</b>                               |      |                                               |                                         |
| <i>Acute</i>                                 |      |                                               |                                         |
| Algae                                        | EC50 | Green algae (Selenastrum capricornutum)       | 0.35 mg/l, 96 hours Measured            |
|                                              | NOEC | Algae                                         | 0.26 mg/l                               |
| Crustacea                                    | EC50 | Water flea (Daphnia magna)                    | 2.3 mg/l, 48 hours Measured             |
|                                              | NOEC | Daphnia                                       | < 0.56 mg/l                             |
| Fish                                         | EC50 | Rainbow trout (Juvenile Oncorhyncus mykiss)   | 2.8 mg/l, 96 hours Static renewal test  |
|                                              | NOEC | Rainbow trout (Juvenile Oncorhyncus mykiss)   | 1.1 mg/l                                |
| PARACETAMOL (CAS 103-90-2)                   |      |                                               |                                         |
| <b>Aquatic</b>                               |      |                                               |                                         |
| <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    |
| Polyvinylpyrrolidone (CAS 9003-39-8)         |      |                                               |                                         |
| <i>Acute</i>                                 |      |                                               |                                         |
|                                              | IC50 | Activated sludge                              | > 1000 mg/l, 3 hours Static test        |
| <b>Aquatic</b>                               |      |                                               |                                         |
| <i>Acute</i>                                 |      |                                               |                                         |
| Crustacea                                    | EC50 | Water flea (Daphnia magna)                    | 84 mg/l, 48 hours Static test           |
|                                              | NOEC | Water flea (Daphnia magna)                    | 32 mg/l, 48 hours Static test           |
| Talc (CAS 14807-96-6)                        |      |                                               |                                         |
| <b>Aquatic</b>                               |      |                                               |                                         |
| <i>Acute</i>                                 |      |                                               |                                         |
| Fish                                         | EC50 | Zebra fish (Adult Brachydanio rerio)          | > 100 g/l, 24 hours Static renewal test |

\* Estimates for product may be based on additional component data not shown.

**12.2. Persistence and degradability** No data is available on the degradability of this product.

### Biodegradability

#### Percent degradation (Aerobic biodegradation-inherent)

|                               |                                                                                                 |
|-------------------------------|-------------------------------------------------------------------------------------------------|
| DIPHENHYDRAMINE HYDROCHLORIDE | < 1 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge |
| PARACETAMOL                   | 99 %, 5 days Modified Zahn-Wellens, Activated sludge                                            |
| Polyvinylpyrrolidone          | 0 %, 28 days Modified MITI test, Activated sludge                                               |

### 12.3. Bioaccumulative potential

#### Partition coefficient n-octanol/water (log Kow)

|                               |                  |
|-------------------------------|------------------|
| DIPHENHYDRAMINE HYDROCHLORIDE | 3.27 (Measured). |
| PARACETAMOL                   | 0.36             |

### 12.4. Mobility in soil

#### Mobility in general

#### Volatility

#### Henry's law

|             |                                     |
|-------------|-------------------------------------|
| PARACETAMOL | 0 atm m <sup>3</sup> /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

|                                     |                                                                                                                                                                                                                  |
|-------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Residual waste</b>               | 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). |
| <b>Contaminated packaging</b>       | 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.       |
| <b>EU waste code</b>                | The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.                                                                                                   |
| <b>Disposal methods/information</b> | 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.      |
| <b>Special precautions</b>          | Dispose in accordance with all applicable regulations.                                                                                                                                                           |

## SECTION 14: Transport information

### ADR

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

## 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**

Not listed.

**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**

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

R22 Harmful if swallowed.  
R41 Risk of serious damage to eyes.  
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
H302 Harmful if swallowed.  
H318 Causes serious eye damage.  
H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.  
H412 Harmful to aquatic life with long lasting effects.

### Revision information

Product and Company Identification: Product and Company Identification  
Composition / Information on Ingredients: Undisclosed Ingredient Statement  
Physical & Chemical Properties:  
Regulatory Information: 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.