

## 1. Identification

|                                      |  |
|--------------------------------------|--|
| <b>Product identifier</b>            | <b>Preparation H Pain Relief Wipes</b>   |
| <b>Other means of identification</b> |  |
| <b>Product code</b>                  | WH-1906-0002   |
| <b>Synonyms</b>                      | PREPARATION H PAIN RELIEF WIPES * PREPARATION H RAPID RELIEF HEMORRHOIDAL WIPES with LIDOCAINE<br>* PREPARATION H RAPID RELIEF TOTABLES WIPES * WH-1906-0002 |
| <b>Recommended use</b>               | Consumer Healthcare Product  |

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

**Recommended restrictions** No other uses are advised.

### Manufacturer/Importer/Supplier/Distributor information

|                     |   |
|---------------------|---|
| <b>COMPANY NAME</b> | GlaxoSmithKline US                                    |
| <b>Address:</b>     | 5 Moore Drive<br>Research Triangle Park, NC 27709 USA |
| <b>Telephone:</b>   | +1-888-825-5249 (General Inquiries)                   |
| <b>Email:</b>       | msds@gsk.com  |
| <b>Website:</b>     | www.gsk.com   |

### EMERGENCY CONTACTS

|                         |  |
|-------------------------|--|
| <b>Telephone:</b>       | 3E GLOBAL INCIDENT RESPONSE<br>+(1) 760 476 3971 (In country)<br>+(1) 760 476 3962 or +(1) 866 519 4752 (International)<br>24/7; multi-language response |
| <b>Contract Number:</b> | 335879   |

## 2. Hazard(s) identification

|                              |  |            |
|------------------------------|--|------------|
| <b>Physical hazards</b>      | Not classified.  |            |
| <b>Health hazards</b>        | Not classified.  |            |
| <b>Environmental hazards</b> | Hazardous to the aquatic environment, acute hazard     | Category 3 |
|                              | Hazardous to the aquatic environment, long-term hazard | Category 3 |
| <b>OSHA defined hazards</b>  | Not classified.  |            |

### Label elements

|                                |   |
|--------------------------------|---|
| <b>Hazard symbol</b>           | None.   |
| <b>Signal word</b>             | None.   |
| <b>Hazard statement</b>        | Harmful to aquatic life. Harmful to aquatic life with long lasting effects.                         |
| <b>Precautionary statement</b> |   |
| <b>Prevention</b>              | Avoid release to the environment.   |
| <b>Response</b>                | Not available.  |
| <b>Storage</b>                 | Not available.  |
| <b>Disposal</b>                | Dispose of contents/container in accordance with local/regional/national/international regulations. |

**Hazard(s) not otherwise classified (HNOC)**

None known.

**Supplemental information**

6% of the mixture consists of component(s) of unknown acute dermal toxicity. 25% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 25% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

### 3. Composition/information on ingredients

#### Mixtures

| Chemical name         | Common name and synonyms  | CAS number | %         |
|-----------------------|---|------------|-----------|
| GLYCERIN              | GLYCEROL<br>GLYCERIN ANHYDROUS<br>GLYCERINE<br>GLYCERITOL<br>GLYCYL ALCOHOL<br>1,2,3-PROPANETRIOL<br>PROPANETRIOL<br>GLYROL<br>GLYSANIN<br>TRIHIDROXYPROPANE<br>1,2,3-TRIHIDROXYPROPANE<br>OSMOGLYN   | 56-81-5    | 20 - < 30 |
| LIDOCAINE             | 2-(DIETHYLAMINO)-N-(2,6-DIMETHYLPHENYL)ACETAMIDE ACETAMIDE,<br>2-(DIETHYLAMINO)-N-(2,6-DIMETHYLPHENYL)-2,6-DIETHYLAMINO)-2',6'-ACETOXYLIDIDE DUNCAINE<br>LIGNOCAINE<br>XYLOCAIN<br>XYLOCAINE<br>2',6'-ACETOXYLIDIDE,<br>2-(DIETHYLAMINO)-   | 137-58-6   | 5 - < 10  |
| BENZYL ALCOHOL        | BENZENEMETHANOL<br>BENZENECARBINOL<br>(HYDROXYMETHYL)BENZENE<br>ALPHA-HYDROXYTOLUENE<br>PHENYLCARBINOL<br>PHENYLMETHANOL<br>PHENYLMETHYL ALCOHOL<br>ALPHA-TOLUENOL<br>OHS02800<br>RTECS DN3150000   | 100-51-6   | 1 - < 3   |
| CITRIC ACID ANHYDROUS | BETA-HYDROXYTRICARBALLYLIC ACID ANHYDROUS CITRIC ACID<br>2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID<br>CITIRIC ACID  | 77-92-9    | 1 - < 3   |
| PROPYLENE GLYCOL      | 1,2-PROPANEDIOL<br>1,2-DIHYDROXYPROPANE<br>2-HYDROXYPROPANOL<br>ISOPROPYLENE GLYCOL<br>METHYLETHYLENE GLYCOL<br>METHYLETHYL GLYCOL<br>MONOPROPYLENE GLYCOL<br>2,3-PROPANEDIOL<br>ALPHA-PROPYLENE GLYCOL<br>1,2-PROPYLENE GLYCOL<br>(RS)-1,2-PROPANEDIOL<br>1,2-(RS)-PROPANEDIOL<br>1,2-PROPANDIOL<br>DL-1,2-PROPANEDIOL<br>DL-PROPYLENE GLYCOL<br>PROPANE-1,2-DIOL (PROPYLENE GLYCOL)<br>PROPANE-1-2-DIOL<br>PROPANEDIOL,1,2- | 57-55-6    | 1 - < 3   |
| SODIUM BENZOATE       | BENZOIC ACID, SODIUM SALT<br>BENZOATE OF SODA<br>SODIUM BENZOIC ACID  | 532-32-1   | < 1       |

| Chemical name   | Common name and synonyms  | CAS number | %         |
|---|---|------------|-----------|
| PHENYLEPHRINE<br>HYDROCHLORIDE                            | (-)-M-HYDROXY-ALPHA-((METHYLAMINO)METHYL)BENZYL<br>ISOPHRIN HYDROCHLORIDE<br>LEVOPHENYLEPHRINE<br>HYDROCHLORIDE<br>METAOXEDRINE HYDROCHLORIDE<br>META-SYNEPHRINE HYDROCHLORIDE<br>NEOPHRYN<br>NEO-SYNEPHRINE HYDROCHLORIDE<br>L-PHENYLEPHRINE HYDROCHLORIDE<br>BENZENEMETHANOL,<br>3-HYDROXY-ALPHA-(METHYLAMINO)METHYL-, HYDROCHLORIDE, (R)-  | 61-76-7    | < 0.3     |
| ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE | (ETHYLENEDINITRILLO)TETRA-ACETIC ACID, DISODIUM SALT, DIHYDRATE<br>DISODIUM DIHYDROGEN<br>ETHYLENEDIAMINETETRAACETATE DIHYDRATE<br>DISODIUM EDTA DIHYDRATE<br>DISODIUM<br>ETHYLENEDIAMINETETRAACETATE DISODIUM<br>ETHYLENEDIAMINETETRAACETATE DIHYDRATE<br>EDETATE DISODIUM<br>EDTA, DISODIUM DIHYDRATE<br>ETHYLENEDIAMINE TETRAACETATE ACID DISODIUM SALT, DIHYDRATE<br>ETHYLENEDIAMINETETRAACETIC ACID DISODIUM SALT DIHYDRATE<br>RTECS AH4410000 | 6381-92-6  | < 0.1     |
| Other components below reportable levels                  |   |            | 60 - < 70 |

#### 4. First-aid measures

|   |  |
|---|--|
| <b>Inhalation</b>   | Move to fresh air. Call a physician if symptoms develop or persist.  |
| <b>Skin contact</b>   | Wash off with soap and water. Get medical attention if irritation develops and persists.                         |
| <b>Eye contact</b>  | Rinse with water. Get medical attention if irritation develops and persists.                                     |
| <b>Ingestion</b>  | Rinse mouth. Get medical attention if symptoms occur.  |
| <b>Most important symptoms/effects, acute and delayed</b>                     | Direct contact with eyes may cause temporary irritation.   |
| <b>Indication of immediate medical attention and special treatment needed</b> | Treat symptomatically.   |
| <b>General information</b>  | Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. |

#### 5. Fire-fighting measures

|  |   |
|--|---|
| <b>Suitable extinguishing media</b>                                  | Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).               |
| <b>Unsuitable extinguishing media</b>                                | Do not use water jet as an extinguisher, as this will spread the fire.                        |
| <b>Specific hazards arising from the chemical</b>                    | During fire, gases hazardous to health may be formed.   |
| <b>Special protective equipment and precautions for firefighters</b> | Self-contained breathing apparatus and full protective clothing must be worn in case of fire. |
| <b>Fire fighting equipment/instructions</b>                          | Move containers from fire area if you can do so without risk.                                 |
| <b>Specific methods</b>  | Use standard firefighting procedures and consider the hazards of other involved materials.    |
| <b>General fire hazards</b>  | No unusual fire or explosion hazards noted.   |

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

### Methods and materials for containment and cleaning up

Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: 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. For waste disposal, see section 13 of the SDS.

### Environmental precautions

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

### Precautions for safe handling

Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

### Conditions for safe storage, including any incompatibilities

Store in tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

#### GSK

| Components  | Type     | Value       | Form |
|---|----------|-------------|------|
| CITRIC ACID ANHYDROUS (CAS 77-92-9)                                       | 8 HR TWA | 5000 mcg/m3 |      |
|   | OHC      | 1           |      |
| ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE (CAS 6381-92-6) | 8 HR TWA | 3000 mcg/m3 |      |
|   | OHC      | 1           |      |
| LIDOCAINE (CAS 137-58-6)  | 8 HR TWA | 200 mcg/m3  | SKIN |
|   | OHC      | 2           | SKIN |
| PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)                                 | 8 HR TWA | 40 mcg/m3   | SKIN |
|   | OHC      | 3           | SKIN |
| SODIUM BENZOATE (CAS 532-32-1)  | 8 HR TWA | 5000 mcg/m3 |      |

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

| Components             | Type | Value    | Form                 |
|------------------------|------|----------|----------------------|
| GLYCERIN (CAS 56-81-5) | PEL  | 5 mg/m3  | Respirable fraction. |
|                        |      | 15 mg/m3 | Total dust.          |

#### US. Workplace Environmental Exposure Level (WEEL) Guides

| Components                    | Type | Value      | Form |
|-------------------------------|------|------------|------|
| BENZYL ALCOHOL (CAS 100-51-6) | TWA  | 44.2 mg/m3 |      |
|                               |      | 10 ppm     |      |

**US. Workplace Environmental Exposure Level (WEEL) Guides**

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

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Exposure guidelines****US ACGIH Threshold Limit Values: Skin designation**

SODIUM BENZOATE (CAS 532-32-1)

Danger of cutaneous absorption

**Appropriate engineering controls**

Good general ventilation 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. General ventilation normally adequate.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection** Wear safety glasses with side shields (or goggles).

**Skin protection**

**Hand protection** Wear appropriate chemical resistant gloves.

**Other**

Wear suitable protective clothing as protection against splashing or contamination.

**Respiratory protection**

No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

**Thermal hazards**

Not applicable.

**General hygiene considerations**

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.

**9. Physical and chemical properties****Appearance**

Aqueous solution.

**Physical state**

Liquid.

**Form**

Liquid saturated on wipe.

**Color**

White.

**Odor**

Not available.

**Odor threshold**

Not available.

**pH**

> 4 - < 5

**Melting point/freezing point**

Not available.

**Initial boiling point and boiling range**

Not available.

**Flash point**

Not available.

**Evaporation rate**

Not available.

**Flammability (solid, gas)**

Not applicable.

**Upper/lower flammability or explosive limits****Explosive limit - lower (%)**

Not available.

**Explosive limit - upper (%)**

Not available.

**Vapor pressure**

Not available.

**Vapor density**

Not available.

**Relative density**

Not available.

**Solubility(ies)****Solubility (water)**

Not available.

**Partition coefficient (n-octanol/water)**

Not available.

**Auto-ignition temperature**

Not available.

**Decomposition temperature**

Not available.

**Viscosity**

Not available.

## Other information

|                             |                 |
|-----------------------------|-----------------|
| <b>Explosive properties</b> | Not explosive.  |
| <b>Oxidizing properties</b> | Not oxidizing.  |
| <b>Percent volatile</b>     | 68 % estimated  |
| <b>Specific gravity</b>     | > 0.95 - < 1.05 |

## 10. Stability and reactivity

|   |   |
|---|---|
| <b>Reactivity</b>                         | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| <b>Chemical stability</b>                 | Material is stable under normal conditions.   |
| <b>Possibility of hazardous reactions</b> | No dangerous reaction known under conditions of normal use.                                   |
| <b>Conditions to avoid</b>                | Contact with incompatible materials.  |
| <b>Incompatible materials</b>             | Strong oxidizing agents.  |
| <b>Hazardous decomposition products</b>   | Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.      |

## 11. Toxicological information

### Information on likely routes of exposure

|                     |  |
|---------------------|--|
| <b>Inhalation</b>   | Prolonged inhalation may be harmful.                     |
| <b>Skin contact</b> | No adverse effects due to skin contact are expected.     |
| <b>Eye contact</b>  | Direct contact with eyes may cause temporary irritation. |
| <b>Ingestion</b>    | Expected to be a low ingestion hazard.                   |

**Symptoms related to the physical, chemical and toxicological characteristics** Direct contact with eyes may cause temporary irritation.

### Information on toxicological effects

**Acute toxicity** Based on available data, the classification criteria are not met.

| <b>Components</b>                         | <b>Species</b> | <b>Test Results</b>    |
|---|----------------|------------------------|
| BENZYL ALCOHOL (CAS 100-51-6)             |                |                        |
| <b>Acute</b>                              |                |                        |
| <b>Inhalation</b>                         |                |                        |
| LC50                                      | Rat            | 1000 ppm               |
| <b>Oral</b>                               |                |                        |
| LD50                                      | Rat            | 1230 mg/kg             |
| CITRIC ACID ANHYDROUS (CAS 77-92-9)       |                |                        |
| <b>Acute</b>                              |                |                        |
| <b>Dermal</b>                             |                |                        |
| LD50                                      | Rat            | > 2000 mg/kg, 24 Hours |
| <b>Oral</b>                               |                |                        |
| LD50                                      | Rat            | 11700 mg/kg            |
| GLYCERIN (CAS 56-81-5)                    |                |                        |
| <b>Acute</b>                              |                |                        |
| <b>Oral</b>                               |                |                        |
| LD50                                      | Rat            | > 2000 mg/kg           |
| LIDOCAINE (CAS 137-58-6)                  |                |                        |
| <b>Acute</b>                              |                |                        |
| <b>Oral</b>                               |                |                        |
| LD50                                      | Rat            | 317 mg/kg              |
| PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7) |                |                        |
| <b>Acute</b>                              |                |                        |
| <b>Oral</b>                               |                |                        |
| LD50                                      | Rat            | 350 mg/kg              |

| Components                                       | Species  | Test Results   |
|--|--|--|
| <b><u>Subacute</u></b>                           |  |  |
| <b>Oral</b>                                      |  |  |
| NOAEL  | Mouse  | 2000 ppm, 14 Day Dietary study, highest dose tested. |
|  | Rat  | 2000 ppm, 14 Day Dietary study, highest dose tested. |
| <b><u>Subchronic</u></b>                         |  |  |
| <b>Oral</b>                                      |  |  |
| LD   | Mouse  | 5000 - 20000 ppm, 12 weeks dietary study             |
|  | Rat  | 5000 - 20000 ppm, 12 weeks dietary study             |
| LOAEL  | Mouse  | 1250 ppm, 12 weeks dietary study                     |
|  | Rat  | 1250 ppm, 12 weeks dietary study                     |
| SODIUM BENZOATE (CAS 532-32-1)                   |  |  |
| <b><u>Acute</u></b>                              |  |  |
| <b>Oral</b>                                      |  |  |
| LD50   | Rat  | 2000 mg/kg   |
| <b>Skin corrosion/irritation</b>                 | Based on available data, the classification criteria are not met.                                    |  |
| <b>Corrosivity</b>                               |  |  |
| PHENYLEPHRINE HYDROCHLORIDE                      | 0, Supplier SDS<br>Result: Non-irritant<br>Species: Rabbit<br>Notes: US Pharmacopeia                 |  |
| SODIUM BENZOATE                                  | OECD 404<br>Result: Negative<br>Species: Rabbit  |  |
| <b>Irritation Corrosion - Skin: P.I.I. value</b> |  |  |
| CITRIC ACID ANHYDROUS                            | OECD 404<br>Result: Mild to moderate irritant.<br>Species: Rabbit                                    |  |
| <b>Serious eye damage/eye irritation</b>         | Based on available data, the classification criteria are not met.                                    |  |
| <b>Eye</b>                                       |  |  |
| PHENYLEPHRINE HYDROCHLORIDE                      | 0, Supplier SDS<br>Result: Irritant  |  |
| SODIUM BENZOATE                                  | Acute ocular irritation; OECD 405<br>Result: Mild irritant<br>Species: Rabbit                        |  |
| CITRIC ACID ANHYDROUS                            | Acute ocular irritation; OECD 405<br>Result: Severe Irritant<br>Species: Rabbit                      |  |
| PHENYLEPHRINE HYDROCHLORIDE                      | Clinical use<br>Result: Pharmacological, cardiovascular effects.<br>Species: Human                   |  |
| <b>Respiratory or skin sensitization</b>         |  |  |
| <b>Respiratory sensitization</b>                 | Based on available data, the classification criteria are not met.                                    |  |
| <b>Skin sensitization</b>                        | Based on available data, the classification criteria are not met.                                    |  |
| <b>Sensitization</b>                             |  |  |
| PHENYLEPHRINE HYDROCHLORIDE                      | Clinical use - Ophthalmology<br>Result: Low incidence of contact hypersensitivity.<br>Species: Human |  |
| SODIUM BENZOATE                                  | Local lymph node assay<br>Result: Negative<br>Species: Mouse   |  |
| <b>Germ cell mutagenicity</b>                    | Based on available data, the classification criteria are not met.                                    |  |
| <b>Mutagenicity</b>                              |  |  |
| SODIUM BENZOATE                                  | Ames<br>Result: Negative   |  |

**Mutagenicity**

PHENYLEPHRINE HYDROCHLORIDE

Ames

Result: Negative

Notes: NTP Study report - Phenylephrine.

Chromosomal Aberration Assay In Vitro, CHO cells

Result: Negative

Notes: NTP Study report - Phenylephrine.

SODIUM BENZOATE

Chromosomal aberration assay

Result: Negative

Species: Rat

PHENYLEPHRINE HYDROCHLORIDE

L5178Y mouse lymphoma thymidine kinase locus assay

Result: Equivocal

Notes: NTP Study report - Phenylephrine.

sister chromatid exchange

Result: Positive

Notes: NTP Study report - Phenylephrine.

**Carcinogenicity**

Based on available data, the classification criteria are not met.

PHENYLEPHRINE HYDROCHLORIDE

133 - 270 mg/kg/day

Result: Negative

Species: Mouse

Test Duration: 103 weeks

Notes: NTP Report - Tox and carc studies with phenylephrine hydrochloride.

SODIUM BENZOATE

2 year study, Male + Female

Result: Negative - dietary

Species: Rat

PHENYLEPHRINE HYDROCHLORIDE

24 - 50 mg/kg/day

Result: Negative

Species: Rat

Test Duration: 103 weeks

Notes: NTP Report - Tox and carc studies with phenylephrine hydrochloride.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**Reproductive toxicity**

Based on available data, the classification criteria are not met.

**Reproductivity**

SODIUM BENZOATE

Embryofetal Development

Result: Negative

PHENYLEPHRINE HYDROCHLORIDE

Epidemiology

Result: Equivocal, evidence of malformations, or other adverse foetal effects from clinical use. Other studies show no such association.

Species: Human

SODIUM BENZOATE

Reproduction/Fertility Study

Result: Negative

Species: Rat

PHENYLEPHRINE HYDROCHLORIDE

Result: Foetal growth retardation and onset of early delivery at doses equivalent to clinical exposure.

Species: Rabbit

**Specific target organ toxicity - single exposure**

Based on available data, the classification criteria are not met.

PHENYLEPHRINE HYDROCHLORIDE

Clinical use

Organ: Cardiovascular effects, some marked.

**Specific target organ toxicity - repeated exposure**

Based on available data, the classification criteria are not met.

**Aspiration hazard**

Based on available data, the classification criteria are not met.

**Chronic effects**

Prolonged inhalation may be harmful.

## 12. Ecological information

### Ecotoxicity

There is insufficient information to determine the scope of the environmental effects this material may cause. Harmful to aquatic life with long lasting effects.

| Components   |      | Species  | Test Results                              |
|--|------|--|---|
| <b>BENZYL ALCOHOL (CAS 100-51-6)</b>   |      |  |   |
| <b>Aquatic</b>   |      |  |   |
| <i>Acute</i>   |      |  |   |
| Activated Sludge Respiration   | IC50 | Mixed industrial/residential sludge.                 | 2100 mg/l, 49 hours                       |
| Algae  | EC50 | Green algae ( <i>Scenedesmus quadricauda</i> )       | 640 mg/l, 96 hours                        |
| Crustacea  | EC50 | Water flea ( <i>Daphnia magna</i> )                  | 360 mg/l, 48 hours                        |
| Fish   | EC50 | Bluegill sunfish (Adult <i>Lepomis macrochirus</i> ) | 10 mg/l, 96 hours Static test             |
|  |      | Fathead minnow (Adult <i>Pimephales promelas</i> )   | 460 mg/l, 96 hours Static test            |
| Microtox   | EC50 | Microtox   | 63.7 mg/l, 15 minutes                     |
| <b>CITRIC ACID ANHYDROUS (CAS 77-92-9)</b>                                       |      |  |   |
| <b>Aquatic</b>   |      |  |   |
| <i>Acute</i>   |      |  |   |
| Algae  | NOEC | Green algae ( <i>Scenedesmus quadricauda</i> )       | 425 mg/l, 8 days Static Test              |
| Crustacea  | EC50 | Water flea ( <i>Daphnia magna</i> )                  | 120 mg/l, 72 hours Static test            |
| Fish   | EC50 | Bluegill sunfish (Adult <i>Lepomis macrochirus</i> ) | 1516 mg/l, 96 hours Static test           |
|  |      | Golden ide/orfe (Adult <i>Leuciscus idus</i> )       | > 440 to < 760 mg/l, 96 hours Static test |
| <b>ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE (CAS 6381-92-6)</b> |      |  |   |
| <b>Aquatic</b>   |      |  |   |
| <i>Acute</i>   |      |  |   |
| Crustacea  | EC50 | Water flea ( <i>Daphnia magna</i> )                  | 21.6 mg/l, 48 hours Static test           |
|  | NOEC | Water flea ( <i>Daphnia magna</i> )                  | 4.1 mg/l, 48 hours Static test            |
| Fish   | EC50 | Bluegill sunfish (Adult <i>Lepomis macrochirus</i> ) | 52.5 mg/l, 96 hours Static test           |
|  |      | Channel catfish (Adult <i>Ictalurus punctatus</i> )  | 164 mg/l, 96 hours Static test            |
|  |      | Fathead minnow (Adult <i>Pimephales promelas</i> )   | 75.9 mg/l, 96 hours Static test           |
| <b>PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)</b>                                 |      |  |   |
| <b>Aquatic</b>   |      |  |   |
| <i>Acute</i>   |      |  |   |
| Algae  | EC50 | Green algae ( <i>Selenastrum capricornutum</i> )     | > 124 mg/l, 72 hours Measured             |
|  | NOEC | Algae  | 31 mg/l, 72 hours                         |
| Crustacea  | EC50 | Water flea ( <i>Daphnia magna</i> )                  | 0.86 mg/l, 48 hours Measured              |
|  | NOEC | Daphnia  | 0.21 mg/l, 48 hours                       |
| Fish   | EC50 | Rainbow trout (Adult <i>Oncorhynchus mykiss</i> )    | > 100 mg/l, 96 hours Measured             |
|  | NOEC | Rainbow trout (Adult <i>Oncorhynchus mykiss</i> )    | 100 mg/l, 96 hours                        |
| <b>PROPYLENE GLYCOL (CAS 57-55-6)</b>  |      |  |   |
| <i>Acute</i>   |      |  |   |
|  | IC50 | Activated sludge                                     | > 1000 mg/l, 3 hours                      |

| Components     |      | Species                                    | Test Results                     |
|----------------|------|--|----------------------------------|
| <b>Aquatic</b> |      |  |                                  |
| <i>Acute</i>   |      |  |                                  |
| Algae          | EC50 | Green algae (Selenastrum capricornutum)    | 19000 mg/l, 14 days              |
|                | NOEC | Green algae (Selenastrum capricornutum)    | 15000 mg/l, 14 days              |
| Crustacea      | EC50 | Daphnia                                    | 43500 mg/l, 48 hours             |
|                | NOEC | Daphnia                                    | 28500 mg/l, 48 hours             |
| Fish           | EC50 | Fathead minnow (Adult Pimephales promelas) | 51400 mg/l, 96 hours Static test |
|                |      | Rainbow trout (Adult Oncorhynchus mykiss)  | 51600 mg/l, 96 hours Static test |
|                | NOEC | Fathead minnow (Adult Pimephales promelas) | 41000 mg/l, 96 hours Static test |
|                |      | Rainbow trout (Adult Oncorhynchus mykiss)  | 42000 mg/l, 96 hours Static test |
| Microtox       | EC50 | Microtox                                   | 51400 mg/l, 30 minutes           |

**SODIUM BENZOATE (CAS 532-32-1)**

**Aquatic**

*Acute*

|           |      |   |                                      |
|-----------|------|---|--------------------------------------|
| Crustacea | EC50 | Water flea (Daphnia magna)                    | > 100 mg/L, 96 hours Static test     |
| Fish      | EC50 | Fathead minnow (Juvenile Pimephales promelas) | 484 mg/L, 96 hours Flow-through test |

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

**Photolysis**

**Half-life (Photolysis-aqueous)**

PROPYLENE GLYCOL 1.3 - 2.3 Years Estimated

**Half-life (Photolysis-atmospheric)**

BENZYL ALCOHOL 2 Days Estimated  
 PROPYLENE GLYCOL 32 Hours Estimated

**Biodegradability**

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

CITRIC ACID ANHYDROUS 98 %, 2 days Modified Zahn-Wellens, Activated sludge  
 ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE 37 %, 14 days Zahn-Wellens, Activated sludge  
 PHENYLEPHRINE HYDROCHLORIDE 81 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge  
 99 %, 7 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge  
 PROPYLENE GLYCOL 62 %, 5 days BOD5, Activated sludge  
 79 %, 20 Days BOD20, Activated sludge

**Percent degradation (Aerobic biodegradation-ready)**

BENZYL ALCOHOL > 90 %, 30 days Closed bottle test, Activated sludge  
 ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE 28 %, 28 days Sturm test  
 SODIUM BENZOATE 100 %, 28 days Modified OECD Screening Test (OECD 301E), Sea water  
 90 %, 7 days Modified Sturm test., Activated sludge

**Percent degradation (Aerobic biodegradation-soil)**

ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE 13 - 45 %, 15 weeks

**Percent degradation (Anaerobic biodegradation)**

BENZYL ALCOHOL 100 %, 14 days Serum Bottle, Anaerobic sludge  
 PROPYLENE GLYCOL 100 %, 9 days  
 SODIUM BENZOATE 93 %, 7 days Other degradation test system, Mixed Residential/Industrial

**Bioaccumulative potential** Not available.

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

BENZYL ALCOHOL 1.1

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

|                             |                  |
|-----------------------------|------------------|
| CITRIC ACID ANHYDROUS       | -1.64            |
| GLYCERIN                    | -1.76            |
| LIDOCAINE                   | 2.26             |
| PHENYLEPHRINE HYDROCHLORIDE | 0.49 (Measured). |
| PROPYLENE GLYCOL            | -1.35            |
| SODIUM BENZOATE             | 1.89             |
|                             | -2.27            |

**Bioconcentration factor (BCF)**

|   |   |
|---|---|
| BENZYL ALCOHOL  | 4 Estimated   |
| ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE | 0.8 - 1.8 Measured, Lepomis macrochirus, bluegill sunfish |
| PROPYLENE GLYCOL  | < 1 Estimated   |

**Mobility in soil** No data available.

**Adsorption****Soil/sediment sorption - log Koc**

|                 |                 |
|-----------------|-----------------|
| BENZYL ALCOHOL  | < 0.7 Measured  |
| LIDOCAINE       | 2.06            |
| SODIUM BENZOATE | 1.16 Calculated |

**Mobility in general****Volatility****Henry's law**

|                       |   |
|-----------------------|---|
| BENZYL ALCOHOL        | 0 atm m <sup>3</sup> /mol, 25 C Estimated     |
| CITRIC ACID ANHYDROUS | < 0 atm m <sup>3</sup> /mol Calculated, 25 °C |
| LIDOCAINE             | 0 atm m <sup>3</sup> /mol Estimated           |
| PROPYLENE GLYCOL      | 0 atm m <sup>3</sup> /mol Estimated           |

**Distribution****Octanol/water distribution coefficient log DOW**

|           |             |
|-----------|-------------|
| LIDOCAINE | -0.05, pH 5 |
|           | 1.76, pH 7  |
|           | 2.77, pH 9  |

**Other adverse effects** None known.

**13. Disposal considerations**

|  |  |
|--|--|
| <b>Disposal instructions</b>                 | Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations. |
| <b>Local disposal regulations</b>            | Dispose in accordance with all applicable regulations.   |
| <b>Hazardous waste code</b>                  | The waste code should be assigned in discussion between the user, the producer and the waste disposal company.   |
| <b>Waste from residues / unused products</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>                | Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.   |

**14. Transport information****DOT**

Not regulated as a dangerous good.  
Read safety instructions, SDS and emergency procedures before handling.

**IATA**

Not regulated as dangerous goods.

**IMDG**

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not established.

## 15. Regulatory information

**US federal regulations** This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

### Toxic Substances Control Act (TSCA)

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

Not regulated.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

### SARA 304 Emergency release notification

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### SARA 302 Extremely hazardous substance

Not listed.

#### SARA 311/312 Hazardous chemical

No

#### SARA 313 (TRI reporting)

Not regulated.

### Other federal regulations

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

Not regulated.

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

Not regulated.

#### Safe Drinking Water Act (SDWA)

Not regulated.

#### FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace

GLYCERIN (CAS 56-81-5)

Other Flavoring Substances with OSHA PEL's

### US state regulations

#### California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

### International Inventories

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

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

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

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

**Issue date** 04-12-2023

|                             |  |
|-----------------------------|--|
| <b>Revision date</b>        | 04-12-2023   |
| <b>Version #</b>            | 03   |
| <b>HMIS® ratings</b>        | Health: 0<br>Flammability: 0<br>Physical hazard: 0   |
| <b>NFPA ratings</b>         | Health: 0<br>Flammability: 0<br>Instability: 0   |
| <b>References</b>           | GSK Hazard Determination.  |
| <b>Disclaimer</b>           | Haleon cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available. 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. |
| <b>Revision information</b> | This document has undergone significant changes and should be reviewed in its entirety.  |