# SAFETY DATA SHEET

## 1. Identification

**Product identifier** **EXCEDRIN RAPID RELIEF (FN-2466-0001)**

**Other means of identification**

**Product code** FN-2466-0001

**Synonyms** FN-2466-0001

**Recommended use** 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.

Consumer Healthcare Product

Medicinal Product

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

**Manufacturer/Importer/Supplier/Distributor information**

**COMPANY NAME** Haleon PLC

**Address:** 184 Liberty Corner Road, Suite 200
Warren, NJ 07059 USA

**Telephone:** +1-908-293-4000 (General Inquiries)

**Email:** msds@haleon.com

**Website:** www.haleon.com

**EMERGENCY CONTACTS**

3E GLOBAL INCIDENT RESPONSE

**Telephone:** +(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

**Contract Number:** 335879

## 2. Hazard(s) identification

**Physical hazards** Not classified.

**Health hazards**

| | |
|---|---|
| Skin corrosion/irritation | Category 2 |
| Serious eye damage/eye irritation | Category 2 |

**Environmental hazards**

| | |
|---|---|
| Hazardous to the aquatic environment, acute hazard | Category 3 |
| Hazardous to the aquatic environment, long-term hazard | Category 3 |

**OSHA defined hazards** Not classified.

**Label elements**

**Signal word** Warning

**Hazard statement** Causes skin irritation. Causes serious eye irritation. Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

**Precautionary statement**

| | |
|---|---|
| **Prevention** | Wash thoroughly after handling. Avoid release to the environment. Wear eye protection/face protection. Wear protective gloves. |
| **Response** | Specific treatment (see on this label). If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If skin irritation occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. |
| **Storage** | Not available. |
| **Disposal** | Dispose of contents/container in accordance with local/regional/national/international regulations. |

**Hazard(s) not otherwise classified (HNOC)** None known.

**Supplemental information** 11.156% of the mixture consists of component(s) of unknown acute oral toxicity. 13.387% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 13.387% 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 | % |
|---|---|---|---|
| PARACETAMOL | ACETAMIDE, N-(4-HYDROXYPHENYL)-<br>N-(4-HYDROXYPHENYL) ACETAMIDE<br>ACETANILIDE, 4'-HYDROXY-<br>4'-HYDROXYACETANILIDE<br>PARACETAMOL<br>PARA-ACETAMIDOPHENOL<br>4-ACETAMINOPHENOL<br>PARA-HYDROXYACETANILIDE | 103-90-2 | 70 - < 80 |
| STARCH | ARROWROOT STARCH<br>CORN STARCH<br>CORN STARCH 400-L NF<br>MAIZE STARCH<br>POTATO STARCH<br>PREGELATINIZED STARCH NF<br>RICE STARCH<br>STARCH 1500 | 9005-25-8 | 10 - < 20 |
| CALCIUM CARBONATE | CARBONIC ACID, CALCIUM SALT<br>CALCIUM MONOCARBONATE<br>PRECIPITATED CALCIUM CARBONATE<br>CHALK | 471-34-1 | 5 - < 10 |
| ALGINIC ACID | KELACID<br>NORGINE<br>POLYMANNURONIC ACID | 9005-32-7 | 1 - < 3 |
| POLYVINYLPYRROLIDONE | 1-ETHENYL-2-PYRROLIDINONE<br>HOMOPOLYMER<br>2-PYRROLIDINONE, 1-ETHENYL,<br>HOMOPOLYMER<br>CROSPOVIDONE<br>KOLLIDON 25<br>KOLLIDON 30<br>PLASDONE<br>PLASDONE K29/32<br>POLY(N-VINYLPYRROLIDONE)<br>POLY[1-(2-OXO-1-PYRROLIDINYL)ETH<br>YLENE] Polyplasdone XL<br>POLYVINYLPYRROLIDONE<br>POVIDONE<br>POVIDONE 30<br>PROVIDONE<br>PVP | 9003-39-8 | 1 - < 3 |

| Chemical name | Common name and synonyms | CAS number | % |
|---|---|---|---|
| HYDROXYPROPYL METHYL CELLULOSE | 2-Hydroxypropyl cellulose methyl ether<br>METHOCEL K4M<br>GONIOSOL<br>ISOPRO ALKALINE<br>METHOCEL E,F,K<br>METHOCEL HG<br>METHYL CELLULOSE PROPYLENE GLYCOL ETHER<br>HYPROMELLOSE<br>CELLULOSE, 2-HYDROXYPROPYL METHYL ESTER<br>METHYLHYDROXYPROPYLCELLULOSE PHARMACOAT 603 | 9004-65-3 | < 0.2 |
| MAGNESIUM STEARATE | STEARIC ACID, MAGNESIUM SALT<br>MAGNESIUM DISTEARATE<br>DIBASIC MAGNESIUM STEARATE<br>MAGNESIUM DISTEARATE, PURE | 557-04-0 | < 0.2 |
| POLYETHYLENE GLYCOL 400 | PEG 400<br>ALPHA-HYDRO-OMEGA-HYDROXY-POLY(OXY-1,2-ETHANEDIYL) PEG<br>CARBOWAX<br>POLYOXYETHYLENE 400<br>CARBOWAX POLYETHYLENE GLYCOL 400<br>CARBOWAX PEG 400<br>POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-HYDRO-.OMEGA.<br>POLYETHYLENEGLYCOL 6000<br>ETHYLENE GLYCOL HOMOPOLYMER<br>ETHYLENE GLYCOL POLYMER<br>ETHYLENE OXIDE POLYMER<br>ETHYLENE OXIDE, HOMOPOLYMER<br>ETHYLENE POLYOXIDE | 25322-68-3 | < 0.1 |
| SILICON DIOXIDE | SILICA<br>SILICA GEL<br>AMORPHOUS SILICA<br>DIATOMACEOUS EARTH<br>SIDENT<br>COLLOIDAL SILICON DIOXIDE<br>SILICON DIOXIDE, CRYSTALLINE<br>SILICON DIOXIDE, AMORPHOUS<br>SILICA, AMORPHOUS HYDRATED | 7631-86-9 | < 0.1 |
| TITANIUM DIOXIDE | TITANIUM OXIDE<br>TITANIUM(IV) OXIDE<br>TITANIUM PEROXIDE (TiO2)<br>PIGMENT WHITE 6 | 13463-67-7 | < 0.1 |
| Other components below reportable levels | | | < 1 |

## 4. First-aid measures

**Inhalation** Move to fresh air. Call a physician if symptoms develop or persist.

**Skin contact** Remove contaminated clothing. Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

**Eye contact** Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

**Ingestion** Rinse mouth. Get medical attention if symptoms occur.

**Most important symptoms/effects, acute and delayed** Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

**Indication of immediate medical attention and special treatment needed** Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

**General information** Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

**Suitable extinguishing media** Foam. Powder. Carbon dioxide (CO2).

| | |
|---|---|
| **Unsuitable extinguishing media** | Do not use water jet as an extinguisher, as this will spread the fire. |
| **Specific hazards arising from the chemical** | During fire, gases hazardous to health may be formed. |
| **Special protective equipment and precautions for firefighters** | Self-contained breathing apparatus and full protective clothing must be worn in case of fire. |
| **Fire fighting equipment/instructions** | Move containers from fire area if you can do so without risk. |
| **Specific methods** | Use standard firefighting procedures and consider the hazards of other involved materials. |
| **General fire hazards** | 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. 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 of the SDS. |
| **Methods and materials for containment and cleaning up** | Prevent product from entering drains.<br><br>Large Spills: Stop the flow of material, if this is without risk. Following product recovery, flush area with water.<br><br>Small Spills: Clean surface thoroughly to remove residual contamination.<br><br>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 contact with eyes, skin, and clothing. 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.

**Haleon Exposure Limits**

| Components | Type | Value | Form |
|---|---|---|---|
| ALGINIC ACID (CAS 9005-32-7) | OHC | 1 | |
| CALCIUM CARBONATE (CAS 471-34-1) | OHC | 1 | >1000 - </=5000 mcg/m3 |
| HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3) | OHC | 1 | |
| PARACETAMOL (CAS 103-90-2) | 8 HR TWA | 3000 mcg/m3 | |
| | OHC | 1 | |

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

| Components | Type | Value | Form |
|---|---|---|---|
| CALCIUM CARBONATE (CAS 471-34-1) | PEL | 5 mg/m3 | Respirable fraction. |
| | | 15 mg/m3 | Total dust. |
| STARCH (CAS 9005-25-8) | PEL | 5 mg/m3 | Respirable fraction. |
| | | 15 mg/m3 | Total dust. |
| TITANIUM DIOXIDE (CAS 13463-67-7) | PEL | 15 mg/m3 | Total dust. |

**US. OSHA Table Z-3 Permissible Exposure Limits (PEL) for Mineral Dusts (29 CFR 1910.1000)**

| Components | Type | Value | Form |
|---|---|---|---|
| SILICON DIOXIDE (CAS 7631-86-9) | TWA | 0.8 mg/m3 | |
| | | 20 mppcf | |
| TITANIUM DIOXIDE (CAS 13463-67-7) | TWA | 5 mg/m3 | Respirable fraction. |
| | | 15 mg/m3 | Total dust. |
| | | 50 mppcf | Total dust. |
| | | 15 mppcf | Respirable fraction. |

**US. ACGIH Threshold Limit Values (TLV)**

| Components | Type | Value | Form |
|---|---|---|---|
| MAGNESIUM STEARATE (CAS 557-04-0) | TWA | 3 mg/m3 | Respirable fraction. |
| | | 10 mg/m3 | Inhalable fraction. |
| STARCH (CAS 9005-25-8) | TWA | 10 mg/m3 | |
| TITANIUM DIOXIDE (CAS 13463-67-7) | TWA | 2.5 mg/m3 | Respirable finescale particles |
| | | 0.2 mg/m3 | Respirable nanoscale particles |

**US. NIOSH: Pocket Guide to Chemical Hazards Recommended Exposure Limits (REL)**

| Components | Type | Value | Form |
|---|---|---|---|
| CALCIUM CARBONATE (CAS 471-34-1) | TWA | 5 mg/m3 | Respirable. |
| | | 10 mg/m3 | Total |
| SILICON DIOXIDE (CAS 7631-86-9) | TWA | 6 mg/m3 | |
| STARCH (CAS 9005-25-8) | TWA | 5 mg/m3 | Respirable. |
| | | 10 mg/m3 | Total |

**US. OARS. Workplace Environmental Exposure Level (WEEL) Guide**

| Components | Type | Value | Form |
|---|---|---|---|
| POLYETHYLENE GLYCOL 400 (CAS 25322-68-3) | TWA | 10 mg/m3 | Aerosol. |

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

**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. Provide eyewash station and safety shower.

**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 appropriate chemical resistant clothing.

**Respiratory protection** In case of insufficient ventilation, wear suitable respiratory equipment.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**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.

## 9. Physical and chemical properties

**Appearance**

**Physical state** Solid.

**Form** Not available.

**Color** Not available.

| | |
|---|---|
| **Odor** | Not available. |
| **Odor threshold** | Not available. |
| **pH** | Not available. |
| **Melting point/freezing point** | Not available. |
| **Initial boiling point and boiling range** | Not available. |
| **Flash point** | Not available. |
| **Evaporation rate** | Not available. |
| **Flammability (solid, gas)** | Not available. |
| **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** | |
| **Explosive properties** | Not explosive. |
| **Oxidizing properties** | Not oxidizing. |

## 10. Stability and reactivity

| | |
|---|---|
| **Reactivity** | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| **Chemical stability** | Material is stable under normal conditions. |
| **Possibility of hazardous reactions** | No dangerous reaction known under conditions of normal use. |
| **Conditions to avoid** | Contact with incompatible materials. |
| **Incompatible materials** | Alkaline metals. Fluorine. |
| **Hazardous decomposition products** | No hazardous decomposition products are known. |

## 11. Toxicological information

**Information on likely routes of exposure**

| | |
|---|---|
| **Inhalation** | Prolonged inhalation may be harmful. |
| **Skin contact** | Causes skin irritation. |
| **Eye contact** | Causes serious eye irritation. |
| **Ingestion** | Expected to be a low ingestion hazard. |
| **Symptoms related to the physical, chemical and toxicological characteristics** | Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. |

**Information on toxicological effects**

**Acute toxicity** Not known.

| **Components** | **Species** | **Test Results** |
|---|---|---|
| ALGINIC ACID (CAS 9005-32-7) | | |
| **Acute** | | |
| **Oral** | | |
| LD50 | Rat | > 5000 mg/kg |

| Components | Species | Test Results |
|---|---|---|
| CALCIUM CARBONATE (CAS 471-34-1) | | |
| **Acute** | | |
| **Oral** | | |
| LD50 | Rat | 6450 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 |
| **Other** | | |
| LOAEL | Mouse | 130 ppm, 61 weeks dietary, continuous |
| NOAEL | Mouse | 3200 ppm, 13 weeks dietary, continuous |
| | | 0.3 %, 41 weeks dietary, continuous |
| TD | Mouse | 6100 ppm, 13 weeks dietary, continuous |
| | | 1.25 %, 41 weeks dietary, continuous |
| POLYETHYLENE GLYCOL 400 (CAS 25322-68-3) | | |
| **Acute** | | |
| **Oral** | | |
| LD50 | Rat | 30.2 g/kg |
| POLYVINYLPYRROLIDONE (CAS 9003-39-8) | | |
| **Acute** | | |
| **Oral** | | |
| LD50 | Rat | > 5000 mg/kg |
| TITANIUM DIOXIDE (CAS 13463-67-7) | | |
| **Acute** | | |
| **Inhalation** | | |
| LC50 | Rat | 6820 mcg/m3 |
| **Oral** | | |
| LD50 | Rat | > 24 g/kg |
| **Chronic** | | |
| **Inhalation** | | |
| LOEC | Rat | 8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophrages in lymphoid tissue. |
| NOAEC | Rat | 250 mg/m3, 2 years Highest dose |
| | | 5 mg/m3, 24 months |
| **Subacute** | | |
| **Inhalation** | | |
| LOEL | Rat | 0.1 - 35 mg/m3, 4 weeks Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid. |
| NOAEC | Guinea pig | 26 mg/m3, 3 weeks No evidence of significant inflammation in respiratory tract. |

| Components | Species | Test Results |
|---|---|---|
| **Oral** | | |
| NOAEL | Rat | 100000 ppm, 14 Day Dietary study, highest dose tested. |
| **Subchronic** | | |
| **Inhalation** | | |
| LOEC | Rat | 3.2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation. |

**Skin corrosion/irritation** Causes skin irritation.

**Irritation Corrosion - Skin**

| | |
|---|---|
| TITANIUM DIOXIDE | 0, Literature data<br>Result: Non-irritant<br>Species: Guinea pig |
| | 0, Literature data<br>Result: Non-irritant<br>Species: Human |
| | Acute dermal irritation; OECD 404, Literature data<br>Result: Non-irritant<br>Species: Rabbit |

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

| | |
|---|---|
| MAGNESIUM STEARATE | 0 |
| PARACETAMOL | OECD 404, Literature data<br>Result: Slight irritant<br>Species: Rabbit |

**Serious eye damage/eye irritation** Causes serious eye irritation.

**Eye**

| | |
|---|---|
| PARACETAMOL | OECD 405<br>Result: Slight irritant<br>Species: Rabbit |
| TITANIUM DIOXIDE | OECD 405, Literature data<br>Result: Mild irritant<br>Species: Rabbit |

**Eye / Initial pain reaction score**

| | |
|---|---|
| PARACETAMOL | 0, Literature data |

**Eye / Kay and Calandra class - Intact**

| | |
|---|---|
| MAGNESIUM STEARATE | 4<br>Recovery Period: 2 days |

**Respiratory or skin sensitization**

**Respiratory sensitization** Not a respiratory sensitizer.

**Skin sensitization** This product is not expected to cause skin sensitization.

**Maximisation assay (Magnusson and Kligman)**

| | |
|---|---|
| HYDROXYPROPYL METHYL CELLULOSE | Result: Negative<br>Species: Guinea pig |

**Sensitization**

| | |
|---|---|
| TITANIUM DIOXIDE | 5 % Optimisation Test, Literature data - Vehicle: petrolatum<br>Result: Negative<br>Species: Guinea pig<br>Test Duration: 48 hour exposure |
| | Patch test, Literature data<br>Result: Negative<br>Species: Human |

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Mutagenicity**

| | |
|---|---|
| PARACETAMOL | Ames, Literature data<br>Result: Negative |
| TITANIUM DIOXIDE | Ames, Literature data<br>Result: Negative |
| PARACETAMOL | Chromosomal Aberration Assay In Vitro, Literature data<br>Result: Positive |
| | HPRT gene mutation in human lymphocytes, Literature data<br>Result: Negative |

**Mutagenicity**

| | |
|---|---|
| PARACETAMOL | In vivo Micronucleus, Literature data<br>Result: Negative<br>Species: Mouse |
| TITANIUM DIOXIDE | Micronucleus Assay in vitro, CHO cells, Literature data<br>Result: Negative<br>Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data<br>Result: Positive<br>Syrian Hamster Embryo (SHE) cell transformation assay<br>Result: Negative<br>WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data<br>Result: Positive |

**Carcinogenicity** Carcinogenic effects are not expected as a result of occupational exposure. Contains a material (TITANIUM DIOXIDE) classified as a carcinogen by external agencies.

| | |
|---|---|
| PARACETAMOL | 0, Literature data<br>Result: Equivocal. Increase in ademomas at toxic dose.<br>Species: Mouse<br>0, Literature data<br>Result: Equivocal. Liver and bladder neoplasms at toxic doses.<br>Species: Rat<br>0, Literature data<br>Result: Negative<br>Species: Mouse<br>0, Literature data<br>Result: Negative<br>Species: Rat |
| TITANIUM DIOXIDE | 0.5 mg/m3, Literature data<br>Result: Negative<br>Species: Rat<br>Test Duration: 24 months<br>0.72 - 14.8 mg/m3, Literature data<br>Result: Negative<br>Species: Mouse<br>10 - 250 mg/m3, Dietary study - Literature data.<br>Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration.<br>Species: Rat<br>Test Duration: 24 months<br>25000 - 50000 ppm, Dietary study - Literature data.<br>Result: Negative<br>Species: Rat<br>25000 - 50000 ppm, Dietary study<br>Result: Negative<br>Species: Mouse<br>7.2 - 14.8 mg/m3, Literature data<br>Result: Lung tumour<br>Species: Rat<br>Test Duration: 24 months |

**IARC Monographs. Overall Evaluation of Carcinogenicity**

| | |
|---|---|
| PARACETAMOL (CAS 103-90-2) | 3 Not classifiable as to carcinogenicity to humans. |
| POLYVINYLPYRROLIDONE (CAS 9003-39-8) | 3 Not classifiable as to carcinogenicity to humans. |
| SILICON DIOXIDE (CAS 7631-86-9) | 3 Not classifiable as to carcinogenicity to humans. |
| TITANIUM DIOXIDE (CAS 13463-67-7) | 2B Possibly carcinogenic to humans. |

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

Not listed.

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

Not listed.

**Reproductive toxicity** This product is not expected to cause reproductive or developmental effects.

**Reproductivity**

| | |
|---|---|
| PARACETAMOL | <= 1400 mg/kg/day Pre- and Post-natal development, Literature data<br>Result: reduced weight gain during nursing.<br>Species: Rat |

**Reproductivity**

PARACETAMOL

250 mg/kg/day Embryofetal Development, Literature data
Result: Foetal NOAEL
Species: Rat

387 mg/kg/day Embryofetal Development, Literature data
Result: Negative
Species: Mouse

750 mg/kg/day Embryofetal Development, Literature data
Result: decrease in foetal weght, minor skeletal abnormalities.
Species: Rat

Epidemiology, Literature data
Result: No clear association with therapeutic use.
Species: Human

**Specific target organ toxicity - single exposure** Not classified.

PARACETAMOL

Species: Human
Organ: Liver

**Specific target organ toxicity - repeated exposure** Not classified.

**Aspiration hazard** Not an aspiration hazard.

**Chronic effects** Prolonged inhalation may be harmful.

## 12. Ecological information

**Ecotoxicity** Harmful to aquatic life with long lasting effects.

| Components | | Species | Test Results |
|---|---|---|---|
| CALCIUM CARBONATE (CAS 471-34-1) | | | |
| **Aquatic** | | | |
| *Acute* | | | |
| Fish | LC50 | Western mosquitofish (Gambusia affinis) | > 56000 mg/l, 24 hours |
| HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3) | | | |
| **Aquatic** | | | |
| *Acute* | | | |
| Fish | EC50 | Fish | > 100 mg/L, 96 hours |
| MAGNESIUM STEARATE (CAS 557-04-0) | | | |
| **Aquatic** | | | |
| *Acute* | | | |
| Fish | EC50 | Orange-red killfish (Adult Oryzias latipes) | 130 mg/l, 96 hours |
| PARACETAMOL (CAS 103-90-2) | | | |
| **Aquatic** | | | |
| *Acute* | | | |
| Algae | EC50 | Green algae (Scenedesmus subspicatus) | 134 mg/l, 72 hours |
| Crustacea | EC50 | Water flea (Daphnia magna) | 50 mg/l, 48 hours Static test |
| Fish | EC50 | Fathead minnow (Juvenile Pimephales promelas) | 814 mg/l, 96 hours Flow-through test |
| POLYETHYLENE GLYCOL 400 (CAS 25322-68-3) | | | |
| **Aquatic** | | | |
| *Acute* | | | |
| Crustacea | EC50 | Water flea (Daphnia magna) | 53000 mg/l, 48 hours |
| Fish | EC50 | Fathead minnow (Adult Pimephales promelas) | 87000 mg/l, 96 hours |
| Microtox | EC50 | Microtox | 100000 mg/l, 15 minutes |
| POLYVINYLPYRROLIDONE (CAS 9003-39-8) | | | |
| *Acute* | | | |
| | IC50 | Activated sludge | > 1000 mg/l, 3 hours Static test |

| Components | | Species | Test Results |
|---|---|---|---|
| **Aquatic** | | | |
| *Acute* | | | |
| 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 |
| SILICON DIOXIDE (CAS 7631-86-9) | | | |
| **Aquatic** | | | |
| *Acute* | | | |
| Algae | EC50 | Green algae (Selenastrum capricornutum) | 440 mg/l, 72 hours |
| | NOEC | Green algae (Selenastrum capricornutum) | 60 mg/l, 72 hours |
| Crustacea | EC50 | Water flea (Daphnia magna) | > 10000 mg/l, 24 hours Static test |
| Fish | EC50 | Common carp (Juvenile Cyprinus carpio) | > 10000 mg/l, 72 hours |
| | | Zebra fish (Adult Brachydanio rerio) | 5000 mg/l, 96 hours Static test |
| Microtox | EC50 | Microtox | 8700 mg/l, 15 minutes |
| TITANIUM DIOXIDE (CAS 13463-67-7) | | | |
| **Aquatic** | | | |
| Fish | LC50 | Mummichog (Fundulus heteroclitus) | > 1000 mg/l, 96 hours |
| *Acute* | | | |
| Crustacea | EC50 | Water flea (Daphnia magna) | > 1000 mg/l, 48 hours Static test |

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

**Photolysis**

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

| | |
|---|---|
| MAGNESIUM STEARATE | 17 Hours Estimated |

**UV/visible spectrum wavelength**

| | |
|---|---|
| MAGNESIUM STEARATE | 210 nm |

**Biodegradability**

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

| | |
|---|---|
| MAGNESIUM STEARATE | 77 %, 28 days BOD |
| PARACETAMOL | 99 %, 5 days Modified Zahn-Wellens, Activated sludge |
| POLYETHYLENE GLYCOL 400 | 40.2 - 70 %, 20 Days BOD20 |
| POLYVINYLPYRROLIDONE | 0 %, 28 days Modified MITI test, Activated sludge |

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

| | |
|---|---|
| MAGNESIUM STEARATE | 95 %, 22 days Sturm test |

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

| | |
|---|---|
| MAGNESIUM STEARATE | 50 %, 13 days |

**Bioaccumulative potential** Not available.

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

| | |
|---|---|
| HYDROXYPROPYL METHYL CELLULOSE | -5 |
| PARACETAMOL | 0.36 |

**Bioconcentration factor (BCF)**

| | |
|---|---|
| HYDROXYPROPYL METHYL CELLULOSE | 3.2 Estimated |
| MAGNESIUM STEARATE | > 9999 Estimated |

**Mobility in soil** No data available.

**Adsorption**

**Soil/sediment sorption - log Koc**

| | |
|---|---|
| MAGNESIUM STEARATE | 5.86 Estimated |

**Mobility in general**

**Volatility**

**Henry's law**

| | |
|---|---|
| HYDROXYPROPYL METHYL CELLULOSE | 0 atm m3/mol Estimated |
| PARACETAMOL | 0 atm m^3/mol Estimated |

**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

| | |
|---|---|
| **Disposal instructions** | 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. |
| **Local disposal regulations** | Dispose in accordance with all applicable regulations. |
| **Hazardous waste code** | The waste code should be assigned in discussion between the user, the producer and the waste disposal company. |
| **Waste from residues / unused products** | Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). |
| **Contaminated packaging** | 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 applicable. |

## 15. Regulatory information

**US federal regulations** This product is 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** | Yes |
| **Classified hazard categories** | Skin corrosion or irritation<br>Serious eye damage or eye irritation |

**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. |

**US state regulations**

**US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))**

TITANIUM DIOXIDE (CAS 13463-67-7)

**California Proposition 65**

**WARNING:** This product can expose you to TITANIUM DIOXIDE, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

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

TITANIUM DIOXIDE (CAS 13463-67-7) Listed: September 2, 2011

**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) | Yes |
| 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) | Yes |
| New Zealand | New Zealand Inventory | Yes |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | Yes |
| Taiwan | Taiwan Chemical Substance Inventory (TCSI) | Yes |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | Yes |

*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** 06-04-2024

**Version #** 01

**HMIS® ratings** Health: 2*
Flammability: 1
Physical hazard: 0

**NFPA ratings** Health: 2
Flammability: 1
Instability: 0

**Disclaimer** 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.