

## 1. Identification

|                                                               |                                                                                                                                                                                               |
|---------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Product identifier</b>                                     | <b>ALBENDAZOLE TABLETS</b>                                                                                                                                                                    |
| <b>Other means of identification</b>                          | Not available.                                                                                                                                                                                |
| <b>Synonym(s)</b>                                             | ALBEN TABLETS 400 MG * AZENTEL TABLETS 400 MG * ESKAZOLE TABLETS 400 MG * ESKAZOLE 400 MG CHEWABLE TABLETS * NEMATIL TABLETS 400 MG * ZENTEL TABLETS 400 MG * ALBENDAZOLE, FORMULATED PRODUCT |
| <b>Recommended use</b>                                        | Medicinal Product                                                                                                                                                                             |
| <b>Recommended restrictions</b>                               | No other uses are advised.                                                                                                                                                                    |
| <b>Manufacturer/Importer/Supplier/Distributor information</b> |                                                                                                                                                                                               |
| <b>Manufacturer</b>                                           |                                                                                                                                                                                               |

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 available 24 hrs/7 days; multi-language response

## 2. Hazard(s) identification

|                                                  |                                                                                                          |
|--------------------------------------------------|----------------------------------------------------------------------------------------------------------|
| <b>Classified hazards</b>                        | Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device. |
| <b>Label elements</b>                            | Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device. |
| <b>Hazard(s) not otherwise classified (HNOG)</b> | Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device. |

## 3. Composition/information on ingredients

### Mixtures

| Chemical name | Common name and synonyms                                                                                                                                                                                                                                                                                                                                              | CAS number | %     |
|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-------|
| ALBENDAZOLE   | (5-(PROPYLTHIO)-1H-BENZIMIDAZOL-2-Y<br>L-)CARBAMIC ACID METHYL ESTER<br>ABZ<br>SKF-62979<br>METHYL<br>5-(PROPYLTHIO)-2-BENZIMIDAZOLECAR<br>BAMATE ((PROPYLTHIO)-5<br>1H-BENZIMIDAZOLYL-2) CARBAMATE DE<br>METHYLE (FRENCH)<br>(5-(PROPYLTHIO)-1H-BENZIMIDAZOL-2-Y<br>L-)CARBAMIC ACID METHYL ESTER<br>5-(PROPYLTHIO)-2-CARBOMETHOXYAMI<br>NOBENZIMIDAZOLE 62979 (SKF) | 54965-21-8 | 38.94 |

| Chemical name                            | Common name and synonyms                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | CAS number | %     |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-------|
| MICROCRYSTALLINE CELLULOSE               | AVICEL PH MICROCRYSTALLINE CELLULOSE<br>ABICEL<br>ALPHA-CELLULOSE<br>ARBOCEL<br>ARBOCELL B 600/30<br>ARBOCELL BC 200<br>AVICEL PH101<br>AVICEL PH102<br>AVICEL PH103<br>AVICEL PH105<br>AVICEL PH112<br>AVICEL PH200<br>BETA-AMYLOSE<br>CELLEX MX<br>CELLULOSE (8CI9CI)<br>CELLULOSE 248<br>CELLULOSE CRYSTALLINE<br>CELLULOSE, FOOD GRADE<br>CELUF<br>CRYSTALLINE CELLULOSE<br>EMOCEL<br>MCC<br>MICROCRYSTALLINE CELLULOSE<br>POWDERED CELLULOSE<br>RTECS FJ5691460<br>SOLKA FLOC BW200<br>CELLULOSA (FIBRA PAPEL)<br>CELLULOSE (PAPER FIBRES)<br>CELLULOSE-PAPER FIBER<br>CELULOSA (FIBRA PAPEL)<br>TSELLULOOS | 9004-34-6  | 25.66 |
| STARCH                                   | ARROWROOT STARCH<br>CORN STARCH<br>POTATO STARCH<br>RICE STARCH                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 9005-25-8  | 15.58 |
| CROSCARMELLOSE SODIUM                    | AC-DI-SOL (R)<br>SODIUM CROSCARMELLOSE<br>AC-DI-SOL (R) CROSCARMELLOSE<br>SODIUM<br>AC-DI-SOL (R) SD-711<br>OHS05522                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 74811-65-7 | 3.89  |
| POLYVINYLPIRROLIDONE                     | 1-ETHENYL-2-PYRROLIDINONE<br>HOMOPOLYMER<br>POLY(N-VINYLPYRROLIDONE)<br>PLASDONE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 9003-39-8  | 1.95  |
| MAGNESIUM STEARATE                       | STEARIC ACID, MAGNESIUM SALT<br>MAGNESIUM DISTEARATE<br>DIBASIC MAGNESIUM STEARATE<br>MAGNESIUM DISTEARATE, PURE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 557-04-0   | 0.9   |
| Other components below reportable levels |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |            | 13.08 |

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

#### 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.<br><br>The possible symptoms of overexposure include: nausea; vomiting; abdominal pain; headache. |
| <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>                                  | Foam. Dry chemical powder. Carbon dioxide (CO2). Water.                                                    |
| <b>Unsuitable extinguishing media</b>                                | None known.                                                                                                |
| <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>                          | Use water spray to cool unopened containers. 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>                                          | Assume that this product is capable of sustaining combustion.                                              |

## 6. Accidental release measures

|                                                                            |                                                                                                                                                                                                                                                                |
|----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Personal precautions, protective equipment and emergency procedures</b> | Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS. |
| <b>Methods and materials for containment and cleaning up</b>               | Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.                                        |
| <b>Environmental precautions</b>                                           | Avoid discharge into drains, water courses or onto the ground.                                                                                                                                                                                                 |

## 7. Handling and storage

|                                                                     |                                                                                                                 |
|---------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|
| <b>Precautions for safe handling</b>                                | Avoid prolonged exposure. Observe good industrial hygiene practices.                                            |
| <b>Conditions for safe storage, including any incompatibilities</b> | Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). |

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### GSK

| Components                                 | Type     | Value      | Note                |
|--------------------------------------------|----------|------------|---------------------|
| ALBENDAZOLE (CAS 54965-21-8)               | 8 HR TWA | 100 mcg/m3 |                     |
|                                            | OHC      | 3          | REPRODUCTIVE HAZARD |
| MAGNESIUM STEARATE (CAS 557-04-0)          | OHC      | 1          |                     |
| MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) | OHC      | 1          |                     |

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

| Components                                 | Type | Value    | Form                 |
|--------------------------------------------|------|----------|----------------------|
| MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) | 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.          |

#### US. ACGIH Threshold Limit Values

| Components                                 | Type | Value    |
|--------------------------------------------|------|----------|
| MAGNESIUM STEARATE (CAS 557-04-0)          | TWA  | 10 mg/m3 |
| MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) | TWA  | 10 mg/m3 |
| STARCH (CAS 9005-25-8)                     | TWA  | 10 mg/m3 |

#### US. NIOSH: Pocket Guide to Chemical Hazards

| Components                                 | Type | Value    | Form        |
|--------------------------------------------|------|----------|-------------|
| MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) | TWA  | 5 mg/m3  | Respirable. |
|                                            |      | 10 mg/m3 | Total       |

| SDS/MSDS Pocket Guide to Chemical Hazards                             |                                                                                                                                                                                                                                                                                                                                                                                               |                     |                      |
|-----------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|
| Components                                                            | Type                                                                                                                                                                                                                                                                                                                                                                                          | Value               | Form                 |
| STARCH (CAS 9005-25-8)                                                | TWA                                                                                                                                                                                                                                                                                                                                                                                           | 5 mg/m3<br>10 mg/m3 | Respirable.<br>Total |
| Biological limit values                                               | No biological exposure limits noted for the ingredient(s).                                                                                                                                                                                                                                                                                                                                    |                     |                      |
| Appropriate engineering controls                                      | Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. |                     |                      |
| Individual protection measures, such as personal protective equipment |                                                                                                                                                                                                                                                                                                                                                                                               |                     |                      |
| Eye/face protection                                                   | Not normally needed.                                                                                                                                                                                                                                                                                                                                                                          |                     |                      |
| Hand protection                                                       | The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.                                                                                                                                                    |                     |                      |
| Other                                                                 | Wear suitable protective clothing.                                                                                                                                                                                                                                                                                                                                                            |                     |                      |
| Respiratory protection                                                | No personal respiratory protective equipment normally required.                                                                                                                                                                                                                                                                                                                               |                     |                      |
| 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

|                                                |                |
|------------------------------------------------|----------------|
| <b>Physical state</b>                          | Solid.         |
| <b>Form</b>                                    | Tablet.        |
| <b>Color</b>                                   | Not available. |
| <b>Odor</b>                                    | Not available. |
| <b>Odor 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. |

### Upper/lower flammability or explosive limits

|                                                |                |
|------------------------------------------------|----------------|
| <b>Flammability limit - lower (%)</b>          | Not available. |
| <b>Flammability limit - upper (%)</b>          | Not available. |
| <b>Explosive limit - lower (%)</b>             | Not available. |
| <b>Explosive limit - upper (%)</b>             | Not available. |
| <b>Vapor pressure</b>                          | Not available. |
| <b>Vapor density</b>                           | Not available. |
| <b>Relative density</b>                        | Not available. |
| <b>Solubility(ies)</b>                         |                |
| <b>Solubility (water)</b>                      | Not available. |
| <b>Partition coefficient (n-octanol/water)</b> | Not available. |
| <b>Auto-ignition temperature</b>               | Not available. |
| <b>Decomposition temperature</b>               | Not available. |
| <b>Viscosity</b>                               | Not available. |

## 10. Stability and reactivity

|                                           |                                                             |
|-------------------------------------------|-------------------------------------------------------------|
| <b>Reactivity</b>                         | Not available.                                              |
| <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. Fluorine.                                                      |
| <b>Hazardous decomposition products</b> | Irritating and/or toxic fumes and gases may be emitted upon the products decomposition. |

## 11. Toxicological information

### Information on likely routes of exposure

|                                                                                     |                                                                                                    |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| <b>Ingestion</b>                                                                    | Expected to be a low ingestion hazard. Health injuries are not known or expected under normal use. |
| <b>Inhalation</b>                                                                   | Health injuries are not known or expected under normal use.                                        |
| <b>Skin contact</b>                                                                 | Health injuries are not known or expected under normal use.                                        |
| <b>Eye contact</b>                                                                  | Direct contact with eyes may cause temporary irritation. Avoid contact with eyes.                  |
| <b>Symptoms related to the physical, chemical and toxicological characteristics</b> | The possible symptoms of overexposure include: nausea, vomiting, abdominal pain, headache.         |

### Information on toxicological effects

|                       |                                                             |
|-----------------------|-------------------------------------------------------------|
| <b>Acute toxicity</b> | Health injuries are not known or expected under normal use. |
|-----------------------|-------------------------------------------------------------|

| Components                                 | Species | Test Results      |
|--------------------------------------------|---------|-------------------|
| ALBENDAZOLE (CAS 54965-21-8)               |         |                   |
| <b>Acute</b>                               |         |                   |
| <i>Oral</i>                                |         |                   |
| LD50                                       | Rat     | 1320 - 2000 mg/kg |
| CROSCARMELLOSE SODIUM (CAS 74811-65-7)     |         |                   |
| <b>Acute</b>                               |         |                   |
| <i>Dermal</i>                              |         |                   |
| LD50                                       | Rabbit  | > 2000 mg/kg      |
| <i>Inhalation</i>                          |         |                   |
| LCLo                                       | Rat     | > 0.1 mg/l        |
| <i>Oral</i>                                |         |                   |
| LD50                                       | Rat     | 5050 mg/kg        |
| MAGNESIUM STEARATE (CAS 557-04-0)          |         |                   |
| <b>Acute</b>                               |         |                   |
| <i>Oral</i>                                |         |                   |
| LD50                                       | Rat     | > 2000 mg/kg      |
| MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) |         |                   |
| <b>Acute</b>                               |         |                   |
| <i>Dermal</i>                              |         |                   |
| LD50                                       | Rabbit  | > 2000 mg/kg      |
| <i>Oral</i>                                |         |                   |
| LD50                                       | Rat     | > 2000 mg/kg      |
| POLYVINYLPIRROLIDONE (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. |
|----------------------------------|-------------------------------------------------------------|

#### Corrosivity

ALBENDAZOLE

Acute dermal irritation  
Result: Non-irritant  
Species: Rabbit

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

MAGNESIUM STEARATE

0

|                                          |                                                                                                                      |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| <b>Serious eye damage/eye irritation</b> | Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use. |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------|

|                                                                           |                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                    |
|---------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Eye</b>                                                                | ALBENDAZOLE                                                                                                   | Acute Ocular irritation<br>Result: Non-Irritating<br>Species: Rabbit                                                                                                                                                                                                                                                                                                                                               |
| <b>Eye / Kay and Calandra class - Intact</b>                              | MAGNESIUM STEARATE                                                                                            | 4<br>Recovery Period: 2 days                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Respiratory or skin sensitization</b>                                  |                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Respiratory sensitization</b>                                          | Health injuries are not known or expected under normal use.                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Skin sensitization</b>                                                 | Health injuries are not known or expected under normal use.                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Sensitization</b>                                                      | ALBENDAZOLE                                                                                                   | Maximisation assay (Magnusson and Kligman)<br>Result: Negative<br>Species: Guinea pig                                                                                                                                                                                                                                                                                                                              |
| <b>Germ cell mutagenicity</b>                                             | Health injuries are not known or expected under normal use.                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Mutagenicity</b>                                                       | ALBENDAZOLE                                                                                                   | Ames<br>Result: Negative<br>Chromosomal Aberration Assay In Vitro<br>Result: Negative<br>In vivo Micronucleus<br>Result: Negative                                                                                                                                                                                                                                                                                  |
| <b>Carcinogenicity</b>                                                    | Health injuries are not known or expected under normal use.                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                    |
| ALBENDAZOLE                                                               |                                                                                                               | 24 Month<br>Result: Negative<br>Species: Mouse<br>24 Month<br>Result: Negative<br>Species: Rat                                                                                                                                                                                                                                                                                                                     |
| <b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>             |                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                    |
| POLYVINYLPYRROLIDONE (CAS 9003-39-8)                                      |                                                                                                               | 3 Not classifiable as to carcinogenicity to humans.                                                                                                                                                                                                                                                                                                                                                                |
| <b>US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b> |                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Not listed.                                                               |                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Reproductive toxicity</b>                                              | Possible risk of affecting the quantity or the quality of breast milk in humans. May damage the unborn child. |                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Reproductivity</b>                                                     | ALBENDAZOLE                                                                                                   | Embryo-foetal development<br>Result: Effects seen at 10 mg/kg/day, NOAEL 5 mg/kg/day<br>Species: Rabbit<br>Embryo-foetal development<br>Result: Effects seen at 10 mg/kg/day, NOAEL 5 mg/kg/day<br>Species: Rat<br>Fertility, Female<br>Result: Negative<br>Species: Rat<br>Fertility, Male<br>Result: Negative<br>Species: Rat<br>Milk effects<br>Result: Excreted in milk, inconclusive effects.<br>Species: Rat |
| <b>Specific target organ toxicity - single exposure</b>                   | None known.                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Specific target organ toxicity - repeated exposure</b>                 | .                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                    |
| ALBENDAZOLE                                                               |                                                                                                               | 30 mg/kg/day Repeat dose non-clinical studies<br>Result: Decrease in size, rat, mouse.<br>Organ: Testes<br>Repeat dose non-clinical studies; clinical observation<br>Result: Human, rat, mouse<br>Organ: Liver<br>Repeat dose non-clinical studies; clinical observation<br>Result: Human, rat, mouse<br>Organ: bone marrow; blood                                                                                 |
| <b>Aspiration hazard</b>                                                  | Not an aspiration hazard.                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Further information</b>                                                | Caution - Pharmaceutical agent.                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                    |

## 12. Ecological information

### Ecotoxicity

No information is available about the potential of this product to produce adverse environmental effects. Contains a substance which causes risk of hazardous effects to the environment. The product contains a substance which may cause long-term adverse effects in the environment.

| Components                           |      | Species                                     | Test Results                        |
|--------------------------------------|------|---------------------------------------------|-------------------------------------|
| ALBENDAZOLE (CAS 54965-21-8)         |      |                                             |                                     |
| <i>Chronic</i>                       |      |                                             |                                     |
| Fish                                 | NOEC | Danio rerio                                 | 0.022 mg/l, 6 days                  |
| <b>Aquatic</b>                       |      |                                             |                                     |
| <i>Acute</i>                         |      |                                             |                                     |
| Activated Sludge Respiration         | IC50 | Residential sludge                          | > 0.27 mg/L, 3 hours                |
| Algae                                | EC50 | Green algae (Selenastrum capricornutum)     | > 50 mg/L, 72 hours                 |
| Crustacea                            | EC50 | Water flea (Daphnia magna)                  | 0.024 mg/L, 48 hours Static test    |
|                                      | NOEC | Water flea (Daphnia magna)                  | 0.017 mg/L, 48 hours Static test    |
| Microtox                             | EC50 | Microtox                                    | 0.36 mg/L, 15 minutes               |
| <b>Terrestrial</b>                   |      |                                             |                                     |
| <i>Acute</i>                         |      |                                             |                                     |
| Earthworm                            | EC50 | Redworm (Lumbricus rubellus)                | 15 mg/kg, 60 days agricultural soil |
| MAGNESIUM STEARATE (CAS 557-04-0)    |      |                                             |                                     |
| <b>Aquatic</b>                       |      |                                             |                                     |
| <i>Acute</i>                         |      |                                             |                                     |
| Fish                                 | EC50 | Orange-red killfish (Adult Oryzias latipes) | 130 mg/l, 96 hours                  |
| Microtox                             | EC50 | Microtox                                    | 12.5 mg/l, 15 minutes               |
| POLYVINYLPIRROLIDONE (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       |

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

### Persistence and degradability

#### Photolysis

##### Half-life (Photolysis-aqueous)

ALBENDAZOLE 0.1 - 1.65 Days Measured

##### Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

##### UV/visible spectrum wavelength

ALBENDAZOLE 295 nm, pH 7

MAGNESIUM STEARATE 210 nm

#### Biodegradability

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

MAGNESIUM STEARATE 50 %, 13 days

### Bioaccumulative potential

#### Bioconcentration factor (BCF)

ALBENDAZOLE 1.16 Measured, Lepomis macrochirus, bluegill sunfish

MAGNESIUM STEARATE > 9999 Estimated

### Mobility in soil

#### Adsorption

##### Soil/sediment sorption - log Koc

ALBENDAZOLE 3.89 - 4.44 Measured

MAGNESIUM STEARATE 5.86 Estimated

## Mobility in general

### Distribution

#### Octanol/water distribution coefficient log DOW

ALBENDAZOLE 3.47

#### Octanol/water distribution coefficient pH

ALBENDAZOLE 7

**Other adverse effects** Not available.

## 13. Disposal considerations

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

**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** 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.

## 14. Transport information

**General information** Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

### DOT

**UN number** UN3077

**UN proper shipping name** Environmentally hazardous substances, solid, n.o.s. (ALBENDAZOLE TABLETS), MARINE POLLUTANT

#### Transport hazard class(es)

**Class** 9

**Subsidiary risk** -

**Label(s)** 9

**Packing group** III

#### Environmental hazards

**Marine pollutant** Yes

**Special precautions for user** Not available.

**Special provisions** 8, 146, 335, A112, B54, IB8, IP3, N20, T1, TP33

**Packaging exceptions** 155

**Packaging non bulk** 213

**Packaging bulk** 240

**Qty limits cargo** No limit

**Qty limits passenger** No limit

### IATA

**UN number** UN3077

**UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (ALBENDAZOLE TABLETS)

**Transport hazard class(es)** 9

**Subsidiary class(es)** -

**Packaging group** III

**Labels required** 9

**Environmental hazards** No.

**ERG Code** 9L

**Special precautions for user** Not available.

#### Other information

**Cargo aircraft only** Allowed.

**Passenger & cargo** Allowed.

#### Additional Information:

**Packaging Instruction** 956

**Pkg Inst cargo only** 956

**Pkg Inst passenger & cargo** Y956

**SP see 44** A97,A158,A179

**Max net qty pkg** 400 kg

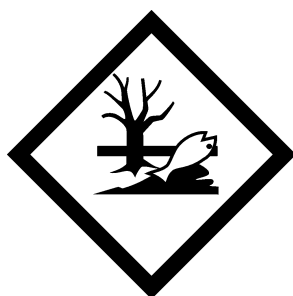
**Max net qty pkg cargo only** 400 kg

|                                                                          |                                                                                                                                                             |
|--------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Max net qty pkg LQ                                                       | 30 kg G                                                                                                                                                     |
| <b>IMDG</b>                                                              |                                                                                                                                                             |
| UN number                                                                | UN3077                                                                                                                                                      |
| UN proper shipping name                                                  | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ALBENDAZOLE TABLETS)                                                                                    |
| Transport hazard class(es)                                               |                                                                                                                                                             |
| Class                                                                    | 9                                                                                                                                                           |
| Subsidiary risk                                                          | -                                                                                                                                                           |
| Label(s)                                                                 | 9                                                                                                                                                           |
| Packing group                                                            | III                                                                                                                                                         |
| Environmental hazards                                                    |                                                                                                                                                             |
| Marine pollutant                                                         | Yes                                                                                                                                                         |
| EmS                                                                      | F-A, S-F                                                                                                                                                    |
| Special precautions for user                                             | Not available.                                                                                                                                              |
| Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code | MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk. |

DOT; IATA; IMDG



Marine pollutant



## 15. Regulatory information

**US federal regulations** One or more components are not listed on 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.

**US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

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

**Hazard categories**

- Immediate Hazard - Yes
- Delayed Hazard - Yes
- Fire Hazard - No
- Pressure Hazard - No
- Reactivity Hazard - No

**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.

## US state regulations

### US. Massachusetts RTK - Substance List

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

STARCH (CAS 9005-25-8)

### US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

### US. Pennsylvania RTK - Hazardous Substances

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

STARCH (CAS 9005-25-8)

### US. Rhode Island RTK

Not regulated.

### US. 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.

## International Inventories

| Country(s) or region        | Inventory name                                                         | On inventory (yes/no)* |
|-----------------------------|------------------------------------------------------------------------|------------------------|
| Australia                   | Australian Inventory of Chemical Substances (AICS)                     | No                     |
| Canada                      | Domestic Substances List (DSL)                                         | No                     |
| 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                                                  | No                     |
| Philippines                 | Philippine Inventory of Chemicals and Chemical Substances (PICCS)      | 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          | 06-18-2014                                                                                                                                                                                                                                                                                                                                                                       |
| Revision date       | 06-18-2014                                                                                                                                                                                                                                                                                                                                                                       |
| Version #           | 14                                                                                                                                                                                                                                                                                                                                                                               |
| Further information | HMIS® is a registered trade and service mark of the NPCA.                                                                                                                                                                                                                                                                                                                        |
| HMIS® ratings       | Health: 2*<br>Flammability: 1<br>Physical hazard: 0                                                                                                                                                                                                                                                                                                                              |
| NFPA ratings        | Health: 2<br>Flammability: 1<br>Instability: 0                                                                                                                                                                                                                                                                                                                                   |
| References          | GSK Hazard Determination                                                                                                                                                                                                                                                                                                                                                         |
| 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. |

## Revision Information

Product and Company Identification: Business Units  
Composition / Information on Ingredients: Ingredients  
Physical & Chemical Properties:  
Toxicological Information: Irritation Corrosion  
Transport Information: Material Transportation Information  
Regulatory Information: United States  
GHS: Classification