SAFETY DATA SHEET

Albendazole Sulfoxide (1.9%) Formulation

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

1.1 Product identifier
   Trade name : Albendazole Sulfoxide (1.9%) Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company : MSD
              20 Spartan Road
              1619 Spartan, South Africa
   Telephone : +27119239300
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms : ⚠️
   Signal word : Warning
   Hazard statements : H317 May cause an allergic skin reaction.
   Precautionary statements : Prevention:
                              P272 Contaminated work clothing should not be allowed out of the workplace.
                              P280 Wear protective gloves.
   Response:
              P333 + P313 If skin irritation or rash occurs: Get medical
Hazardous components which must be listed on the label:
Albendazole Sulfoxide

Additional Labelling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 1.9%

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures
Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albendazole Sulfoxide</td>
<td>54029-12-8</td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox.4; H302 Skin Sens.1B; H317 Repr.2; H361d STOT SE2; H371 STOT RE2; H373</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice:
In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders:
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled:
If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact:
In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
In case of eye contact: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed
Risks: May cause an allergic skin reaction.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Sulphur oxides

5.3 Advice for firefighters
Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
6.2 Environmental precautions

Environmental precautions:
- Discharge into the environment must be avoided.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g. by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up:
- Soak up with inert absorbent material.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures:
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Avoid inhalation of vapour or mist.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
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7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: Keep in properly labelled containers. Store in accordance with the particular national regulations.
Advice on common storage: Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)
Specific use(s): No data available

No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>TWA OEL-RL (Mist)</td>
<td>10 mg/m3</td>
<td>ZA OEL</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albendazole Sulfoxide</td>
<td>54029-12-8</td>
<td>TWA</td>
<td>40 µg/m3 (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Further information:
- **Recommended Limit**
  - Internal
- **Wipe limit**
  - 100 µg/100 cm²

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>56 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>229 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>33 mg/m³</td>
</tr>
</tbody>
</table>

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine</td>
<td>Fresh water</td>
<td>0.885 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.0885 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>8.85 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>3.3 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.33 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.141 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

Engineering measures
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

Personal protective equipment

Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection
Material: Chemical-resistant gloves

Skin and body protection: Work uniform or laboratory coat.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type: Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: suspension
Colour: white
Odour: No data available
Odour Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: No data available
Relative vapour density: No data available
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Relative density: No data available
Density: No data available
Solubility(ies)
- Water solubility: No data available
- Partition coefficient: n-octanol/water: Not applicable
- Auto-ignition temperature: No data available
- Decomposition temperature: No data available
Viscosity
- Viscosity, kinematic: No data available
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.

9.2 Other information
- Flammability (liquids): No data available
- Molecular weight: No data available
- Particle size: Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of: Inhalation
**SAFETY DATA SHEET**

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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>02.08.2019</td>
<td>3903445-00003</td>
<td>24.04.2019</td>
<td>10.12.2018</td>
</tr>
</tbody>
</table>

**Exposure**

<table>
<thead>
<tr>
<th>Contact</th>
<th>Skin contact</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ingestion</td>
</tr>
<tr>
<td></td>
<td>Eye contact</td>
</tr>
</tbody>
</table>

**Acute toxicity**

Not classified based on available information.

**Product:**

**Acute oral toxicity:**

- Acute toxicity estimate: > 2.000 mg/kg
- Method: Calculation method

**Components:**

**Albendazole Sulfoxide:**

- **Acute oral toxicity:**
  - LD50 (Mouse): 1.500 mg/kg
  - LD50 (Rat): 2.400 mg/kg

- **Acute toxicity (other routes of administration):**
  - LD50 (Rat): 265 mg/kg
  - Application Route: Intravenous

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Albendazole Sulfoxide:**

- **Species:** Rabbit
- **Result:** No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**Albendazole Sulfoxide:**

- **Species:** Rabbit
- **Result:** No eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

Not classified based on available information.

**Components:**

**Albendazole Sulfoxide:**

- **Test Type:** Maximisation Test
- **Exposure routes:** Dermal
- **Assessment:** Probability or evidence of low to moderate skin sensitisation rate in humans
### Germ cell mutagenicity

Not classified based on available information.

**Components:**

**Albendazole Sulfoxide:**

- **Genotoxicity in vitro**
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Test Type: Chromosomal aberration
  - Test system: Chinese hamster ovary cells
  - Result: negative

- **Genotoxicity in vivo**
  - Test Type: Micronucleus test
  - Species: Mouse
  - Cell type: Bone marrow
  - Result: negative

### Carcinogenicity

Not classified based on available information.

**Components:**

**Albendazole Sulfoxide:**

- **Species**
  - Mouse
- **Application Route**
  - Oral
- **Exposure time**
  - 2 Years
- **NOAEL**
  - 400 mg/kg body weight
- **Result**
  - negative

- **Species**
  - Rat
- **Application Route**
  - Oral
- **Exposure time**
  - 2 Years
- **NOAEL**
  - 20 mg/kg body weight
- **Result**
  - negative

**Carcinogenicity - Assessment**

No evidence of carcinogenicity in animal studies.

### Reproductive toxicity

Not classified based on available information.

**Components:**

**Albendazole Sulfoxide:**

- **Effects on fertility**
  - Test Type: Fertility
  - Species: Rat
  - Application Route: Oral
  - Fertility: NOAEL: 30 mg/kg body weight
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**Revision Date:** 02.08.2019  
**SDS Number:** 3903445-00003  
**Date of last issue:** 24.04.2019  
**Date of first issue:** 10.12.2018

---

Result: No effects on fertility

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type</th>
<th>Development</th>
<th>Species</th>
<th>Rat</th>
<th>Application Route</th>
<th>Oral</th>
<th>Developmental Toxicity: LOAEL: 10 mg/kg body weight</th>
<th>Result: Embryotoxic effects., Skeletal malformations</th>
</tr>
</thead>
</table>

Test Type: Development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 30 mg/kg body weight  
Result: Embryotoxic effects., Skeletal malformations, Maternal toxicity observed.

Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 5,8 mg/kg body weight  
Result: Effects on postnatal development

Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 7 mg/kg body weight  
Result: Embryotoxic effects and adverse effects on the offspring were detected.

Reproductive toxicity - Assessment: Suspected of damaging the unborn child.

**STOT - single exposure**

Not classified based on available information.

**Components:**

**Albendazole Sulfoxide:**  
**Exposure routes:** Oral  
**Target Organs:** Gastrointestinal tract, Central nervous system  
**Assessment:** May cause damage to organs.

**STOT - repeated exposure**

Not classified based on available information.

**Components:**

**Albendazole Sulfoxide:**  
**Exposure routes:** Oral  
**Target Organs:** Gastrointestinal tract, Central nervous system, Immune system, Liver  
**Assessment:** May cause damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

Components:

Albendazole Sulfoxide:
Species : Rat
LOAEL : 168 mg/kg
Application Route : Oral
Exposure time : 4 Weeks
Target Organs : Gastrointestinal tract, Testis
Symptoms : Diarrhoea, Vomiting

Species : Dog
LOAEL : 48 mg/kg
Application Route : Oral
Exposure time : 4 Weeks
Target Organs : Gastrointestinal tract
Symptoms : Diarrhoea, Vomiting

Species : Mouse
LOAEL : 40 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Blood, Liver, Nose
Symptoms : Hematologic effects, Liver effects

Species : Rat
LOAEL : >= 30 mg/kg
Application Route : Oral
Exposure time : 6 Months
Target Organs : Blood
Symptoms : Hematologic effects

Species : Dog
LOAEL : 40 mg/kg
Application Route : Oral
Exposure time : 6 Months
Target Organs : Blood, Liver
Symptoms : Hematologic effects, Liver effects

Species : Rat
NOAEL : 7 mg/kg
Application Route : Oral
Exposure time : 60 d
Target Organs : Liver, Testis
Symptoms : Liver effects, male reproductive effects

Aspiration toxicity
Not classified based on available information.
Experience with human exposure

Components:

Albendazole Sulfoxide:
General Information: Symptoms: Allergic reactions, hair loss, Gastrointestinal disturbance, Headache, Dizziness
Skin contact: Target Organs: Skin
Symptoms: Allergic reactions
Remarks: May cause sensitisation by skin contact.
Ingestion: Target Organs: Gastrointestinal tract
Symptoms: Gastrointestinal disturbance, Diarrhoea, Abdominal pain
Target Organs: Central nervous system
Symptoms: Headache, Dizziness
Target Organs: Liver
Symptoms: liver function change
Target Organs: Immune system
Symptoms: immune system effects

SECTION 12: Ecological information

12.1 Toxicity

Components:

Albendazole Sulfoxide:
Ecotoxicology Assessment
Acute aquatic toxicity: Toxic effects cannot be excluded
Chronic aquatic toxicity: Toxic effects cannot be excluded

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

Albendazole Sulfoxide:
Partition coefficient: n-octanol/water: log Pow: 2.7

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available
SECTION 13: Disposal considerations

13.1 Waste treatment methods
   - **Product**: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
   - **Contaminated packaging**: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number
   - Not regulated as a dangerous good

14.2 UN proper shipping name
   - Not regulated as a dangerous good

14.3 Transport hazard class(es)
   - Not regulated as a dangerous good

14.4 Packing group
   - Not regulated as a dangerous good

14.5 Environmental hazards
   - Not regulated as a dangerous good

14.6 Special precautions for user
   - Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
   - **Remarks**: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
   - The components of this product are reported in the following inventories:
     - **AICS**: not determined
     - **DSL**: not determined
     - **IECSC**: not determined

15.2 Chemical safety assessment
   - A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

- **Other information**: Items where changes have been made to the previous version
SAFETY DATA SHEET

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Full text of H-Statements

H302 : Harmful if swallowed.
H317 : May cause an allergic skin reaction.
H361d : Suspected of damaging the unborn child.
H371 : May cause damage to organs if swallowed.
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECS - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative
Further information


Classification of the mixture:

- Skin Sens. 1 H317

Classification procedure:

Calculation method