SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Altrenogest Formulation

Version 4.2 Revision Date: 27.08.2021 SDS Number: 657709-00015 Date of last issue: 10.10.2020 Date of first issue: 02.05.2016

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

1.1 Product identifier
Trade name: Altrenogest 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
Kilsheean
Clonmel Tipperary, IE

Telephone: 353-51-601000
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)
Reproductive toxicity, Category 1B H360: May damage fertility or the unborn child.
Long-term (chronic) aquatic hazard, Category 1 H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms:

Signal word: Danger

Hazard statements:
H360 May damage fertility or the unborn child.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
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Response:
P308 + P313  IF exposed or concerned: Get medical advice/attention.
P391  Collect spillage.

Storage:
P405  Store locked up.

Hazardous components which must be listed on the label:
altrenogest

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<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>altrenogest</td>
<td></td>
<td>850-52-2</td>
<td></td>
<td>212-703-1</td>
<td></td>
<td>Acute Tox. 3; H301 Repr. 1B; H360 STOT RE 2; H373 (Immune system, Adrenal gland) Aquatic Chronic 1; H410</td>
<td>&gt;= 0.3 - &lt; 1</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.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May damage fertility or the unborn child.

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

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 (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions: Avoid release to the environment. 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.
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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 : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe vapours or spray 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
Keep container tightly closed.
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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
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</thead>
<tbody>
<tr>
<td>altrenogest</td>
<td>850-52-2</td>
<td>TWA</td>
<td>1 µg/m3 (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
</tbody>
</table>
**8.2 Exposure controls**

**Engineering measures**
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

**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

**Remarks**
Consider double gloving.

**Skin and body protection**

**Work uniform or laboratory coat.** Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**Respiratory protection**

If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143

**Filter type**
Particulates type (P)

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

**Physical state**
liquid

**Colour**
No data available

**Odour**
No data available

**Odour Threshold**
No data available

**Melting point/freezing point**
No data available

**Initial boiling point and boiling range**
No data available

**Flammability (solid, gas)**
Not applicable

**Flammability (liquids)**
No data available
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Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Flash point: No data available

Auto-ignition temperature: No data available

Decomposition temperature: No data available

pH: No data available

Viscosity
   Viscosity, kinematic: No data available

Solubility(ies)
   Water solubility: No data available

Partition coefficient: n-octanol/water
   Vapour pressure: No data available

Relative density: No data available

Density: No data available

Relative vapour density: No data available

Particle characteristics
   Particle size: No data available

**9.2 Other information**

Explosives: Not explosive

Oxidizing properties: The substance or mixture is not classified as oxidizing.

Evaporation rate: No data available

Molecular weight: No data available

**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 hazard classes as defined in Regulation (EC) No 1272/2008
Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:
altrenogest:
Acute oral toxicity: LD50 (Rat): 177 mg/kg
LD50 (Dog): 400 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.

Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Components:
altrenogest:
Genotoxicity in vitro
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: Chromosome aberration test in vitro
  Result: negative
- Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  Result: negative

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
May damage fertility or the unborn child.

Components:

altrenogest:
Effects on fertility
- Test Type: Two-generation reproduction toxicity study
  Species: Rat
  Application Route: Oral
  Fertility: NOAEL: 0.016 mg/kg body weight
  Result: Effects on fertility, No effects on mating performance
- Test Type: Fertility/early embryonic development
  Species: Monkey, female
  Application Route: Oral
  Fertility: NOAEL: 0.004 mg/kg body weight
Reproductive toxicity - Assessment: Clear evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Components:

altrenogest:
Exposure routes: Oral
Target Organs: Immune system, Adrenal gland
Assessment: May cause damage to organs through prolonged or repeated exposure.

Exposure routes: Oral
Target Organs: Pituitary gland
Repeated dose toxicity

Components:

altrenogest:
Species : Rat
NOAEL : 0.06 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Immune system, male reproductive organs, female reproductive organs, Adrenal gland
Remarks : Effects on fertility

Species : Pig
NOAEL : 0.004 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : male reproductive organs, female reproductive organs
Remarks : Effects on fertility

Species : Pig
NOAEL : 0.002 mg/kg
Application Route : Oral
Exposure time : 1 yr
Target Organs : male reproductive organs, Pituitary gland
Remarks : Effects on fertility

Species : Horse
LOAEL : 220 mg/kg
Application Route : Oral
Exposure time : 86 Days
Remarks : No significant adverse effects were reported

Aspiration toxicity
Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

altrenogest:
Inhalation : Symptoms: respiratory tract irritation
Skin contact : Symptoms: Skin irritation
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Eye contact  : Symptoms: Eye irritation

SECTION 12: Ecological information

12.1 Toxicity

Components:

altrenogest:
Toxicity to fish (Chronic toxicity)  : NOEC: 0.0004 µg/l
Exposure time: 32 d
Species: Danio rerio (zebra fish)
Method: OECD Test Guideline 210

M-Factor (Chronic aquatic toxicity)  : 100,000

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

altrenogest:
Partition coefficient: n-octanol/water  : log Pow: 3.78

12.4 Mobility in soil

Components:

altrenogest:
Distribution among environmental compartments  : log Koc: 3.3

12.5 Results of PBT and vPvB assessment

Product:
Assessment  : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:
Assessment  : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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 or ID number

| ADN  | UN 3082 |
| ADR  | UN 3082 |
| RID  | UN 3082 |
| IMDG | UN 3082 |
| IATA | UN 3082 |

14.2 UN proper shipping name

| ADN  | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (altrenogest) |
| ADR  | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (altrenogest) |
| RID  | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (altrenogest) |
| IMDG | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (altrenogest) |
| IATA | Environmentally hazardous substance, liquid, n.o.s. (altrenogest) |

14.3 Transport hazard class(es)

| ADN | 9 |
| ADR | 9 |
| RID | 9 |
| IMDG | 9 |
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## IATA

### 14.4 Packing group

<table>
<thead>
<tr>
<th>Packing group</th>
<th>Classification Code</th>
<th>Hazard Identification Number</th>
<th>Labels</th>
<th>Tunnel restriction code</th>
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<tbody>
<tr>
<td>ADN</td>
<td>III</td>
<td>90</td>
<td>9</td>
<td></td>
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<tr>
<td>ADR</td>
<td>III</td>
<td>90</td>
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<td>(-)</td>
</tr>
<tr>
<td>RID</td>
<td>III</td>
<td>90</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>IMDG</td>
<td>III</td>
<td>90</td>
<td>9</td>
<td>F-A, S-F</td>
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<td></td>
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<tr>
<td>IATA (Passenger)</td>
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</table>

### 14.5 Environmental hazards

<table>
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<th>Packing group</th>
<th>Environmentally hazardous</th>
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<tbody>
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<td>ADN</td>
<td>yes</td>
</tr>
<tr>
<td>ADR</td>
<td>yes</td>
</tr>
<tr>
<td>RID</td>
<td>yes</td>
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<tr>
<td>IMDG</td>
<td>yes</td>
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<tr>
<td>IATA (Passenger)</td>
<td>yes</td>
</tr>
</tbody>
</table>
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Environmentally hazardous : yes

14.6 Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments
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
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

<table>
<thead>
<tr>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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
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are highlighted in the body of this document by two vertical lines.

Full text of H-Statements
H301 : Toxic if swallowed.
H360 : May damage fertility or the unborn child.
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure

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; AIIC - Australian Inventory of Industrial Chemicals; 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; IECSC - 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; KECl - 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; vPvB - Very Persistent and Very Bioaccumulative

Further information
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Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repr. 1B</td>
<td>H360</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
</tr>
</tbody>
</table>

Classification procedure:

- Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

IE / EN