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

Doramectin Formulation

Version: 2.0   Revision Date: 26.11.2019   SDS Number: 5198465-00002   Date of last issue: 22.10.2019
Date of first issue: 22.10.2019

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

1.1 Product identifier
   Trade name: Doramectin 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
   Kilsheelan
   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)
   Effects on or via lactation
   Short-term (acute) aquatic hazard, Category 1
   Long-term (chronic) aquatic hazard, Category 1
   H362: May cause harm to breast-fed children.
   H400: Very toxic to aquatic life.
   H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms: 
   Signal word: Warning
   Hazard statements: H362: May cause harm to breast-fed children. H410: Very toxic to aquatic life with long lasting effects.
   Precautionary statements: Prevention:
   P201 Obtain special instructions before use.
   P263 Avoid contact during pregnancy and while nursing.
Hazardous components which must be listed on the label:

- Doramectin

2.3 Other hazards

None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</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>Doramectin</td>
<td>117704-25-3</td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox.4; H302 Repr.2; H361d Lact.H362 Aquatic Acute1; H400 Aquatic Chronic1; H410 M-Factor (Acute aquatic toxicity): 10.000 M-Factor (Chronic aquatic toxicity): 10.000</td>
<td>&gt;= 1 - &lt; 2.5</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.

**4.2 Most important symptoms and effects, both acute and delayed**

Risks: May cause harm to breast-fed children.

**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 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: Avoid inhalation of vapour or mist. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. 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.

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

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>Doramectin</td>
<td>117704-25-3</td>
<td>TWA</td>
<td>OEB 3 (&gt;= 10 &lt; 100 µg/m³)</td>
<td>Internal</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.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

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
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according to Regulation (EC) No. 1907/2006

**Doramectin Formulation**

<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>
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<tr>
<td>2.0</td>
<td>26.11.2019</td>
<td>5198465-00002</td>
<td>22.10.2019</td>
<td>22.10.2019</td>
</tr>
</tbody>
</table>

**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.
- **Filter type**: Particulates type (P)

### SECTION 9: Physical and chemical properties

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

- **Appearance**: oily
- **Colour**: light yellow
- **Odour**: characteristic
- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: -7 °C
- **Initial boiling point and boiling range**: 270 °C
- **Flash point**: 215,7 °C
- **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
- **Relative density**: 0,89 - 91
- **Density**: No data available
- **Solubility(ies)**
  - **Water solubility**: practically insoluble
  - **Partition coefficient: n-octanol/water**: Not applicable
- **Auto-ignition temperature**: No data available
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Decomposition temperature : No data available

Viscosity
   Viscosity, kinematic : 31.7 - 32.1 m²/s (25 °C)

Explosive properties : Not explosive

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

9.2 Other information

Flammability (liquids) : Not applicable

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 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
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Components:

**Doramectin:**
- Acute oral toxicity: LD50 (Rat, female): > 500 - 1.000 mg/kg
- Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
  Method: OECD Test Guideline 402
  Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation
Not classified based on available information.

Components:

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

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

Components:

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

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

**Doramectin:**
- Test Type: Local lymph node assay (LLNA)
- Exposure routes: Skin contact
- Species: Mouse
- Method: OECD Test Guideline 429
- Result: negative

Germ cell mutagenicity
Not classified based on available information.
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Genotoxicity in vitro:
- **Test Type**: Bacterial reverse mutation assay (AMES)
  - Result: negative
- **Test Type**: In vitro mammalian cell gene mutation test
  - Result: negative
- **Test Type**: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  - Result: negative

Genotoxicity in vivo:
- **Test Type**: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Ingestion
  - Result: negative

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
May cause harm to breast-fed children.

Components:

**Doramectin:**

Effects on fertility:
- **Test Type**: Two-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

Effects on foetal development:
- **Test Type**: Fertility/early embryonic development
  - Species: Rabbit
  - Application Route: Ingestion
  - Result: positive

Reproductive toxicity - Assessment:
- Some evidence of adverse effects on development, based on animal experiments. Studies indicating a hazard to babies during the lactation period

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
Not classified based on available information.

**Aspiration toxicity**
Not classified based on available information.
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SECTION 12: Ecological information

12.1 Toxicity

Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to fish</th>
<th>Exposure time: 96 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doramectin:</td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): 0,005 mg/l</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0,1 µg/l</td>
<td>Exposure time: 48 h</td>
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<tr>
<td></td>
<td>Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 0,026 mg/l</td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td>M-Factor (Acute aquatic toxicity)</td>
<td>10.000</td>
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</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>10.000</td>
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</tr>
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</table>

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Partition coefficient: n-octanol/water</th>
<th>log Pow: 4,4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doramectin:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
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<tr>
<th>ADN</th>
<th>: UN 3082</th>
</tr>
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<tbody>
<tr>
<td>ADR</td>
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<tr>
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<tr>
<td>IMDG</td>
<td>: UN 3082</td>
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<tr>
<td>IATA</td>
<td>: UN 3082</td>
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</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Doramectin)</th>
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<tbody>
<tr>
<td>ADR</td>
<td>: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Doramectin)</td>
</tr>
<tr>
<td>RID</td>
<td>: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Doramectin)</td>
</tr>
<tr>
<td>IMDG</td>
<td>: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Doramectin)</td>
</tr>
<tr>
<td>IATA</td>
<td>: Environmentally hazardous substance, liquid, n.o.s. (Doramectin)</td>
</tr>
</tbody>
</table>

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>ADN</th>
<th>: 9</th>
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<tbody>
<tr>
<td>ADR</td>
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<td>RID</td>
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<tr>
<td>IMDG</td>
<td>: 9</td>
</tr>
<tr>
<td>IATA</td>
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14.4 Packing group

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<table>
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<th>Packing group : III</th>
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<tr>
<td></td>
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<td>Hazard Identification Number : 90</td>
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<td></td>
<td>Labels : 9</td>
</tr>
<tr>
<td></td>
<td>Tunnel restriction code : (-)</td>
</tr>
</tbody>
</table>
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RID
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
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 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
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according to Regulation (EC) No. 1907/2006

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Version: 2.0  Revision Date: 26.11.2019  SDS Number: 5198465-00002  Date of last issue: 22.10.2019  Date of first issue: 22.10.2019

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

Full text of H-Statements
H302: Harmful if swallowed.
H361d: Suspected of damaging the unborn child.
H362: May cause harm to breast-fed children.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox.: Acute toxicity
Aquatic Acute: Short-term (acute) aquatic hazard
Aquatic Chronic: Long-term (chronic) aquatic hazard
Lact.: Effects on or via lactation
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Repr. : Reproductive toxicity

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; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; ISO - International Organization 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 Road; 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:

<table>
<thead>
<tr>
<th>Lact.</th>
<th>H362</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
</tr>
</tbody>
</table>

Classification procedure: Calculation method
to the specific material identified at the top of this SDS and may not be valid when the SDS mate-rial 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.