Tildipirosin (4%) Formulation

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

1.1 Product identifier
   Trade name : Tildipirosin (4%) 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
   Shotton Lane
   NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   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
   Reproductive toxicity, Category 2
   Short-term (acute) aquatic hazard, Category 1
   Long-term (chronic) aquatic hazard, Category 1
   H317: May cause an allergic skin reaction.
   H361f: Suspected of damaging fertility.
   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 : H317 May cause an allergic skin reaction.
   H361f Suspected of damaging fertility.
   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.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:

Tildipirosin

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. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tildipirosin</td>
<td>328898-40-4</td>
<td>Skin Sens. 1A; H317 Repr. 2; H361f STOT RE 2; H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 100</td>
<td>&gt;= 3 - &lt; 10</td>
</tr>
<tr>
<td>Citric acid monohydrate</td>
<td>5949-29-1</td>
<td>Eye Irr. 2; H319</td>
<td>&gt;= 1 - &lt; 10</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.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Tildipirosin (4%) Formulation

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 an allergic skin reaction. Suspected of damaging fertility.

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: In the event of fire, wear self-contained breathing apparatus.
for firefighters

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.
- 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.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. 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

<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>Propylene glycol</td>
<td>57-55-6</td>
<td>OELV - 8 hrs (TWA) (particles)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OELV - 8 hrs (TWA) (total (vapour and particles))</td>
<td>150 ppm 470 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Tildipirosin</td>
<td>328898-40-4</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used.

<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>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</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.
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

- **Appearance**: liquid
- **Colour**: No data available
- **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
- **Relative density**: No data available
- **Density**: 1.0499 g/cm³
- **Solubility(ies)**
  - **Water solubility**: No data available
  - **Partition coefficient: n-octanol/water**: No data available
  - **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
**SAFETY DATA SHEET**
according to Regulation (EC) No. 1907/2006

**Tildipirosin (4%) Formulation**

Version 2.3 Revision Date: 23.03.2020 SDS Number: 1078778-00008 Date of last issue: 13.09.2019 Date of first issue: 18.11.2016

<table>
<thead>
<tr>
<th>Molecular weight : No data available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Particle size : No data available</td>
</tr>
</tbody>
</table>

**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.

**Components:**

**Tildipirosin:**
- Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
  - LD50 (Mouse): > 2,000 mg/kg
- Acute dermal toxicity : Remarks: No data available
- Acute toxicity (other routes of administration) : LD50 (Mouse): 6.25 - 12.5 mg/kg
  - Application Route: Intravenous

**Citric acid monohydrate:**
- Acute oral toxicity : LD50 (Mouse): 5,400 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:

Tildipirosin:
Species: Rabbit
Result: No skin irritation

Citric acid monohydrate:
Species: Rabbit
Result: No skin irritation

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

Components:

Tildipirosin:
Species: Rabbit
Result: No eye irritation

Citric acid monohydrate:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation
May cause an allergic skin reaction.

Respiratory sensitisation
Not classified based on available information.

Components:

Tildipirosin:
Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Result: Sensitiser

Germ cell mutagenicity
Not classified based on available information.
Tildipirosin (4%) Formulation

Components:

Tildipirosin:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Metabolic activation: with and without metabolic activation
Result: negative

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Metabolic activation: with and without metabolic activation
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Result: negative

Genotoxicity in vivo:
Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Citric acid monohydrate:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: in vitro micronucleus test
Result: positive

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo:
Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Suspected of damaging fertility.

Components:

Tildipirosin:
Effects on fertility:
Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
General Toxicity F1: LOAEL: 80 mg/kg body weight
Symptoms: Effects on F1 offspring
Result: Effects on reproduction parameters
Effects on foetal development:

- Test Type: Embryo-foetal development
  - Species: Rabbit, females
  - Embryo-foetal toxicity: NOAEL: 30 mg/kg body weight
  - Symptoms: Reduced body weight
  - Result: No teratogenic potential
  - Remarks: The effects were seen only at maternally toxic doses.

- Test Type: Embryo-foetal development
  - Species: Rat, female
  - Embryo-foetal toxicity: NOAEL: 30 mg/kg body weight
  - Symptoms: Reduced body weight
  - Result: No teratogenic potential
  - Remarks: The effects were seen only at maternally toxic doses.

Reproductive toxicity - Assessment:

- Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

Citric acid monohydrate:

Effects on foetal development:

- Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Components:

Tildipirosin:

- Target Organs: Heart, Cardio-vascular system, Nervous system, eye - retina, Thyroid, thymus gland, spleen, Pancreas
- Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Tildipirosin:

- Species: Rat
- NOAEL: 20 mg/kg
- LOAEL: 60 mg/kg
- Application Route: Oral
- Exposure time: 90 d
- Target Organs: spleen, thymus gland
- Symptoms: Salivation
Tildipirosin (4%) Formulation

Species: Dog
LOAEL: 20 mg/kg
Application Route: Oral
Exposure time: 28 d
Target Organs: Heart, Central nervous system, Blood
Symptoms: Tremors

Species: Dog
NOAEL: 6 mg/kg
Application Route: Oral
Exposure time: 90 d
Target Organs: Heart, Cardio-vascular system
Symptoms: Irritability

Species: Dog
NOAEL: 10 mg/kg
LOAEL: 50 mg/kg
Application Route: Oral
Exposure time: 55 Weeks
Target Organs: Nervous system, eye - retina, Heart, Thyroid, spleen, thymus gland, Pancreas

Citric acid monohydrate:
Species: Rat
NOAEL: 4,000 mg/kg
LOAEL: 8,000 mg/kg
Application Route: Ingestion
Exposure time: 10 Days

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:
Tildipirosin:
General Information: No human information is available.

SECTION 12: Ecological information

12.1 Toxicity

Components:
Tildipirosin:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 138 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 32 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): 0.12 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 0.047 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- EC50 (Anabaena flos-aquae (cyanobacterium)): 0.027 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- NOEC (Anabaena flos-aquae (cyanobacterium)): 0.00011 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 10

Toxicity to microorganisms:
- EC50: 112.4 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209
- NOEC: 0.23 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209

M-Factor (Chronic aquatic toxicity): 100

Citric acid monohydrate:

Toxicity to fish:
- LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 1,535 mg/l
  Exposure time: 24 h

12.2 Persistence and degradability

Components:

Tildipirosin:

Biodegradability: Result: Not readily biodegradable.
  Biodegradation: 14.7 %
  Exposure time: 28 d
  Method: OECD Test Guideline 301B

Citric acid monohydrate:

12.3 Bioaccumulative potential

Components:

Citric acid monohydrate:
Partition coefficient: n-octanol/water: log Pow: -1.72

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

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. (Tildipirosin)
ADR: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin)
Tildipirosin (4%) Formulation

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Tildipirosin)

IATA : Environmentally hazardous substance, liquid, n.o.s. (Tildipirosin)

14.3 Transport hazard class(es)

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADN
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

ADR
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

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

Full text of H-statements

- H317: May cause an allergic skin reaction.
- H319: Causes serious eye irritation.
- H361f: Suspected of damaging fertility.
- H373: May cause damage to organs through prolonged or repeated exposure.
- H400: Very toxic to aquatic life.
- H410: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

- Aquatic Acute: Short-term (acute) aquatic hazard
- Aquatic Chronic: Long-term (chronic) aquatic hazard
- Eye Irrit.: Eye irritation
- Repr.: Reproductive toxicity
- Skin Sens.: Skin sensitisation
- STOT RE: Specific target organ toxicity - repeated exposure
- IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
- IE OEL / OELV - 8 hrs (TWA): Occupational exposure limit value (8-hour reference period)
Further information


Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification procedure:</th>
<th>Classification of the mixture:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calculation method</td>
<td>Skin Sens. 1</td>
</tr>
<tr>
<td></td>
<td>H317</td>
</tr>
<tr>
<td>Calculation method</td>
<td>Repr. 2</td>
</tr>
<tr>
<td></td>
<td>H361f</td>
</tr>
<tr>
<td>Calculation method</td>
<td>Aquatic Acute 1</td>
</tr>
<tr>
<td></td>
<td>H400</td>
</tr>
<tr>
<td>Calculation method</td>
<td>Aquatic Chronic 1</td>
</tr>
<tr>
<td></td>
<td>H410</td>
</tr>
</tbody>
</table>

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.