SAFETY DATA SHEET

Ceftiofur Formulation

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

1.1 Product identifier
   Trade name : Ceftiofur 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
   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)
   Respiratory sensitisation, Category 1
   H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   Signal word : Danger
   Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
   Precautionary statements : Response:
   P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
   P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

   Hazardous components which must be listed on the label:
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Ceftiofur Formulation

Version 4.0  Revision Date: 27.08.2021  SDS Number: 7674005-00004  Date of last issue: 09.04.2021  Date of first issue: 15.12.2020

Ceftiofur

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.

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>Ceftiofur</td>
<td>103980-44-5</td>
<td>Resp. Sens. 1; H334 STOT RE 2; H373</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6 202-859-9 603-057-00-5</td>
<td>Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 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.

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. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

In case of skin contact: Wash with water and soap as a precaution. Get medical attention if symptoms occur.

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 if symptoms occur. Rinse mouth thoroughly with water.
4.2 Most important symptoms and effects, both acute and delayed

Risks: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive Airways dysfunction syndrome).

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.

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 breathe mist or vapours.
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
Keep container tightly closed.
Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.
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. 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.

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>Ceftiofur</td>
<td>103980-44-5</td>
<td>TWA</td>
<td>100 mcg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: RSEN

| Silicon, amorphous | 112945-52-5 | TWA OEL-RL (Respirable dust) | 3 mg/m3            | ZA OEL        |

Further information: Recommended Limit

| TWA OEL-RL (inhalable dust) | 6 mg/m3 | ZA OEL                |

Further information: Recommended Limit

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>Benzyl alcohol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>22 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>110 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>8 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>40 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>5.4 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>27 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>20 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>20 mg/kg bw/day</td>
</tr>
<tr>
<td>Glycerides, mixed</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic</td>
<td>177.79 mg/m3</td>
</tr>
</tbody>
</table>
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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 to off-white, cream
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 : 0.850 - 1.050 g/cm³
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 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

Acute inhalation toxicity: Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Ceftiofur:
Acute oral toxicity: LD50 (Rat): > 7.760 mg/kg

Benzy alcohol:
Acute oral toxicity: LD50 (Rat): 1.620 mg/kg
Acute toxicity estimate: 1.620 mg/kg
Method: Calculation method
Acute inhalation toxicity: LC50 (Rat): > 4,178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Skin corrosion/irritation
Not classified based on available information.

Components:
Benzyl alcohol:
- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation

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

Components:
Benzyl alcohol:
- Species: Rabbit
- Method: OECD Test Guideline 405
- Result: Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:
Ceftiofur:
- Exposure routes: Inhalation
- Result: Sensitiser
- Remarks: May cause sensitisation by inhalation.

Components:
Benzyl alcohol:
- Test Type: Maximisation Test
- Exposure routes: Skin contact
- Species: Guinea pig
- Method: OECD Test Guideline 406
- Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:
Ceftiofur:
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: Unscheduled DNA synthesis assay
  - Result: negative

Genotoxicity in vivo:
- Test Type: Micronucleus test
  - Species: Rat
  - Application Route: Intraperitoneal
  - Result: negative

Benzyl alcohol:
- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Result: negative
- Genotoxicity in vivo:
  - Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
    - Species: Mouse
    - Application Route: Intraperitoneal injection
    - Result: negative

Carcinogenicity
Not classified based on available information.

Components:
- Benzyl alcohol:
  - Species: Mouse
  - Application Route: Ingestion
  - Exposure time: 103 weeks
  - Method: OECD Test Guideline 451
  - Result: negative

Reproductive toxicity
Not classified based on available information.

Components:
- Ceftiofur:
  - Effects on fertility:
    - Test Type: Fertility
      - Application Route: Oral
      - Fertility: NOAEL: 1.000 mg/kg body weight
      - Result: No adverse effects
  - Effects on foetal development:
    - Test Type: Development
      - Application Route: Oral
      - Developmental Toxicity: NOAEL: 1.000 mg/kg body weight
      - Result: No adverse effects

- Benzyl alcohol:
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Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Components:

Ceftiofur:
- Exposure routes: Oral
- Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity
Components:

Ceftiofur:
- Species: Rat
- NOAEL: 30 mg/kg
- Application Route: Oral
- Exposure time: 90 d
- Target Organs: Gastrointestinal tract
- Symptoms: Gastrointestinal disturbance
- Remarks: May cause damage to organs.
- Species: Dog
- NOAEL: 30 mg/kg
- Application Route: Oral
- Exposure time: 90 d
- Target Organs: Blood, Central nervous system
- Remarks: May cause damage to organs.

Benzyl alcohol:
- Species: Rat
- NOAEL: 1,072 mg/l
- Application Route: inhalation (dust/mist/fume)
- Exposure time: 28 Days
- Method: OECD Test Guideline 412

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

**Components:**

**Ceftiofur:**
- **General Information**: Repeated contact may cause allergic reactions in very susceptible persons.
- **Inhalation**: Symptoms: Nausea, Vomiting, Abdominal pain, vaginitis, Headache, Dizziness, dry mouth, Fatigue, constipation, colitis

**SECTION 12: Ecological information**

### 12.1 Toxicity

**Components:**

**Benzyl alcohol:**
- **Toxicity to fish**: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
  Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): 230 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202
- **Toxicity to algae/aquatic plants**: EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**: NOEC: 51 mg/l
  Exposure time: 21 d
  Species: Daphnia magna (Water flea)
  Method: OECD Test Guideline 211

### 12.2 Persistence and degradability

**Components:**

**Benzyl alcohol:**
- **Biodegradability**: Result: Readily biodegradable.
  Biodegradation: 92 - 96 %
  Exposure time: 14 d

### 12.3 Bioaccumulative potential

**Components:**

**Benzyl alcohol:**
- **Partition coefficient: n-**: log Pow: 1.05
12.4 Mobility in soil
No data available

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 Other adverse effects

**Product:**
**Endocrine disrupting potential**: 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
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
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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:
- DSL : not determined
- AICS : 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
H302 : Harmful if swallowed.
H319 : Causes serious eye irritation.
H332 : Harmful if inhaled.
H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.

Full text of other abbreviations
- Acute Tox. : Acute toxicity
- Eye Irrit. : Eye irritation
- Resp. Sens. : Respiratory sensitisation
- STOT RE : Specific target organ toxicity - repeated 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; 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; 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; TECI - Thailand Existing Chemicals 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:
Resp. Sens. 1 H334

Classification procedure:
Calculation method

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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.

ZA / EN