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

Benzylpenicillin Formulation

Version 1.4
Revision Date: 23.03.2020
SDS Number: 3937856-00005
Date of last issue: 13.09.2019
Date of first issue: 02.01.2019

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

1.1 Product identifier
Trade name: Benzylpenicillin 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)
Respiratory sensitisation, Category 1: H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitisation, Category 1: H317: May cause an allergic skin reaction.
Short-term (acute) aquatic hazard, Category 1: H400: Very toxic to aquatic life.
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: H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
Prevention:
P273 Avoid release to the environment.
P280 Wear protective gloves.

Response:
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
P391 Collect spillage.

Hazardous components which must be listed on the label:
6-(2-Phenylacetamido)penicillanic acid

2.3 Other hazards
None known.

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>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-(2-Phenylacetamido)penicillanic acid</td>
<td>61-33-6</td>
<td>200-506-3</td>
<td></td>
<td></td>
<td>Resp. Sens.1A; H334 Skin Sens.1B; H317 Aquatic Acute1; H400 Aquatic Chronic1; H410 M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 100</td>
<td>&gt;= 25 - &lt; 30</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: 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 if symptoms occur. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May cause an allergic skin reaction. 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.
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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
Metal oxides

5.3 Advice for firefighters
Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

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

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

6.3 Methods and material for containment and cleaning up
Methods for cleaning up: Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.
SECTION 7: Handling and storage

7.1 Precautions for safe handling

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

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Avoid inhalation of vapour or mist.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitizers.
- 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>6-(2-Phenylacetamido)penicillanic acid</td>
<td>61-33-6</td>
<td>TWA</td>
<td>2000 µg/m3 (OEB 1)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: DSEN

Further information: RSEN
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 NS EN 143
Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : suspension
Colour : white
Odour : No data available
Odour Threshold : No data available
pH : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : No data available
Evaporation rate : No data available
Flammability (solid, gas) : Not applicable
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
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Vapour pressure : No data available
Relative vapour density : No data available
Relative density : No data available
Density : No data available
Solubility(ies)
  Water solubility : soluble
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) : 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.

Components:

6-(2-Phenylacetamido)penicillanic acid:

Acute oral toxicity:
- LD50 (Rat): 8,000 mg/kg
- LD50 (Mouse): > 5,000 mg/kg

Acute toxicity (other routes of administration):
- LD50 (Mouse): 3,500 mg/kg
  Application Route: Intraperitoneal
- LD50 (Mouse): 329 mg/kg
  Application Route: Intravenous

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
May cause an allergic skin reaction.

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

Components:

6-(2-Phenylacetamido)penicillanic acid:

Test Type
- Local lymph node assay (LLNA)

Exposure routes
- Dermal
Species
- Mouse
Result
- Weak sensitizer

Test Type
- Maximisation Test
Exposure routes
- Dermal
Species
- Guinea pig
Result
- positive
Remarks
- Based on data from similar materials

Result
- Strong sensitizer
Remarks
- Based on human experience.
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Germ cell mutagenicity
Not classified based on available information.

Components:
6-(2-Phenylacetamido)penicillanic acid:
Germ cell mutagenicity- Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Not classified based on available information.

Components:
6-(2-Phenylacetamido)penicillanic acid:
Effects on fertility:
Test Type: Fertility
Species: Mouse
Result: No effects on fertility

Test Type: Fertility
Species: Rat
Result: No effects on fertility

Test Type: Fertility
Species: Rabbit
Result: No effects on fertility

Effects on foetal development:
Test Type: Development
Species: Mouse
Result: No effects on foetal development

Test Type: Development
Species: Rat
Result: No effects on foetal development

Test Type: Development
Species: Rabbit
Result: No effects on foetal development

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.
Experience with human exposure

Components:

6-(2-Phenylacetamido)penicillanic acid:

Inhalation: Symptoms: Allergic reactions, Abdominal pain, bronchospasm, skin rash

SECTION 12: Ecological information

12.1 Toxicity

Components:

6-(2-Phenylacetamido)penicillanic acid:

Toxicity to fish:
- LC50 (Oryzias latipes (Japanese medaka)): 1.000 mg/l
- Exposure time: 96 hrs
- Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): > 1.000 mg/l
- Exposure time: 48 hrs
- Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:
- EC50 (Anabaena flos-aquae): 0.006 mg/l
- Exposure time: 96 hrs
- Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
- Exposure time: 72 hrs
- Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity) = 100

M-Factor (Chronic aquatic toxicity) = 100

12.2 Persistence and degradability

Components:

6-(2-Phenylacetamido)penicillanic acid:

Biodegradability:
- Biodegradation: 27 %
- Exposure time: 28 d
- Method: OECD Test Guideline 301D
- Remarks: Not inherently biodegradable.
- Based on data from similar materials

12.3 Bioaccumulative potential

Components:

6-(2-Phenylacetamido)penicillanic acid:
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Partition coefficient: n-octanol/water: \( \log P_{\text{ow}} = 1.83 \)

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>
<thead>
<tr>
<th>Code</th>
<th>Number</th>
</tr>
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<tbody>
<tr>
<td>ADN</td>
<td>UN 3082</td>
</tr>
<tr>
<td>ADR</td>
<td>UN 3082</td>
</tr>
<tr>
<td>RID</td>
<td>UN 3082</td>
</tr>
<tr>
<td>IMDG</td>
<td>UN 3082</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 3082</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (6-(2-Phenylacetamido)penicillanic acid)</td>
</tr>
<tr>
<td>ADR</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (6-(2-Phenylacetamido)penicillanic acid)</td>
</tr>
<tr>
<td>RID</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (6-(2-Phenylacetamido)penicillanic acid)</td>
</tr>
<tr>
<td>IMDG</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (6-(2-Phenylacetamido)penicillanic acid)</td>
</tr>
<tr>
<td>IATA</td>
<td>Environmentally hazardous substance, liquid, n.o.s. (6-(2-Phenylacetamido)penicillanic acid)</td>
</tr>
</tbody>
</table>
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
- Packing group: III
- Labels: Miscellaneous

14.5 Environmental hazards

- **ADN**: Environmentally hazardous: yes
- **ADR**: Environmentally hazardous: yes
- **RID**: Environmentally hazardous: yes
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
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). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
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>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

Other regulations:
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined
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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**

H317 : May cause an allergic skin reaction.
H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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
Resp. Sens. : Respiratory sensitisation
Skin Sens. : Skin sensitisation

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; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative
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Further information
Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Code</th>
<th>Calculation method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resp. Sens. 1</td>
<td>H334</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>H317</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td>Calculation method</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.

NO / EN