

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Ampicillin Formulation

| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/09/28 |
| 3.0 | 2025/04/14 | 10082467-00009 | Date of first issue: 2021/10/27 |

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ampicillin Formulation

Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

| | |
|------------|----------------------|
| Appearance | : suspension |
| Colour | : white to off-white |
| Odour | : No data available |

May cause allergy or asthma symptoms or breathing difficulties if inhaled. Toxic to aquatic life.
Harmful to aquatic life with long lasting effects.

GHS Classification

Respiratory sensitisation : Category 1

Short-term (acute) aquatic hazard : Category 2

Long-term (chronic) aquatic hazard : Category 3

GHS label elements

Hazard pictograms :



Signal word : Danger

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| | | |
|--------------------------|---|--|
| Hazard statements | : | H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H401 Toxic to aquatic life. H412 Harmful to aquatic life with long lasting effects. |
| Precautionary statements | : | Prevention: P233 Keep container tightly closed. P261 Avoid breathing mist or vapours. P273 Avoid release to the environment. P284 Wear respiratory protection. Response: P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342 + P316 If experiencing respiratory symptoms: Get emergency medical help immediately. Disposal: P501 Dispose of contents/ container to an approved waste disposal plant. |

Physical and chemical hazards

Not classified based on available information.

Health hazards

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

Environmental hazards

Toxic to aquatic life. Harmful to aquatic life with long lasting effects.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------|---------|-----------------------|
| ampicillin | 69-53-4 | >= 10 -< 20 |

4. 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. |
| If inhaled | : | If inhaled, remove to fresh air. If not breathing, give artificial respiration. |

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| | | |
|---|---|--|
| | | 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. |
| Most important symptoms and effects, both acute and delayed | : | Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome). May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| 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). |
| Notes to physician | : | Treat symptomatically and supportively. |

5. FIREFIGHTING MEASURES

| | | |
|---|---|---|
| Suitable extinguishing media | : | Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire-fighting | : | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Nitrogen oxides (NO _x) Carbon oxides Sulphur oxides |
| 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. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |

6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
|---|---|--|

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- 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.
- Methods and materials for containment and 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.

7. HANDLING AND STORAGE

Handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not 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, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.
Take care to prevent spills, waste and minimize release to the environment.
- Avoidance of contact : Oxidizing agents

Storage

- Conditions for safe storage : Keep in properly labelled containers.
Keep tightly closed.
Keep in a cool, well-ventilated place.

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Materials to avoid : Store in accordance with the particular national regulations.
Do not store with the following product types:
Strong oxidizing agents

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---------------------------|---------|----------------------------------|--|----------|
| ampicillin | 69-53-4 | TWA | 0.6 mg/m ³ (OEB 2) | Internal |
| Further information: RSEN | | | | |

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

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

Eye/face 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.

Skin and body protection : Work uniform or laboratory coat.

Hand protection : Chemical-resistant gloves

Material : Chemical-resistant gloves

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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|--|---|--------------------|
| Appearance | : | suspension |
| Colour | : | white to off-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 |
| Flammability (liquids) | : | No data available |
| 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 | : | No data available |
| 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 |

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Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics
Particle size : Not applicable

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

ampicillin:

Acute oral toxicity : LD50 (Rat): 10,000 mg/kg
LD50 (Mouse): 15,200 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 6,200 mg/kg
Application Route: Intravenous
LD50 (Mouse): 4,600 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.

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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:

ampicillin:

| | |
|-----------------|--------------|
| Exposure routes | : Inhalation |
| Result | : Sensitiser |

Germ cell mutagenicity

Not classified based on available information.

Components:

ampicillin:

| | | |
|-----------------------|---|--------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) | |
| | Result: negative | |
| | Test Type: In vitro mammalian cell gene mutation test | |
| | Test system: mouse lymphoma cells | |
| | Result: negative | |
| | Test Type: sister chromatid exchange assay | |
| | Test system: Chinese hamster ovary cells | |
| | Result: negative | |
| | Test Type: Chromosomal aberration | |
| | Test system: Chinese hamster ovary cells | |
| | Result: negative | |
| | Test Type: Chromosomal aberration | |
| | Test system: Human lymphocytes | |
| | Result: negative | |
| | Genotoxicity in vivo | : Test Type: Micronucleus test |
| | Species: Rat | |
| | Application Route: Oral | |
| | Result: negative | |

Carcinogenicity

Not classified based on available information.

Components:

ampicillin:

| | |
|---------|-------|
| Species | : Rat |
|---------|-------|

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| | |
|-------------------|-------------------------------------|
| Application Route | : Oral |
| Exposure time | : 2 Years |
| | : 750 mg/kg body weight |
| Tumor Type | : adrenal, Leukaemia, breast tumors |

| | |
|-------------------|---------------------------|
| Species | : Mouse |
| Application Route | : Oral |
| Exposure time | : 2 Years |
| | : 3,000 mg/kg body weight |
| Tumor Type | : Lungs |
| Remarks | : Benign tumor(s) |

| | |
|------------------------------|--|
| Carcinogenicity - Assessment | : Weight of evidence does not support classification as a carcinogen |
|------------------------------|--|

Reproductive toxicity

Not classified based on available information.

Components:

ampicillin:

| | |
|-------------------------------|--|
| Effects on fertility | : Test Type: Fertility Species: Guinea pig Target Organs: Uterus (including cervix) |
| Effects on foetal development | : Test Type: Development Species: Rat Developmental Toxicity: NOAEL: 250 mg/kg body weight Result: No effects on foetal development |

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

ampicillin:

| | |
|-------------------|---------------|
| Species | : Rat |
| LOAEL | : 3,000 mg/kg |
| Application Route | : Oral |
| Exposure time | : 13 Weeks |
| Symptoms | : Diarrhoea |

| | |
|-------------------|---------------|
| Species | : Mouse |
| LOAEL | : 2,000 mg/kg |
| Application Route | : Oral |
| Exposure time | : 13 Weeks |

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| | |
|-------------------|---|
| Symptoms | : Diarrhoea |
| Species | : Rat |
| LOAEL | : 750 mg/kg |
| Application Route | : Oral |
| Exposure time | : 2 yr |
| Target Organs | : Thyroid, forestomach |
| Symptoms | : Diarrhoea, Salivation, decreased activity |
| Species | : Mouse |
| LOAEL | : 2,000 mg/kg |
| Application Route | : Oral |
| Exposure time | : 2 yr |
| Target Organs | : forestomach |
| Symptoms | : Ulceration, Inflammation, fungal infections |

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

ampicillin:

| | |
|------------|--|
| Inhalation | : Symptoms: Asthma, Hay fever Remarks: May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| Ingestion | : Symptoms: skin rash, Nausea, Diarrhoea, Vomiting, colitis, urticaria |

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

ampicillin:

| | |
|---|--|
| Toxicity to fish | : LC50 (<i>Oryzias latipes</i> (Japanese medaka)): > 1,000 mg/l Exposure time: 96 h LC50 (<i>Oncorhynchus mykiss</i> (rainbow trout)): > 100 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (<i>Daphnia magna</i> (Water flea)): > 100 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : EC50 (<i>Anabaena flos-aquae</i>): 190 µg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (<i>Anabaena flos-aquae</i>): 13 µg/l |

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Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 9 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Persistence and degradability

Components:

ampicillin:

Biodegradability : Result: rapidly degradable
Biodegradation: 35 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

ampicillin:

Partition coefficient: n-octanol/water : log Pow: -2.0
pH: 7

Mobility in soil

No data available

Other adverse effects

No data available

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13. DISPOSAL CONSIDERATIONS

Disposal methods

| | | |
|------------------------|---|---|
| Waste from residues | : | Do not dispose of waste into sewer. Dispose of in accordance with local regulations. |
| 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. |

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

| | | |
|---------------------------|---|----------------|
| UN number | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| Environmentally hazardous | : | no |

IATA-DGR

| | | |
|--|---|----------------|
| UN/ID No. | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| Packing instruction (cargo aircraft) | : | Not applicable |
| Packing instruction (passenger aircraft) | : | Not applicable |

IMDG-Code

| | | |
|----------------------|---|----------------|
| UN number | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| EmS Code | : | Not applicable |
| Marine pollutant | : | no |

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

GB 6944/12268

| | | |
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| UN number | : | Not applicable |
| Proper shipping name | : | Not applicable |

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| | |
|------------------|------------------|
| Class | : Not applicable |
| Subsidiary risk | : Not applicable |
| Packing group | : Not applicable |
| Labels | : Not applicable |
| Marine pollutant | : no |

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

| | |
|----------------------------------|---|
| Catalogue of Hazardous Chemicals | : This product is not listed in the catalogue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of determination. |
|----------------------------------|---|

| | |
|---|--------------|
| Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218) | : Not listed |
|---|--------------|

| | |
|--|--------------|
| Hazardous Chemicals for Priority Management under SAWS | : Not listed |
|--|--------------|

| | |
|---|--------------|
| Catalogue of Specially Controlled Hazardous Chemicals | : Not listed |
|---|--------------|

| | |
|------------------------------|--------------|
| List of Explosive Precursors | : Not listed |
|------------------------------|--------------|

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

| | |
|-------------------------------------|--------------|
| Catalogue of Highly Toxic Chemicals | : Not listed |
|-------------------------------------|--------------|

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

| | |
|---|--------------|
| China Severely Restricted Toxic Chemicals for Import and Export | : Not listed |
|---|--------------|

Regulation on the Administration of Precursor Chemicals

| | |
|---|--------------|
| Catalogue and Classification of Precursor Chemicals | : Not listed |
|---|--------------|

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

Regulations of Ozone Depleting Substances Management

| | |
|--|--------------|
| List of Controlled Ozone Depleting Substances Import | : Not listed |
|--|--------------|

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and Export
List of Controlled Ozone Depleting Substances : Not listed

Environmental Protection Law

List of Priority Controlled Chemicals : Not listed
List of Key Controlled New Pollutants : Not listed

The components of this product are reported in the following inventories:

AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2025/04/14

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

Date format : yyyy/mm/dd

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect

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Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

Disclaimer

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.

CN / EN