SAFETY DATA SHEET

Cloprostenol (with Propylene Glycol) Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Cloprostenol (with Propylene Glycol) Formulation

Manufacturer or supplier's details

Company: MSD
Address: Briahnager - Off Pune Nagar Road
          Wagholi - Pune - India 412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (%) w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>59-50-7</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
</tr>
<tr>
<td>Sodium [1α(Z),2β(1E,3R*),3α,5α-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate</td>
<td>55028-72-3</td>
<td>&lt; 0.1</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES
| If inhaled                      | If inhaled, remove to fresh air. Get medical attention if symptoms occur. |
| 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 | None known. |
| Protection of first-aiders     | No special precautions are necessary for first aid responders. |
| Notes to physician             | Treat symptomatically and supportively. |

5. FIREFIGHTING MEASURES

| Suitable extinguishing media  | Water spray |
| Unsuitable extinguishing media | None known. |
| Specific hazards during firefighting | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | Carbon 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 | Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment. |

6. ACCIDENTAL RELEASE MEASURES

| Personal precautions, protective equipment and emergency procedures | Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| 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 spills 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 contain- |
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Date of last issue: 10.10.2020  Date of first issue: 14.11.2019

- 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

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

**Local/Total ventilation:** Use only with adequate ventilation.

**Advice on safe handling:** Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Take care to prevent spills, waste and minimize release to the environment.

**Conditions for safe storage:** Keep in properly labelled containers. Store in accordance with the particular national regulations.

**Materials to avoid:** Do not store with the following product types: Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Components with workplace control parameters**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [1α(Z),2β(1E,3R*)]-[3α,5α]- (3-chlorophenoxy) -3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate</td>
<td>55028-72-3</td>
<td>TWA</td>
<td>0.01 ug/m3 (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: RSEN, Skin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.1 ug/100 cm2</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**Engineering measures:** Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. No open handling permitted. Totally enclosed processes and materials transport systems
are required. Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

**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**: Particulates type
- **Hand protection**: 

**Material**: Chemical-resistant gloves

**Remarks**: Consider double gloving.

**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.

**Skin and body protection**: Work uniform or laboratory coat.

- Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
- Use appropriate degowning techniques to remove potentially contaminated clothing.

**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.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

- **Appearance**: Aqueous solution
- **Colour**: colourless
- **Odour**: characteristic
- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: -6 °C
- **Initial boiling point and boiling range**: 99 °C
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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 : 1.02 - 1.08
Density : No data available
Solubility(ies)
Water solubility : soluble
Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, kinematic : 1.56 - 1.62 mm²/s
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
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 : No hazardous decomposition products are known.
11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Components:

4-Chloro-3-methylphenol:
- Acute oral toxicity: LD50 (Mouse): 600 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 2.871 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
- Acute dermal toxicity: LD50 (Rat): > 5,000 mg/kg

Sodium [1α(Z),2β(1E,3R*)₂,3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:
- Acute oral toxicity: LD50 (Rat): > 25 mg/kg
  Remarks: No mortality observed at this dose.
- Acute toxicity (other routes of administration): LD50 (Rat): > 50 mg/kg
  Application Route: Subcutaneous
  LD50 (Rat): > 50 mg/kg
  Application Route: Intramuscular
  LD50 (Rat): 5 mg/kg
  Application Route: Intravenous
  Remarks: No mortality observed at this dose.
  LD50 (Mouse): 350 mg/kg
  Application Route: Intramuscular
  LD50 (Mouse): 54.7 mg/kg
  Application Route: Intravenous
  TDLo (Monkey): 0.0025 - 0.025 mg/kg
  Application Route: Intramuscular
  Target Organs: Lungs
  Symptoms: Diarrhoea, Vomiting, Rapid respiration
  TDLo (Monkey): 0.0013 mg/kg
  Application Route: Intramuscular
  Target Organs: ovaries
Skin corrosion/irritation
Not classified based on available information.

Components:
4-Chloro-3-methylphenol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: Corrosive after 1 to 4 hours of exposure

Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxo)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:
Remarks: Not classified due to lack of data.
Can be absorbed through skin.

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

Components:
4-Chloro-3-methylphenol:
Species: Rabbit
Method: OECD Test Guideline 405
Result: Irreversible effects on the eye

Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxo)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:
Remarks: Not classified due to lack of data.

Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
4-Chloro-3-methylphenol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Assessment: Probability or evidence of low to moderate skin sensitisation rate in humans

Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxo)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:
Result: Sensitiser
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Germ cell mutagenicity
Not classified based on available information.

Components:

4-Chloro-3-methylphenol:
Genotoxicity in vitro  Test Type: Bacterial reverse mutation assay (AMES)  Result: negative

Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:
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: Chromosomal aberration  Test system: Human lymphocytes  Result: equivocal
Genotoxicity in vivo  Test Type: Micronucleus test  Species: Mouse  Cell type: Bone marrow  Application Route: Intraperitoneal  Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:
Remarks  Not classified due to lack of data.

Reproductive toxicity
Not classified based on available information.

Components:

4-Chloro-3-methylphenol:
Effects on fertility  Test Type: One-generation reproduction toxicity study  Species: Rat  Application Route: Ingestion  Result: negative
Effects on foetal development  Test Type: Reproduction/Developmental toxicity screening test  Species: Rat
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<td>2.2</td>
<td>27.08.2021</td>
<td>5266457-00004</td>
<td>10.10.2020</td>
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</tr>
</tbody>
</table>

Application Route: Ingestion  
Result: negative

**Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:**

Effects on fertility  
Test Type: Three-generation study  
Species: Rat  
Application Route: Oral  
General Toxicity F1: NOAEL: 0.015 mg/kg body weight  
Fertility: NOAEL: > 0.04 mg/kg body weight  
Result: Animal testing did not show any effects on fertility.

Species: Cattle  
Application Route: Intramuscular  
General Toxicity - Parent: LOAEL: 0.16 µg/kg  
Result: positive  
Remarks: Abortion

Effects on foetal development  
Test Type: Development  
Species: Rabbit  
Application Route: Subcutaneous  
Teratogenicity: NOAEL: 0.250 µg/kg  
Result: No teratogenic effects

Test Type: Development  
Species: Rat  
Application Route: Oral  
Teratogenicity: NOAEL: 100 µg/kg  
Result: No teratogenic effects

Reproductive toxicity - Assessment  
May damage fertility.

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

**Components:**

**4-Chloro-3-methylphenol:**
Assessment  
May cause respiratory irritation.

**Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:**

Target Organs  
Lungs  
Assessment  
Causes damage to organs.

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

**Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:**

- **Target Organs:** Ovary
- **Assessment:** Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

**Components:**

**4-Chloro-3-methylphenol:**

- **Species:** Rat
- **NOAEL:** 200 mg/kg
- **LOAEL:** 400 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 28 Days

**Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:**

- **Species:** Rat
- **NOAEL:** 0.05 mg/kg
- **LOAEL:** 0.15 mg/kg
- **Application Route:** Oral
- **Exposure time:** 3 Months
- **Target Organs:** Ovary

- **Species:** Rat
- **LOAEL:** 0.0125 mg/kg
- **Application Route:** Subcutaneous
- **Exposure time:** 30 Days
- **Target Organs:** Ovary

- **Species:** Monkey
- **NOAEL:** 0.05 mg/kg
- **LOAEL:** 0.15 mg/kg
- **Application Route:** Oral
- **Exposure time:** 3 Months
- **Target Organs:** Heart, Testis

Aspiration toxicity

Not classified based on available information.

**Components:**

**Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:**

Not applicable
Experience with human exposure

**Components:**

**Sodium [1α(Z),2β(1E,3R*),3α,5α]-(+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:**

**General Information:**
- Target Organs: Uterus (including cervix)
- Symptoms: Embryo-foetal toxicity, foetal mortality, menstrual irregularities, miscarriage
- Target Organs: Lungs
- Symptoms: Asthma, bronchospasm

**Inhalation:**
- Target Organs: Lungs
- Symptoms: bronchospasm, Asthma
- Remarks: May cause sensitisation of susceptible persons by inhalation of aerosol or dust.
- Target Organs: Uterus (including cervix)
- Symptoms: Embryolethal effects, menstrual irregularities

**Skin contact:**
- Target Organs: Lungs
- Symptoms: bronchospasm
- Remarks: Can be absorbed through skin.
- Target Organs: Uterus (including cervix)
- Symptoms: Embryolethal effects

12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**4-Chloro-3-methylphenol:**

**Toxicity to fish**
- LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l
- Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates**
- EC50 (Daphnia magna (Water flea)): 1.5 mg/l
- Exposure time: 48 h
- Method: OECD Test Guideline 202

**Toxicity to algae/aquatic plants**
- ErC50 (Chlorella pyrenoidosa (algae)): 15 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

- EC10 (Chlorella pyrenoidosa (algae)): 2.3 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

**M-Factor (Acute aquatic toxicity)**
- 1

**Toxicity to microorganisms**
- EC50: 22.86 mg/l
- Exposure time: 60 h

**Toxicity to fish (Chronic toxicity)**
- NOEC: 0.15 mg/l
- Exposure time: 28 d
- Species: Oncorhynchus mykiss (rainbow trout)
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Method: OECD Test Guideline 204

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: 0.32 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- Method: OECD Test Guideline 211

Sodium [1α(Z),2β(1E,3R*),3α,5α](+/-)-7-[2-[4-(3-chlorophenoxy)-3-hydroxybut-1-enyl]-3,5-dihydroxycyclopentyl]hept-5-enoate:

Ecotoxicology Assessment
- Acute aquatic toxicity: Toxic effects cannot be excluded
- Chronic aquatic toxicity: Toxic effects cannot be excluded

Persistence and degradability

Components:
- 4-Chloro-3-methylphenol:
  - Biodegradability: Result: Readily biodegradable.
  - Biodegradation: 78 %
  - Exposure time: 15 d
  - Method: OECD Test Guideline 301

Bioaccumulative potential

Components:
- 4-Chloro-3-methylphenol:
  - Bioaccumulation: Species: Cyprinus carpio (Carp)
  - Bioconcentration factor (BCF): 5.5 - 13

Mobility in soil
- No data available

Other adverse effects
- No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
- Waste from residues: 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.
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14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to IMO instruments
Not applicable for product as supplied.

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Further information

Date format : dd.mm.yyyy

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 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

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.

IN / EN