SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Progesterone Formulation (Veterinary)

Version 1.2  Revision Date: 2018/10/16  SDS Number: 2183769-00003  Date of last issue: 2018/03/26
Date of first issue: 2017/11/15

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Progesterone Formulation (Veterinary)

Manufacturer or supplier's details
Company: MSD
Address: No. 485 Jing Tai Road
          Pu Tuo District - Shanghai - China  200331
Telephone: 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

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance: solid
Colour: light green
Odour: No information available.

May cause cancer by inhalation. Suspected of causing cancer. May damage fertility or the unborn child. May cause harm to breast-fed children. Causes damage to organs through prolonged or repeated exposure. Harmful to aquatic life with long lasting effects.

GHS Classification
Carcinogenicity (Inhalation): Category 1A
Carcinogenicity: Category 2
Reproductive toxicity: Category 1A
Effects on or via lactation
Specific target organ toxicity - repeated exposure: Category 1
Short-term (acute) aquatic hazard: Category 3
Long-term (chronic) aquatic hazard: Category 3

GHS label elements
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Hazard pictograms : 

Signal word : Danger

Hazard statements :
H350i May cause cancer by inhalation.
H351 Suspected of causing cancer.
H360 May damage fertility or the unborn child.
H362 May cause harm to breast-fed children.
H372 Causes damage to organs through prolonged or repeated exposure.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements :
**Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P263 Avoid contact during pregnancy/ while nursing.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**
P405 Store locked up.

**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 cancer by inhalation. Suspected of causing cancer. May damage fertility or the unborn child. May cause harm to breast-fed children. Causes damage to organs through prolonged or repeated exposure.

Environmental hazards
Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

Additional Labelling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 6.609 %

Other hazards which do not result in classification
None known.
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3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mixture</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quartz</td>
<td>14808-60-7</td>
<td>&gt;= 30 &lt; 50</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>&gt;= 20 &lt; 30</td>
</tr>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>&gt;= 1 &lt; 10</td>
</tr>
<tr>
<td>Bis(alpha,alpha-dimethylbenzyl) peroxide</td>
<td>80-43-3</td>
<td>&gt;= 0.25 &lt; 1</td>
</tr>
</tbody>
</table>

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. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: May cause cancer by inhalation. Suspected of causing cancer. May damage fertility or the unborn child. May cause harm to breast-fed children. Causes damage to organs through prolonged or repeated exposure.

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.

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES


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.

6. ACCIDENTAL RELEASE MEASURES

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

environmental precautions: Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. 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: Sweep up or vacuum up spillage and collect in suitable container for disposal. 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: Use with local exhaust ventilation.
Advice on safe handling: Do not get on skin or clothing. 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. Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact: Oxidizing agents

Storage
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Store in accordance with the particular national regulations.

Materials to avoid: 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

<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>Quartz</td>
<td>14808-60-7</td>
<td>PC-TWA (Total dust)</td>
<td>0.5 mg/m³</td>
<td>GBZ 2.1-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PC-TWA (Respirable dust)</td>
<td>0.2 mg/m³</td>
<td>GBZ 2.1-2007</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>TWA (Respirable fraction)</td>
<td>0.025 mg/m³ (Silica)</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>TWA</td>
<td>5 μg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: G1 - Carcinogenic to humans, crystalline

Engineering measures: Minimize workplace exposure concentrations. Use with local exhaust ventilation.

Personal protective equipment

Respiratory protection: Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.

Filter type: Particulates type

Eye/face protection: Wear the following personal protective equipment:
Safety glasses

Skin and body protection: Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Hand protection

Material: Chemical-resistant gloves

Remarks: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to
Hygiene measures: Ensure that eye flushing systems and safety showers are located close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: solid
Colour: light green
Odour: No information 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: Not applicable
Evaporation rate: Not applicable
Flammability (solid, gas): Not classified as a flammability hazard
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: Not applicable
Relative vapour density: Not applicable
Relative density: No data available
Density: 1.1 g/cm³
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: Not applicable
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: Not applicable
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: Skin contact
Ingestion
Eye contact

Acute toxicity:
Not classified based on available information.

Components:

Quartz:
Acute oral toxicity: LD50 (Rat): > 22,500 mg/kg

Silicon dioxide:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity: LC50 (Rat): > 2.08 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg

Progesterone:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg

Bis(alpha,alpha-dimethylbenzyl) peroxide:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 401
Assessment: The substance or mixture has no acute oral tox-
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Acute inhalation toxicity : LC50 (Rat): > 0.224 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
   Method: OECD Test Guideline 402
   Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation
Not classified based on available information.

Components:

Quartz:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

Silicon dioxide:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Bis(alpha,alpha-dimethylbenzyl) peroxide:
Result : Skin irritation
Remarks : Based on harmonised classification in EU regulation 1272/2008, Annex VI

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

Components:

Quartz:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Silicon dioxide:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Bis(alpha,alpha-dimethylbenzyl) peroxide:
Species : Rabbit
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Result : Irritation to eyes, reversing within 7 days
Method : OECD Test Guideline 405

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Bis(alpha,alpha-dimethylbenzyl) peroxide:
Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative

Germ cell mutagenicity
Not classified based on available information.

Components:

Silicon dioxide:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

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

Progesterone:
Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Method: OECD Test Guideline 482
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Monkey
Application Route: Subcutaneous
Result: negative

Bis(alpha,alpha-dimethylbenzyl) peroxide:
Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
Result: negative
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Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Carcinogenicity
May cause cancer by inhalation.
Suspected of causing cancer.

Components:

Quartz:
Species: Humans
Application Route: inhalation (dust/mist/fume)
Result: positive
Remarks: IARC: (International Agency for Research on Cancer)

Carcinogenicity - Assessment: Positive evidence from human epidemiological studies (inhalation)

Silicon dioxide:
Species: Rat
Application Route: Ingestion
Exposure time: 103 weeks
Result: negative

Progesterone:
Species: Mouse
Application Route: Subcutaneous
Exposure time: 19 weeks
Result: positive

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in animal studies

Reproductive toxicity
May damage fertility or the unborn child.
May cause harm to breast-fed children.

Components:

Silicon dioxide:
Effects on foetal development:
Species: Rat
Application Route: Ingestion
Result: negative

Progesterone:
Effects on fertility:
Species: Rat
Application Route: Subcutaneous
Result: positive
Effects on foetal development: Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Skin contact  
Result: positive

Reproductive toxicity - Assessment: Positive evidence of adverse effects on sexual function, fertility and/or development from human epidemiological studies., Studies indicating a hazard to babies during the lactation period

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

STOT - repeated exposure: Causes damage to organs through prolonged or repeated exposure.

Components:

Quartz:
Exposure routes: inhalation (dust/mist/fume)  
Target Organs: Lungs  
Assessment: Shown to produce significant health effects in animals at concentrations of 0.02 mg/l/6h/d or less.

Bis(alpha,alpha-dimethylbenzyl) peroxide:
Exposure routes: Ingestion  
Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

Quartz:
Species: Humans  
LOAEL: 0.053 mg/m3  
Application Route: Inhalation

Silicon dioxide:
Species: Rat  
NOAEL: 1.3 mg/m3  
Application Route: inhalation (dust/mist/fume)  
Exposure time: 13 Weeks

Bis(alpha,alpha-dimethylbenzyl) peroxide:
Species: Rat  
NOAEL: 60 mg/kg  
LOAEL: 200 mg/kg  
Application Route: Ingestion  
Exposure time: 28 Days  
Method: OECD Test Guideline 407
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Aspiration toxicity
Not classified based on available information.

12. ECOLOGICAL INFORMATION

Ecotoxicity

**Product:**

**Components:**

**Quartz:**

Toxicity to fish: LC50 (Danio rerio (zebra fish)): 508 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 731 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

**Silicon dioxide:**

Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 24 h
Method: OECD Test Guideline 202

Toxicity to algae: EC50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

**Progesterone:**

Ecotoxicology Assessment

Acute aquatic toxicity: Toxic effects cannot be excluded

Chronic aquatic toxicity: Toxic effects cannot be excluded

**Bis(alpha,alpha-dimethylbenzyl) peroxide:**

Toxicity to daphnia and other: EC50 (Daphnia magna (Water flea)): > 0.397 mg/l
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aquatic invertebrates
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility

Toxicity to algae:
ErC50 (Pseudokirchneriella subcapitata (green algae)): > 20 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

NOEC (Pseudokirchneriella subcapitata (green algae)): 8 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Daphnia magna (Water flea)): 0.177 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms:
NOEC: > 1,000 mg/l
Exposure time: 30 min
Remarks: No toxicity at the limit of solubility

Ecotoxicology Assessment

Acute aquatic toxicity:
Very toxic to aquatic life.
Remarks: Based on the Catalogue of Hazardous Chemicals of China

Chronic aquatic toxicity:
Very toxic to aquatic life with long lasting effects.
Remarks: Based on the Catalogue of Hazardous Chemicals of China

Persistence and degradability

Components:

Bis(alpha,alpha-dimethylbenzyl) peroxide:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 20.2 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Bioaccumulative potential

Components:

Progesterone:
Partition coefficient: n-octanol/water: Pow: 3.65

Bis(alpha,alpha-dimethylbenzyl) peroxide:
Bioaccumulation: Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 137 - 1,470
Method: OECD Test Guideline 305C
Partition coefficient: n-octanol/water: log Pow: 5.6

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.

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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

GB 6944/12268
Not regulated as a dangerous good

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

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: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA: 8-hour, time-weighted average
GBZ 2.1-2007 / PC-TWA: Permissible concentration - time weighted average

AICS - Australian Inventory of Chemical Substances; 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; CPR - Controlled Products Regulations; 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; IECS - 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; 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