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

Progesterone Formulation (Veterinary)

Version 4.0  Revision Date: 2021/08/27  SDS Number: 2183769-00009  Date of last issue: 2021/04/09
Rewritten 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: +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

2. HAZARDS IDENTIFICATION

Emergency Overview

| Appearance | solid |
| Colour     | light green |
| Odour      | No data 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 :
H350 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.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Quartz</td>
<td>14808-60-7</td>
<td>&gt;= 30 -&lt; 50</td>
</tr>
<tr>
<td></td>
<td>Progesterone</td>
<td>57-83-0</td>
<td>&gt;= 1 -&lt; 10</td>
</tr>
<tr>
<td></td>
<td>Bis(alpha,alpha-dimethylbenzyl) peroxide</td>
<td>80-43-3</td>
<td>&gt;= 0.3 -&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 (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Silicon 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).

Environmental precautions: Avoid release to the environment. 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: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling: Avoid contact during pregnancy and while nursing. Do not get on skin or clothing. Do not breathe dust, fume, gas, mist, vapours or spray. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact: Oxidizing agents
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**Version**: 4.0  
**Revision Date**: 2021/08/27  
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**Date of first issue**: 2017/11/15

### Storage

**Conditions for safe storage**:  
Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.  
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>CN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PC-TWA (Respirable dust)</td>
<td>0.2 mg/m³</td>
<td>CN OEL</td>
</tr>
<tr>
<td>Progesterone</td>
<td>57-83-0</td>
<td>TWA (Respirable particulate matter)</td>
<td>0.025 mg/m³ (Silica)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

**Engineering measures**:  
Minimize workplace exposure concentrations.  
If sufficient ventilation is unavailable, use with local exhaust ventilation.

**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**:  
Self-contained breathing apparatus

**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 chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>solid</td>
</tr>
<tr>
<td>Colour</td>
<td>light green</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not classified as a flammability hazard</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1.1 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
</tbody>
</table>
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

**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 toxicity.
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

**Bis(alpha,alpha-dimethylbenzyl) peroxide:**
- **Result:** Skin irritation

**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

**Bis(alpha,alpha-dimethylbenzyl) peroxide:**
- **Species:** Rabbit
- **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
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Species: Mouse
Method: OECD Test Guideline 429
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

**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)
Specie: Monkey
Application Route: Subcutaneous
Result: negative

**Bis(alpha,alpha-dimethylbenzyl) peroxide:**
Genotoxicity in vitro:
Test Type: Chromosome aberration test in vitro
Result: negative

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

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

**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:

Progesterone:
Effects on fertility: Test Type: 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

Bis(alpha,alpha-dimethylbenzyl) peroxide:
Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: positive

Reproductive toxicity - Assessment: Clear evidence of adverse effects on development, based on animal experiments.

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.
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Repeated dose toxicity

**Components:**

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

**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

Aspiration toxicity
Not classified based on available information.

12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

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

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

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

- Toxicity to algae/aquatic plants: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 20 mg/l
  Exposure time: 72 h
 прогестеронная формула (ветеринарная)

по данным ГБ/Т 16483 и ГБ/Т 17519

версия 4.0

дата последнего выпуска: 2021/04/09
дата первого выпуска: 2017/11/15

метод: OECD Test Guideline 201
заметки: Нет токсичности на предел растворимости

NOEC (Pseudokirchneriella subcapitata (зелёные водоросли)): 8 мг/л

edu time: 72 ч

метод: OECD Test Guideline 201

токсичность к дапхниям и другим водным насекомым (хроническая токсичность)

NOEC (Daphnia magna (Water flea)): 0,177 мг/л

edu time: 21 d

метод: OECD Test Guideline 211

токсичность к микробным организмам

NOEC: > 1,000 мг/л

edu time: 30 мин

заметки: Нет токсичности на предел растворимости

экотоксикологическая оценка

ожидаемая токсичность

очень токсична для водных организмов.

заметки: На основании Каталога опасных химических веществ Китая

хроническая токсичность

очень токсична для водных организмов с длительными эффектами.

заметки: На основании Каталога опасных химических веществ Китая

стойкость и разлагаемость

состав:

Bis(alpha, alpha-dimethylbenzyl) peroxide:

биоразлагаемость:

результат: не разлагается.

биоразложение: 20,2 %

edu time: 28 d

метод: OECD Test Guideline 301F

аккумулятивная способность

состав:

progesterone:

коеффициент распределения: n-octanol/water

pow: 3,65

Bis(alpha, alpha-dimethylbenzyl) peroxide:

аккумулятивная способность:

специфика: Cyprinus carpio (Carp)

биоаккумуляция фактор (BCF): 137 - 1,470

метод: OECD Test Guideline 305C

коэффициент распределения: n-octanol/water

log Pow: 5,6

-mobile in soil

очередь данных
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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
- UN number: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
- Labels: Not applicable

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: Not applicable

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
- UN number: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
# Progesterone Formulation (Veterinary)

## 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:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Report Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

## 16. OTHER INFORMATION

**Further information**

Sources of key data used to compile the Safety Data Sheet:


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**

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **CN OEL**: Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.
- **ACGIH / TWA**: 8-hour, time-weighted average
- **CN OEL / PC-TWA**: Permissible concentration - time weighted average

Abbreviations:

- AICL - 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; ICS0 - 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 Or-
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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