SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Desloratadine Solid Formulation

Manufacturer or supplier’s details
Company : Organon & Co.
Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil  B-2220
Telephone : 551-430-6000
Emergency telephone : 215-631-6999
E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Serious eye damage : Category 1
Carcinogenicity (Inhalation) : Category 2
Reproductive toxicity : Category 2
Short-term (acute) aquatic hazard : Category 3
Long-term (chronic) aquatic hazard : Category 3

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms : 

Signal Word : Danger
Hazard Statements : H318 Causes serious eye damage.
H351 Suspected of causing cancer if inhaled.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements : Prevention:
P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**
P405 Store locked up.

**Other hazards which do not result in classification**
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
</tr>
</tbody>
</table>

### SECTION 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:
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention immediately.

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:
Causes serious eye damage.
Suspected of causing cancer if inhaled.
Suspected of damaging fertility. Suspected of damaging the unborn child.
Contact with dust can cause mechanical irritation or drying of the skin.

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.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media:
None known.

Specific hazards during fire fighting:
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
Carbon oxides
Metal oxides
Oxides of phosphorus

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 fire-fighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 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. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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.

SECTION 7. HANDLING AND STORAGE

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Do not breathe dust. Do not swallow. Do not get in 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. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

Conditions for safe storage: Keep in properly labeled 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.
SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Desloratadine</td>
<td>100643-71-8</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>TWA</td>
<td>Wipe limit 200 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Respirable particulate matter)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Titanium dioxide)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Engineering measures: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

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: Chemical-resistant gloves

Remarks: Choose gloves to protect hands against chemicals depending on the concentration 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.

Eye protection: Wear the following personal protective equipment: Chemical resistant goggles must be worn. If splashes are likely to occur, wear: Face-shield

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.).

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Color: white

Odor: No data available

Odor 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): May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids): No data available

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapor pressure: No data available

Relative vapor 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: No data available

Autoignition temperature: No data available

Decomposition temperature: No data available

Viscosity

Viscosity, dynamic: No data available

Viscosity, kinematic: No data available

Explosive properties: Not explosive

Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks. Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skint contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:
Cellulose:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5,8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Desloratadine:
Acute oral toxicity : LD50 (Rat): > 549 mg/kg
LD50 (Mouse): 353 mg/kg
LD50 (Monkey): > 250 mg/kg
Symptoms: Vomiting
Remarks: No mortality observed at this dose.
Desloratadine Solid Formulation

Talc:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Remarks: Based on data from similar materials

Titanium dioxide:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Skin corrosion/irritation
Not classified based on available information.

Components:

Desloratadine:
Species : Rabbit
Result : No skin irritation

Talc:
Species : Rabbit
Result : No skin irritation

Titanium dioxide:
Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation
Causes serious eye damage.

Components:

Desloratadine:
Species : Rabbit
Remarks : Severe eye irritation

Talc:
Species : Rabbit
Result : No eye irritation

Titanium dioxide:
Species : Rabbit
Result : No eye irritation
Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Desloratadine:
Test Type: Maximization Test
Routes of exposure: Dermal
Species: Guinea pig
Result: negative

Talc:
Routes of exposure: Skin contact
Species: Humans
Result: negative

Titanium dioxide:
Test Type: Local lymph node assay (LLNA)
Routes of exposure: Skin contact
Species: Mouse
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

Cellulose:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: In vitro mammalian cell gene mutation test
Result: negative

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

Desloratadine:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: negative
Genotoxicity in vivo: Test Type: Micronucleus test  
Species: Mouse  
Cell type: Bone marrow  
Application Route: Oral  
Result: negative

Talc:
Genotoxicity in vitro: Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

Genotoxicity in vivo: Test Type: Chromosome aberration test in vitro  
Species: Rat  
Application Route: Ingestion  
Result: negative

Titanium dioxide:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vivo: Test Type: In vivo micronucleus test  
Species: Mouse  
Result: negative

Carcinogenicity
Suspected of causing cancer if inhaled.

Components:

Cellulose:
Species: Rat  
Application Route: Ingestion  
Exposure time: 72 weeks  
Result: negative

Desloratadine:
Species: Mouse  
Application Route: Oral  
Exposure time: 2 Years  
Result: negative

Species: Rat  
Application Route: Oral  
LOAEL: 10 mg/kg body weight  
Result: equivocal  
Target Organs: Liver  
Remarks: Based on data from similar materials  
The mechanism or mode of action may not be relevant in humans.

Talc:
Species: Mouse
Application Route: inhalation (dust/mist/fume)
Exposure time: 2 Years
Result: negative

Titanium dioxide:
Species: Rat
Application Route: inhalation (dust/mist/fume)
Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: positive
Remarks: The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in inhalation studies with animals.

Reproductive toxicity
Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:

Cellulose:
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on fetal development: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

Desloratadine:
Effects on fertility: Test Type: Fertility
Species: Rat, male
Application Route: Oral
Fertility: LOAEL: 12 mg/kg body weight
Symptoms: Reduced fertility
Result: positive
Remarks: The mechanism or mode of action may not be relevant in humans.

Test Type: Fertility
Species: Rat, female
Fertility: NOAEL: 3 mg/kg body weight
Symptoms: No effects on fertility.
Result: negative

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 30 mg/kg body weight
Result: No teratogenic effects.
Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 9 mg/kg body weight  
Symptoms: Preimplantation loss., Reduced body weight  
Result: Specific developmental abnormalities.  
Remarks: The mechanism or mode of action may not be relevant in humans.

Test Type: Two-generation study  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 18 mg/kg body weight  
Result: No adverse effects.

Reproductive toxicity - Assessment: Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

Talc:  
Effects on fetal development: Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

STOT-single exposure  
Not classified based on available information.

STOT-repeated exposure  
Not classified based on available information.

Repeated dose toxicity

Components:

Cellulose:  
Species: Rat  
NOAEL: >= 9.000 mg/kg  
Application Route: Ingestion  
Exposure time: 90 Days

Desloratadine:  
Species: Rat  
LOAEL: 30 mg/kg  
Application Route: Oral  
Exposure time: 3 Months  
Target Organs: Kidney  
Remarks: Significant toxicity observed in testing. The mechanism or mode of action may not be relevant in humans.

Species: Monkey


SAFETY DATA SHEET

Desloratadine Solid Formulation

<table>
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<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
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<td>02.10.2020</td>
<td>49973-00014</td>
<td>23.03.2020</td>
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</tr>
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<td></td>
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<td>23.01.2015</td>
</tr>
</tbody>
</table>

NOAEL : 6 mg/kg
LOAEL : 12 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Central nervous system
Symptoms : Gastrointestinal disturbance

Species : Monkey
NOAEL : 40 mg/kg
Application Route : Oral
Exposure time : 17 Months
Remarks : No significant adverse effects were reported

Species : Monkey
NOAEL : 6 mg/kg
Application Route : Oral
Exposure time : 3 Months
Symptoms : Gastrointestinal disturbance, Fatigue

**Titanium dioxide:**
Species : Rat
NOAEL : 24.000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

Species : Rat
NOAEL : 10 mg/m³
Application Route : inhalation (dust/mist/fume)
Exposure time : 2 y

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**Desloratadine:**
Inhalation : Remarks: May cause respiratory tract irritation.
Eye contact : Symptoms: Eye irritation
Ingestion : Symptoms: dry mouth, muscle pain, Fatigue, Drowsiness, sore throat, painful menstration

**Cellulose:**
Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Cellulose:**
Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials
Desloratadine:  
**Toxicity to fish**: LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.2 mg/l  
Exposure time: 96 h  
Method: FDA 4.11

**Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): 9.6 mg/l  
Exposure time: 48 h  
Method: FDA 4.08

**Toxicity to algae/aquatic plants**: EC50 (Pseudokirchneriella subcapitata (green algae)): 1.6 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
NOEC (Pseudokirchneriella subcapitata (green algae)): 0.36 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

**Toxicity to fish (Chronic toxicity)**: NOEC (Pimephales promelas (fathead minnow)): 0.12 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**: NOEC (Daphnia magna (Water flea)): 0.48 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

**Toxicity to microorganisms**: EC50 (Natural microorganism): 53.7 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209  
NOEC (Natural microorganism): 12 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**Talc**:  
**Toxicity to fish**: LC50 (Brachydanio rerio (zebrafish)): > 100,000 mg/l  
Exposure time: 24 h

**Titanium dioxide**:  
**Toxicity to fish**: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

**Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h

**Toxicity to algae/aquatic plants**: EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l  
Exposure time: 72 h

**Toxicity to microorganisms**: EC50: > 1.000 mg/l
Exposure time: 3 h  
Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

**Cellulose:**  
Biodegradability: Result: Readily biodegradable.

**Desloratadine:**  
Biodegradability: Result: Not readily biodegradable.  
Biodegradation: 67.4 %  
Exposure time: 28 d  
Method: OECD Test Guideline 314

Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: FDA 3.11

Stability in water: Hydrolysis: < 10 % at 50 °C (5 d)  
Method: FDA 3.09

### Bioaccumulative potential

#### Components:

**Desloratadine:**  
Partition coefficient: n-octanol/water: log Pow: 1.24  
Method: OECD Test Guideline 107

### Mobility in soil

#### Components:

**Desloratadine:**  
Distribution among environmental compartments: log Koc: 3.00  
Method: OECD Test Guideline 106

### Other adverse effects

No data available

### SECTION 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.
SECTION 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.

Domestic regulation

ANTT
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH)

Group 2B: Possibly carcinogenic to humans
Titanium dioxide 13463-67-7

Brazil. List of chemicals controlled by the Federal Police
: Not applicable

International Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

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

BR / Z8