1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ezetimibe Granules Formulation

Manufacturer or supplier's details
Company : Organon & Co.
Address : 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
Emergency telephone number : 215-631-6999
E-mail address : EHSSTEWARD@organon.com

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

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
Skin corrosion/irritation : Category 3
Long-term (chronic) aquatic hazard : Category 2

GHS label elements
Hazard pictograms : 

Signal word : Warning
Hazard statements : H316 Causes mild skin irritation.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:
P273 Avoid release to the environment.
Response:
P332 + P317 If skin irritation occurs: Get medical help.
P391 Collect spillage.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</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>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Sodium n-dodecyl sulfate</td>
<td>151-21-3</td>
<td>&gt;= 1 - &lt; 2.5</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 if symptoms occur.

In case of skin contact: In case of contact, immediately flush skin with 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: If in eyes, rinse well with water. 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: Causes mild skin irritation. Dust contact with the eyes can lead to mechanical irritation.

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)
Dry chemical

Unsuitable extinguishing media: None known.
Specific hazards during firefighting:
Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Nitrogen oxides (NOx)
- Fluorine compounds
- Sulphur oxides
- Metal 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.
- 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.

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 get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
SAFETY DATA SHEET

Ezetimibe Granules Formulation

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
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.

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>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Ezetimibe</td>
<td>163222-33-1</td>
<td>TWA</td>
<td>25 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>250 µg/100 cm²</td>
<td>Internal</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:
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.

Eye protection:
Wear the following personal protective equipment:
Safety goggles

Skin and body protection:
Skin should be washed after contact.

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>granular</td>
</tr>
<tr>
<td>Colour</td>
<td>white</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>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</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>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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

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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation

Skin 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

Ezetimibe:

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

LD50 (Mouse): > 5,000 mg/kg

LD50 (Dog): > 3,000 mg/kg
Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration): LD50 (Rat): > 2,000 mg/kg
Application Route: Intraperitoneal
LD50 (Mouse): > 1,000 - < 2,000 mg/kg
Application Route: Intraperitoneal

**Sodium n-dodecyl sulfate:**

Acute oral toxicity: LD50 (Rat): 1,200 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

Skin corrosion/irritation
Causes mild skin irritation.

**Components:**

**Ezetimibe:**
Species : Rabbit
Result : No skin irritation

**Sodium n-dodecyl sulfate:**
Species : Rabbit
Result : Skin irritation

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

**Components:**

**Ezetimibe:**
Species : Rabbit
Result : No eye irritation

**Sodium n-dodecyl sulfate:**
Species : Rabbit
Method : OECD Test Guideline 405
Result : Irreversible effects on the eye

**Respiratory or skin sensitisation**

Skin sensitisation
Not classified based on available information.
# SAFETY DATA SHEET

**Ezetimibe Granules Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.3</td>
<td>09.04.2021</td>
<td>1567796-00009</td>
<td>10.10.2020</td>
<td>18.04.2017</td>
</tr>
</tbody>
</table>

## Respiratory sensitisation
Not classified based on available information.

### Components:

#### Ezetimibe:
- **Test Type**: Maximisation Test
- **Species**: Guinea pig
- **Result**: negative

#### Sodium n-dodecyl sulfate:
- **Test Type**: Maximisation Test
- **Exposure routes**: Skin contact
- **Species**: Guinea pig
- **Result**: negative
- **Remarks**: Based on data from similar materials

## Germ cell mutagenicity
Not classified based on available information.

### Components:

#### Cellulose:
- **Genotoxicity in vitro**: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
- **Genotoxicity in vivo**: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative

#### Ezetimibe:
- **Genotoxicity in vitro**: Test Type: Bacterial reverse mutation assay (AMES) Metabolic activation: with and without metabolic activation Result: negative
- **Genotoxicity in vivo**: Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Oral Result: negative

#### Sodium n-dodecyl sulfate:
- **Genotoxicity in vitro**: Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo
Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Application Route: Ingestion
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

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

Ezetimibe:
Species: Rat, female
Application Route: oral (feed)
Exposure time: 104 weeks
Result: negative

Species: Rat, male
Application Route: oral (feed)
Exposure time: 104 weeks
Result: negative

Species: Mouse
Application Route: oral (feed)
Exposure time: 104 weeks
Result: negative

Sodium n-dodecyl sulfate:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: negative
Remarks: Based on data from similar materials

Reproductive toxicity
Not classified based on available information.

Components:

Cellulose:
Effects on fertility: Test Type: One-generation reproduction toxicity study
Effects on foetal development:

- **Test Type:** Fertility/early embryonic development
- **Species:** Rat
- **Application Route:** Ingestion
- **Result:** negative

**Ezetimibe:**

- **Effects on fertility**
  - **Test Type:** Fertility/early embryonic development
  - **Species:** Rat, male and female
  - **Fertility:** NOAEL: > 1,000 mg/kg body weight
  - **Result:** No effects on fertility, No fetotoxicity

- **Effects on foetal development**
  - **Test Type:** Development
  - **Species:** Rat
  - **Application Route:** Oral
  - **Developmental Toxicity:** NOAEL: > 1,000 mg/kg body weight
  - **Result:** No adverse effects

- **Test Type:** Development
  - **Species:** Rabbit
  - **Application Route:** Oral
  - **Developmental Toxicity:** NOAEL: > 1,000 mg/kg body weight
  - **Result:** No adverse effects

**Sodium n-dodecyl sulfate:**

- **Effects on fertility**
  - **Test Type:** Two-generation reproduction toxicity study
  - **Species:** Rat
  - **Application Route:** Ingestion
  - **Method:** OECD Test Guideline 416
  - **Result:** negative
  - **Remarks:** Based on data from similar materials

- **Effects on foetal development**
  - **Test Type:** Embryo-foetal development
  - **Species:** Rat
  - **Application Route:** Ingestion
  - **Result:** negative
  - **Remarks:** Based on data from similar materials

**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

**Ezetimibe:**
Species: Dog
NOAEL: 1,000 mg/kg
Application Route: Oral
Exposure time: 90 d
Remarks: No significant adverse effects were reported

Species: Rat
NOAEL: 1,500 mg/kg
Application Route: Oral
Exposure time: 90 d
Remarks: No significant adverse effects were reported

Species: Mouse
NOAEL: 500 mg/kg
Application Route: Oral
Exposure time: 90 d
Remarks: No significant adverse effects were reported

Species: Dog
NOAEL: 300 mg/kg
Application Route: Oral
Exposure time: 1 yr
Remarks: No significant adverse effects were reported

**Sodium n-dodecyl sulfate:**
Species: Rat
NOAEL: 488 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

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

**Components:**
**Ezetimibe:**
Not applicable

**Experience with human exposure**

**Components:**
**Ezetimibe:**
Ingestion: Symptoms: Headache, Nausea, Vomiting, Diarrhoea, flatulence, muscle pain, upper respiratory tract infection, Back pain, joint pain
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

**Ezetimibe:**
- **Toxicity to fish:**
  - LC50 (Pimephales promelas (fathead minnow)): > 0.125 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
  - Remarks: No toxicity at the limit of solubility

- **Toxicity to daphnia and other aquatic invertebrates:**
  - EC50 (Daphnia magna (Water flea)): > 4 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
  - Remarks: No toxicity at the limit of solubility

- **Toxicity to algae/aquatic plants:**
  - EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.317 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 201
  - Remarks: No toxicity at the limit of solubility

  NOEC (Pseudokirchneriella subcapitata (green algae)): 0.317 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 201
  - Remarks: No toxicity at the limit of solubility

- **Toxicity to microorganisms:**
  - EC50: > 4.4 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209
  - Remarks: No toxicity at the limit of solubility

  NOEC: 4.4 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209
  - Remarks: No toxicity at the limit of solubility

- **Toxicity to fish (Chronic toxicity):**
  - NOEC: 0.051 mg/l
  - Exposure time: 33 d
  - Species: Pimephales promelas (fathead minnow)
  - Method: OECD Test Guideline 210

  NOEC: 4 mg/l
  - Exposure time: 7 d
  - Species: Cyprinodon variegatus (sheepshead minnow)
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: 0.282 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity):
- 1

**Sodium n-dodecyl sulfate:**

Toxicity to fish:
- LC50 (Pimephales promelas (fathead minnow)): 29 mg/l
- Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l
- Exposure time: 48 h

Toxicity to algae/aquatic plants:
- EC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l
- Exposure time: 72 h

NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l
- Exposure time: 72 h

Toxicity to microorganisms:
- EC50: 135 mg/l
- Exposure time: 3 h

Toxicity to fish (Chronic toxicity):
- NOEC: >= 1.357 mg/l
- Exposure time: 42 d
- Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: 0.88 mg/l
- Exposure time: 7 d
- Species: Ceriodaphnia dubia (water flea)

**Persistence and degradability**

**Components:**

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

**Ezetimibe:**
- Biodegradability: Result: Not readily biodegradable.
- Biodegradation: 6.8 %
- Exposure time: 28 d

**Stability in water:**
- Hydrolysis: 50 % (4.5 d)
- Method: OECD Test Guideline 111

**Sodium n-dodecyl sulfate:**
- Biodegradability: Result: Readily biodegradable.
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 : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe)

Class : 9
Packing group : III
Labels : 9
SAFETY DATA SHEET

Ezetimibe Granules Formulation

Version 3.3  Revision Date: 09.04.2021  SDS Number: 1567796-00009  Date of last issue: 10.10.2020

Date of first issue: 18.04.2017

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Ezetimibe)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft): 956
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ezetimibe)
Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

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

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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
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