SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Etoricoxib 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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Carcinogenicity (Inhalation) : Category 2
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Kidney, Liver, Gastrointestinal tract)

GHS label elements
Hazard pictograms :

Signal word : Warning

Hazard statements : H351 Suspected of causing cancer if inhaled.
                   H361d Suspected of damaging the unborn child.
                   H373 May cause damage to organs (Kidney, Liver, Gastrointestinal tract) through prolonged or repeated exposure if swallowed.

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.
             P281 Use personal protective equipment as required.

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.

**Other hazards which do not result in classification**
Dust contact with the eyes can lead to mechanical irritation.
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>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>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>Etoricoxib</td>
<td>202409-33-4</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>&gt;= 1 - &lt; 10</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
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.
Rinse mouth thoroughly with water.

**Most important symptoms and effects, both acute and delayed**
Suspected of causing cancer if inhaled.
Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated exposure if swallowed.
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. FIREFIGHTING MEASURES

- **Suitable extinguishing media:** Water spray, Alcohol-resistant foam, Carbon dioxide (CO2), Dry chemical
- **Unsuitable extinguishing media:** None known.
- **Specific hazards during firefighting:**
  - 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, Nitrogen oxides (NOx), Sulphur oxides, Chlorine compounds, 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 firefighters:** In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
- **Hazchem Code:** 2Z

### 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 spills 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 deter-
mine 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. Avoid contact with 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. 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 labelled containers. Store locked up. 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

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>
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</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: This value is for inhalable dust containing no asbestos and &lt; 1% crystalline silica</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Etoricoxib</td>
<td>202409-33-4</td>
<td>TWA</td>
<td>400 ug/m³ (OEL 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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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:
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

Colour: coloured

Odour: odourless

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: No data available

Evaporation rate: No data available
SAFETY DATA SHEET

Etoricoxib 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>
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<tr>
<td>4.13</td>
<td>02.10.2020</td>
<td>26525-00018</td>
<td>23.03.2020</td>
<td>29.10.2014</td>
</tr>
</tbody>
</table>

- **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
- **Vapour pressure**: No data available
- **Relative vapour density**: No data available
- **Relative density**: No data available
- **Solubility(ies)**
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: No data available
- **Auto-ignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**
  - **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

Exposure routes:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2,000 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

Etoricoxib:
Acute oral toxicity: LD50 (Rat): 1,499 mg/kg
LD50 (Mouse): 1,499 mg/kg
Acute toxicity (other routes of administration): LD50 (Rat): 238 mg/kg
Application Route: Intraperitoneal
LD50 (Mouse): 599 mg/kg
Application Route: Intraperitoneal

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:

Etoricoxib:
Species: Rabbit
Result: No skin irritation
Titanium dioxide:
Species: Rabbit
Result: No skin irritation

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

**Components:**

**Etoricoxib:**
Species: Rabbit
Result: Mild eye irritation

**Titanium dioxide:**
Species: Rabbit
Result: No eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Etoricoxib:**
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Assessment: Did not cause sensitisation on laboratory animals.
Result: negative

**Titanium dioxide:**
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: negative

**Chronic toxicity**

**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

### Etoricoxib:

- **Genotoxicity in vitro:**  
  Test Type: reverse mutation assay  
  Result: negative

- **Test Type:** In vitro mammalian cell gene mutation test  
  Test system: human lymphoblastoid cells  
  Result: negative

- **Test Type:** Chromosomal aberration  
  Test system: Chinese hamster ovary cells  
  Result: negative

- **Test Type:** Alkaline elution assay  
  Result: negative

- **Genotoxicity in vivo:**  
  Test Type: Chromosomal aberration  
  Species: Rat  
  Cell type: Bone marrow  
  Application Route: Oral  
  Result: negative

- **Test Type:** Alkaline elution assay  
  Species: Rat  
  Application Route: Oral  
  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
Etoricoxib:
Species: Rat, male and female
Application Route: oral (gavage)
Exposure time: 2 Years
Result: positive

Species: Mouse, male and female
Application Route: oral (gavage)
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 the unborn child.

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

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

Etoricoxib:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat, female
Application Route: Oral
General Toxicity - Parent: NOAEL: 10 mg/kg body weight
Result: positive

Test Type: Fertility/early embryonic development
Species: Rat, male
Application Route: Oral
Result: negative
Effects on foetal development:
- Species: Rat
  - Application Route: Oral
  - Result: positive
- Species: Rabbit
  - Application Route: Oral
  - Result: positive

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

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

**STOT - repeated exposure**
May cause damage to organs (Kidney, Liver, Gastrointestinal tract) through prolonged or repeated exposure if swallowed.

**Components:**

**Etoricoxib:**
- Exposure routes: Ingestion
- Target Organs: Kidney, Liver, Gastrointestinal tract
- Assessment: May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Cellulose:**
- Species: Rat
- NOAEL: $\geq 9,000$ mg/kg
- Application Route: Ingestion
- Exposure time: 90 Days

**Etoricoxib:**
- Species: Rat
- LOAEL: 30 mg/kg
- Application Route: Oral (gavage)
- Exposure time: 27 Weeks
- Target Organs: Gastrointestinal tract, Kidney

- Species: Rat
  - NOAEL: 30 mg/kg
  - Application Route: Oral (gavage)
  - Exposure time: 53 Weeks
  - Target Organs: Liver

- Species: Dog
  - NOAEL: 50 mg/kg
  - Application Route: Oral (gavage)
  - Exposure time: 53 Weeks
  - Target Organs: Liver
Species : Dog
LOAEL : 200 mg/kg
Application Route : oral (gavage)
Exposure time : 14 Weeks
Target Organs : Gastrointestinal tract, Kidney

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 yr

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Etoricoxib:
Ingestion : Symptoms: upper respiratory tract infection, Headache, hypertension, Diarrhoea, urinary tract infection, flu-like symptoms, heartburn, Nausea, bronchitis, Dizziness, asthenia, Rash, Back pain, Cough, Abdominal pain, pharyngitis, Oedema

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

Etoricoxib:
Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)) : > 30 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)) : > 30 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)) : > 10 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity):
NOEC (Pimephales promelas (fathead minnow)): 7.93 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)): 0.75 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms:
EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

**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.

**Etoricoxib:**
Biodegradability: Result: not rapidly degradable
Biodegradation: 0.2 %
Exposure time: 28 d

**Bioaccumulative potential**

**Components:**

**Etoricoxib:**
Partition coefficient: n-octanol/water: log Pow: 2.3

Mobility in soil:
No data available

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
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Etoricoxib)
- Class: 9
- Packing group: III
- Labels: 9

IATA-DGR
- UN/ID No.: UN 3077
- Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Etoricoxib)
- 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. (Etoricoxib)
- Class: 9
- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F
- Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.
National Regulations

ADG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Etoricoxib)
Class : 9
Packing group : III
Labels : 9
Hazchem Code : 2Z

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.

SECTION 15. REGULATORY INFORMATION

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

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information
Revision Date : 02.10.2020
Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.
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.

AU / EN