SAFETY DATA SHEET

Olmesartan / Amlodipine Besylate Formulation

Version: 2.9  Revision Date: 10.10.2020  SDS Number: 402504-00011  Date of last issue: 13.09.2019
Date of first issue: 07.01.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Olmesartan / Amlodipine Besylate 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
Reproductive toxicity: Category 1A

GHS label elements
Hazard pictograms:

Signal word: Danger
Hazard statements: H360D May damage the unborn child.
Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
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.
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
<td>Olmesartan</td>
</tr>
<tr>
<td></td>
<td>Amlodipine Besylate</td>
</tr>
<tr>
<td></td>
<td>Titanium dioxide</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.

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 damage 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. FIREFIGHTING 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
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:**
- If sufficient ventilation is unavailable, use with local exhaust ventilation.

**Advice on safe handling:**
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Do not get in 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.
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.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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

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>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>AU OEL, TWA</td>
</tr>
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<td></td>
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<tr>
<td>Olmesartan</td>
<td>144689-63-4</td>
<td>TWA</td>
<td>30 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 300 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Amlodipine Besylate</td>
<td>652969-01-2</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 100 µg/100 cm²</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, TWA</td>
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</table>

Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica

Engineering measures:
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds.
are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

**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
- **Material**: Chemical-resistant gloves
- **Remarks**: Consider double gloving.

**Eye protection**: Wear safety glasses with side shields or goggles.
- If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
- Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection**: Work uniform or laboratory coat.
- Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
- Use appropriate degowning techniques to remove potentially contaminated clothing.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- **Appearance**: powder
- **Colour**: No data available
- **Odour**: No data available
- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: Not applicable
- **Evaporation rate**: Not applicable
- **Flammability (solid, gas)**: May form explosive dust-air mixture during processing, handling or other means.
- **Flammability (liquids)**: No data available
- **Upper explosion limit / Upper** : No data available
flammbility limit

Lower explosion limit / Lower flammaibility limit : No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)
Water solubility : No data available

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.

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 reac-
tions : May form explosive dust-air mixture during processing, han-
dling 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.
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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

Olmesartan:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
  LD50 (Mouse): > 2,000 mg/kg
  LD50 (Dog): > 1,500 mg/kg
Acute inhalation toxicity: Remarks: No data available
Acute dermal toxicity: Remarks: No data available

Amlodipine Besylate:
Acute oral toxicity: LD50 (Rat): 393 mg/kg

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:
Olmesartan:
Remarks: No data available

Titanium dioxide:
Species: Rabbit
Result: No skin irritation
Serious eye damage/eye irritation
Not classified based on available information.

**Components:**

**Olmesartan:**
Species: Rabbit  
Result: Moderate eye irritation  
Method: Draize Test

**Amlodipine Besylate:**
Species: Rabbit  
Result: Severe 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:**

**Olmesartan:**
Exposure routes: Skin contact  
Remarks: No data available

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

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

**Olmesartan:**

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

- Test Type: Mutagenicity (in vitro mammalian cytogenetic test)
  Result: negative

- Test Type: Chromosome aberration test in vitro
  Test system: Chinese hamster lung cells
  Result: positive

- Test Type: Mouse Lymphoma
  Result: negative

Genotoxicity in vivo:
- Test Type: Micronucleus test
  Species: Mouse
  Cell type: Bone marrow
  Application Route: Oral
  Result: negative

Germ cell mutagenicity - Assessment:
Weight of evidence does not support classification as a germ cell mutagen.

**Amlodipine Besylate:**

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

- Test Type: Chromosome aberration test in vitro
  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**
Not classified based on available information.

**Components:**

**Cellulose:**
- Species: Rat
- Application Route: Ingestion
- Exposure time: 72 weeks
Olmesartan:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
Result: negative

Amlodipine Besylate:
Species: Mouse
Application Route: Oral
Exposure time: 6 Months
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
May damage 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
Olmesartan:
Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 1,000 mg/kg body weight
Result: No effects on fertility

Effects on foetal development:
Species: Rat
Application Route: Oral
Dose: 1000 milligram per kilogram
Result: No effects on fertility

Species: Rabbit
Application Route: Oral
Dose: 1 milligram per kilogram
Result: No teratogenic effects

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: >= 1.6 mg/kg body weight
Symptoms: Malformations were observed., Reduced body weight
Result: Effects on postnatal development

Amlodipine Besylate:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Fertility: NOAEL: 10 mg/kg body weight
Result: No effects on fertility

Species: Rabbit
Application Route: Ingestion
Fertility: NOAEL: 25 mg/kg body weight
Result: No effects on fertility

Effects on foetal development:
Species: Rat
Application Route: Ingestion
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: Effects on foetal development

Species: Rabbit
Application Route: Ingestion
Developmental Toxicity: NOAEL: 10 mg/kg body weight
Result: No effects on foetal development

Reproductive toxicity - Assessment:
Positive evidence of adverse effects on development from human epidemiological studies.
Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Ingestion  
Developmental Toxicity: LOAEL: 1.6 mg/kg body weight  
Result: Effects on foetal development  
Remarks: Maternal toxicity observed.

**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

**Olmesartan:**
Species: Rat  
NOAEL: 2,000 mg/kg  
Application Route: Oral  
Exposure time: 24 Months  
Remarks: No significant adverse effects were reported

**Amlodipine Besylate:**
Species: Rat  
NOAEL: 15 mg/kg  
Application Route: Oral  
Exposure time: 90 d  
Remarks: No significant adverse effects were reported

**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

**Product:**
- **Ingestion:** Symptoms: Fatigue, Dizziness, Headache, Nausea

**Components:**

**Olmesartan:**
- **Eye contact:** Symptoms: Eye irritation
- **Ingestion:** Symptoms: hypotension
  Remarks: May cause harm to the unborn child. Based on Human Evidence

**Amlodipine Besylate:**
- **Eye contact:** Symptoms: Severe irritation
- **Ingestion:** Symptoms: Nausea, Abdominal pain, Fatigue, Headache, Oedema, Palpitation

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**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

**Amlodipine Besylate:**
- **Toxicity to fish:** LC50 (Pimephales promelas (fathead minnow)): 2.7 mg/l
  Exposure time: 96 h
  **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): 3.2 mg/l
  Exposure time: 48 h
  **Toxicity to algae/aquatic plants:** IC50 (Pseudokirchneriella subcapitata (green algae)): 5.6 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

**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.

Bioaccumulative potential

Components:

Amlodipine Besylate:
Partition coefficient: n-octanol/water: log Pow: 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
Not regulated as a dangerous good
IATA-DGR
Not regulated as a dangerous good
IMDG-Code
Not regulated as a dangerous good
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

ADG
Not regulated as a dangerous good

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: 10.10.2020
- Sources of key data used to compile the Safety Data Sheet:
- 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.
- **ACGIH / TWA**: 8-hour, time-weighted average
- **AU OEL / TWA**: Exposure standard - time weighted average

Abbreviations:

- AIIC: 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
- IC50: 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)
- KCSC: Korea Existing Chemicals Inventory
- LC50: Lethal Concentration to 50% of a test population
- LD50: Lethal Dose to 50% of a test population
- MARPOL: International Convention for the Prevention of Pollution from Ships
- n.o.s.: Not Otherwise Specified
- NO(A)EC: No Observed (Adverse) Effect Concentration
- NO(A)EL: No Observed (Adverse) Effect Level
- NOELR: No Observable Effect Loading Rate
- NOM: Official Mexican Norm
- NTP: National Toxicology Program
- NZIoC: New Zealand Inventory of Chemicals
Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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