SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name : Betamethasone (0.05%) Ointment Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company : Organon & Co.
30 Hudson Street, 33nd floor
07302 Jersey City, New Jersey, U.S.A
Telephone : 551-430-6000
E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number
215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Reproductive toxicity, Category 1B
Specific target organ toxicity - repeated exposure, Category 1
Long-term (chronic) aquatic hazard, Category 1
H360D: May damage the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure.
H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms :

Signal word : Danger
Hazard statements :
H360D May damage the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :
Prevention:
P201 Obtain special instructions before use.
Betamethasone (0.05%) Ointment Formulation

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>206-825-4</td>
<td></td>
<td>&gt;= 0.025 - &lt; 0.1</td>
</tr>
</tbody>
</table>

M-Factor (Chronic aquatic toxicity): 1.000

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

If inhaled: If inhaled, remove to fresh air. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty.
of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed
Risks : May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

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

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting : Vapours may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

5.3 Advice for firefighters
Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions
Environmental precautions: Discharge into the environment must be avoided. 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.

6.3 Methods and material for containment and cleaning up
Methods for cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling: Do not get on skin or clothing. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA OEL-RL (particulate)</td>
<td>10 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Recommended Limit</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA OEL-RL (Vapour + particulates)</td>
<td>150 ppm 470 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit 10 µg/100 cm²</td>
<td></td>
<td>Internal</td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>168 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>50 mg/m³</td>
<td></td>
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</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

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<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>Oral (Secondary Poisoning)</td>
<td>9.33 mg/kg food</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Fresh water</td>
<td>260 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>26 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>183 mg/l</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

Engineering measures
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies.

Personal protective equipment

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.

Hand protection

Material
Chemical-resistant gloves

Remarks
Consider double gloving.

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.

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 (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance
ointment

Colour
white to off-white

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
> 93.3 °C
Evaporation rate : Not applicable
Flammability (solid, gas) : Not classified as a flammability hazard
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 : 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.

9.2 Other information
  Flammability (liquids) : Not applicable
  Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity
  Not classified as a reactivity hazard.

10.2 Chemical stability
  Stable under normal conditions.

10.3 Possibility of hazardous reactions
  Hazardous reactions : Vapours may form explosive mixture with air. Can react with strong oxidizing agents.

10.4 Conditions to avoid
  Conditions to avoid : None known.
10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure:
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Components:
betamethasone:
- Acute oral toxicity: LD50 (Rat): > 5.000 mg/kg
  LD50 (Mouse): > 4.500 mg/kg
- Acute inhalation toxicity: LC50 (Rat): 0.4 mg/l
  Exposure time: 4 h

Skin corrosion/irritation
Not classified based on available information.

Components:
betamethasone:
- Species: Rabbit
  Result: Mild skin irritation

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

Components:
betamethasone:
- 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:

betamethasone:
Exposure routes: Dermal
Species: Guinea pig
Result: Weak sensitizer

Germ cell mutagenicity
Not classified based on available information.

Components:

betamethasone:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  Result: negative
- Test Type: Chromosome aberration test in vitro
  Result: positive

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Oral
  Result: equivocal

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

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
May damage the unborn child.

Components:

betamethasone:
Effects on foetal development:
- Species: Rabbit
  Application Route: Intramuscular
  Developmental Toxicity: LOAEL: 0,05 mg/kg body weight
  Result: Fetotoxicity, Malformations were observed.
- Species: Rat
  Application Route: Subcutaneous
  Developmental Toxicity: LOAEL: 0,42 mg/kg body weight
  Result: Malformations were observed.
- Species: Mouse
  Application Route: Intramuscular
  Developmental Toxicity: LOAEL: 1 mg/kg body weight
  Result: Malformations were observed.
Reproductive toxicity - Assessment: Clear evidence of adverse effects on development, based on animal experiments.

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

**STOT - repeated exposure**
Causes damage to organs through prolonged or repeated exposure.

**Components:**

**betamethasone:**
Target Organs: Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland
Assessment: Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**betamethasone:**
Species: Rabbit
LOAEL: 0.05 %
Application Route: Skin contact
Exposure time: 10 - 30 d
Target Organs: Pituitary gland, Immune system, muscle

Species: Rat
LOAEL: 0.05 %
Application Route: Skin contact
Exposure time: 8 Weeks
Target Organs: thymus gland

Species: Mouse
LOAEL: 0.1 %
Application Route: Skin contact
Exposure time: 8 Weeks
Target Organs: thymus gland

Species: Dog
LOAEL: 0.05 mg/kg
Application Route: Oral
Exposure time: 28 d
Target Organs: Blood, thymus gland, Adrenal gland

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

**Experience with human exposure**

**Components:**

**betamethasone:**
Inhalation: Target Organs: Adrenal gland
SECTION 12: Ecological information

12.1 Toxicity

**Components:**

**betamethasone:**

<table>
<thead>
<tr>
<th>Component Description</th>
<th>Toxicity</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Americamysis): &gt; 50 mg/l</td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 34 mg/l</td>
<td>Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC: 0.052 mg/l</td>
<td>Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC: 8 mg/l</td>
<td>Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>1.000</td>
<td></td>
</tr>
</tbody>
</table>

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

**Components:**

**betamethasone:**

<table>
<thead>
<tr>
<th>Component Description</th>
<th>Partition coefficient: n-octanol/water</th>
<th>Log Pow:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2.11</td>
</tr>
</tbody>
</table>

12.4 Mobility in soil

No data available
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12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
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

14.1 UN number

<table>
<thead>
<tr>
<th></th>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN number</td>
<td>UN 3077</td>
<td>UN 3077</td>
<td>UN 3077</td>
<td>UN 3077</td>
<td>UN 3077</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th></th>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper shipping name</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)</td>
<td>Environmentally hazardous substance, solid, n.o.s. (betamethasone)</td>
</tr>
</tbody>
</table>

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th></th>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transport hazard class</td>
<td>9</td>
<td>9</td>
<td>9</td>
</tr>
</tbody>
</table>
### 14.4 Packing group

#### ADN
- **Packing group**: III
- **Classification Code**: M7
- **Hazard Identification Number**: 90
- **Labels**: 9 (ENVIRONM.)

#### ADR
- **Packing group**: III
- **Classification Code**: M7
- **Hazard Identification Number**: 90
- **Labels**: 9 (ENVIRONM.)
- **Tunnel restriction code**: (-)

#### RID
- **Packing group**: III
- **Classification Code**: M7
- **Hazard Identification Number**: 90
- **Labels**: 9 (ENVIRONM.)

#### IMDG
- **Packing group**: III
- **Labels**: 9 (ENVIRONM.)
- **EmS Code**: F-A, S-F

#### IATA (Cargo)
- **Packing instruction (cargo aircraft)**: 956
- **Packing instruction (LQ)**: Y956
- **Packing group**: III
- **Labels**: Miscellaneous,

#### IATA (Passenger)
- **Packing instruction (passenger aircraft)**: 956
- **Packing instruction (LQ)**: Y956
- **Packing group**: III
- **Labels**: Miscellaneous,

### 14.5 Environmental hazards

#### ADN
- Environmentally hazardous: yes

#### ADR
- Environmentally hazardous: yes

#### RID
- Environmentally hazardous: yes

#### IMDG
- Marine pollutant: yes

#### IATA (Passenger)
- Environmentally hazardous: yes
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IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements
H330 : Fatal if inhaled.
H360D : May damage the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN
SAFETY DATA SHEET

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<table>
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<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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<td>3.3</td>
<td>23.03.2020</td>
<td>1681939-00007</td>
<td>13.09.2019</td>
<td>18.05.2017</td>
</tr>
</tbody>
</table>

Further information


Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Classification procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rep. 1B</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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.