SAFETY DATA SHEET

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Section 1: Identification

Product name : Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Manufacturer or supplier's details
Company : MSD
Address : 33 Whakatiki Street - Private Bag 908 Upper Hutt - New Zealand
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

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

Section 2: Hazard identification

GHS Classification
Respiratory sensitisation : Category 1

GHS label elements
Hazard pictograms :

Signal word : Danger
Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements : Prevention:
P261 Avoid breathing mist or vapours.
P284 Wear respiratory protection.

Response:
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.
Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients
Substance / Mixture : Mixture
Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin Trihydrate</td>
<td>61336-70-7</td>
<td>&gt;= 10 -&lt; 30</td>
</tr>
<tr>
<td>Aluminum tristearate</td>
<td>637-12-7</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&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. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
In case of skin contact : Wash with water and soap as a precaution. Get medical attention if symptoms occur.
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 if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed : May cause allergy or asthma symptoms or breathing difficulties if inhaled. Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician : Treat symptomatically and supportively.

Section 5: Fire-fighting measures
Suitable extinguishing media : Water spray
                   Alcohol-resistant foam
                   Carbon dioxide (CO2)
                   Dry chemical
Unsuitable extinguishing media : None known.
Specific hazards during firefighting : Exposure to combustion products may be a hazard to health.
Hazardous combustion products : Carbon oxides
                               Metal oxides
Nitrogen oxides (NOx)

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: 3Z

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.
- Prevent spreading over a wide area (e.g. by containment or oil barriers).
- 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:
- Soak up with inert absorbent material.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- 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:
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Avoid breathing mist or vapours.
- 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.
- Keep container tightly closed.
- Already sensitised individuals should consult their physician.
regarding working with respiratory irritants or sensitisers. 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. 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>Amoxicillin Trihydrate</td>
<td>61336-70-7</td>
<td>TWA</td>
<td>1 mg/m3 (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Aluminum tristearate</td>
<td>637-12-7</td>
<td>WES-TWA</td>
<td>10 mg/m3</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>1 mg/m3 (Aluminium)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

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: Combined particulates and organic vapour 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 glasses

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

Section 9: Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>suspension</td>
</tr>
<tr>
<td>Colour</td>
<td>cream</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>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</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>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>0.900 - 1.100 g/cm³</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>
</tbody>
</table>
Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Section 10: Stability and reactivity

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
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

Acute inhalation toxicity: Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Amoxicillin Trihydrate:
Acute oral toxicity: LD50 (Rat): > 8,000 mg/kg
                      LD50 (Mouse): > 10,000 mg/kg
                      LD50 (Dog): > 3,000 mg/kg

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
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Version 1.3  Revision Date: 27.08.2021  SDS Number: 8845217-00002  Date of last issue: 13.07.2021  Date of first issue: 13.07.2021

Aluminum tristearate:
Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 5.15 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: Based on data from similar materials

Benzyl alcohol:
Acute oral toxicity : LD50 (Rat): 1,620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:

Aluminum tristearate:
Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 439
Remarks : Based on data from similar materials
Result : No skin irritation

Benzyl alcohol:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

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

Components:

Aluminum tristearate:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Benzyl alcohol:
Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405
Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:

Amoxicillin Trihydrate:
Result: Sensitiser
Remarks: May cause sensitisation by inhalation. largely based on human evidence

Aluminum tristearate:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Method: OECD Test Guideline 429
Result: negative
Remarks: Based on data from similar materials

Benzyl alcohol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Mouse
Result: negative

Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Result: negative
SAFETY DATA SHEET

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 1.3
Revision Date: 27.08.2021
SDS Number: 8845217-00002
Date of last issue: 13.07.2021
Date of first issue: 13.07.2021

Genotoxicity in vitro:
- Test Type: In vitro mammalian cell gene mutation test
  Method: OECD Test Guideline 476
  Result: negative
  Remarks: Based on data from similar materials
- Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: negative
  Remarks: Based on data from similar materials

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Rat
  Application Route: Ingestion
  Method: OECD Test Guideline 474
  Result: negative
  Remarks: Based on data from similar materials

Benzyl alcohol:
- 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: Intraperitoneal injection
  Result: negative

Carcinogenicity:
Not classified based on available information.

Components:

Benzyl alcohol:
- Species: Mouse
- Application Route: Ingestion
- Exposure time: 103 weeks
- Method: OECD Test Guideline 451
- Result: negative

Reproductive toxicity:
Not classified based on available information.

Components:

Amoxicillin Trihydrate:
- Effects on fertility: Test Type: Fertility
  Species: Rat
  Application Route: Oral
  Fertility: NOAEL: 200 mg/kg body weight
  Result: Reduced fertility
  Remarks: Not classified due to inconclusive data.
Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 500 mg/kg body weight  
Result: Reduced fertility  
Remarks: Not classified due to inconclusive data.

Effects on foetal development:  
Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: >= 1,000 mg/kg body weight  
Result: No embryo-foetal toxicity  
Remarks: Not classified due to inconclusive data.

Test Type: Development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: LOAEL: 200 mg/kg body weight  
Result: Some evidence of adverse effects on development, based on animal experiments.  
Remarks: Not classified due to inconclusive data.

Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 200 mg/kg body weight  
Result: Reduced embryonic survival, Reduced offspring weight gain  
Remarks: Not classified due to inconclusive data.

Aluminum tristearate:  
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: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Benzyl alcohol:  
Effects on fertility:  
Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development:  
Test Type: Embryo-foetal development
SAFETY DATA SHEET

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Version 1.3  Revision Date: 27.08.2021  SDS Number: 8845217-00002  Date of last issue: 13.07.2021

Species: Mouse
Application Route: Ingestion
Result: negative

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Components:

Amoxicillin Trihydrate:
Remarks : Not classified due to inconclusive data.

Repeated dose toxicity

Components:

Amoxicillin Trihydrate:
Species : Rat
Application Route : Oral
Exposure time : 6 Months
Remarks : No significant adverse effects were reported
Species : Dog
Application Route : Oral
Exposure time : 6 Months
Remarks : No significant adverse effects were reported

Aluminum tristearate:
Species : Rat
NOAEL : >= 5,000 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Remarks : Based on data from similar materials

Benzyl alcohol:
Species : Rat
NOAEL : 1.072 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 28 Days
Method : OECD Test Guideline 412

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Amoxicillin Trihydrate:
**Section 12: Ecological information**

**Ecotoxicity**

**Components:**

**Amoxicillin Trihydrate:**
- **Toxicity to fish**: LC50 (Carassius auratus (goldfish)): 0.035 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
- **Toxicity to algae/aquatic plants**: NOEC (green algae): 530 mg/l
  - Exposure time: 72 h
  - EC50 (Synechococcus leopoliensis (blue-green algae)): 0.0022 mg/l
  - Exposure time: 96 h
  - NOEC (blue-green algae): 0.0057 mg/l
  - Exposure time: 72 h

**Aluminum tristearate:**
- **Ecotoxicology Assessment**
  - Acute aquatic toxicity: Toxic effects cannot be excluded
  - Chronic aquatic toxicity: Toxic effects cannot be excluded

**Benzyl alcohol:**
- **Toxicity to fish**: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
  - Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): 230 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
- **Toxicity to algae/aquatic plants**: EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
- **Toxicity to daphnia and other aquatic invertebrates (Chronic)**: NOEC (Daphnia magna (Water flea)): 51 mg/l
  - Exposure time: 21 d
SAFETY DATA SHEET

Amoxicillin Trihydrate / Potassium Clavulanate Formulation

Persistence and degradability

Components:

Amoxicillin Trihydrate:

Benzyl alcohol:
- Biodegradability: Result: Readily biodegradable. Biodegradation: 92 - 96 % Exposure time: 14 d

Bioaccumulative potential

Components:

Amoxicillin Trihydrate:

Benzyl alcohol:
- Partition coefficient: n-octanol/water: log Pow: 1.05

Mobility in soil
No data available

Other adverse effects

Components:

Amoxicillin Trihydrate:
- Results of PBT and vPvB assessment: This substance is not considered to be persistent, bioaccumulating and toxic (PBT). This mixture contains no substance considered to be very persistent and very bioaccumulating (vPvB).

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 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Amoxicillin Trihydrate)
Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Amoxicillin Trihydrate)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Amoxicillin Trihydrate)
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

NZS 5433
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Amoxicillin Trihydrate)
Class : 9
Packing group : III
Labels : 9
Hazchem Code : 3Z

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.
Section 15: Regulatory information

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

HSNO Approval Number
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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
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)
- NZ OEL: New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
- ACGIH / TWA: 8-hour, time-weighted average
- NZ OEL / WES-TWA: Workplace Exposure Standard - Time Weighted average

AIIIC - 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 con-
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.

NZ / EN