SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Amiloride / Hydrochlorothiazide Formulation

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

1.1 Product identifier

   Trade name : Amiloride / Hydrochlorothiazide 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 : MSD
              Piercetown
              A86 HD21 Dunboyne, Ireland
   Telephone : 908-740-4000
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

   Classification (REGULATION (EC) No 1272/2008)
   Specific target organ toxicity - repeated exposure, Category 1
   H372: Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements

   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms : ❌
   Signal word : Danger
   Hazard statements : H372 Causes damage to organs through prolonged or repeated exposure.

   Precautionary statements : Prevention:
   P260 Do not breathe dust.
   P264 Wash skin thoroughly after handling.
   P270 Do not eat, drink or smoke when using this product.

   Response:
P314 Get medical advice/attention if you feel unwell.

**Hazardous components which must be listed on the label:**
Hydrochlorothiazide

**2.3 Other hazards**
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

#### 3.2 Mixtures

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochlorothiazide</td>
<td>58-93-5</td>
<td>200-403-3</td>
<td></td>
<td></td>
<td>STOT RE 1; H372 (Kidney, Parathyroid gland)</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Amiloride</td>
<td>17440-83-4</td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 2; H300 Eye Irrit. 2; H319 Aquatic Chronic 3; H412</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
</tbody>
</table>

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).
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Revision Date: 27.08.2021
SDS Number: 44150-00017
Date of last issue: 09.04.2021
Date of first issue: 05.01.2015

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

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Get medical attention if symptoms occur.

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 unless directed to do so by medical personnel. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed
Risks: Causes damage to organs through prolonged or repeated exposure.
Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

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: 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)
Chlorine compounds
Sulphur oxides
Metal oxides
Oxides of phosphorus
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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 (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

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. 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.

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: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding.
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.
- Wash skin thoroughly after handling.
- 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.
- Do not eat, drink or smoke when using this product.
- 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 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>Hydrochlorothiazide</td>
<td>58-93-5</td>
<td>TWA</td>
<td>100 µg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>OELV - 8 hrs (TWA) (Respirable dust)</td>
<td>4 mg/m3</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

Engineering measures

Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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

Skin and body protection: Work uniform or laboratory coat.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| Physical state | powder |
| Colour         | pale red-brown |
| Odour          | odourless |
| Odour Threshold| No data available |
| Melting point/freezing point | No data available |
| Initial boiling point and boiling range | No data available |
| 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 |
| Flash point | No data available |
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Auto-ignition temperature : No data available
Decomposition temperature : No data available
pH : No data available
Viscosity
  Viscosity, dynamic : No data available
  Viscosity, kinematic : No data available
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Vapour pressure : No data available
Relative density : No data available
Density : No data available
Relative vapour density : No data available
Particle characteristics
  Particle size : No data available

9.2 Other information
Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : No data available
Molecular weight : 302.10 g/mol

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 : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Product:
Acute oral toxicity:
- Acute toxicity estimate: > 2,000 mg/kg
- Method: Calculation method

Components:

Hydrochlorothiazide:
Acute oral toxicity:
- LD50 (Rat): > 2,750 mg/kg
- LD50 (Mouse): > 2,830 mg/kg

Acute toxicity (other routes of administration):
- LD50 (Rat): 990 mg/kg
- Application Route: Intravenous
- LD50 (Mouse): 590 mg/kg
- Application Route: Intravenous

Amiloride:
Acute oral toxicity:
- LD50 (Mouse): 56 mg/kg
- LD50 (Rat): > 150 mg/kg

Skin corrosion/irritation:
Not classified based on available information.

Components:

Hydrochlorothiazide:
Species: Rabbit
Result: No skin irritation
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**Amiloride:**
Species: Rabbit
Result: Mild skin irritation
Remarks: slight irritation

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

**Components:**

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

**Amiloride:**
Species: Rabbit
Remarks: Severe eye irritation

**Respiratory or skin sensitisation**

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

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

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

**Components:**

**Hydrochlorothiazide:**
Genotoxicity in vitro
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: Chromosomal aberration
  Test system: Chinese hamster ovary cells
  Result: negative
- Test Type: sister chromatid exchange assay
  Test system: Chinese hamster ovary cells
  Result: positive
- Test Type: in vitro assay
  Test system: mouse lymphoma cells
  Result: positive

Genotoxicity in vivo
- Test Type: Chromosomal aberration
  Species: Chinese hamster
  Cell type: Bone marrow
  Result: negative
- Test Type: in vivo assay
Species: Mouse
Cell type: Bone marrow
Result: negative

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

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

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Hydrochlorothiazide:**
Species: Mouse, female
Application Route: Oral
Exposure time: 2 Years
Result: negative

Species: Mouse, male
Application Route: Oral
Exposure time: 2 Years
Result: equivocal

Species: Rat, male and female
Application Route: Oral
Exposure time: 2 Years
Result: negative

**Amiloride:**
Species: Rat
Application Route: Oral
Exposure time: 92 weeks
Result: negative

Species: Mouse
Application Route: Oral
Exposure time: 104 weeks
Result: negative

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

**Components:**

**Hydrochlorothiazide:**
Effects on fertility: Test Type: Fertility
Species: Rat, male and female  
Application Route: oral (feed)  
Fertility: NOAEL: 4 mg/kg body weight  
Result: Effects on fertility

Test Type: Fertility  
Species: Mouse, male and female  
Application Route: oral (feed)  
Fertility: NOAEL: 100 mg/kg body weight  
Result: Effects on fertility

Effects on foetal development:  
Test Type: Development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: NOAEL: 3,000 mg/kg body weight  
Result: No teratogenic effects

Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight  
Result: No teratogenic effects

Amiloride:  
Effects on foetal development:  
Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
Result: No effects on fertility and early embryonic development were detected.

Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Oral  
Result: No effects on fertility and early embryonic development were detected.

STOT - single exposure  
Not classified based on available information.

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

Components:

Hydrochlorothiazide:  
Target Organs: Kidney, Parathyroid gland  
Assessment: Causes damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

**Components:**

**Hydrochlorothiazide:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, male and female</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>10 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 yr</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney, Parathyroid gland</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse, male and female</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>300 - 550 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 yr</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>50 - 200 mg/kg</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Parathyroid gland</td>
</tr>
</tbody>
</table>

Aspiration toxicity

Not classified based on available information.

**Components:**

**Hydrochlorothiazide:**

No aspiration toxicity classification

11.2 Information on other hazards

**Endocrine disrupting properties**

**Product:**

| Assessment | The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. |

**Experience with human exposure**

**Components:**

**Hydrochlorothiazide:**

<table>
<thead>
<tr>
<th>Eye contact</th>
<th>Symptoms: Eye irritation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>Symptoms: Dizziness, Headache, Fatigue, Nausea, Abdominal pain, hypotension, dry mouth, electrolyte imbalance, eye pain</td>
</tr>
</tbody>
</table>

**Amiloride:**

| Ingestion | Symptoms: hyperkalemia |


SECTION 12: Ecological information

12.1 Toxicity

**Components:**

**Hydrochlorothiazide:**
- **Toxicity to fish:** LC50 (Pimephales promelas (fathead minnow)): > 500 mg/l
  - Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): > 500 mg/l
  - Exposure time: 48 h

**Amiloride:**
- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): 56.3 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202

12.2 Persistence and degradability

**Components:**

**Hydrochlorothiazide:**
- **Stability in water:** Hydrolysis: 46.2 % (96 h)

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

**Product:**
- **Assessment:** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

**Product:**
- **Assessment:** The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 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 or ID number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Maritime transport in bulk according to IMO instruments
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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

REACH - List of substances subject to authorisation (Annex XIV): Not applicable

Not applicable

Other regulations:
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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
H300 : Fatal if swallowed.
H319 : Causes serious eye irritation.
H372 : Causes damage to organs through prolonged or repeated exposure.
H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
STOT RE : Specific target organ toxicity - repeated exposure
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

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; AIIC - Australian Inventory of Industrial Chemicals; 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 - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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
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Version 4.6 Revision Date: 27.08.2021 SDS Number: 44150-00017 Date of last issue: 09.04.2021 Date of first issue: 05.01.2015

Further information:

Classification of the mixture:
STOT RE 1 H372

Classification procedure:
Calculation method

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.

IE / EN