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

1.1 Product identifier

Trade name: Losartan 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
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone: 44 1 670 59 30 00
Telefax: 908-735-1496
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)

Acute toxicity, Category 4: H302: Harmful if swallowed.
Serious eye damage, Category 1: H318: Causes serious eye damage.
Skin sensitisation, Category 1: H317: May cause an allergic skin reaction.
Reproductive toxicity, Category 1B: H360D: May damage the unborn child.
Effects on or via lactation: H362: May cause harm to breast-fed children.
Specific target organ toxicity - repeated exposure, Category 2: H373: May cause 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:

H302: Harmful if swallowed.
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.
Losartan Formulation

Precautionary statements:

H360D May damage the unborn child.
H362 May cause harm to breast-fed children.
H373 May cause damage to organs through prolonged or repeated exposure.

Prevention:
P201 Obtain special instructions before use.
P260 Do not breathe dust.
P263 Avoid contact during pregnancy and while nursing.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response:
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
P308 + P313 IF exposed or concerned: Get medical advice/attention.

Hazardous components which must be listed on the label:
Losartan

2.3 Other hazards
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. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Losartan</td>
<td>124750-99-8</td>
<td>Acute Tox. 4; H302 Eye Dam. 1; H318 Skin Sens. 1; H317 Repr. 1B; H360D Lact. H362 STOT RE 2; H373</td>
<td>&gt;= 30 - &lt; 50</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).

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.

If swallowed: If swallowed, DO NOT induce vomiting. 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: Harmful if swallowed. May cause an allergic skin reaction. Causes serious eye damage. May damage the unborn child. May cause harm to breast-fed children. May cause damage to organs through prolonged or repeated exposure.

Contact with dust can cause mechanical irritation or drying of the skin.

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

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
- Chlorine compounds
- Nitrogen oxides (NOx)

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. 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.
Losartan Formulation

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 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.
- 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.

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

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Further information

For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m\(^{-3}\) 8-hour TWA of inhalable dust or 4 mg.m\(^{-3}\) 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhalable' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4. Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with.

<table>
<thead>
<tr>
<th>Material</th>
<th>TWA (inhalable dust)</th>
<th>STEL (inhalable dust)</th>
<th>GB EH40</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>10 mg/m(^3)</td>
<td>20 mg/m(^3)</td>
<td></td>
</tr>
<tr>
<td>Losartan</td>
<td>100 µg/m(^3) (OEB 2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Starch</td>
<td>10 mg/m(^3)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Further information

For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m\(^{-3}\) 8-hour TWA of inhalable dust or 4 mg.m\(^{-3}\) 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhalable' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4. Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with.
WEL, all the relevant limits should be complied with. Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.

<table>
<thead>
<tr>
<th>Engineering measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimize workplace exposure concentrations.</td>
</tr>
<tr>
<td>Apply measures to prevent dust explosions.</td>
</tr>
<tr>
<td>Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).</td>
</tr>
<tr>
<td>If sufficient ventilation is unavailable, use with local exhaust ventilation.</td>
</tr>
</tbody>
</table>

**Personal protective equipment**

**Eye protection**

Wear the following personal protective equipment:

- Chemical resistant goggles must be worn.
- If splashes are likely to occur, wear:
  - Face-shield
- Equipment should conform to BS EN 166

**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.

**Skin and body protection**

Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.

- Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

**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**: powder
- **Colour**: White to light yellow
- **Odour**: No data available
- **Odour Threshold**: No data available
Losartan Formulation

pH : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : No data available
Evaporation rate : No data available
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : No data available
Relative vapour density : No data available
Relative density : No data available
Density : 1 g/cm3
Solubility(ies)
   Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
   Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
Flammability (liquids) : No data available
Molecular weight : No data available
Minimum ignition energy : > 300 mJ
Particle size : No data available
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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 toxicological effects
   Information on likely routes of exposure:
   Inhalation
   Skin contact
   Ingestion
   Eye contact

   Acute toxicity
   Harmful if swallowed.

   **Product:**
   Acute oral toxicity : Acute toxicity estimate: 1,502 mg/kg
                        Method: Calculation method

   **Components:**
   Losartan:
   Acute oral toxicity : LD50 (Mouse): 1,257 - 1,590 mg/kg
                         LDLo (Rat): 200 mg/kg
                         LDLo (Mouse): 400 mg/kg

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

Losartan:
Species : Rabbit
Result : Mild skin irritation

**Serious eye damage/eye irritation**
Causes serious eye damage.

Components:

Losartan:
Species : Rabbit
Result : Severe irritation

**Respiratory or skin sensitisation**

Skin sensitisation
May cause an allergic skin reaction.

Respiratory sensitisation
Not classified based on available information.

Components:

Losartan:
Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Assessment : Probability or evidence of skin sensitisation in humans
Result : positive

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

Components:

Losartan:
Genotoxicity in vitro : Test Type: in vitro assay
Result: negative
---
Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Result: negative
---
Test Type: Alkaline elution assay
Result: negative
---
Test Type: Chromosomal aberration
Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration
Result: negative
## Carcinogenicity

Not classified based on available information.

### Components:

**Losartan:**

- **Species**: Mouse
- **Application Route**: Oral
- **Exposure time**: 92 weeks
- **Dose**: 200 mg/kg body weight
- **Result**: negative

- **Species**: Rat
- **Application Route**: Oral
- **Exposure time**: 105 weeks
- **Dose**: 270 mg/kg body weight
- **Result**: negative

## Reproductive toxicity

May damage the unborn child.
May cause harm to breast-fed children.

### Components:

**Losartan:**

- **Effects on fertility**: Test Type: Fertility
  - **Species**: Rat, female
  - **Application Route**: Oral
  - **Fertility**: LOAEL: 200 mg/kg body weight
  - **Result**: female reproductive effects
  - **Remarks**: Maternal toxicity observed.

- **Effects on foetal development**: Test Type: Development
  - **Species**: Rabbit
  - **Application Route**: Oral
  - **General Toxicity Maternal**: NOAEL: 10 mg/kg body weight
  - **Developmental Toxicity**: NOAEL F1: 20 mg/kg body weight
  - **Result**: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects

- **Test Type**: Development
  - **Species**: Rat
  - **Application Route**: Oral
  - **Developmental Toxicity**: LOAEL: 10 mg/kg body weight
  - **Result**: Fetoxicity, No teratogenic effects

- **Reproductive toxicity - Assessment**: Clear evidence of adverse effects on development, based on animal experiments.
  - Studies indicating a hazard to babies during the lactation period
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STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:

Losartan:
- Exposure routes: Ingestion
- Target Organs: Blood, Cardio-vascular system, Stomach, Kidney
- Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Losartan:
- Species: Rat
  - LOAEL: 15 mg/kg
  - Application Route: Oral
  - Exposure time: 309 d
  - Number of exposures: daily
  - Target Organs: Blood, Kidney, Cardio-vascular system, Stomach

- Species: Dog
  - NOAEL: 5 mg/kg
  - Application Route: Oral
  - Exposure time: 1 Months
  - Symptoms: Salivation, Vomiting

- Species: Dog
  - LOAEL: 25 mg/kg
  - Application Route: Oral
  - Exposure time: 53 Weeks
  - Number of exposures: daily
  - Symptoms: Salivation, Vomiting

Aspiration toxicity
Not classified based on available information.

Components:

Losartan:
- No aspiration toxicity classification

Experience with human exposure

Components:

Losartan:
- Eye contact: Symptoms: Eye irritation
- Ingestion: Symptoms: hypotension, tachycardia
SECTION 12: Ecological information

12.1 Toxicity

Components:

Losartan:

Toxicity to fish:
- LC50 (Oncorhynchus mykiss (rainbow trout)): > 929 mg/l
  Exposure time: 96 h
  Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 331 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:
- NOEC (Microcystis aeruginosa (blue-green algae)): 949 mg/l
  Exposure time: 10 d
  Method: FDA 4.01

  NOEC (Selenastrum capricornutum (green algae)): 143 mg/l
  Exposure time: 10 d
  Method: FDA 4.01

Toxicity to fish (Chronic toxicity):
- NOEC: 10 mg/l
  Exposure time: 32 d
  Species: Pimephales promelas (fathead minnow)
  Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: 100 mg/l
  Exposure time: 21 d
  Species: Daphnia magna (Water flea)
  Method: OECD Test Guideline 211

12.2 Persistence and degradability

Components:

Losartan:

Stability in water:
- Hydrolysis: < 10 % (5 d)

12.3 Bioaccumulative potential

Components:

Losartan:

Partition coefficient: n-octanol/water:
- log Pow: 1.2

12.4 Mobility in soil

No data available

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
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 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
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants: 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 - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)
Not applicable

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
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
H302 : Harmful if swallowed.
H317 : May cause an allergic skin reaction.
H318 : Causes serious eye damage.
H360D : May damage the unborn child.
H362 : May cause harm to breast-fed children.
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Eye Dam. : Serious eye damage
Lact. : Effects on or via lactation
Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL : Short-term exposure limit (15-minute 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; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regu-
Losartan Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

Further information


Classification of the Mixture:

- **Acute Tox. 4**: H302 - Calculation method
- **Eye Dam. 1**: H318 - Calculation method
- **Skin Sens. 1**: H317 - Calculation method
- **Repr. 1B**: H360D - Calculation method
- **Lact.**: H362 - Calculation method
- **STOT RE 2**: H373 - 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.