SAFETY DATA SHEET

Betamethasone Ointment Formulation

Version 3.4   Revision Date: 10.10.2020   SDS Number: 1841091-00008   Date of last issue: 23.03.2020
Date of first issue: 19.07.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Betamethasone Ointment Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil 13106-054
Telephone: 908-740-4000
Emergency telephone: 55 19 3758 2000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Long-term (chronic) aquatic hazard: Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms: 
Signal Word: Danger
Hazard Statements: H360D May damage the unborn child.
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements: Prevention:
P201 Obtain special instructions before use.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
SAFETY DATA SHEET

Betamethasone Ointment Formulation

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

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>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>Aspiration hazard, Category 1</td>
<td>&gt;= 90 &lt;= 100</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>Acute toxicity (Inhalation), Category 2</td>
<td>&gt;= 5 &lt; 10</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland), Category 1 Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 0,025 &lt; 0,1</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

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

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

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

**Betamethasone Ointment Formulation**

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<thead>
<tr>
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</tbody>
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**If swallowed:**
- If swallowed, DO NOT induce vomiting.
- Get medical attention.
- Rinse mouth thoroughly with water.

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

**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 fire fighting:**
- Vapors may form explosive mixtures with air.
- Exposure to combustion products may be a hazard to health.

**Hazardous combustion products:**
- Carbon oxides

**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 fire-fighters:**
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures:**
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**Environmental precautions:**
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

**Methods and materials for containment and cleaning up:**
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- 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/PERSOAL 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 breathe dust, fume, gas, mist, vapors or spray.
Do not swallow.
Avoid contact with eyes. Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Keep container tightly closed.
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.

Conditions for safe storage: Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</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>
</tbody>
</table>
Further information: Skin

Wipe limit | 10 µg/100 cm² | Internal

**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**

**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 partculates and organic vapor type

**Hand protection**

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

**Eye protection**

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

**Skin and body protection**

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

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**

ointment

**Color**

No data available

**Odor**

No data available

**Odor 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

Flammability (liquids): Not applicable

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapor pressure: No data available

Relative vapor 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

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

**Acute toxicity**

Not classified based on available information.

**Components:**

**Petrolatum:**
- **Acute oral toxicity**: LD50 (Rat): > 5.000 mg/kg
  Method: OECD Test Guideline 401
  Remarks: Based on data from similar materials
- **Acute dermal toxicity**: LD50 (Rat): > 2.000 mg/kg
  Method: OECD Test Guideline 402
  Assessment: The substance or mixture has no acute dermal toxicity
  Remarks: Based on data from similar materials

**Paraffin oil:**
- **Acute oral toxicity**: LD50 (Rat): > 5.000 mg/kg
- **Acute dermal toxicity**: LD50 (Rabbit): > 2.000 mg/kg
  Assessment: The substance or mixture has no acute dermal toxicity

**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:**

**Petrolatum:**
- **Species**: Rabbit
- **Method**: OECD Test Guideline 404
- **Result**: No skin irritation
- **Remarks**: Based on data from similar materials

**Paraffin oil:**
- **Species**: Rabbit
- **Result**: No skin irritation

**Betamethasone:**
- **Species**: Rabbit
Result: Mild skin irritation

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

**Components:**

**Petrolatum:**
- **Species:** Rabbit
- **Result:** No eye irritation
- **Method:** OECD Test Guideline 405
- **Remarks:** Based on data from similar materials

**Paraffin oil:**
- **Species:** Rabbit
- **Result:** No eye irritation

**Betamethasone:**
- **Species:** Rabbit
- **Result:** No eye irritation

**Respiratory or skin sensitization**

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

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

**Components:**

**Petrolatum:**
- **Test Type:** Buehler Test
- **Routes of exposure:** Skin contact
- **Species:** Guinea pig
- **Result:** negative
- **Remarks:** Based on data from similar materials

**Betamethasone:**
- **Routes of exposure:** Dermal
- **Species:** Guinea pig
- **Result:** Weak sensitizer

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

**Components:**

**Petrolatum:**
- **Genotoxicity in vitro:**
  - **Test Type:** Chromosome aberration test in vitro
  - **Result:** negative
  - **Remarks:** Based on data from similar materials
Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
- Species: Mouse
- Application Route: Intraperitoneal injection
- Method: OECD Test Guideline 474
- Result: negative
- Remarks: Based on data from similar materials

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.

Components:
Petrolatum:
- Species: Rat
- Application Route: Ingestion
- Exposure time: 2 Years
- Result: negative

Reproductive toxicity
May damage the unborn child.

Components:
Petrolatum:
Effects on fertility:
- Test Type: Reproduction/Developmental toxicity screening test
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative
  - Remarks: Based on data from similar materials

Effects on fetal development:
- Test Type: Embryo-fetal development
  - Species: Rat
Betamethasone Ointment Formulation

Application Route: Skin contact  
Result: negative  
Remarks: Based on data from similar materials

Betamethasone:
Effects on fetal 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 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) 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:
Petrolatum:
Species : Rat
NOAEL : 5.000 mg/kg
Application Route : Ingestion
Exposure time : 2 y

Paraffin oil:
Species : Rat, female
LOAEL : 161 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
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.

Components:
Paraffin oil:
The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

Experience with human exposure
Components:
Betamethasone:
Inhalation: Target Organs: Adrenal gland
Skin contact: Symptoms: Redness, pruritis, Irritation

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity
Components:
Petrolatum:
Toxicity to fish: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
## Method: OECD Test Guideline 203

**Remarks:** Based on data from similar materials

### Toxicity to daphnia and other aquatic invertebrates

**EC50 (Daphnia magna (Water flea)):** > 10.000 mg/l  
**Exposure time:** 48 h  
**Test substance:** Water Accommodated Fraction  
**Remarks:** Based on data from similar materials

### Toxicity to algae/aquatic plants

**NOEL (Pseudokirchneriella subcapitata (green algae)):** >= 100 mg/l  
**Exposure time:** 72 h  
**Test substance:** Water Accommodated Fraction  
**Method:** OECD Test Guideline 201  
**Remarks:** Based on data from similar materials

### Paraffin oil:

**Toxicity to fish**  
**LL50 (Scophthalmus maximus (turbot)):** > 1.028 mg/l  
**Exposure time:** 96 h  
**Test substance:** Water Accommodated Fraction  
**Remarks:** Based on data from similar materials

**Toxicity to daphnia and other aquatic invertebrates**  
**EL50 (Acartia tonsa):** > 3.193 mg/l  
**Exposure time:** 48 h  
**Test substance:** Water Accommodated Fraction  
**Remarks:** Based on data from similar materials

**Toxicity to algae/aquatic plants**  
**EL50 (Skeletonema costatum (marine diatom)):** > 3.200 mg/l  
**Exposure time:** 72 h  
**Test substance:** Water Accommodated Fraction  
**Remarks:** Based on data from similar materials

**NOELR (Skeletonema costatum (marine diatom)):** 993 mg/l  
**Exposure time:** 72 h  
**Test substance:** Water Accommodated Fraction  
**Remarks:** Based on data from similar materials

### Betamethasone:

**Toxicity to daphnia and other aquatic invertebrates**  
**EC50 (Americamysis):** > 50 mg/l  
**Exposure time:** 96 h

**Toxicity to algae/aquatic plants**  
**EC50 (Pseudokirchneriella subcapitata (green algae)):** > 34 mg/l  
**Exposure time:** 72 h  
**Method:** OECD Test Guideline 201  
**Remarks:** No toxicity at the limit of solubility.

**NOEC (Pseudokirchneriella subcapitata (green algae)):** 34 mg/l  
**Exposure time:** 72 h
Toxicity to fish (Chronic toxicity):

- NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l
  Exposure time: 32 d
  Method: OECD Test Guideline 210
- NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l
  Exposure time: 219 d
  Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- NOEC (Daphnia magna (Water flea)): 8 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity):

- 1.000

Persistence and degradability

**Components:**

**Petrolatum:**

Biodegradability:

- Result: Not readily biodegradable.
- Biodegradation: 31 %
- Exposure time: 28 d
- Method: OECD Test Guideline 301F
- Remarks: Based on data from similar materials

**Paraffin oil:**

Biodegradability:

- Result: Readily biodegradable.
- Biodegradation: 82 %
- Exposure time: 24 d
- Method: OECD Test Guideline 301F
- Remarks: Based on data from similar materials

Bioaccumulative potential

**Components:**

**Betamethasone:**

- Partition coefficient: n-octanol/water
  - log Pow: 2.11

Mobility in soil

- No data available

Other adverse effects

- No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

- Waste from residues: Dispose of in accordance with local regulations.
SECTION 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Betamethasone)
- Class: 9
- Packing group: III
- Labels: 9

**IATA-DGR**
- UN/ID No.: UN 3077
- Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Betamethasone)
- Class: 9
- Packing group: III
- Labels: Miscellaneous
- Packing instruction (cargo aircraft): 956
- Packing instruction (passenger aircraft): 956
- Environmentally hazardous: yes

**IMDG-Code**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Betamethasone)
- 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.

**Domestic regulation**

**ANTT**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Betamethasone)
- Class: 9
- Packing group: III
- Labels: 9
- Hazard Identification Number: 90

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.
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Date of first issue: 19.07.2017

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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
National List of Carcinogenic Agents for Humans - (LINACH): Not applicable

Brazil. List of chemicals controlled by the Federal Police: Not applicable

International Regulations

The ingredients of this product are reported in the following inventories:
AICS: not determined

DSL: not determined

IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA: 8-hour, time-weighted average

AICl - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Or-
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.