1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Posaconazole Injection Formulation

Manufacturer or supplier’s details
Company : MSD
Address : JL Raya Pandaan KM. 48
          Pandaan, Jawa Timur - Indonesia
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

2. HAZARDS IDENTIFICATION

GHS Classification
Skin sensitisation : Category 1
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Adrenal gland, Bone marrow, Kidney, Liver, Nervous system, Reproductive organs)
Long-term (chronic) aquatic hazard : Category 3

GHS label elements
Hazard pictograms : 

Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.
H373 May cause damage to organs (Adrenal gland, Bone marrow, Kidney, Liver, Nervous system, Reproductive organs) through prolonged or repeated exposure if swallowed.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : Prevention:
P260 Do not breathe mist or vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
SAFETY DATA SHEET
Posaconazole Injection Formulation

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SDS Number: 22502-00015
Date of last issue: 2019/04/24
Date of first issue: 2014/10/16

- **P280** Wear protective gloves.

**Response:**
- **P302 + P352** IF ON SKIN: Wash with plenty of water.
- **P314** Get medical advice/attention if you feel unwell.
- **P333 + P313** If skin irritation or rash occurs: Get medical advice/attention.
- **P362 + P364** Take off contaminated clothing and wash it before reuse.

**Disposal:**
- **P501** Dispose of contents/container to an approved waste disposal plant.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>L beta-Cyclodextrin, sulfobutyl ethers, sodium salts</td>
<td>182410-00-0</td>
<td>&gt;= 30 -&lt; 60</td>
</tr>
<tr>
<td></td>
<td>Posaconazole</td>
<td>171228-49-2</td>
<td>&gt;= 1 -&lt; 2.5</td>
</tr>
</tbody>
</table>

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.

- **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:** Diarrhoea
  - Fever
  - Headache
  - Nausea
  - Vomiting
  - May cause an allergic skin reaction.
  - May cause damage to organs through prolonged or repeated
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.

5. FIREFIGHTING 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
Sulphur oxides
Metal 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 firefighters: In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions: Discharge into the environment must be avoided.
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.
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:
- Do not get on skin or clothing.
- Avoid inhalation of vapour or mist.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labelled containers.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

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>Posaconazole</td>
<td>171228-49-2</td>
<td>TWA</td>
<td>300 µg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures:
- Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- Laboratory operations do not require special containment.

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
- Hand protection Material: Chemical-resistant gloves

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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Aqueous solution

Colour: Colorless to pale yellow

Odour: Odourless

Odour Threshold: No data available

pH: 2.6

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): Not applicable

Flammability (liquids): No data available

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: 1.15 g/cm³

Solubility(ies):
- Water solubility: No data available

Partition coefficient: n-octanol/water: Not applicable
SAFETY DATA SHEET

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Date of first issue: 2014/10/16

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.
Molecular weight : No data available
Particle size : Not applicable

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.

11. TOXICOLOGICAL INFORMATION
Information on likely routes of exposure
  Inhalation
  Skin contact
  Ingestion
  Eye contact

Acute toxicity
Not classified based on available information.

Components:

\textbf{beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:}
Acute oral toxicity : LD50 (Rat): > 8,800 mg/kg

\textbf{Posaconazole:}
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
  LD50 (Mouse): > 3,000 mg/kg
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

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

Posaconazole:
- Species: Rabbit
- Result: No skin irritation

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

Components:

Posaconazole:
- Species: Rabbit
- Result: Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation
- May cause an allergic skin reaction.

Respiratory sensitisation
- Not classified based on available information.

Components:

.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:
- Assessment: Probability or evidence of skin sensitisation in humans

Components:

Posaconazole:
- Test Type: Magnusson-Kligman-Test
- Exposure routes: Skin contact
- Species: Guinea pig
- Result: negative

Germ cell mutagenicity
- Not classified based on available information.

Components:

Posaconazole:
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

  Test Type: Chromosomal aberration
  Result: negative

- Genotoxicity in vivo: Test Type: Micronucleus test
  Species: Mouse
  Cell type: Bone marrow
  Application Route: Intravenous
  Result: negative
### Carcinogenicity

- Not classified based on available information.

### Components:

#### Posaconazole:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>oral (feed)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
<tr>
<td>Remarks</td>
<td>The mechanism or mode of action is not relevant in humans.</td>
</tr>
</tbody>
</table>

#### Species: Mouse

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
<tr>
<td>Remarks</td>
<td>The mechanism or mode of action is not relevant in humans.</td>
</tr>
</tbody>
</table>

### Reproductive toxicity

- Not classified based on available information.

#### Components:

##### beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Intravenous injection</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

##### Posaconazole:

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency of Treatment</td>
<td>6 - 15 days</td>
</tr>
<tr>
<td>Developmental Toxicity</td>
<td>LOAEL: 29 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>Fetotoxicity, Malformations were observed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency of Treatment</td>
<td>6 - 15 days</td>
</tr>
<tr>
<td>Developmental Toxicity</td>
<td>LOAEL: 45 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Intravenous injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developmental Toxicity</td>
<td>LOAEL: 180 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Intravenous injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developmental Toxicity</td>
<td>LOAEL: 45 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, male</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Toxicity - Parent</td>
<td>NOAEL: 180 mg/kg body weight</td>
</tr>
<tr>
<td>Symptoms</td>
<td>No effects on mating performance</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, female</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Toxicity - Parent</td>
<td>NOAEL: 45 mg/kg body weight</td>
</tr>
<tr>
<td>Symptoms</td>
<td>No effects on mating performance</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

### General Toxicity

- NOAEL: 180 mg/kg body weight
- Symptoms: No effects on mating performance
- Result: negative
Test Type: Embryo-foetal development
Species: Rabbit, female
Frequency of Treatment: 7 - 19 days
Developmental Toxicity: LOAEL: 40 mg/kg body weight
Result: Fetotoxicity

Reproductive toxicity - Assessment: Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs (Adrenal gland, Bone marrow, Kidney, Liver, Nervous system, Reproductive organs) through prolonged or repeated exposure if swallowed.

Components:

Posaconazole:

Exposure routes: Ingestion
Target Organs: Adrenal gland, Bone marrow, Kidney, Liver, Reproductive organs, Nervous system
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Posaconazole:

Species: Rat, female
LOAEL: 5 mg/kg
Application Route: Oral
Exposure time: 6 Months
Target Organs: Adrenal gland, Lungs, Heart, Liver, spleen, Kidney, Ovary

Species: Dog
LOAEL: 3 mg/kg
Application Route: Oral
Exposure time: 392 Days
Target Organs: Lungs, Liver, Brain, small intestine, Adrenal gland, Spinal cord, lymphoid tissue

Species: Monkey
LOAEL: 15 mg/kg
Application Route: Oral
Exposure time: 1 Months
Target Organs: Bone marrow, Adrenal gland, Lymph nodes, Blood

Species: Dog
LOAEL: 3 mg/kg
Application Route: Oral
Exposure time: 56 Weeks
Target Organs: Adrenal gland, Bone marrow, Kidney, Nervous system, spleen, thymus gland, Testis, lymphoid tissue
Species: Monkey
LOAEL: 180 mg/kg
Application Route: Oral
Exposure time: 12 Months
Target Organs: Blood, Gastrointestinal tract, spleen

Species: Monkey
LOAEL: 8 mg/kg
Application Route: Intravenous
Exposure time: 1 Months
Target Organs: Cardio-vascular system, Lungs, Adrenal gland, Blood

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Posaconazole:
Ingestion: Symptoms: Cough, Headache, Nausea, Vomiting, Fever, Liver effects, Rash, pruritis, Diarrhoea, hypertension, neutropenia, electrolyte imbalance

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

.beta.-Cyclodextrin, sulfobutyi ethers, sodium salts:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 220 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 96 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: EC50 (Selenastrum capricornutum (green algae)): > 100 mg/l
Exposure time: 72 h

Posaconazole:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.95 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0.276 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.509 mg/l
Exposure time: 72 h
## Method

- **NOEC (Pseudokirchneriella subcapitata (green algae))**: 0.041 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

- **M-Factor (Acute aquatic toxicity)**: 1

- **Toxicity to fish (Chronic toxicity)**: NOEC (Pimephales promelas (fathead minnow)): 0.206 mg/l
  - Exposure time: 33 d
  - Method: OECD Test Guideline 210

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**: NOEC (Daphnia magna (Water flea)): 0.244 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211
  - Remarks: No toxicity at the limit of solubility

- **M-Factor (Chronic aquatic toxicity)**: 1

- **Toxicity to microorganisms**: EC50 (Natural microorganism): > 1,000 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

- **Posaconazole**
  - **Biodegradability**: Result: Not readily biodegradable.
    - Biodegradation: 50%
    - Exposure time: 28 h
    - Method: OECD Test Guideline 314
  - **Stability in water**: Degradation half life (DT50): > 30 d
    - Method: OECD Test Guideline 111

### Bioaccumulative potential

#### Components:

- **Posaconazole**
  - **Bioaccumulation**: Species: Lepomis macrochirus (Bluegill sunfish)
    - Bioconcentration factor (BCF): 20
    - Method: OECD Test Guideline 305
  - **Partition coefficient: n-octanol/water**: log Pow: 4.15

### Mobility in soil

#### Components:

- **Posaconazole**
SAFETY DATA SHEET

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Distribution among environmental compartments: log Koc: 5.52

Other adverse effects:
No data available

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.

14. TRANSPORT INFORMATION

International Regulations:

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health:
Hazardous substances that must be registered: Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances:
Hazardous substances approved for use: Not applicable
Prohibited substances: Not applicable
Restricted substances: Not applicable
Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials

Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

The components of this product are reported in the following inventories:

- AICS : not determined
- DSL : not determined
- IECSC : not determined

16. OTHER INFORMATION

Further information

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

Date format : yyyy/mm/dd

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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 Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature
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.