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

Posaconazole Solid Formulation

Version 4.2  Revision Date: 09/13/2019  SDS Number: 23521-00013  Date of last issue: 24.04.2019

1.1 Product identifier
Trade name : Posaconazole Solid 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
Innishannon
County Cork - Ireland
Telephone : 353 214329300
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)
Reproductive toxicity, Category 2 : H361d: Suspected of damaging the unborn child.
Specific target organ toxicity - repeated exposure, Category 1 : H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 2 : H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms :

Signal word : Danger
Hazard statements : H361d  Suspected of damaging the unborn child.
H372  Causes damage to organs through prolonged or repeated exposure.
H411  Toxic to aquatic life with long lasting effects.

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

**Prevention:**
- P201 Obtain special instructions before use.
- P260 Do not breathe dust.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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

Hazardous components which must be listed on the label:
Posaconazole

2.3 Other hazards
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

<table>
<thead>
<tr>
<th>Components</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>Posaconazole</td>
<td>171228-49-2</td>
<td>49-2</td>
<td>2</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
<td></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.

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.
Get medical attention.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms

Diarrhoea
Headache
Vomiting
Nausea
Fever

Risks

Suspected of damaging the unborn child.
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 fire-fighting: 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

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.
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: 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. 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. 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 locked up. 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 of exposure)</th>
<th>Control parameters</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>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used

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.
  - Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- **Appearance**: Powder
- **Colour**: No data available
- **Odour**: No data available
- **Odour 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**: Not applicable
Evaporation rate : Not applicable

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 : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies) : No data available

Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity : Not applicable

Viscosity, kinematic : Not applicable

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

Particle size : Not applicable

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, han-
Posaconazole Solid Formulation

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
Not classified based on available information.

Components:
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
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Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

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

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

Carcinogenicity
Not classified based on available information.

Components:

Posaconazole:
Species: Rat
Application Route: oral (feed)
Exposure time: 2 Years
Result: positive
Remarks: The mechanism or mode of action is not relevant in humans.

Species: Mouse
Application Route: Oral
Exposure time: 2 Years
Result: positive
Remarks: The mechanism or mode of action is not relevant in humans.
Reproductive toxicity
Suspected of damaging the unborn child.

Components:

Posaconazole:
Effects on fertility
Test Type: Fertility/early embryonic development
Species: Rat, male
General Toxicity - Parent: NOAEL: 180 mg/kg body weight
Symptoms: No effects on mating performance
Result: negative

Test Type: Fertility/early embryonic development
Species: Rat, female
General Toxicity - Parent: NOAEL: 45 mg/kg body weight
Symptoms: No effects on mating performance
Result: negative

Effects on foetal development
Test Type: Embryo-foetal development
Species: Rat, female
Application Route: Oral
Frequency of Treatment: 6 - 15 days
Developmental Toxicity: LOAEL: 29 mg/kg body weight
Result: Fetotoxicity, Malformations were observed.

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
Causes damage to organs through prolonged or repeated exposure.

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:
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<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>

#### Species and LOAEL

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat, female</td>
<td>5 mg/kg</td>
<td>Oral</td>
<td>6 Months</td>
<td>Adrenal gland, Lungs, Heart, Liver, spleen, Kidney, Ovary</td>
</tr>
<tr>
<td>Dog</td>
<td>3 mg/kg</td>
<td>Oral</td>
<td>392 Days</td>
<td>Lungs, Liver, Brain, small intestine, Adrenal gland, Spinal cord, lymphoid tissue</td>
</tr>
<tr>
<td>Monkey</td>
<td>15 mg/kg</td>
<td>Oral</td>
<td>1 Months</td>
<td>Bone marrow, Adrenal gland, Lymph nodes, Blood</td>
</tr>
<tr>
<td>Dog</td>
<td>3 mg/kg</td>
<td>Oral</td>
<td>56 Weeks</td>
<td>Adrenal gland, Bone marrow, Kidney, Nervous system, spleen, thymus gland, Testis, lymphoid tissue</td>
</tr>
<tr>
<td>Monkey</td>
<td>180 mg/kg</td>
<td>Oral</td>
<td>12 Months</td>
<td>Blood, Gastrointestinal tract, spleen</td>
</tr>
<tr>
<td>Monkey</td>
<td>8 mg/kg</td>
<td>Intravenous</td>
<td>1 Months</td>
<td>Cardio-vascular system, Lungs, Adrenal gland, Blood</td>
</tr>
</tbody>
</table>

#### 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
SECTION 12: Ecological information

12.1 Toxicity

**Components:**

**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: OECD Test Guideline 201
  - 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 microorganisms:**
  - EC50 (Natural microorganism): > 1,000 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

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

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

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

12.2 Persistence and degradability

**Components:**

**Posaconazole:**
- **Biodegradability:**
  - Result: Not readily biodegradable.
12.3 Bioaccumulative potential

**Components:**

**Posaconazole:**
- Bioaccumulation
- Species: Lepomis macrochirus (Bluegill sunfish)
- Bioconcentration factor (BCF): 20
- Method: OECD Test Guideline 305

**Components:**

**Posaconazole:**
- Partition coefficient: n-octanol/water
- \( \log \text{Pow} \): 4.15

12.4 Mobility in soil

**Components:**

**Posaconazole:**
- Distribution among environmental compartments
- \( \log \text{Koc} \): 5.52

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

**ADN:**
- UN 3077

**ADR:**
- UN 3077

**RID:**
- UN 3077
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according to Regulation (EC) No. 1907/2006

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Revision Date: 09/13/2019
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Date of last issue: 24.04.2019
Date of first issue: 21.10.2014

14.2 UN proper shipping name

| ADN       | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Posaconazole) |
| ADR       | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Posaconazole) |
| RID       | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Posaconazole) |
| IMDG      | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Posaconazole) |
| IATA      | Environmentally hazardous substance, solid, n.o.s. (Posaconazole) |

14.3 Transport hazard class(es)

| ADN       | 9 |
| ADR       | 9 |
| RID       | 9 |
| IMDG      | 9 |
| IATA      | 9 |

14.4 Packing group

| ADN       | Packing group: III  Classification Code: M7  Hazard Identification Number: 90  Labels: 9 |
| ADR       | Packing group: III  Classification Code: M7  Hazard Identification Number: 90  Labels: 9  Tunnel restriction code: (-) |
| RID       | Packing group: III  Classification Code: M7  Hazard Identification Number: 90  Labels: 9 |
| IMDG      | Packing group: III  Labels: 9 |
EmS Code: F-A, S-F

IATA (Cargo)
- Packing instruction (cargo aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

IATA (Passenger)
- Packing instruction (passenger aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous: yes

ADR
Environmentally hazardous: yes

RID
Environmentally hazardous: yes

IMDG
Marine pollutant: yes

IATA (Passenger)
Environmentally hazardous: yes

IATA (Cargo)
Environmentally hazardous: yes

14.6 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.

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 Parlia-
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ment and the Council concerning the export and import of dangerous chemicals
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)

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
H361d : Suspected of damaging the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Repr. : Reproductive toxicity
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; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regula-
**Classification of the mixture:**

<table>
<thead>
<tr>
<th>Category</th>
<th>Classification</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repr. 2</td>
<td>H361d</td>
<td>Calculation</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
<td>Calculation</td>
</tr>
<tr>
<td>Aquatic Chronic 2</td>
<td>H411</td>
<td>Calculation</td>
</tr>
</tbody>
</table>

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.