Suvorexant Formulation

SECTION 1. IDENTIFICATION

Product name : Suvorexant Formulation
Other means of identification : No data available

Manufacturer or supplier's details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
          Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Central nervous system)

GHS label elements
Hazard pictograms :

Signal Word : Warning

Hazard Statements :
H373 May cause damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Precautionary Statements :
Prevention:
P260 Do not breathe dust.

Response:
P314 Get medical attention if you feel unwell.

Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suvorexant</td>
<td>No data available</td>
<td>1030377-33-3</td>
<td>&gt;= 5 - &lt; 10 *</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret

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 if symptoms occur.

In case of skin contact: Wash with water and soap. Get medical attention if symptoms occur.

In case of eye contact: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

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

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: 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
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 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 spills cannot be contained.

Methods and materials for containment and 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

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.
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>Suvorexant</td>
<td>1030377-33-3</td>
<td>TWA</td>
<td>14 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>140 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

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: Particulates type

Hand Protection: 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.

### 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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Color</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.
Incompatible materials : Avoid dust formation.
Hazardous decomposition products : Oxidizing agents

SECTION 11. TOXICOLOGICAL INFORMATION

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

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

**Components:**

**Suvorexant:**
Acute oral toxicity : LD50 (Rat): > 1,200 mg/kg
                     : LD50 (Dog): > 1,125 mg/kg
                     : LDLo (Mouse): 2,000 mg/kg

**Magnesium stearate:**
Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
                      Method: OECD Test Guideline 423
                      Assessment: The substance or mixture has no acute oral toxicity
                      Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
                       Remarks: Based on data from similar materials

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

**Components:**

**Suvorexant:**
Species : Rabbit
Result : No skin irritation

**Magnesium stearate:**
Species : Rabbit
Result : No skin irritation
Remarks : Based on data from similar materials

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

**Components:**

**Suvorexant:**
Species : Bovine cornea
Result : Mild eye irritation
Method : Bovine cornea (BCOP)

**Magnesium stearate:**
Species : Rabbit
Result : No eye irritation
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Remarks: Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Suvorexant:
Test Type: Local lymph node assay (LLNA)
Species: Mouse
Assessment: Does not cause skin sensitization.
Result: negative

Magnesium stearate:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Genotoxicity in vitro: Test Type: Alkaline elution assay
Test system: rat hepatocytes
Result: negative

Genotoxicity in vitro: Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: negative

Magnesium stearate:
Genotoxicity in vitro:
- Test Type: In vitro mammalian cell gene mutation test
  - Result: negative
  - Remarks: Based on data from similar materials

- Test Type: Chromosome aberration test in vitro
  - Method: OECD Test Guideline 473
  - Result: negative
  - Remarks: Based on data from similar materials

- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Remarks: Based on data from similar materials

Carcinogenicity
Not classified based on available information.

Components:

Suvorexant:
- Species: Mouse
- Application Route: Oral
- Exposure time: 6 month(s)
- Result: negative

- Species: Rat
- Application Route: Oral
- Exposure time: 2 Years
- Result: negative

Reproductive toxicity
Not classified based on available information.

Components:

Suvorexant:
- Effects on fertility:
  - Test Type: Fertility/early embryonic development
  - Species: Rat, male and female
  - Application Route: Oral
  - General Toxicity Parent: NOAEL: >= 325 mg/kg body weight
  - Result: negative

- Effects on fetal development:
  - Test Type: Embryo-fetal development
  - Species: Rabbit, female
  - Application Route: Oral
  - Developmental Toxicity: NOAEL: 150 mg/kg body weight
  - Result: negative

  - Test Type: Embryo-fetal development
    - Species: Rat
    - Application Route: Oral
    - Developmental Toxicity: NOAEL: 80 mg/kg body weight
    - Result: negative
SAFETY DATA SHEET
according to the Hazardous Products Regulations

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Version 6.1  Revision Date: 09/26/2023  SDS Number: 21525-00025  Date of last issue: 03/20/2023  Date of first issue: 10/14/2014

Magnesium stearate:
Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

STOT-single exposure
Not classified based on available information.

Components:
Suvorexant:
Remarks : Based on human experience.

STOT-repeated exposure
May cause damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Components:
Suvorexant:
Routes of exposure : Ingestion
Target Organs : Central nervous system
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:
Suvorexant:
Species : Rat
NOAEL : 325 mg/kg
LOAEL : 1,200 mg/kg
Application Route : Oral
Exposure time : 30 d
Target Organs : Blood, Pancreas

Species : Dog
NOAEL : 50 mg/kg
LOAEL : 125 mg/kg
Application Route : Oral
Exposure time : 30 d
Target Organs : Blood, Liver, Central nervous system
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according to the Hazardous Products Regulations

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Species: Rat
NOAEL: 75 mg/kg
LOAEL: 300 mg/kg
Application Route: Oral
Exposure time: 180 d
Target Organs: Pancreas, Blood, Stomach

Species: Dog
NOAEL: 50 mg/kg
LOAEL: 125 mg/kg
Application Route: Oral
Exposure time: 270 d
Target Organs: Blood

Species: Rat
NOAEL: 40 mg/kg
LOAEL: 80 mg/kg
Application Route: Oral
Exposure time: 18 Months
Target Organs: Eye, Central nervous system

Magnesium stearate:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Suvorexant:
Ingestion:
Symptoms: Drowsiness, Headache, abnormal dreams, Fatigue, Dizziness, dry mouth, Nausea, liver function change, upper respiratory tract infection, urinary tract infection, Cough, Diarrhea, Palpitation, tachycardia

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Suvorexant:
Toxicity to daphnia and other aquatic invertebrates:
EC50 (Mysidopsis bahia (opossum shrimp)): 0.56 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035
**Toxicity to algae/aquatic plants:**

- EC50 (Pseudokirchneriella subcapitata (green algae)): > 5 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 2.5 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

**Toxicity to fish (Chronic toxicity):**

- NOEC (Pimephales promelas (fathead minnow)): 0.14 mg/l
  - Exposure time: 32 d
  - Method: OECD Test Guideline 210

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

- NOEC (Daphnia magna (Water flea)): 0.5 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211

**Toxicity to microorganisms:**

- EC50: > 1,000 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209
- NOEC: 1,000 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

**Magnesium stearate:**

**Toxicity to fish:**

- LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
  - Exposure time: 48 h
  - Method: DIN 38412
  - Remarks: Based on data from similar materials

**Toxicity to daphnia and other aquatic invertebrates:**

- EL50 (Daphnia magna (Water flea)): > 1 mg/l
  - Exposure time: 47 h
  - Test substance: Water Accommodated Fraction
  - Remarks: Based on data from similar materials
  - No toxicity at the limit of solubility.

**Toxicity to algae/aquatic plants:**

- EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
  - Exposure time: 72 h
  - Test substance: Water Accommodated Fraction
  - Method: OECD Test Guideline 201
  - Remarks: Based on data from similar materials
  - No toxicity at the limit of solubility.
- NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
  - Exposure time: 72 h
  - Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms:
EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Persistence and degradability

Components:

Suvorexant:
Biodegradability:
Result: Not readily biodegradable.
Biodegradation: 81 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Stability in water:
Hydrolysis: < 10 % (5 d)
Method: OECD Test Guideline 111

Magnesium stearate:
Biodegradability:
Result: Not biodegradable
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Suvorexant:
Bioaccumulation:
Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 358
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water:
log Pow: 4.04

Magnesium stearate:
Partition coefficient: n-octanol/water:
log Pow: > 4

Mobility in soil:
No data available

Other adverse effects:
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods:
Waste from residues:
Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.

Contaminated packaging:
Empty containers should be taken to an approved waste
SECTION 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.

Domestic regulation

TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

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

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA QC OEL / TWAEV : Time-weighted average exposure value

AIIC - 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 -
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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 Chemicals 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; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System


Revision Date: 09/26/2023
Date format: mm/dd/yyyy

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.

CA / Z8