SECTION 1. IDENTIFICATION

Product name: Zilpaterol Formulation

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: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Specific target organ toxicity - repeated exposure: Category 1 (Cardio-vascular system, Central nervous system, Lungs)

GHS label elements

Hazard pictograms: 

Signal Word: Danger

Hazard Statements: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air. H372 Causes damage to organs (Cardio-vascular system, Central nervous system, Lungs) through prolonged or repeated exposure.

Precautionary Statements: Prevention:
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
Response:
P314 Get medical attention if you feel unwell.
Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Zilpaterol Formulation

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**Other hazards**
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

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

**Chemical name** | **CAS-No.** | **Concentration (% w/w)**  
Zilpaterol       | 119520-06-8 | >= 1 - < 5  

Actual concentration 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
In case of contact, immediately flush skin with soap and plenty of water.
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**
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.

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.
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Zilpaterol Formulation

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)

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.
- 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 Advice on safe handling:
- Use only with adequate ventilation.
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- Avoid prolonged or repeated contact with skin.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure.
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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.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

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

Materials to avoid:
Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

inert or nuisance dust
50 Million particles per cubic foot
Value type (Form of exposure): TWA (total dust)
Basis: OSHA Z-3

15 mg/m³
Value type (Form of exposure): TWA (total dust)
Basis: OSHA Z-3

5 mg/m³
Value type (Form of exposure): TWA (respirable fraction)
Basis: OSHA Z-3

15 Million particles per cubic foot
Value type (Form of exposure): TWA (respirable fraction)
Basis: OSHA Z-3

Dust, nuisance dust and particulates
10 mg/m³
Value type (Form of exposure): PEL (Total dust)
Basis: CAL PEL

5 mg/m³
Value type (Form of exposure): PEL (respirable dust fraction)
Basis: CAL PEL

Components
CAS-No.
Value type (Form of exposure)
Control parameters / Permissible concentration
Basis

Zilpaterol
119520-06-8
TWA
1 µg/m³
Internal

Wipe limit
10 µg/100 cm²
Internal

Engineering measures:
Ensure adequate ventilation, especially in confined areas.
Minimize workplace exposure concentrations.
Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipment
Respiratory protection: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection
Material: Chemical-resistant gloves
Remarks: Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection: Wear the following personal protective equipment:
Safety goggles

Skin and body protection: Skin should be washed after contact.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Color: tan
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: No data available
## SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

**Zilpaterol Formulation**

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Range</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
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</tr>
<tr>
<td>Evaporation rate</td>
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</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>
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</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
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<tr>
<td>Lower explosion limit / Lower flammability limit</td>
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<tr>
<td>Vapor pressure</td>
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</tr>
<tr>
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</tr>
<tr>
<td>Relative density</td>
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</tr>
<tr>
<td>Solubility(ies)</td>
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</tr>
<tr>
<td>Water solubility</td>
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</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
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</tr>
<tr>
<td>Autoignition temperature</td>
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</tr>
<tr>
<td>Decomposition temperature</td>
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</tr>
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<td>Viscosity</td>
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<td>Viscosity, dynamic</td>
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</tr>
<tr>
<td>Viscosity, kinematic</td>
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<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### 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.
- Avoid dust formation.

**Incompatible materials**
- Oxidizing agents

**Hazardous decomposition products**
- No hazardous decomposition products are known.

### SECTION 11. TOXICOLOGICAL INFORMATION

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

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

**Product:**

- **Acute oral toxicity**
  - Acute toxicity estimate: > 5,000 mg/kg
  - Method: Calculation method

- **Acute inhalation toxicity**
  - Acute toxicity estimate: 104.17 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Method: Calculation method

**Components:**

- **Zilpaterol:**
  - **Acute oral toxicity**
    - LD50 (Mouse, male and female): 430 - 580 mg/kg
    - LD50 (Rat, male and female): 890 - 1,325 mg/kg
  - **Acute inhalation toxicity**
    - LC50 (Rat): > 5 mg/l
    - Exposure time: 4 h
    - Test atmosphere: dust/mist
    - Symptoms: Tremors, Breathing difficulties
  - **Acute dermal toxicity**
    - LD50 (Rat): > 2,000 mg/kg
  - **Acute toxicity (other routes of administration)**
    - TDL0 (Rabbit): 9.6 %
    - Application Route: see user defined free text
    - Symptoms: Increased pulse rate

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

**Components:**

- **Zilpaterol:**
  - **Species**
    - Rabbit
Zilpaterol Formulation

Result: No skin irritation

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

**Components:**

**Zilpaterol:**
Species: Rabbit
Result: Mild eye irritation

**Respiratory or skin sensitization**

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

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

**Components:**

**Zilpaterol:**
Test Type: Maximization Test
Species: Guinea pig
Assessment: Does not cause skin sensitization.
Result: negative

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

**Components:**

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

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Result: negative

Test Type: Mouse Lymphoma
Test system: mouse lymphoma cells
Result: negative

Test Type: unscheduled DNA synthesis assay
Test system: rat hepatocytes
Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative
Test Type: in vivo assay
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Zilpaterol:
Species: Rat, male and female
Application Route: oral (feed)
Exposure time: 104 weeks
: 0.05 mg/kg body weight
: 0.125 mg/kg body weight
Result: negative
Target Organs: Ovary

Species: Mouse
Application Route: Oral
Exposure time: 18 Months
: 0.02 mg/kg body weight
: 0.05 mg/kg body weight
Result: negative
Target Organs: Blood

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Not classified based on available information.

Components:

Zilpaterol:
Effects on fertility: Test Type: Two-generation study
Species: Rat, male
Application Route: oral (feed)
Fertility: NOAEL: 1.8 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Test Type: Two-generation study
Species: Rat, male
Application Route: oral (feed)
Fertility: NOAEL: 0.94 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Effects on fetal development
Test Type: Embryo-fetal development
Species: Rat, female
Application Route: Oral
Developmental Toxicity: NOAEL: 10 mg/kg body weight
Embryo-fetal toxicity: LOAEL: 50 mg/kg body weight
Result: No teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Causes damage to organs (Cardio-vascular system, Central nervous system, Lungs) through prolonged or repeated exposure.

Components:

Zilpaterol:
Target Organs: Cardio-vascular system, Central nervous system, Lungs
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Zilpaterol:
Species: Monkey
NOAEL: 0.01 mg/kg
LOAEL: 0.05 mg/kg
Application Route: Oral
Exposure time: 4 Weeks
Target Organs: Cardio-vascular system
Symptoms: Increased pulse rate, Lowered blood pressure

Species: Rat, male and female
NOAEL: 0.05 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Cardio-vascular system
Symptoms: Lowered blood pressure

Species: Pig, male and female
NOAEL: 0.05 mg/kg
LOAEL: 1 mg/kg
Application Route: Oral
Exposure time: 13 Weeks
Target Organs: Heart
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Species: Rat, male and female
NOAEL: 0.250 mg/kg
Application Route: oral (feed)
Exposure time: 52 Weeks
Target Organs: Cardio-vascular system
Symptoms: slow pulse

Species: Dog
Application Route: Dermal
Remarks: No significant adverse effects were reported

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

**Experience with human exposure**

**Components:**

**Zilpaterol:**
Ingestion
Target Organs: Lungs
Symptoms: Tremors, Increased pulse rate
Target Organs: Central nervous system

**SECTON 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Zilpaterol:**
Toxicity to algae/aquatic plants
NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.

EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.

**Persistence and degradability**

**Components:**

**Zilpaterol:**
Stability in water: Hydrolysis: 0 % (5 d)
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</tr>
</tbody>
</table>

## Bioaccumulative potential

**Components:**

**Zilpaterol:**
- Partition coefficient: n-octanol/water: \( \log \text{Pow}: 1 \)

## Mobility in soil

**Components:**

**Zilpaterol:**
- Distribution among environmental compartments: \( \log \text{Koc}: 2.8 \)

## Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

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

**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**

**49 CFR**
- Not regulated as a dangerous good

**Special precautions for user**
- Not applicable

## SECTION 15. REGULATORY INFORMATION

**CERCLA Reportable Quantity**
- This material does not contain any components with a CERCLA ROQ.
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SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards:
- Combustible dust
- Specific target organ toxicity (single or repeated exposure)

SARA 313:
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- Corn Cobs Not Assigned
- Polyethylene glycol castor oil 61791-12-6
- Zilpaterol 119520-06-8

California List of Hazardous Substances
- Polyvinyl pyrrolidone 9003-39-8

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
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

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NFPA 704:

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
<th>Special hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
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HMIS® IV:

<table>
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<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations:

CAL PEL: California permissible exposure limits for chemical contaminants (Title 8, Article 107)
OSHA Z-3: USA, Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
CAL PEL / PEL: Permissible exposure limit
OSHA Z-3 / TWA: 8-hour time weighted average

AIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act;
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REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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


Revision Date: 09/30/2023

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.

US / Z8