SAFETY DATA SHEET

Formoterol Formulation

Version 4.1  Revision Date: 2020/10/10  SDS Number: 525385-00013  Date of last issue: 2020/03/23
Date of first issue: 2016/02/23

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Formoterol Formulation

Supplier’s company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd.
Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : 1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Specific target organ toxicity - single exposure (Oral) : Category 1 (Cardio-vascular system, Central nervous system)
Specific target organ toxicity - single exposure (Inhalation) : Category 1 (Cardio-vascular system, Central nervous system)
Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Heart)
Specific target organ toxicity - repeated exposure (Inhalation) : Category 1 (Heart)

GHS label elements
Hazard pictograms : 

Signal word : Danger
Hazard statements : H370 Causes damage to organs (Cardio-vascular system, Central nervous system) if swallowed.
H370 Causes damage to organs (Cardio-vascular system, Central nervous system) if inhaled.
H372 Causes damage to organs (Heart) through prolonged or repeated exposure if swallowed.
H372 Causes damage to organs (Heart) through prolonged or repeated exposure if inhaled.
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:**
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.

**Storage:**
P405 Store locked up.

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

Other hazards which do not result in classification:

Important symptoms and outlines of the emergency assumed:
- 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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formoterol</td>
<td>43229-80-7</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
<td></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:**
- 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 unless directed to do so by medical personnel.
- Get medical attention.
- Rinse mouth thoroughly with water.
- Never give anything by mouth to an unconscious person.

**Most important symptoms and effects, both acute and delayed:**
- Causes damage to organs if swallowed.
- Causes damage to organs if inhaled.
- Causes damage to organs through prolonged or repeated
exposure if swallowed.
Causes damage to organs through prolonged or repeated exposure if inhaled.
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.

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: 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

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 (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.

7. HANDLING AND STORAGE

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: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling: 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 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.

Avoidance of contact: Oxidizing agents

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.

Storage

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

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

Packaging material: Unsuitable material: None known.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>Formoterol</td>
<td>43229-80-7</td>
<td>TWA</td>
<td>0.05 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 0.5 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures:
Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. No open handling permitted. Totally enclosed processes and materials transport systems are required. Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

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:
Material: Chemical-resistant gloves
Remarks: Consider double gloving.

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

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: powder
Colour: No data available
Odour: No data available
<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odour Threshold</td>
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<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</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>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit and upper explosion limit / flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
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<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
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<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
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<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
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<tr>
<td>Density and / or relative density</td>
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</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
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<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Particle characteristics</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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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.

11. TOXICOLOGICAL INFORMATION

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

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

**Components:**

**Formoterol:**
- Acute oral toxicity: LD50 (Rat): 3,130 mg/kg
  - LD50 (Mouse): 6,700 mg/kg
- Acute inhalation toxicity: LC50 (Rat): 1.5 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
- Acute dermal toxicity: Remarks: No data available
- Acute toxicity (other routes of administration): LD50 (Rat): 1,000 mg/kg
  - Application Route: Subcutaneous
  - LD50 (Mouse): 640 mg/kg
  - Application Route: Subcutaneous

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

**Components:**

**Formoterol:**
- Species: Rabbit
- Result: No skin irritation
- Remarks: slight irritation
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Components:

Formoterol:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.

Components:

Formoterol:
Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

Germ cell mutagenicity
Not classified based on available information.

Components:

Formoterol:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosomal aberration
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Test Type: Micronucleus test
Species: Rat
Application Route: Oral
Result: negative

Carcinogenicity
Not classified based on available information.
Components:

Formoterol:

Species: Rat
Application Route: Oral
Exposure time: 2 Years
LOAEL: 0.5 mg/kg body weight
Target Organs: Ovary
Remarks: The mechanism or mode of action may not be relevant in humans.

Species: Mouse
Application Route: Oral
Exposure time: 18 month(s)
LOAEL: 2 mg/kg body weight
Target Organs: Adrenal gland, Liver, Uterus (including cervix)
Remarks: The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in animal studies

Reproductive toxicity
Not classified based on available information.

Components:

Formoterol:

Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Fertility: NOAEL: 3 mg/kg body weight
Result: No effects on fertility

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 0.2 mg/kg body weight
Result: Embryo-foetal toxicity, No malformations were observed.

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 3 mg/kg body weight
Result: Malformations were observed.

Test Type: Embryo-foetal development
Species: Rat
Application Route: inhalation (dust/mist/fume)
Developmental Toxicity: NOAEL: 1.2 mg/kg body weight
Result: No embryo-foetal toxicity

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 60 mg/kg body weight
Result: Embryo-foetal toxicity, No malformations were observed.

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

STOT - single exposure
Causes damage to organs (Cardio-vascular system, Central nervous system) if swallowed.
Causes damage to organs (Cardio-vascular system, Central nervous system) if inhaled.

Product:
- Exposure routes: Ingestion, Inhalation
- Target Organs: Cardio-vascular system, Central nervous system
- Assessment: Causes damage to organs.

Components:

Formoterol:
- Exposure routes: Ingestion, inhalation (dust/mist/fume)
- Target Organs: Cardio-vascular system, Central nervous system
- Assessment: Causes damage to organs.

STOT - repeated exposure
Causes damage to organs (Heart) through prolonged or repeated exposure if swallowed.
Causes damage to organs (Heart) through prolonged or repeated exposure if inhaled.

Product:
- Exposure routes: Inhalation, Ingestion
- Target Organs: Heart
- Assessment: Causes damage to organs through prolonged or repeated exposure.

Components:

Formoterol:
- Exposure routes: Ingestion, inhalation (dust/mist/fume)
- Target Organs: Heart
- Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Formoterol:
- Species: Dog
- LOAEL: >= 1.5 mg/kg
- Application Route: Inhalation
- Exposure time: 13 Weeks
- Target Organs: Heart
- Species: Rat
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<tr>
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</tr>
</tbody>
</table>

- **NOAEL**: 0.14 mg/kg
- **Application Route**: Inhalation
- **Exposure time**: 13 Weeks
- **Target Organs**: Heart

- **Species**: Dog
- **LOAEL**: 0.003 mg/kg
- **Application Route**: Oral
- **Exposure time**: 1 yr
- **Target Organs**: Heart

- **Species**: Rat
- **LOAEL**: 0.3 mg/kg
- **Application Route**: Oral
- **Exposure time**: 1 yr
- **Target Organs**: Heart

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

**Experience with human exposure**

**Components:**

**Formoterol:**
- **Inhalation**
  - **Target Organs**: Heart
  - **Symptoms**: Palpitation, Tremors, Dizziness, Headache, dry mouth, Nausea, Fatigue

12. **ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Formoterol:**
- **Toxicity to fish**
  - **LC50 (Oncorhynchus mykiss (rainbow trout))**: > 120 mg/l
  - **Exposure time**: 96 h
  - **Method**: OECD Test Guideline 203

- **Toxicity to daphnia and other aquatic invertebrates**
  - **EC50 (Daphnia magna (Water flea))**: > 114 mg/l
  - **Exposure time**: 48 h
  - **Method**: OECD Test Guideline 202

- **Toxicity to algae/aquatic plants**
  - **EC50 (Pseudokirchneriella subcapitata (green algae))**: 94 mg/l
  - **Exposure time**: 72 h
  - **Method**: OECD Test Guideline 201
  - **NOEC (Pseudokirchneriella subcapitata (green algae))**: 30 mg/l
  - **Exposure time**: 72 h
  - **Method**: OECD Test Guideline 201
Persistence and degradability
No data available

Bioaccumulative potential

Components:

Formoterol:
Partition coefficient: n-octanol/water
: log Pow: 0.41

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

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.

National Regulations
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.
Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law
Harmful Substances Prohibited from Manufacture
Not applicable
Harmful Substances Required Permission for Manufacture
Not applicable
Substances Prevented From Impairment of Health
Not applicable
Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable
Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable
Substances Subject to be Notified Names
Not applicable
Substances Subject to be Indicated Names
Not applicable
Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable
Ordinance on Prevention of Lead Poisoning
Not applicable
Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable
Ordinance on Prevention of Organic Solvent Poisoning
Not applicable
Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable
Poisonous and Deleterious Substances Control Law
Not applicable
Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable
High Pressure Gas Safety Act
Not applicable
Explosive Control Law
Not applicable
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Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation: Not classified as noxious liquid substance
Pack transportation: Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste
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
Date format: yyyy/mm/dd

Full text of other abbreviations

AICIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Con-
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.

JP / EN