SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Formoterol Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Rua Treze de Maio, 1161
           Campinas, São Paulo, Brazil 13106-054
Telephone : 908-740-4000
Emergency telephone : 55 19 3758 2000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
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 in accordance with ABNT NBR 14725 Standard
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
SAFETY DATA SHEET
Formoterol Formulation

Version 3.5  Revision Date: 09/13/2019  SDS Number: 525366-0001  Date of last issue: 24.04.2019
Date of first issue: 23.02.2016

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.

Other hazards which do not result in classification:
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

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formoterol</td>
<td>43229-80-7</td>
<td>Acute toxicity (Inhalation), Category 4 Carcinogenicity, Category 2 Reproductive toxicity, Category 2 Specific target organ toxicity - single exposure (Cardio-vascular system, Central nervous system), Category 1 Specific target organ toxicity - repeated exposure (Heart), Category 1 Short-term (acute) aquatic hazard, Category 3</td>
<td>&gt;= 0,025 &lt; 0,1</td>
</tr>
</tbody>
</table>

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 immediately.

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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.

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

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: Use personal protective equipment.
<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>SAFETY DATA SHEET</strong></td>
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<td><strong>Revision Date:</strong></td>
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</tr>
<tr>
<td>525366-0001</td>
<td><strong>Date of first issue:</strong> 23.02.2016</td>
</tr>
<tr>
<td><strong>tive equipment and emer-</strong></td>
<td><strong>Follow safe handling advice and personal protective</strong></td>
</tr>
<tr>
<td><strong>gency procedures</strong></td>
<td><strong>equipment recommendations.</strong></td>
</tr>
<tr>
<td><strong>Environmental precautions</strong></td>
<td><strong>Discharge into the environment must be avoided.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Prevent further leakage or spillage if safe to do so.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Retain and dispose of contaminated wash water.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Local authorities should be advised if significant spillages cannot be contained.</strong></td>
</tr>
<tr>
<td><strong>Methods and materials for containment and cleaning up</strong></td>
<td><strong>Sweep up or vacuum up spillage and collect in suitable container for disposal.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).</strong></td>
</tr>
<tr>
<td></td>
<td><strong>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.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>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.</strong></td>
</tr>
</tbody>
</table>

**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** | **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.** |
|  | **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.** |

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### Conditions for safe storage
- Keep in properly labeled 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
  - Organic peroxides
  - Explosives
  - Gases

### 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>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>Wipe limit</td>
<td>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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- **Appearance**: powder
- **Color**: No data available
- **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 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.
- **Flammability (liquids)**: No data available
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapor pressure**: Not applicable
- **Relative vapor density**: Not applicable
- **Relative density**: No data available
- **Density**: No data available
- **Solubility(ies)**
  - **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: Not applicable
- **Autoignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**
  - **Viscosity, kinematic**: Not applicable
- **Explosive properties**: Not explosive
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Oxidizing properties: The substance or mixture is not classified as oxidizing.

Particle size: No data available

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.

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

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

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:
Formoterol:
Test Type: Maximization Test
Routes of exposure: 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 fetal development
Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 0.2 mg/kg body weight
Result: Embryo-fetal toxicity, No malformations were observed.

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

Test Type: Embryo-fetal development
Species: Rat
Application Route: inhalation (dust/mist/fume)
Developmental Toxicity: NOAEL: 1.2 mg/kg body weight
Result: No embryo-fetal toxicity.
Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 60 mg/kg body weight  
Result: Embryo-fetal 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:**  
Routes of exposure : Ingestion, Inhalation  
Target Organs : Cardio-vascular system, Central nervous system  
Assessment : Causes damage to organs.

**Components:**  
Formoterol:  
Routes of exposure : 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:**  
Routes of exposure : Inhalation, Ingestion  
Target Organs : Heart  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Components:**  
Formoterol:  
Routes of exposure : 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
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 y

Target Organs: Heart

Species: Rat
LOAEL: 0,3 mg/kg
Application Route: Oral
Exposure time: 1 y

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

SECTION 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

Other adverse effects
No data available

SECTION 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.

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

ANTT
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH): Not applicable

Brazil. Ordinance No. 1274 on the control and: Not applicable
monitoring of chemicals.

**International Regulations**

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**

Sources of key data used to compile the Material Safety Data Sheet:


**Full text of other abbreviations**

- **AICS** - Australian Inventory of Chemical Substances; **ANTT** - National Agency for Transport by Land of Brazil; **ASTM** - American Society for the Testing of Materials; **bw** - Body weight; **CMR** - Carcinogen, Mutagen or Reproductive Toxicant; **DIN** - Standard of the German Institute for Standardisation; **DSL** - Domestic Substances List (Canada); **ECx** - Concentration associated with x% response; **ELx** - Loading rate associated with x% response; **EmS** - Emergency Schedule; **ENCS** - Existing and New Chemical Substances (Japan); **ErCx** - Concentration associated with x% growth rate response; **ERG** - Emergency Response Guide; **GHS** - Globally Harmonized System; **GLP** - Good Laboratory Practice; **IARC** - International Agency for Research on Cancer; **IATA** - International Air Transport Association; **IBC** - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; **IC50** - Half maximal inhibitory concentration; **ICAO** - International Civil Aviation Organization; **IECSC** - Inventory of Existing Chemical Substances in China; **IMDG** - International Maritime Dangerous Goods; **IMO** - International Maritime Organization; **ISHL** - Industrial Safety and Health Law (Japan); **ISO** - International Organisation for Standardization; **KECI** - Korea Existing Chemicals Inventory; **LD50** - Lethal Dose to 50% of a test population; **LC50** - Lethal Concentration to 50% of a test population; **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; **PCCS** - 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; **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
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.

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