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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Formoterol Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address Rua Treze de Maio, 1161

Campinas, São Paulo, Brazil 13106-054

Telephone +55 (19) 3758-2000

Emergency telephone : +55 (11) 3173-4931

E-mail address EHSSTEWARD@organon.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 ABNT NBR 14725 Standard

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

single exposure (Oral)

single exposure (Inhalation)

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

Specific target organ toxicity - : Category 1 (Heart)

repeated exposure (Oral)

Specific target organ toxicity - : Category 1 (Heart)

repeated exposure

(Inhalation)

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,



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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.

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

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Formoterol	43229-80-7	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	>= 0,025 -< 0,1

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical





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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. Contact with dust can cause mechanical irritation or drying of

Most important symptoms : and effects, both acute and

delayed

the skin

Dust contact with the eyes can lead to mechanical irritation.

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.

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 prod: :

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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

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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

Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air. Add excess liquid to allow the material to enter into solution.

Soak up with inert absorbent material.

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. Clean up remaining materials from spill with suitable

absorbent.

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 : 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.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place.

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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.

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

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Formoterol	43229-80-7	TWA	0.05 μg/m3 (OEB 5)	Internal
		Wipe limit	0.5 µg/100 cm ²	Internal

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 Hand protection Particulates type

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.

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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

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No data available Autoignition temperature

Decomposition temperature No data available

Viscosity

Viscosity, kinematic Not applicable

Explosive properties Not explosive

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 reac-

tions

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. Oxidizing agents

Incompatible materials

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

LC50 (Rat): 1,5 mg/l Acute inhalation toxicity

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

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Application Route: Subcutaneous

Skin corrosion/irritation

Not classified based on available information.

Components:

Formoterol:

Species : Rabbit

Result : No skin irritation
Remarks : slight irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Formoterol:

Species : Rabbit

Result : No eye 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 syn-

thesis in mammalian cells (in vitro)

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test



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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 hu-

mans.

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 hu-

mans.

Carcinogenicity - Assess-

ment

: 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



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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 - As-

sessment

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.

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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 : EC50 (Daphnia magna (Water flea)): > 114 mg/l



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aquatic invertebrates 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.

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

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ANTT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - : Not applicable

(LINACH)

Brazil. List of chemicals controlled by the Federal

Police

: Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

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Further information

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Data Sheet cy, http://echa.europa.eu/

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of other abbreviations

AlIC - 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 Chemi-



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cal 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; 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

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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