

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

Formoterol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
4.0	04.04.2023	530776-00019	Date of first issue: 23.02.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Formoterol Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-
stance/Mixture : Pharmaceutical

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.
30 Hudson Street, 33rd floor
07302 Jersey City, New Jersey, U.S.A

Telephone : +1-551-430-6000

E-mail address of person
responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number

+1-215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Specific target organ toxicity - single exposure, Category 1, Cardio-vascular system, Central nervous system H370: Causes damage to organs if swallowed.

Specific target organ toxicity - single exposure, Category 1, Cardio-vascular system, Central nervous system H370: Causes damage to organs if inhaled.

Specific target organ toxicity - repeated exposure, Category 1, Heart H372: Causes damage to organs through prolonged or repeated exposure if swallowed.

Specific target organ toxicity - repeated exposure, Category 1, Heart H372: Causes damage to organs through prolonged or repeated exposure if inhaled.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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- 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.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)

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Formoterol	43229-80-7	Acute Tox. 4; H332 Carc. 2; H351 Repr. 2; H361d STOT SE 1; H370 (Cardio-vascular system, Central nervous system) STOT RE 1; H372 (Heart)	< 0.1
		Acute toxicity estimate	
		Acute inhalation toxicity (dust/mist): 1.5 mg/l	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
- 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).
- 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.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.
- Causes damage to organs if swallowed.
Causes damage to organs if inhaled.

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Causes damage to organs through prolonged or repeated exposure if swallowed.
Causes damage to organs through prolonged or repeated exposure if inhaled.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.

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Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Surround spill with absorbents and place a damp covering over the area to minimise 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working

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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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

	dusts non-specific	4 mg/m ³ Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust) Basis: IE OEL
		10 mg/m ³ Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust) Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Formoterol	43229-80-7	TWA	0.05 µg/m ³ (OEB 5)	Internal
		Wipe limit	0.5 µg/100 cm ²	Internal

8.2 Exposure controls

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.

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Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

Personal protective equipment

Eye/face 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.
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
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.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
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
Flash point	:	Not applicable
Auto-ignition temperature	:	No data available

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Decomposition temperature : No data available

pH : No data available

Viscosity

|| Viscosity, kinematic : Not applicable

Solubility(ies)

Water solubility : No data available

|| Partition coefficient: n-octanol/water : Not applicable

|| Vapour pressure : Not applicable

|| Relative density : No data available

Density : No data available

|| Relative vapour density : Not applicable

Particle characteristics

Particle size : No data available

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

|| Evaporation rate : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Formoterol:

Species : Rabbit
Result : No eye irritation

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Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory 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 hu-

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|| 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 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.

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

Species : Dog

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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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

Formoterol:

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

SECTION 12: Ecological information

12.1 Toxicity

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

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NOEC (Pseudokirchneriella subcapitata (green algae)): 30 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

Formoterol:



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

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods



Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. 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.

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SECTION 14: Transport information

14.1 UN number or ID number

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

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SECTION 15: Regulatory information

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

- REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable
- REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
- Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
- Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
- Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
- REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
- Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

		Quantity 1	Quantity 2
H3	STOT SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE	50 t	200 t

Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

- Other information : 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 H-Statements

- H332 : Harmful if inhaled.
- H351 : Suspected of causing cancer.
- H361d : Suspected of damaging the unborn child.
- H370 : Causes damage to organs.
- H372 : Causes damage to organs through prolonged or repeated

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exposure.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Carc. : Carcinogenicity
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure
Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Classification of the mixture:

STOT SE 1 H370
STOT SE 1 H370

Classification procedure:

Based on product data or assessment
Based on product data or assessment

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Formoterol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
4.0	04.04.2023	530776-00019	Date of first issue: 23.02.2016

STOT RE 1	H372	Based on product data or assessment
STOT RE 1	H372	Based on product data or assessment

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

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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