

SAFETY DATA SHEETS

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P272 Contaminated work clothing must not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P391 Collect spillage.

Disposal:

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

Other hazards

SUSPENSION IN DELIVERY DEVICE:

As a result of the physical presentation of the product, the risk to health in the normal handling of the product is expected to be low.

Exposure to the content of crushed container may cause adverse health effects.

Liquid splashes or spray may cause freeze burns to skin and eyes.

High exposures by inhalation may produce anesthetic effects.

Higher concentrations may cause asphyxiation due to the reduced oxygen content of the atmosphere.

Can be absorbed through skin causing systemic toxic effects.

See Section 11.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
1,1,1,2,3,3,3-heptafluoropropane (HFC 227)	431-89-0	98 - <= 100
Budesonide	51333-22-3	0.06 - 0.243
Formoterol fumarate dihydrate	43229-80-7	0.007

SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure, keep warm and at rest. Obtain medical attention.

In case of skin contact : Thaw affected areas with water. Remove contaminated clothing. Caution: clothing may adhere to the skin in the case of freeze burns. After contact with skin, wash immediately with plenty of warm water. Obtain medical attention if ill effects occur.

In case of eye contact : Immediately irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain immediate medical attention.

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- If swallowed : Unlikely route of exposure.
Wash out mouth with water and give 200-300ml of water to drink.
Do NOT induce vomiting.
Obtain immediate medical attention.
- Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11
May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.
- Notes to physician : Symptomatic treatment and supportive therapy as indicated.
For further detail consult the prescribing information.
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SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : water spray, foam, dry chemical or CO₂.
Water spray should be used to cool containers.
- Unsuitable extinguishing media : Do not use water jet.
- Specific hazards during fire fighting : Thermal decomposition will evolve toxic and corrosive vapours.
Heating of containers may cause pressure rise with risk of explosion.
- Special protective equipment for fire-fighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.
Prevent fire extinguishing water from contaminating surface water or the ground water system.
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SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Ensure adequate ventilation.
Do not breathe vapor.
Ensure suitable personal protection during removal of spillages.
See Section 8.
- Environmental precautions : Avoid release of gas to the environment.
Collect spillage.
- Methods and materials for containment and cleaning up : Isolate the source of the leak if safe to do so.
Ventilate area.
Allow small spillages to evaporate provided there is adequate ventilation.
Take care to avoid broken containers.
Transfer spilled containers to a suitable container for disposal.

See section 13.
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SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : Avoid contact with skin and eyes.
Avoid inhalation.
Liquid splashes or spray may cause freeze burns to skin and eyes.
See Section 8.
Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50 °C. Do not pierce or

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Conditions for safe storage : burn, even after use.
 : Keep container tightly closed in a dry and well-ventilated place.
 Do not freeze.
 Keep away from heat and direct sunlight.
 Store away from incompatible materials (see Section 10).

Recommended storage temperature : < 77 °F / < 77 °F

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Budesonide	51333-22-3	TWA	0.01 mg/m ³	COM; HYG; Sk
Formoterol fumarate dihydrate	43229-80-7	TWA	0.0002 mg/m ³	COM; HYG

Engineering measures : The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Prevent entry into drains, sewers or watercourses.
 See Section 6 for environmental precautions.

Personal protective equipment

Respiratory protection : As necessary, use NIOSH approved respiratory protection device consistent with the work place risk assessment.

Eye protection : Wear appropriate eye protection.

Skin and body protection : Use impervious clothing to protect against direct contact with the liquid or for repeated, excessive handling use full chemical protective suit if the risk assessment does not support the selection of other protection. Use chemical protective gloves with a permeation time greater than the activity duration. Take note of the information given by the PPE producer/supplier concerning permeability and breakthrough times and special workplace conditions.

Protective measures : Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc. All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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Appearance : Liquefied gas

Color : colorless

Odor : odorless

Odor Threshold : No data available

pH : No data available

Melting point/range : No data available

Initial boiling point and boiling range : 2.30 °F / 2.30 °F

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : The product is not flammable.

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : 390 hPa (68 °F / 68 °F)

Relative vapor density : No data available

Relative density : 1.41 (77 °F / 77 °F)

Solubility(ies)

 Water solubility : 0.23 g/l (77 °F / 77 °F)

 Solubility in other solvents : No data available

Partition coefficient: n-octanol/water : log Pow: 2.3

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

 Viscosity, dynamic : No data available

 Viscosity, kinematic : No data available

Explosive properties : No data available

Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No known reactivity hazard under normal conditions.
Chemical stability : Stable under normal conditions.

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Possibility of hazardous reactions : Can react with strong oxidizing agents
alkali metals
alkaline earth metals

Conditions to avoid : Contains gas under pressure; may explode if heated.
Incompatible materials : Light metals
Alkali metals
Alkaline earth metals
Powdered metals
Oxidizing agents

Hazardous decomposition products : Hydrogen fluoride

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Acute toxicity

Not classified based on available information.

Components:

1,1,1,2,3,3,3-heptafluoropropane (HFC 227):

Acute oral toxicity : Remarks: Low acute oral toxicity.

Acute inhalation toxicity : Remarks: High atmospheric concentrations may lead to anesthetic effects.

Acute dermal toxicity : Remarks: Spray may cause freeze burns.

Budesonide:

Acute oral toxicity : LD50 Oral (Rat): 400 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.

Acute inhalation toxicity : Remarks: May cause effects as described under single exposure.(STOT)

Acute dermal toxicity : Remarks: Can be absorbed through skin causing systemic toxic effects.

Formoterol fumarate dihydrate:

Acute oral toxicity : Remarks: May cause effects as described under single exposure.(STOT)

Acute inhalation toxicity : LC50 (Rat): 1.35 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : Remarks: No information available.

11.2 Skin corrosion/irritation

Not classified based on available information.

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Components:**1,1,1,2,3,3,3-heptafluoropropane (HFC 227):**

Remarks : Spray may cause freeze burns.

Budesonide:

Remarks : May cause slight skin irritation.

Formoterol fumarate dihydrate:

Remarks : No information available.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:**1,1,1,2,3,3,3-heptafluoropropane (HFC 227):**

Remarks : Spray may cause freeze burns.

Budesonide:Remarks : May cause slight eye irritation.
May cause corneal ulcers and reduced visual function.
May cause cataracts and viral infection.**Formoterol fumarate dihydrate:**

Remarks : No information available.

11.4 Respiratory or skin sensitization**Skin sensitization**

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:**1,1,1,2,3,3,3-heptafluoropropane (HFC 227):**

Remarks : No information available.

Budesonide:

Result : May cause sensitization by skin contact.

Formoterol fumarate dihydrate:

Remarks : No information available.

11.5 Germ cell mutagenicity

Not classified based on available information.

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Components:**1,1,1,2,3,3,3-heptafluoropropane (HFC 227):**

Germ cell mutagenicity - Assessment : There is no evidence of mutagenic potential in in vitro tests.

Budesonide:

Germ cell mutagenicity - Assessment : There is no evidence of genotoxic potential in in vitro and in vivo tests.

Formoterol fumarate dihydrate:

Germ cell mutagenicity - Assessment : There is no evidence of genotoxic potential in in vitro and in vivo tests.

11.6 Carcinogenicity

Not classified based on available information.

Components:**1,1,1,2,3,3,3-heptafluoropropane (HFC 227):**

Carcinogenicity - Assessment : No information available.

Budesonide:

Carcinogenicity - Assessment : No evidence of carcinogenicity in animal studies.

Formoterol fumarate dihydrate:

Carcinogenicity - Assessment : The substance is not considered to be carcinogenic.

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

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

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

11.7 Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Components:**1,1,1,2,3,3,3-heptafluoropropane (HFC 227):**

Reproductive toxicity - Assessment : No toxicity to reproduction

Budesonide:

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

Formoterol fumarate dihydrate:

Reproductive toxicity - Assessment : Some embryofetal development effects in rats and rabbits at high doses.

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11.8 STOT-single exposure

Not classified based on available information.

Components:

1,1,1,2,3,3,3-heptafluoropropane (HFC 227):

Remarks : No specific effects reported.

Budesonide:

Routes of exposure : Inhalation
Remarks : May cause Candida infections and mild irritation in the throat, coughing and hoarseness.
May cause effects as described under repeated exposure.(STOT)

Routes of exposure : Dermal
Remarks : May cause eruption-like acne.
May cause effects as described under repeated exposure.(STOT)

Formoterol fumarate dihydrate:

Routes of exposure : inhalation (dust/mist/fume)
Target Organs : Heart
Assessment : Causes damage to organs.

Routes of exposure : Oral
Target Organs : Heart
Assessment : Causes damage to organs.

Remarks : These effects are derived from studies in animals.
Dust, if inhaled even in small amounts, can cause violent palpitation, trembling, headache and widening of the bronchii.
Rare cases of hypersensitivity reactions have been reported.

11.9 STOT-repeated exposure

Not classified based on available information.

Components:

1,1,1,2,3,3,3-heptafluoropropane (HFC 227):

Remarks : No information available.

Budesonide:

Routes of exposure : inhalation (dust/mist/fume)
Target Organs : Adrenal gland
Assessment : Causes damage to organs through prolonged or repeated exposure.

Routes of exposure : Oral
Target Organs : Adrenal gland
Assessment : Causes damage to organs through prolonged or repeated exposure.

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Routes of exposure : Dermal
Target Organs : Adrenal gland
Assessment : Causes damage to organs through prolonged or repeated exposure.

Remarks : Repeated exposure may produce oedema (water retention), high blood pressure, blurred vision, peptic ulcers, demineralization of bone, fatigue and suppression of adrenal gland function.

Formoterol fumarate dihydrate:

Routes of exposure : inhalation (dust/mist/fume)
Target Organs : Heart
Assessment : Causes damage to organs through prolonged or repeated exposure.

Routes of exposure : Oral
Target Organs : Heart
Assessment : Causes damage to organs through prolonged or repeated exposure.

Remarks : Tachycardia and musculoskeletal and connective tissue disorders and muscle cramps have been reported. Common side effects reported from patients include palpitations, headache and tremor.

11.10 Aspiration toxicity

Not classified based on available information.

Components:

1,1,1,2,3,3,3-heptafluoropropane (HFC 227):

No information available.

Budesonide:

No data available

Formoterol fumarate dihydrate:

No information available.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Budesonide:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 13 mg/l
End point: mortality
Exposure time: 96 h
Method: OECD Test Guideline 203

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Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 14 mg/l
End point: Immobilization
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (green algae): > 7.9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (green algae): 7.9 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 0.000032 mg/l
End point: mortality
Exposure time: 28 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 3.4 mg/l
Exposure time: 21 d
Test Type: Reproduction Test
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1,000

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Formoterol fumarate dihydrate:

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 : ErC50 (Selenastrum capricornutum (green algae)): 94 mg/l
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201

Persistence and degradability

Components:

Budesonide:

Biodegradability : aerobic
Biodegradation: < 5 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Result: not rapidly degradable

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IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Not On TSCA Inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CHINV - China Inventory; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM - In-house occupational exposure limit; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; HYG - Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; 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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; Sen - Capable of causing respiratory sensitization; Sk - Can be absorbed through skin, thus contributing to systemic effects; STEL - Short-term exposure limit 15-minutes time-weighted average; TLV - Threshold Limit Value (ACGIH); TLV-C - Threshold Limit Value Ceiling limit (ACGIH); TRINV - Turkey Inventory; TSCA - Toxic Substances Control Act (United States); TWA - Long-term exposure limit 8h time-weighted average; UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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