

Formoterol Fumarate

sc-203050



The Power to Question

Material Safety Data Sheet

Hazard Alert Code
Key:

EXTREME

HIGH

MODERATE

LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

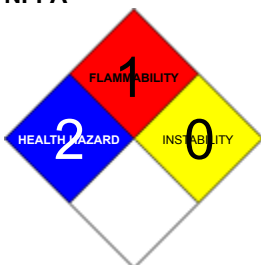
PRODUCT NAME

Formoterol Fumarate

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER

Santa Cruz Biotechnology, Inc.
2145 Delaware Avenue
Santa Cruz, California 95060
800.457.3801 or 831.457.3800

EMERGENCY

ChemWatch
Within the US & Canada: 877-715-9305
Outside the US & Canada: +800 2436 2255
(1-800-CHEMCALL) or call +613 9573 3112

SYNONYMS


(C₁₉H₂₄N₂O₄)·2C₄H₄O₄·2H₂O, C₁₉H₂₄N₂O₄·1/2(C₄H₄O₄)·2H₂O, "formamide, N-[2-hydroxy-5-(1-hydroxy-2-((2-(4-methoxyphenyl)-1-), "methylethyl)amino)ethyl)phenyl]-, (E)-2-butenedioate (21) (salt) dihydrate", "(R*, R*)-(+/-)-N-[2-hydroxy-5-(1-hydroxy-2-((2-(4-methoxyphenyl)-1-), "methylethyl)amino)ethyl)phenyl]formamide fumarate dihydrate", 3-formylamino-4-hydroxy-alpha-[N-(1-methyl-2-(p-methoxyphenyl)ethyl)-, "aminomethyl]benzyl alcohol fumarate dihydrate", "(+/-)-2'-hydroxy-5' -[(RS)-1-hydroxy-2-(((RS)-p-methoxy-alpha-, methylphenethyl)amino)ethylformanilide, Atock, BD-40A, "anti-asthmatic/ bronchodilator/ beta-2-adrenergic sympathomimetic"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

	Min	Max
Flammability	1	Min/Nil=0 Low=1
Toxicity	4	Moderate=2 High=3
Body Contact	0	Extreme=4



Reactivity	1	
Chronic	2	

CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

Toxic by inhalation.

Possible risk of impaired fertility.

Possible risk of harm to the unborn child.

Toxic danger of serious damage to health by prolonged exposure through inhalation.

Very toxic danger of very serious irreversible effects if swallowed.

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- Toxic effects may result from the accidental ingestion of the material; animal experiments indicate that ingestion of less than 40 gram may be fatal or may produce serious damage to the health of the individual.

- There is strong evidence to suggest that this material, if swallowed once, can cause very serious, irreversible damage of organs.

- At sufficiently high doses, the material may be toxic to the heart.

- Phenethylamines produce effects similar to amphetamines.

They excite the nervous system, causing shortness of breath, cough, narrowing of the airways and throat spasms.

EYE

- Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn).

Slight abrasive damage may also result.

SKIN

- Skin contact is not thought to produce harmful health effects (as classified under EC Directives using animal models).

Systemic harm, however, has been identified following exposure of animals by at least one other route and the material may still produce health damage following entry through wounds, lesions or abrasions.

- Open cuts, abraded or irritated skin should not be exposed to this material.

- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.

Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

- Inhalation of dusts, generated by the material, during the course of normal handling, may produce toxic effects.

- The material is not thought to produce respiratory irritation (as classified by EC Directives using animal models).

Nevertheless inhalation of dusts, or fumes, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.

- Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.

- Sympathomimetics, which mimic stimulation of the sympathetic nerves, cause a stimulatory effect on the heart and central nervous system, constriction of blood vessels supplying the skin and mucous membranes, dilation of blood vessels supplying muscles of movement, and widening of the airways.

These drugs may act on the receptor or the release of the neurotransmitter noradrenaline.

- Stimulation of heart beta-1 adrenergic receptors may cause increased heart rate and irregularity of heartbeat,

tightness and a constricting pain in the chest, palpitations and heart stoppage; low blood pressure with dizziness, fainting and flushing may also occur.

Beta-1 receptors mediate the action of sympathomimetics; beta-2 receptors control dilation of the airways.

CHRONIC HEALTH EFFECTS

■ Toxic danger of serious damage to health by prolonged exposure through inhalation.

This material can cause serious damage if one is exposed to it for long periods. It can be assumed that it contains a substance which can produce severe defects. This has been demonstrated via both short- and long-term experimentation.

Ample evidence from experiments exists that there is a suspicion this material directly reduces fertility.

Based on experience with animal studies, exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother.

Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.

Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung. Prime symptom is breathlessness; lung shadows show on X-ray.

Chronic exposure to phenethylamines excite the central nervous system and induce tolerance; in extreme cases they produce amphetamine-like responses including personality changes, compulsive and stereotyped behaviour and may induce psychosis with auditory and visual hallucinations and paranoid delusions.

Repeated exposure of animals to low levels produce adverse effects on the heart.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
formoterol fumarate dihydrate	43229-80-7	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

- IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.
- For advice, contact a Poisons Information Centre or a doctor.
- Urgent hospital treatment is likely to be needed.
- In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition.

EYE

If this product comes in contact with the eyes

- Immediately hold eyelids apart and flush the eye continuously with running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.
- Transport to hospital or doctor without delay.

SKIN

If skin or hair contact occurs

- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

INHALED

- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.

NOTES TO PHYSICIAN

■ for isoprenaline intoxication

- Tachycardia and cardiac arrhythmias induced by beta-2-adrenergic agonists may be diminished by propranolol but this must NOT be given to asthmatics because of the risk of increasing bronchoconstriction.
- Cautious use of cardioselective beta-adrenergic blocking agents such as metoprolol (5-10 mg by slow intravenous injection, repeated if necessary after 5 minutes) may be indicated in asthma patients.

MARTINDALE & AAP Guide.

Section 5 - FIRE FIGHTING MEASURES

Vapor Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available
Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available

EXTINGUISHING MEDIA

- Water spray or fog.
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.
- Prevent, by any means available, spillage from entering drains or water course.
- Use fire fighting procedures suitable for surrounding area.

When any large container (including road and rail tankers) is involved in a fire, consider evacuation by 800 metres in all directions.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

- Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds.; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.
- In the same way as gases and vapors, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL).are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC)
- A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people.

Combustion products include carbon monoxide (CO), carbon dioxide (CO₂), nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

FIRE INCOMPATIBILITY

- Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Clean up waste regularly and abnormal spills immediately.

- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.

MAJOR SPILLS

- Clear area of personnel and move upwind.
- Alert Fire Brigade and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.
- Prevent, by any means available, spillage from entering drains or water course.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.

- Do NOT cut, drill, grind or weld such containers.
- In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS

- Glass container is suitable for laboratory quantities
- Lined metal can, lined metal pail/ can.
- Plastic pail.
- Polyliner drum.
- Packing as recommended by manufacturer.

For low viscosity materials

- Drums and jerricans must be of the non-removable head type.
- Where a can is to be used as an inner package, the can must have a screwed enclosure.

<. All inner and sole packagings for substances that have been assigned to Packaging Groups I or II on the basis of inhalation toxicity criteria, must be hermetically sealed.

STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- formoterol fumarate dihydrate CAS43229-80-7 CAS83536-10-1 CAS87481-49-0 CAS183814-30-4

PERSONAL PROTECTION



RESPIRATOR

- Particulate. (AS/NZS 1716 & 1715, EN 1432000 & 1492001, ANSI Z88 or national equivalent)

EYE

- Chemical protective goggles with full seal
- Shielded mask (gas-type)
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]

HANDS/FEET

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity
- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Protective shoe covers. [AS/NZS 2210]

OTHER

- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.

ENGINEERING CONTROLS

- For potent pharmacological agents

Powders

To prevent contamination and overexposure, no open handling of powder should be allowed.

- Powder handling operations are to be done in a powders weighing hood, a glove box, or other equivalent ventilated containment system.
- In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used.
- Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs.
- An air-purifying respirator should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.).

Unless written procedures, specific to the workplace are available, the following is intended as a guide

- For Laboratory-scale handling of Substances assessed to be toxic by inhalation. Quantities of up to 25 grams may be handled in Class II biological safety cabinets *; Quantities of 25 grams to 1 kilogram may be handled in Class II biological safety cabinets* or equivalent containment systems; Quantities exceeding 1 kg may be handled either using specific containment, a hood or Class II biological safety cabinet*,
- HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.
- The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated. Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated. When handling Quantities of up to 25 grams, an approved respirator with HEPA filters or cartridges should be considered; Quantities of 25 grams to 1 kilogram, a

half-face negative pressure, full negative pressure, or powered helmet-type air purifying respirator should be considered. Quantities in excess of 1 kilogram, a full face negative pressure, helmet-type air purifying, or supplied air respirator should be considered.

Written procedures, specific to a particular work-place, may replace these recommendations

* For Class II Biological Safety Cabinets, Types B2 or B3 should be considered.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.

Mixes with water.

State	Divided solid	Molecular Weight	840.9
Melting Range (°F)	280- 284;154-155	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Miscible
Flash Point (°F)	Not available	pH (1% solution)	Not available
Decomposition Temp (°F)	Not Available	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available	Vapor Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	Not applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

APPEARANCE

Crystalline powder; mixes with water. Occurs as an A and B racemate.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

STORAGE INCOMPATIBILITY

- Protect from light.
- Avoid reaction with oxidizing agents

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

formoterol fumarate dihydrate

TOXICITY AND IRRITATION

- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

Section 12 - ECOLOGICAL INFORMATION

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

This material and its container must be disposed of as hazardous waste.

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

- Containers may still present a chemical hazard/ danger when empty.
- Return to supplier for reuse/ recycling if possible.

Otherwise:

- If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.
- Where possible retain label warnings and MSDS and observe all notices pertaining to the product.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. In most instances the supplier of the material should be consulted.

- DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
- Where in doubt contact the responsible authority.
- Recycle wherever possible.
- Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
- Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or Incineration in a licenced apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14 - TRANSPORTATION INFORMATION

DOT:

Symbols:	None	Hazard class or Division:	6.1
Identification Numbers:	UN3249	PG:	II
Label Codes:	6.1	Special provisions:	T3, TP33
Packaging: Exceptions:	153	Packaging: Non-bulk:	212
Packaging: Exceptions:	153	Quantity limitations: Passenger aircraft/rail:	5 kg
Quantity Limitations: Cargo aircraft only:	5 kg	Vessel stowage: Location:	C
Vessel stowage: Other:	40		

Hazardous materials descriptions and proper shipping names:

Medicine, solid, toxic, n.o.s.

Air Transport IATA:

ICAO/IATA Class:	6.1	ICAO/IATA Subrisk:	None
UN/ID Number:	3249	Packing Group:	II
Special provisions:	A3		
Cargo Only			
Packing Instructions:	676	Maximum Qty/Pack:	100 kg

Passenger and Cargo		Passenger and Cargo	
Packing Instructions:	669	Maximum Qty/Pack:	25 kg
Passenger and Cargo Limited Quantity		Passenger and Cargo Limited Quantity	
Packing Instructions:	Y644	Maximum Qty/Pack:	1 kg
Shipping name: MEDICINE, SOLID, TOXIC, N.O.S. (contains formoterol fumarate dihydrate)			
Maritime Transport IMDG:			
IMDG Class:	6.1	IMDG Subrisk:	None
UN Number:	3249	Packing Group:	II
EMS Number:	F-A,S-A	Special provisions:	221
Limited Quantities:	500 g		
Shipping name: MEDICINE, SOLID, TOXIC, N.O.S. (contains formoterol fumarate dihydrate)			

Section 15 - REGULATORY INFORMATION

No data for formoterol fumarate dihydrate (CAS: , 43229-80-7, 83536-10-1, 87481-49-0, 183814-30-4)

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Cumulative effects may result following exposure*.
- * (limited evidence).

Ingredients with multiple CAS Nos

Ingredient Name	CAS
formoterol fumarate dihydrate	43229-80-7, 83536-10-1, 87481-49-0, 183814-30-4

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- Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references. A list of reference resources used to assist the committee may be found at: www.chemwatch.net/references.
- The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings.

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