

Mometasone Furoate

sc-211919

Material Safety Data Sheet



The Power is Question

Hazard Alert Code Key:

EXTREME

HIGH

MODERATE

LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

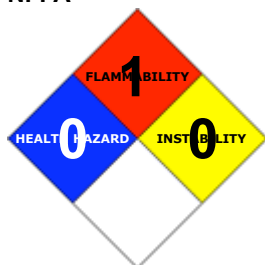
PRODUCT NAME

Mometasone Furoate

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER

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

SYNONYMS

C27-H30-Cl2-O6, "mometasone furoate monohydrate (CAS 102113-40-6)", "pregna-1, 4-diene-3, 20-dione, 9, 21-dichloro-17-[(2", furanylcarbonyl)oxy]-, "11-hydroxy-16-methyl-, (11beta, 16alpha)", "9alpha, 21-dichloro-11beta, 17-dihydroxy-16alpha-methylpregna-1, 4-diene-", "3, 20-dione 17-(2-furoate)", Elocon, SCH-32088, "synthetic corticosteroid", corticoid

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

| | | Min | Max | |
|---------------|---|-----|-----|---------------------|
| Flammability: | 1 | | | |
| Toxicity: | 2 | | | |
| Body Contact: | 3 | | | Min/Nil=0 Low=1 |
| Reactivity: | 1 | | | Moderate=2 |
| Chronic: | 3 | | | High=3 Extreme=4 |

CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- Accidental ingestion of the material may be damaging to the health of the individual.
- The corticosteroids cause alterations in metabolism of fats, proteins and carbohydrates, and affect a range of organs in the body including the heart, muscle and kidneys. Blood chemistry may change and there is decreased activity and shrinkage of the thymus gland, adrenal glands, spleen and lymph nodes.

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EYE

- If applied to the eyes, this material causes severe eye damage.
- When applied to the eye, corticosteroids may produce ulceration of the cornea, raised eye pressure and reduced vision; internal administration can cause cataracts.

SKIN

- The material is not thought to be a skin irritant (as classified using animal models). Abrasive damage however, may result from prolonged exposures.

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- Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.
- 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.
- Topically applied corticosteroids may be absorbed in sufficient quantity to produce systemic effects. Application to the skin may result in collagen loss and subcutaneous atrophy and local bleaching of deeply pigmented skin.

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INHALED

- The material is not thought to produce respiratory irritation (as classified using animal models). Nevertheless inhalation of dusts, or fume, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.
- Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual.
- 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.
- Systemic absorption of aerosols containing corticosteroids may produce adrenal insufficiency and collapse.

CHRONIC HEALTH EFFECTS

- Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

There is limited evidence that, skin contact with this product is more likely to cause a sensitization reaction in some persons compared to the general population.

There is some evidence that human exposure to the material may result in developmental toxicity. This evidence is based on animal studies where effects have been observed in the absence of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not secondary non-specific consequences of the other toxic effects.

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.

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Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Chronic exposure to glucocorticoids can lead to changes in hormone production, a characteristic "moon face" appearance and a "lemon with matchsticks" fat distribution (central obesity with wasting of limbs), susceptibility to infections, osteoporosis, cataracts, glaucoma, mental disturbance, high blood sugar and sugar in the urine. There may be muscular weakness and fatigue, acne, period disturbances in women and peptic ulcers.

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In a paediatric one-month gavage study with rats, at doses ranging from 0.5 to 125 micrograms/kg, thymus and mesenteric lymph nodes were identified as target organs. The no-effect level for the corticosteroid and progesterone-like pharmacological properties of mometasone furoate, was 5 microgram/kg and greater than or equal to 125 micrograms/kg, respectively. In a paediatric one-month study with dogs at doses ranging from 0.05 to 2.5 micrograms/kg, the liver, lymphoid tissues, adrenal gland and skin were identified as target organs. The no-effect level for these corticosteroid-like pharmacological effects of the material were not identified in this study.

Long term animal studies have not been performed to establish the potential for carcinogenicity or effects on fertility. Genetic toxicity studies (Ames test, mouse lymphoma assay and micronucleus test) did not show mutagenic potential.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

| NAME | CAS RN | % |
|--------------------|------------|-----|
| mometasone furoate | 83919-23-7 | >98 |

Section 4 - FIRST AID MEASURES

SWALLOWED

· If swallowed do NOT induce vomiting. · If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

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.

SKIN

■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

INHALED

· If fumes or combustion products are inhaled remove from contaminated area. · Lay patient down. Keep warm and rested.

NOTES TO PHYSICIAN

■ The adverse effects of corticosteroids are almost always due to their use in excess of physiological requirements. Symptomatic treatment is called for.

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Section 5 - FIRE FIGHTING MEASURES

| | |
|-----------------------------|---------------|
| Vapour Pressure (mmHG): | Negligible |
| Upper Explosive Limit (%): | Not available |
| Specific Gravity (water=1): | Not available |
| Lower Explosive Limit (%): | Not available |

EXTINGUISHING MEDIA

· Foam.
· Dry chemical powder.

FIRE FIGHTING

· Alert Emergency Responders and tell them location and nature of hazard.
· Wear breathing apparatus plus protective gloves.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

· Combustible solid which burns but propagates flame with difficulty.
· 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 may burn rapidly and fiercely if ignited.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO₂), hydrogen chloride, phosgene, other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

May emit corrosive fumes.

FIRE INCOMPATIBILITY

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

PERSONAL PROTECTION

Glasses:

Chemical goggles.

Gloves:

Respirator:

Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

· Remove all ignition sources.
· Clean up all spills immediately.
· Avoid contact with skin and eyes.
· Control personal contact by using protective equipment.
· Use dry clean up procedures and avoid generating dust.
· Place in a suitable, labelled container for waste disposal.

MAJOR SPILLS

■ Moderate hazard.

· CAUTION: Advise personnel in area.

· Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
 - Wear protective clothing when risk of exposure occurs.
- 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

- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.

NOTE: Store in the dark.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- mometasone furoate: CAS:83919-23-7

PERSONAL PROTECTION



RESPIRATOR

Particulate

Consult your EHS staff for recommendations

EYE

- Safety glasses with side shields.
- Chemical goggles.

HANDS/FEET

■ NOTE: The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.

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

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
- Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- polychloroprene
- nitrile rubber
- butyl rubber
- fluorocautchouc
- polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

OTHER

- Overalls.
- P.V.C. apron.
- Barrier cream.
- Skin cleansing cream.

- Eye wash unit.

ENGINEERING CONTROLS

- Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction.
- Exhaust ventilation should be designed to prevent accumulation and recirculation of particulates in the workplace.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.

Does not mix with water.

| | | | |
|---------------------------|---------------|--------------------------------|-----------------|
| State | Divided solid | Molecular Weight | 521.47 |
| Melting Range (°F) | 419- 442.4 | Viscosity | Not Applicable |
| Boiling Range (°F) | Not available | Solubility in water (g/L) | Partly miscible |
| Flash Point (°F) | Not available | pH (1% solution) | Not applicable |
| Decomposition Temp (°F) | Not available | pH (as supplied) | Not applicable |
| Autoignition Temp (°F) | Not available | Vapour 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 available |

APPEARANCE

White to off-white powder; does not mix well with water.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.

STORAGE INCOMPATIBILITY

- Avoid reaction with oxidizing agents.
- Heat and light accelerate decomposition.

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

Section 11 - TOXICOLOGICAL INFORMATION

MOMETASONE FUROATE

TOXICITY AND IRRITATION

MOMETASONE FUROATE:

- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.
 - Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).
- * Schering Plough

Respiratory depression, body temperature increase, respiratory tract changes, adrenal cortex hypoplasia, changes in spleen, liver changes, blood changes, effects on fertility, fetotoxicity, specific developmental abnormalities (musculoskeletal system, craniofacial, cardiovascular system), effects on newborn recorded.

Section 12 - ECOLOGICAL INFORMATION

No data

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

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

! 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.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

Section 15 - REGULATORY INFORMATION

No data for mometasone furoate (CAS: , 83919-23-7)

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Inhalation, skin contact and/or ingestion may produce health damage*.
- Cumulative effects may result following exposure*.
- Eye contact may produce serious damage*.
- Possible skin sensitiser*.
- May be harmful to the foetus/ embryo*.

* (limited evidence).

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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. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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