SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product name: Mometasone Furoate Aqueous Nasal Suspension

Synonyms, Trade Names:
Allermax, Allermax Aqueous Nasal Spray, Furoate de Mome, Nasomet, Nasonex, Nasonex Aqueous Nasal Spray, Nasonex Aqueous Nasal Suspension 0.05%
Unscented, Nasonex Aqueous Nasal Suspension 0.05%
Fragrance Free, Nasonex Aquosum Nasenspray, Nasonex Nasal Spray 0.05%, Nasonex Nasenspray Suspension, Nasonex Neusspray, Nasonex Orrspray, Nasonex Presentacion Pediatrica, Rinelon Aqueous Nasal Spray, Rinelon Suspension, Uniclar Nasal Spray, Uniclar PNS, SP001205, FORMULA CODE KTLB - KTLD

SDS No: P00000021608

Manufacturer: Merck
One Merck Drive P.O. Box 100
Whitehouse Station, NJ, USA 08889-0100

Telephone: 908-423-1000 (General Information Only)
Fax: 908-735-1496

Contact Person: EHS Data Steward
e-mail: MSDS@merck.com

Emergency telephone: 1-908-423-6000 (24/7/365) English Only

Intended Use: Finished pharmaceutical product. Intended to be used as an anti-inflammatory corticosteroid.

2 HAZARDS IDENTIFICATION

Emergency Overview:

Appearance:
Color: Opaque, White to off-white
Form: Suspension
Odor: Unknown

Signal words
CAUTION!

Potential Health Effects:
General
Finished pharmaceutical product. Avoid breathing mist or vapor. Avoid contact with eyes, skin, and clothing. Use only with adequate ventilation. Wash thoroughly after handling.

Potential Physical / Chemical Effects:
The physical-chemical properties of this material have not been fully investigated.

Inhalation:
May cause respiratory tract irritation.

skin:
May cause skin irritation.
eye: May irritate eyes.

Ingestion: No data available.

Signs and Symptoms: No data available for finished product. Active pharmaceutical ingredient: As a class, corticosteroids are known to cause systemic effects such as: reversible suppression of the hypothalamic-pituitary-adrenal (HPA axis), increased blood sugar, sugar in the urine, impairment of glucose tolerance and changes in general metabolism, bone metabolism, white blood cell counts, and some blood serum chemistry levels. Reported occupational effects for some corticosteroids include nasal irritation or burning, occasional sneezing, runny or bloody nose, and allergic skin reactions such as dermatitis and rash. Rare instances of nasal ulceration, septum perforation and increased intraocular pressure have been reported. Persons with pre-existing skin conditions including dermatitis and acne, a history of asthma, or those taking or those with a history of taking systemic steroids are most susceptible to allergic reactions from steroids.

Routes of Exposure: Inhalation

OSHA Regulatory Status This product is hazardous according to OSHA 29CFR 1910.1200.

Environment: Toxic to aquatic life with long lasting effects.

OTHER INFORMATION No additional information

3 COMPOSITION / INFORMATION ON INGREDIENTS

General information: The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the composition table. Active ingredients in any concentration are listed.

Hazardous Component(s):

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin</td>
<td>56-81-5</td>
<td>&gt;=1 - &lt;=5%</td>
</tr>
<tr>
<td>Benzalkonium Chloride</td>
<td>8001-54-5</td>
<td>&gt;=0.1 - &lt;=1.0%</td>
</tr>
<tr>
<td>Mometasone Furoate</td>
<td>83919-23-7</td>
<td>&lt;=0.1%</td>
</tr>
</tbody>
</table>
* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4 FIRST AID MEASURES

Inhalation: Move into fresh air and keep at rest. For breathing difficulties, oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.

Skin contact: Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.

Eye contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel.
give liquid to an unconscious person. Get medical attention.

Notes to the physician:
Hazards: See Sections 2 and 11. Active pharmaceutical ingredient: Mometasone furoate is a steroid hormone.
Treatment: Treat supportively and symptomatically.

5 FIRE-FIGHTING MEASURES

Extinguishing media: Water spray, fog, CO2, dry chemical, or alcohol resistant foam.
Unsuitable extinguishing media: None known.
Unusual Fire & Explosion Hazards: Emits toxic fumes under fire conditions.
Special Fire Fighting Procedures: Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6 ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all fire fighting procedures.
Environmental precautions: Do not release into the environment.
Spill Cleanup Methods: Small liquid spills: Absorb up with sand or other non-combustible absorbent material. Large quantities should not be discharged into the drain but removed with absorbing material. For waste disposal, see section 13 of the MSDS. Prevent runoff from entering drains, sewers, or streams.

7 HANDLING AND STORAGE

Handling: Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapor. Do not get in eyes, on skin, on clothing. Wash thoroughly after handling.
Storage: Keep container tightly closed in a cool, well-ventilated place. Store in a dry place.
8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limits:

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Type</th>
<th>Exposure Limit values</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin - Mist.</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>US. ACGIH Threshold Limit Values (2009)</td>
</tr>
<tr>
<td>Glycerin - Respirable fraction.</td>
<td>PEL</td>
<td>5 mg/m³</td>
<td>US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)</td>
</tr>
<tr>
<td>Glycerin - Total dust.</td>
<td>PEL</td>
<td>15 mg/m³</td>
<td>US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)</td>
</tr>
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<td>PEL</td>
<td>5 mg/m³</td>
<td>US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)</td>
</tr>
<tr>
<td>Mometasone Furoate</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)⁴</td>
<td>Merck</td>
</tr>
<tr>
<td></td>
<td>Wipe Limit</td>
<td>10 µg/100 cm²</td>
<td>Merck</td>
</tr>
</tbody>
</table>

OEB (Occupational Exposure Band) is an internal Merck control band.
- Listed.
- Listed.
- Listed.
- Listed.
- Listed.
- A skin notation has been assigned to this compound because cutaneous exposure may contribute significantly to the overall exposure and produce systemic effects.

Protective Measures:

Observe occupational exposure limits and minimize the risk of inhalation of vapors and mist. Essentially no open handling permitted. Use a properly designed containment device. Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., seal less pumps, all welded piping system, lock ring fittings, etc.). If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. It this potential does not exist, handle over lined trays or benchtops.

Respiratory Protection:

Use an appropriate approved air-purifying respirator equipped with HEPA cartridges/canisters where there is the potential for exceeding established occupational exposure limits or occupational exposure bands. When handling a compound in solution, a cartridge/canister appropriate for the solution may also be needed. Powered air filter respirator. Use a positive pressure, air-supplied, pressure demand tight fitting respirator (e.g., SCBA or airline equipped with emergency escape bottle) where there is a potential for uncontrolled releases in excess of the respirator's capabilities, where exposure levels are unknown or where air-purifying respirators may not provide adequate protection.

Hand protection:
Chemical resistant gloves. Consider double gloving.

Eye protection:
Reference standard: EN 166. 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. 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.
Skin and Body Protection: 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.

Hygiene measures: Wash skin thoroughly with soap and water.

### 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

**Appearance:**
- Physical State: Liquid
- Form: Suspension
- Color: Opaque, White to off-white
- Odor: Unknown
- pH: 4.3 - 4.9
- Solubility(ies):
  - Solubility in Water: Soluble

### 10 STABILITY AND REACTIVITY

**Stability:** Stable

**Possibility of hazardous reactions:** Stable

**Conditions to avoid:** None at ambient temperatures.

**Incompatible materials:** No data available.

**Hazardous decomposition products:** Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors.

### 11 TOXICOLOGICAL INFORMATION

**General information:** The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.
### Specified substance(s):

#### Acute Toxicity (Oral):

<table>
<thead>
<tr>
<th>Name</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin</td>
<td>LD50 (Rat): &gt; 10,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat): 12,600 mg/kg</td>
</tr>
<tr>
<td>Benzalkonium Chloride</td>
<td>LD50 (Mouse): 150 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat): 300 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat): 240 mg/kg</td>
</tr>
<tr>
<td>Mometasone Furoate</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>No mortality observed.</td>
</tr>
</tbody>
</table>

#### Acute Toxicity (Dermal):

<table>
<thead>
<tr>
<th>Name</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzalkonium Chloride</td>
<td>LD50 (Rat): 1,420 mg/kg</td>
</tr>
<tr>
<td>Mometasone Furoate</td>
<td>LD50 (Rat): 300 mg/kg (Subcutaneous)</td>
</tr>
</tbody>
</table>

#### Acute Toxicity (Inhalation):

<table>
<thead>
<tr>
<th>Name</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mometasone Furoate</td>
<td>MAC (Rat): &gt; 0.68 mg/l (Maximum attainable concentration.) Effects observed include: rales, emaciation and body weight losses. No mortality observed.</td>
</tr>
</tbody>
</table>

#### Repeated dose toxicity:

<table>
<thead>
<tr>
<th>Name</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin</td>
<td>NOAEL (Rat, Inhalation, 6 h/day, 5d/week): 0.167 mg/l Minimal to mild squamous cell metaplasia at the base of the epiglottis.</td>
</tr>
<tr>
<td></td>
<td>Carcinogenicity (Rat, Oral, 730 d): 5 - 10 g/kg No increase in tumor incidence.</td>
</tr>
<tr>
<td></td>
<td>TWO GENERATION STUDY (Rat, Oral, 56 - 84 d, daily): 0.2 g/kg No specific health warnings noted.</td>
</tr>
<tr>
<td>Mometasone Furoate</td>
<td>NOAEL (Rat, Oral, 30 d, daily): 5 ug/kg (Target Organ(s): thymus, lymph nodes, liver, adrenal gland, skin)</td>
</tr>
<tr>
<td></td>
<td>LOAEL (Dog, Oral, 30 d, daily): 500 ug/kg (Target Organ(s): thymus, lymph nodes, liver, adrenal gland, skin)</td>
</tr>
<tr>
<td></td>
<td>NOAEL (Rat, Inhalation, 90 d, daily): 0.13 ug/l The systemic effects observed are typical of corticosteroids as a class and include reversible changes in body weights, adrenal glands, lungs, thymus, lymph nodes, spleen, trachea, bone marrow, kidneys and liver.</td>
</tr>
<tr>
<td></td>
<td>NOAEL (Dog, Inhalation, 90 d, daily): 0.5 ug/l The systemic effects observed are typical of corticosteroids as a class and include reversible changes in body weights, adrenal glands, lungs, thymus, lymph nodes, spleen, trachea, bone marrow, kidneys and liver.</td>
</tr>
</tbody>
</table>

#### Inhalation:

- May cause irritation to the respiratory system.

#### Ingestion:

- No data available.

#### Skin corrosion/irritation:

- May cause skin irritation.

#### Serious eye damage/eye irritation:

- May cause eye irritation.

#### Respiratory sensitizer/Skin sensitizer:

- No data available for finished product. Active pharmaceutical ingredient: Guinea pig maximization test. Weak skin sensitizer.

#### Carcinogenicity:

- No component in this product is listed as a carcinogen by OSHA, NTP, or IARC. No data available for finished product. Active pharmaceutical ingredient: There were no statistically significant increases in tumors in inhalation carcinogenicity studies in rats at doses up to 67 ug/kg/day for 2 years and in mice at doses up to 160 ug/kg/day for 19 months. Not listed as carcinogen by OSHA, NTP or IARC.
**Mutagenesis:**
No data available for finished product. Active pharmaceutical ingredient: Negative in a battery of in vitro and in vivo genotoxicity assays.

**Reproductive toxicity:**
No data available for finished product. Active pharmaceutical ingredient: Developmental toxicity studies were conducted in rats, rabbits, and mice using subcutaneous, topical dermal, and oral administration. Developmental and/or teratogenic effects were observed in all animals treated with dosages between 15 and 2800 μg/kg/day. No adverse effects on fertility were seen in rats.

**Other Effects:**
Active pharmaceutical ingredient: Mometasone furoate is a very potent intranasal steroid. When given as a nasal suspension or applied as an ointment to intact skin without occlusion (0.1%) the bioavailability is < 1%. Several factors including degree of occlusion, inflammation, and/or integrity of skin will increase percutaneous absorption of topical corticosteroids. Results from pharmacokinetic studies in adults and children suggest that systemic exposure to mometasone furoate after intranasal administration is negligible (most likely due to the inherent low aqueous solubility). Clinical trials have shown mometasone furoate nasal spray has a favorable safety profile with no clinically relevant interactions with other tested medications. Mometasone furoate appears to have little or no effect on HPA axis function as measured by cortisol levels in plasma and urine after long-term treatment with recommended therapeutic doses and studies using higher than therapeutic doses (up to 4 mg/day by inhalation and 8 mg/day orally). Due to its lack of bioavailability, the systemic toxicity of Mometasone furoate is significantly lower than that of traditional steroids and is not observed at therapeutic doses. The most common adverse events associated with mometasone furoate therapy are headache, allergic rhinitis, pharyngitis, upper respiratory tract infection, sinusitis, oral candidiasis, dysmenorrhea, musculoskeletal pain, back pain and dyspepsia. These reactions are generally mild to moderate and limited in duration. Reported occupational effects for some corticosteroids include nasal irritation or burning, occasional sneezing, runny or bloody nose, and allergic skin reactions such as dermatitis and rash. Rare instances of nasal ulceration, septum perforation and increased intraocular pressure have been reported.

12 ECOLOGICAL INFORMATION
General information: The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

Ecotoxicity: There are no data on the ecotoxicity of this product. Active pharmaceutical ingredient: Mixture Multiplying Factor (M): 100

Specified substance(s):

Acute toxicity(Fish):

Name | Test results
---|---
Glycerin | LC50 (Carp (Leuciscus idus melanotus), 48 h): > 10,000 mg/l Mortality  
| LC50 (Rainbow trout, donaldson trout (Oncorhynchus mykiss), 96 h): 51,000 - 57,000 mg/l Mortality  
| LC50 (Goldfish (Carassius auratus), 24 h): > 5,000 mg/l Mortality
Benzalkonium Chloride | LC50 (Medaka, high-eyes (Oryzias latipes), 72 h): 2.5 mg/l Mortality  
| LC50 (Guppy (Poecilia reticulata), 72 h): 2.4 mg/l Mortality
Mometasone Furoate | LC50 (Sheepshead minnow (Cyprinodon variegatus), 7 d): > 5 mg/l Non-toxic up to the limit of solubility.

Chronic Toxicity(Fish):

Name | Test results
---|---
Mometasone Furoate | NOEC (Fathead minnow (Pimephales promelas), 32 d): 0.00014 mg/l (growth)  
| Bioconcentration factor (BCF) (17 d): 107.0 mg/l Low  
| Bioconcentration factor (BCF) (17 d): 104.9 mg/l High

Acute toxicity(Aquatic invertebrates):

Name | Test results
---|---
Glycerin | LC50 (Water flea (Daphnia magna), 24 h): > 10,000 mg/l Mortality  
| Benzalkonium Chloride | LC50 (Redtail prawn (Penaeus penicillatus), 24 h): 1.3 - 2.1 mg/l Mortality  
| LC50 (Shrimp (Penaeus semisulcatus), 24 h): 1.1 - 2.1 mg/l Mortality
Mometasone Furoate | EC 50 (Water flea (Daphnia magna), 48 h): > 5 mg/l Non-toxic up to the limit of solubility.  
| EC 50 (Mysid (Americamysis bahia), 96 h): > 5 mg/l Non-toxic up to the limit of solubility.

Chronic Toxicity(Aquatic invertebrates):

Name | Test results
---|---
Mometasone Furoate | NOEC (Water flea (Daphnia magna), 21 d): 0.34 mg/l Non-toxic up to the limit of solubility.  
| NOEC (Midge (Chironomus riparius), 28 d): 10 mg/kg

Acute toxicity(Aquatic plants):

Name | Test results
---|---
Mometasone Furoate | EC 50 (Green algae (Pseudokirchneriella subcapitata), 72 h): > 3.2 mg/l Non-toxic up to the limit of solubility.  
| NOEC (Green algae (Pseudokirchneriella subcapitata), 72 h): 3.2 mg/l Non-toxic up to the limit of solubility.

Persistence and degradability: No data available for finished product. Active pharmaceutical ingredient: Not expected to be biodegradable.

Bioaccumulative potential: No data available for finished product. Active pharmaceutical ingredient: Not expected to bioaccumulate.

Mobility: No data available for finished product. Active pharmaceutical ingredient: Expected to be immobile in soil.
13 DISPOSAL CONSIDERATIONS

Disposal Methods: Disposal must be in accordance with applicable national, state/provincial, and/or local regulations.

Measures for Avoidance and Recovery: Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14 TRANSPORT INFORMATION

DOT
Not regulated.

IMDG - International Maritime Dangerous Goods Code
UN number UN3082
Proper Shipping Name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.(MOMETASONE FUROATE)
Class 9
Packing group III
Label(s) 9
Subsidiary risk label
Marine Pollutant Envir. Hazardous, Labels Only
EmS No. F-A; S-F

IATA - International Air Transport Association
UN number UN3082
Proper Shipping Name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.(MOMETASONE FUROATE)
Class 9
Packing group III
Label(s) 9MI
Subsidiary risk label

15 REGULATORY INFORMATION

US Regulations
- CERCLA Hazardous Substance List (40 CFR 302.4):
  None

- Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):
  None

- Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):
  None

SARA Title III
- Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):
  None

- Section 313 Toxic Release Inventory (40 CFR 372):
  None present or none present in regulated quantities.
State Regulations

- **California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):**
  No ingredient regulated by CA Prop 65 present.

- **Massachusetts Right-To-Know List:**
  Glycerin Listed

- **New Jersey Right-To-Know List:**
  No ingredient regulated by NJ Right-to-Know Law present.

- **Pennsylvania Right-To-Know List:**
  Glycerin Listed

16 OTHER INFORMATION

OTHER INFORMATION

This SDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate SDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

**NFPA Hazard ID**

- Flammability: 0
- Health: 0
- Reactivity: 0
- Special hazard: 0

Hazard rating: 0 - Minimal; 1 - Slight; 2 - Moderate; 3 - Serious; 4 - Severe

**Revision Information:** Not relevant.

**Issue Date:** 30.07.2013

**Disclaimer:** This information is provided without warranty. The information is believed to be correct. This information should be used to make an independent determination of the methods to safeguard workers and the environment.