## 1. Product and Company Identification

**PRODUCT NAME: NASACORT® AQ (triamcinolone acetonide)**
**Nasal Spray**

**Substance name: Triamcinolone acetonide**

**Supplier:**
**Sanofi-aventis U.S. LLC**
**A SANOFI COMPANY**
**55 Corporate Drive**
**Bridgewater, NJ 08807**

| | |
|---|---|
| **24-Hour Transport Emergency, US (Chemtrec):** | **(800) 424-9300** |
| **24-Hour Transport Emergency, outside US (Chemtrec):** | **(703) 527-3887** |
| **US Customer Service** | **(800) 207-8049** |
| **24-Hour Emergency, sanofi-aventis US:** | **(908) 981-5550** |

**Product use: Pharmaceutical product.**

## 2. Hazards Identification

### 2.1 Classification in accordance with 29 CFR 1910.1200

Classification: Not classified as a hazardous mixture.

### 2.2 Label elements in accordance with 29 CFR 1910.1200

**Labeling of the finished drug product is not required according to OSHA 29 CFR 1900.1200. The following information is provided for the product mixture:**

Signal Word: None required.

Hazard Statement(s): None required.

Symbol(s): None required.

Precautionary Statement(s):

- Prevention: None required.
- Response: None required.
- Storage: None required.
- Disposal: None required.

**2.3 Hazards Not Otherwise Classified (HNOC)**

Not classified.

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**3. Composition/Information on Ingredients**

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| **Chemical Name:** | **Common Name:** | **CAS #:** | **Percentage or concentration range** |
|---|---|---|---|
| 9-Fluoro-11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with acetone | Triamcinolone acetonide (TAA) | 76-25-5 | 0.055 % w/w |

Inactive Ingredients: Water, microcrystalline cellulose, carboxymethylcellulose sodium, polysorbate 80, dextrose, benzalkonium chloride, and edetate disodium.

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**4. First Aid Measures**

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**4.1 First aid procedures**

Eye contact: In case of contact with product, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention.

Skin contact: In case of contact with product, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists.

Ingestion: If swallowed, call a poison center or physician immediately. Do NOT induce vomiting unless directed to do so by a physician. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water.

Inhalation: If product is inhaled, remove to fresh air. If breathing is difficult, trained personnel should give oxygen. Get medical attention.

**4.2 Most important symptoms and effects, both acute and delayed**

Most common adverse reactions (>2% incidence) were pharyngitis, epistaxis, flu syndrome, cough increased, bronchitis, dyspepsia, tooth disorder, headache, pharyngolaryngeal pain, nasopharyngitis, abdominal upper pain, diarrhea, and excoriation.

**4.3 Indication of any immediate medical attention and special treatment needed**

Acute overdosing with the intranasal dosage form is unlikely in view of the total amount of active ingredient present and low bioavailability of triamcinolone acetonide. In the event that the entire contents of the bottle were administered all at once, via either oral or nasal application, clinically significant systemic adverse events would most likely not result.

Treat symptomatically and supportively.

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**5. Fire Fighting Measures**

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**5.1 Extinguishing media**

Suitable extinguishing media: All means: water, carbon dioxide, foam or dry chemical.

Unsuitable extinguishing media: Strong water jet.

**5.2 Specific hazards arising from the chemical**

Hazardous combustion products: Carbon monoxide, carbon dioxide, oxides of nitrogen.

**5.3 Special Protective Equipment and Precautions for Fire-fighters**

In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. Move container from fire area if you can do it without risk. Do not scatter spilled material with high-pressure water streams. Dike fire-control water for later disposal.

## 6. Accidental Release Measures

### 6.1 Personal precautions and Protective Equipment:

Eye protection, respiratory protective equipment, and suitable protective clothing should be worn (see Section 8).

### 6.2 Emergency Procedures:

Follow local workplace procedures. Prevent the product from entering the environment. Avoid discharges to sewers, drains, waterways, or onto the ground.

### 6.3 Methods for containment:

Absorb spilled liquid with a suitable inert material, place in suitable container for disposal and mop area.

### 6.4 Methods for clean-up:

Wash the floor with plenty of water, absorb or retain the cleaning water for disposal.

## 7. Handling and Storage

### 7.1 Precautions for Safe Handling

Product should be used in a controlled work area. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Place a disposable absorbent pad under the product preparation area. Do not eat, smoke or drink while handling product. Wash thoroughly after handling.

### 7.2 Conditions for Safe Storage

Keep container tightly closed. Protect from light. Store in a cool, well-ventilated area.

## 8. Exposure Controls/Personal Protection

### 8.1 Exposure Limits

Sanofi-aventis occupational exposure limit, triamcinolone acetonide: 0.001 mg/$m^3$, 8-hour TWA.

### 8.2 Appropriate Engineering Controls

Provide adequate ventilation. No other specific controls are needed under normal handling conditions.

### 8.3 Individual Protection Measures

Eye/face protection: Safety glasses or safety goggles should be worn if there is a potential for eye contact with the product.

Skin protection: Suitable protective gloves should be worn. Use of a protective or disposable gown or laboratory coat is recommended if there exists a potential for contact with the product.

Respiratory protection: None normally required for routine handling of the product. However, approved respiratory protection should be worn if there is a potential for exposure to the product. A respiratory protection program that meets OSHA 29 CFR 1910.134 and ANSI Z88.2 must be followed whenever workplace conditions warrant respirator usage.

General hygiene considerations: Wash hands before breaks and at the end of the work shift.

## 9. Physical and Chemical Properties

Appearance: liquid.
Odor: none known.
Odor threshold: none known.
pH: 5.0 (target pH); range 4.5 – 6.0.
Melting point/ Freezing point: no data available.
Initial boiling point/boiling point range: no data available.
Flash point: no data available.
Evaporation rate: no data available.
Flammability: no data available.
Upper/lower flammability or explosive limits: no data available.
Vapor pressure: no data available.
Vapor density: no data available.
Relative density: no data available.
Solubility: no data available.

Partition coefficient: n-octanol/water (triamcinolone acetonide): Log Kow = 2.53 (experimental).
Auto-ignition temperature: no data available.
Decomposition temperature: no data available.
Viscosity: no data available.

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## 10. Stability and Reactivity

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### 10.1 Reactivity

Not a reactive material under normal handling conditions.

### 10.2 Chemical Stability

Stable under normal handling conditions.

### 10.3 Possibility of hazardous reactions

None known.

### 10.4 Conditions to Avoid

Store at controlled room temperature, 20 to 25°C (68 to 77°F).

### 10.5 Incompatible materials

Strong oxidizing and reducing agents.

### 10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide, oxides of nitrogen.

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## 11. Toxicological Information

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**The following information is for the active ingredient triamcinolone acetonide unless otherwise noted:**

Information on likely routes of exposure: Not expected under normal handling conditions. Unintended spills or releases could result in exposure to eyes, skin and respiratory tract.

Symptoms related to the physical, chemical and toxicological characteristics: Pharyngitis, epistaxis, flu syndrome, cough increased, bronchitis, dyspepsia, tooth disorder, headache, pharyngolaryngeal pain, nasopharyngitis, abdominal upper pain, diarrhea, and excoriation.

Effects of short-term (acute) exposure: Harmful if swallowed.

Effects of long-term (chronic) exposure: Causes damage to organs (endocrine system) through prolonged or repeated exposure. In addition, nasal corticosteroids have been associated with nasal septal perforation, glaucoma and cataracts, and impaired wound healing.

Acute toxicity (LD50):
Oral route, rat: 1,451 mg/kg.
Oral route, mouse: 2,168 mg/kg.

Skin corrosion/irritation: Not a skin irritant in animal studies.

Serious eye damage/irritation: Transient eye irritant in animal studies.

Sensitization: Non-sensitizing based on animal studies.

Specific target organ toxicity – single exposure (STOT-SE): No data available.

Specific target organ toxicity – repeated exposure (STOT-RE): Causes damage to organs (endocrine system) through prolonged or repeated exposure.

Carcinogenicity: In a two-year study in rats, triamcinolone acetonide caused no treatment-related carcinogenicity at oral doses up to 1.0 mcg/kg (less than the maximum recommended daily intranasal dose in adults and children on a mcg/$m^2$ basis, respectively). In a two-year study in mice, triamcinolone acetonide caused no treatment-related carcinogenicity at oral doses up to 3.0 mcg/kg (less than the maximum recommended daily intranasal dose in adults and children on a mcg/$m^2$ basis, respectively).

Not listed by NTP, not found to be a potential carcinogen by IARC or OSHA.

Reproductive toxicity and teratogenicity: Triamcinolone acetonide was teratogenic in rats, rabbits, and monkeys. Experience with oral corticosteroids in pharmacologic as opposed to physiologic doses suggests that rodents are more prone to teratogenic effects from corticosteroids than humans.

In reproduction studies in rats and rabbits, triamcinolone acetonide administered by inhalation produced cleft palate and/or internal hydrocephaly and axial skeletal defects at exposures less than and 2 times, respectively, the maximum recommended daily intranasal dose in adults on a mcg/$m^2$ basis. In a monkey reproduction study, triamcinolone acetonide administered by inhalation produced cranial malformations at an exposure approximately 37 times the maximum recommended daily intranasal dose in adults on a mcg/$m^2$ basis.

Mutagenicity: No evidence of mutagenicity was detected from in vitro tests (a reverse mutation test in Salmonella bacteria and a forward mutation test in Chinese hamster ovary cells) conducted with triamcinolone acetonide.

Aspiration hazard: No data available.

## 12. Ecological Information

**The following information is for the active ingredient triamcinolone acetonide unless otherwise noted:**

### 12.1. Ecotoxicity

Toxicity on invertebrates: (EC50): > 100 mg/l
Species: Daphnia magna
Duration of exposure: 48 h
Method: Tested according to OECD 202.

Algae toxicity (EC50): > 10 mg/l
Duration of exposure: 72 h
Method: OECD 201

### 12.2. Persistence and degradability

Biological degradability: 4.8%
Duration of test: 28 d
Method: OECD 301B
The product is not readily biodegradable according to OECD criteria.

### 12.3. Bioaccumulative potential

Unlikely to be bioaccumulative in living organisms (Log Kow < 3).

### 12.4 Mobility in soil

No data available.

### 12.5 Other adverse effects

No data available.

## 13. Disposal Considerations

### 13.1 Disposal of product waste

Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

### 13.2 Disposal of packaging waste

Dispose of in a safe manner in accordance with federal, state and local environmental regulations. Empty packages, containers or liners may contain product residue.

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## 14. Transport Information

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### 14.1 Basic shipping information, finished product

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| U.S. DOT | Not a regulated material. |
| ICAO/IATA | Not a regulated material. |
| IMDG | Not a regulated material. |

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## 15. Regulatory Information

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US Regulations
CERCLA Hazardous Substance List (40 CFR 302.4): Not listed.
Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): Not listed.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): Not listed.
SARA Title III:
Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): Not listed.
Section 313 Toxic Release Inventory (40 CFR 372): Not listed.

State Regulations
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): Not listed.
Massachusetts Right-To-Know List: Not listed.
New Jersey Right-To-Know List: Not listed.
Pennsylvania Right-To-Know List: Not listed.

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## 16. Other Information

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Other Information: The information contained herein is based upon data considered true and accurate. Sanofi-aventis U.S. LLC. makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

Abbreviations and Acronyms
CAS: Chemical Abstracts Service
DOT: U.S. Department of Transportation
EST: Eastern standard time (U.S.)
IATA: International Air Transport Association
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
OEL: Occupational Exposure Limit
PPE: Personal Protection Equipment
SDS: Safety Data Sheet
STEL: Short-term exposure limit
TWA: Time-weighted average
U.S.: United States

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First version.