



Safety Data Sheet

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SECTION 1: Identification

1.1. Product identifier

Beclomethasone Impurities - Reference Standard

Product Identification Numbers

26-1016-8212-3, 26-1016-8213-1, 26-1016-8214-9, 26-1016-8215-6, 26-1016-8216-4, 26-1016-8217-2, 26-1016-8218-0, 26-1016-8219-8, 42-0013-1294-3, 42-0013-1297-6

1.2. Recommended use and restrictions on use

Recommended use

Pharmaceutical

1.3. Supplier's details

| | |
|----------------------|---|
| MANUFACTURER: | 3M |
| DIVISION: | Drug Delivery Sys Div |
| ADDRESS: | 3M Center, St. Paul, MN 55144-1000, USA |
| Telephone: | 1-888-3M HELPS (1-888-364-3577) |

1.4. Emergency telephone number

1-800-364-3577 or (651) 737-6501 (24 hours)

SECTION 2: Hazard identification

2.1. Hazard classification

Acute Toxicity (oral): Category 4.

Reproductive Toxicity: Category 2.

2.2. Label elements

Signal word

Warning

Symbols

Exclamation mark | Health Hazard |

Pictograms

**Hazard Statements**

Harmful if swallowed.

Suspected of damaging fertility or the unborn child.

Precautionary Statements**Prevention:**

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Wear protective gloves.

Do not eat, drink or smoke when using this product.

Wash thoroughly after handling.

Response:

Rinse mouth.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

IF exposed or concerned: Get medical advice/attention.

Storage:

Store locked up.

Disposal:

Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

2.3. Hazards not otherwise classified

None.

SECTION 3: Composition/information on ingredients

| Ingredient | C.A.S. No. | % by Wt |
|-------------------------|-------------------|----------------|
| Beclomethasone Impurity | None | 100 |

SECTION 4: First aid measures**4.1. Description of first aid measures****Inhalation:**

Remove person to fresh air. If you feel unwell, get medical attention.

Skin Contact:

Wash with soap and water. If signs/symptoms develop, get medical attention.

Eye Contact:

Flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms persist, get medical attention.

If Swallowed:

Rinse mouth. If you feel unwell, get medical attention.

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

See Section 11.1. Information on toxicological effects.

4.3. Indication of any immediate medical attention and special treatment required

Not applicable

SECTION 5: Fire-fighting measures

5.1. Suitable extinguishing media

In case of fire: Use a carbon dioxide or dry chemical extinguisher to extinguish.

5.2. Special hazards arising from the substance or mixture

Powdered material may form explosive dust-air mixture. Avoid fire fighting methods that would cause powders to become airborne.

Hazardous Decomposition or By-Products

| <u>Substance</u> | <u>Condition</u> |
|------------------|-------------------|
| Carbon monoxide | During Combustion |
| Carbon dioxide | During Combustion |

5.3. Special protective actions for fire-fighters

No special protective actions for fire-fighters are anticipated.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Evacuate area. Eliminate all ignition sources if safe to do so. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Collect as much of the spilled material as possible using non-sparking tools. Use wet sweeping compound or water to avoid dusting. Sweep up. Place in a closed container approved for transportation by appropriate authorities. Clean up residue. Dispose of collected material as soon as possible.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Decontaminate work surfaces frequently to avoid exposure by contact. Do not handle until all safety precautions have been read and understood. Avoid breathing dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Avoid contact with oxidizing agents (eg. chlorine, chromic acid etc.) Use personal protective equipment (gloves, respirators, etc.) as required.

7.2. Conditions for safe storage including any incompatibilities

No special storage requirements.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

No occupational exposure limit values exist for any of the components listed in Section 3 of this SDS.

8.2. Exposure controls**8.2.1. Engineering controls**

Use general dilution ventilation and/or local exhaust ventilation to control airborne exposures to below relevant Exposure Limits and/or control dust/fume/gas/mist/vapors/spray. If ventilation is not adequate, use respiratory protection equipment.

8.2.2. Personal protective equipment (PPE)**Eye/face protection**

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:

Unvented Goggles

Skin/hand protection

Select and use gloves and/or protective clothing approved to relevant local standards to prevent skin contact based on the results of an exposure assessment. Selection should be based on use factors such as exposure levels, concentration of the substance or mixture, frequency and duration, physical challenges such as temperature extremes, and other use conditions. Consult with your glove and/or protective clothing manufacturer for selection of appropriate compatible gloves/protective clothing.

Gloves made from the following material(s) are recommended: Butyl Rubber

Neoprene

Nitrile Rubber

Select and use body protection to prevent contact based on the results of an exposure assessment. The following protective clothing material(s) are recommended: Coveralls - Disposable

Respiratory protection

An exposure assessment may be needed to decide if a respirator is required. If a respirator is needed, use respirators as part of a full respiratory protection program. Based on the results of the exposure assessment, select from the following respirator type(s) to reduce inhalation exposure:

Half facepiece or full facepiece air-purifying respirator suitable for particulates

Half facepiece or full facepiece supplied-air respirator

For questions about suitability for a specific application, consult with your respirator manufacturer.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | |
|----------------------------------|-------------------------------|
| General Physical Form: | Solid |
| Odor, Color, Grade: | White to cream colored powder |
| Odor threshold | No Data Available |
| pH | Not Applicable |
| Melting point | No Data Available |
| Boiling Point | Not Applicable |
| Flash Point | No flash point |
| Evaporation rate | Not Applicable |
| Flammability (solid, gas) | Not Classified |
| Flammable Limits(LEL) | Not Applicable |
| Flammable Limits(UEL) | Not Applicable |
| Vapor Pressure | No Data Available |

| | |
|---|-------------------|
| Vapor Density | No Data Available |
| Density | No Data Available |
| Specific Gravity | No Data Available |
| Solubility In Water | No Data Available |
| Solubility- non-water | No Data Available |
| Solubility- non-water | No Data Available |
| Partition coefficient: n-octanol/ water | Not Applicable |
| Autoignition temperature | Not Applicable |
| Decomposition temperature | No Data Available |
| Viscosity | Not Applicable |

SECTION 10: Stability and reactivity

10.1. Reactivity

This material is considered to be non reactive under normal use conditions.

10.2. Chemical stability

Stable.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

None known.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

| <u>Substance</u> | <u>Condition</u> |
|------------------|------------------|
| None known. | |

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labeling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

11.1. Information on Toxicological effects

Signs and Symptoms of Exposure

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation:

Respiratory Tract Irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

Skin Contact:

Mechanical Skin irritation: Signs/symptoms may include abrasion, redness, pain, and itching.

Eye Contact:

Mechanical eye irritation: Signs/symptoms may include pain, redness, tearing and corneal abrasion.

Ingestion:

Harmful if swallowed. Gastrointestinal Irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

Reproductive/Developmental Toxicity:

Contains a chemical or chemicals which can cause birth defects or other reproductive harm.

Additional Information:

There is no information which has been developed specifically on this material. Any information which has been presented is based on known properties of individual components and/or professional judgement concerning properties of the material.

Toxicological Data

If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

| Name | Route | Species | Value |
|-----------------|-----------|---------|---|
| Overall product | Ingestion | | No data available; calculated ATE 300 - 2,000 mg/kg |

ATE = acute toxicity estimate

Skin Corrosion/Irritation

| Name | Species | Value |
|------|---------|-------|
|------|---------|-------|

Serious Eye Damage/Irritation

| Name | Species | Value |
|------|---------|-------|
|------|---------|-------|

Skin Sensitization

| Name | Species | Value |
|------|---------|-------|
|------|---------|-------|

Respiratory Sensitization

| Name | Species | Value |
|------|---------|-------|
|------|---------|-------|

Germ Cell Mutagenicity

| Name | Route | Value |
|------|-------|-------|
|------|-------|-------|

Carcinogenicity

| Name | Route | Species | Value |
|------|-------|---------|-------|
|------|-------|---------|-------|

Reproductive Toxicity
Reproductive and/or Developmental Effects

| Name | Route | Value | Species | Test Result | Exposure Duration |
|------|-------|-------|---------|-------------|-------------------|
|------|-------|-------|---------|-------------|-------------------|

Target Organ(s)
Specific Target Organ Toxicity - single exposure

| Name | Route | Target Organ(s) | Value | Species | Test Result | Exposure Duration |
|------|-------|-----------------|-------|---------|-------------|-------------------|
|------|-------|-----------------|-------|---------|-------------|-------------------|

Specific Target Organ Toxicity - repeated exposure

| Name | Route | Target Organ(s) | Value | Species | Test Result | Exposure Duration |
|------|-------|-----------------|-------|---------|-------------|-------------------|
|------|-------|-----------------|-------|---------|-------------|-------------------|

Aspiration Hazard

| Name | Value |
|------|-------|
|------|-------|

Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.

SECTION 12: Ecological information**Ecotoxicological information**

Please contact the address or phone number listed on the first page of the SDS for additional ecotoxicological information on this material and/or its components.

Chemical fate information

Please contact the address or phone number listed on the first page of the SDS for additional chemical fate information on this material and/or its components.

SECTION 13: Disposal considerations**13.1. Disposal methods**

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Incinerate in a permitted waste incineration facility. Proper destruction may require the use of additional fuel during incineration processes. Empty drums/barrels/containers used for transporting and handling hazardous chemicals (chemical substances/mixtures/preparations classified as Hazardous as per applicable regulations) shall be considered, stored, treated & disposed of as hazardous wastes unless otherwise defined by applicable waste regulations. Consult with the respective regulating authorities to determine the available treatment and disposal facilities.

EPA Hazardous Waste Number (RCRA): Not regulated

SECTION 14: Transport Information

For Transport Information, please visit <http://3M.com/Transportinfo> or call 1-800-364-3577 or 651-737-6501.

SECTION 15: Regulatory information**15.1. US Federal Regulations**

Contact 3M for more information.

311/312 Hazard Categories:

Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No Immediate Hazard - Yes Delayed Hazard - Yes

15.2. State Regulations

Contact 3M for more information.

15.3. Chemical Inventories

Contact 3M for more information.

15.4. International Regulations

Contact 3M for more information.

This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.

SECTION 16: Other information

NFPA Hazard Classification

Health: 1 **Flammability:** 1 **Instability:** 0 **Special Hazards:** None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

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