



# US - OSHA SAFETY DATA SHEET

Issue Date 15-Jul-2015

Revision Date Not applicable

Version 1

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### Product identifier

**Product Name** Rhinocort Allergy Spray

### Other means of identification

**Product Code** C-1338-1

**Synonyms** None

### Recommended use of the chemical and restrictions on use

**Recommended Use** Relief from allergies

**Uses advised against** None Known.

### Details of the supplier of the safety data sheet

#### **Supplier Address**

McNeil Consumer Healthcare, Division of McNeil-PPC, Inc.  
7050 Camp Hill Road  
Fort Washington, PA  
19034-2299

### Emergency telephone number

**Company Phone Number** (215) 273-7000

**24 Hour Emergency Phone Number** For 24-hour emergency assistance, call the 3E Company at 1 (877)-236-9871  
Provide the technician with the following product tracking code: 2277

## 2. HAZARDS IDENTIFICATION

### Classification

#### **Health Hazards**

Not Classified.

#### **Physical hazards**

Not Classified.

### **OSHA Regulatory Status**

This product is safe for consumers when used according to the label directions. Potential hazards that may occur if product is not used according to the consumer label are as follows in this Safety Data Sheet (SDS).

**Label elements****Emergency Overview****Hazard statements**

This material does not meet the criteria for classification.

**Hazard Symbol**

None

**Signal word**

None

**Appearance** Aqueous suspension

**Physical state** Liquid

**Odor** Not available.

**Precautionary Statements - Prevention**

Not available.

**Precautionary Statements - Response**

No specific first aid measures noted.

**Precautionary Statements - Storage**

Store at 20 -25 °C (68 - 77 °F).

**Precautionary Statements - Disposal**

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

**Hazards not otherwise classified (HNOC)**

Not classified.

**Other Information****3. COMPOSITION/INFORMATION ON INGREDIENTS****Synonyms**

None

| Chemical Name | CAS No.    | Weight-%  |
|---------------|------------|-----------|
| Budesonide    | 51333-22-3 | 0.06-0.13 |

**4. FIRST AID MEASURES****First aid measures****Eye contact**

In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

**Skin Contact**

Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing if required, then physically remove as much of the product as possible. Wash affected area with soap and water, then thoroughly flush the area with water. If irritation persists, seek medical advice.

**Inhalation**

If symptomatic, move to fresh air. Get medical attention if symptoms persist.

**Ingestion**

If symptomatic, seek medical advice. If ingestion of a large amount does occur, call a poison control center immediately.

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

No information available.

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

**Note to physicians** Treat symptomatically.

## 5. FIRE-FIGHTING MEASURES

### Suitable extinguishing media

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

**Unsuitable extinguishing media** None known.

### Specific hazards arising from the chemical

Not applicable.

### Explosion data

**Sensitivity to Mechanical Impact** None known.

**Sensitivity to Static Discharge** None known.

### Protective equipment and precautions for firefighters

Wear self-contained breathing apparatus and protective clothing.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

**Personal precautions** Wear appropriate personal protective equipment (see Section 8).

### Environmental precautions

**Environmental precautions** See Section 12 for additional ecological information.

### Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Vacuum and place into proper container for disposal.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

**Advice on safe handling** Observe good industrial hygiene practices. Minimize dust generation and accumulation.

### Conditions for safe storage, including any incompatibilities

**Storage Conditions** Keep only in the original container. Store at 20 - 25 °C (68 - 77 °F). Keep away from food, drink, and animal feedingstuffs. Keep out of reach of children.

**Incompatible materials** None known based on information supplied. Strong oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

**Biological limit values** No biological limits noted for this ingredient(s).

### Exposure Guidelines

This product, as supplied, does not contain any hazardous materials with Occupational Exposure Limits (OEL) established by the region specific regulatory bodies.

### Appropriate engineering controls

**Engineering Controls** The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

**Individual protection measures, such as personal protective equipment**

|                                       |  |
|---------------------------------------|--|
| <b>Eye/face protection</b>            | None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.   |
| <b>Skin and body protection</b>       | None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, and hood or head coverings may be necessary. Contact a health and safety professional for specific information.  |
| <b>Hand protection</b>                | Use protective gloves. None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.   |
| <b>Respiratory protection</b>         | None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information. |
| <b>Thermal hazards</b>                | Not applicable.  |
| <b>General Hygiene Considerations</b> | Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.  |

|  |
|--|
| <b>9. PHYSICAL AND CHEMICAL PROPERTIES</b> |
|--|

**Information on basic physical and chemical properties**

|                       |                    |                       |                |
|-----------------------|--------------------|-----------------------|----------------|
| <b>Physical state</b> | Liquid             |                       |                |
| <b>Appearance</b>     | Aqueous suspension | <b>Odor</b>           | Not available. |
| <b>Color</b>          | Not available.     | <b>Odor threshold</b> | Not available. |

| <b><u>Property</u></b>               | <b><u>Values</u></b> | <b><u>Remarks • Method</u></b> |
|--------------------------------------|----------------------|--------------------------------|
| <b>pH</b>                            | Not available.       |                                |
| <b>Melting point/freezing point</b>  | Not available.       |                                |
| <b>Boiling point / boiling range</b> | Not available.       |                                |
| <b>Flash point</b>                   | Not available.       |                                |
| <b>Evaporation rate</b>              | Not available.       |                                |
| <b>Flammability (solid, gas)</b>     | Not available.       |                                |
| <b>Flammability Limit in Air</b>     |                      |                                |
| Upper flammability limit:            | Not available.       |                                |
| Lower flammability limit:            | Not available.       |                                |
| <b>Vapor pressure</b>                | Not available.       |                                |
| <b>Vapor density</b>                 | Not available.       |                                |
| <b>Specific Gravity</b>              | Not available.       |                                |
| <b>Water solubility</b>              | Not available.       |                                |
| <b>Solubility in other solvents</b>  | Not available.       |                                |
| <b>Partition coefficient</b>         | Not available.       |                                |
| <b>Autoignition temperature</b>      | Not available.       |                                |
| <b>Decomposition temperature</b>     | Not available.       |                                |
| <b>Kinematic viscosity</b>           | Not available.       |                                |
| <b>Dynamic viscosity</b>             | Not available.       |                                |
| <b>Explosive properties</b>          | Not available.       |                                |

Lower explosive limit: Not available.  
 Upper explosive limit: Not available.  
 Oxidizing properties: Not available.

## 10. STABILITY AND REACTIVITY

### Reactivity

Stable at normal conditions.

### Chemical stability

Stable.

### Possibility of Hazardous Reactions

Hazardous polymerization does not occur.

### Conditions to avoid

Low and elevated temperatures. Do not freeze. Exposure to light.

### Incompatible materials

None known based on information supplied. Strong oxidizing agents.

### Hazardous Decomposition Products

Carbon oxides. Silicon oxides. Nitrogen oxides. Sodium oxides.

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

#### Product Information

|                     |  |
|---------------------|--|
| <b>Inhalation</b>   | Under normal conditions of intended use, this material is not expected to be an inhalation hazard. |
| <b>Eye contact</b>  | May cause irritation   |
| <b>Skin Contact</b> | This product is not expected to be a skin hazard.  |
| <b>Ingestion</b>    | Expected to be a low ingestion hazard.   |

### Acute Effects

| Chemical Name            | Oral LD50            | Dermal LD50 | Inhalation LC50 | Intravenous LD50 |
|--------------------------|----------------------|-------------|-----------------|------------------|
| Budesonide<br>51333-22-3 | > 3200 mg/kg ( Rat ) | -           | -               | -                |

### Information on toxicological effects

**Symptoms** Not available.

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

|  |   |
|--|---|
| <b>Skin corrosion/irritation</b>         | May cause skin irritation   |
| <b>Serious eye damage/eye irritation</b> | May cause eye irritation  |
| <b>Irritation</b>                        | Not available.  |
| <b>Corrosivity</b>                       | Not available.  |
| <b>Sensitization</b>                     | May cause skin sensitization.   |
| <b>Germ cell mutagenicity</b>            | In animal studies, budesonide was not genotoxic.  |
| <b>Carcinogenicity</b>                   | Budesonide caused an increased risk of gliomas and hepatocellular tumors in male rats (but not female rats) at doses lower than the recommended human dose.   |
| <b>Reproductive toxicity</b>             | Budesonide is teratogenic. Teratology testing in rabbits showed all treated animals to abort at a budesonide dose level of 0.29 nmol/kg/day. At lower dose levels, down to 0.01 nmol/kg, fetal growth restriction and skeletal delay were seen. |
| <b>Developmental Toxicity</b>            | Not available.  |
| <b>Teratogenicity</b>                    | Not available.  |

|                          |   |
|--------------------------|---|
| STOT - single exposure   | Not classified.   |
| STOT - repeated exposure | Not classified.   |
| Chronic toxicity         | Not available.  |
| Subchronic toxicity      | Not available.  |
| Target Organ Effects     | Not available.  |
| Neurological effects     | Not available.  |
| Other adverse effects    | Not available.  |
| Aspiration hazard        | Due to the physical form of the product it is not an aspiration hazard. |

**Numerical measures of toxicity - Not available.****12. ECOLOGICAL INFORMATION****Ecotoxicity**

This product's components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

**Persistence and degradability**

No information available.

**Bioaccumulation**

No information available.

**Mobility**

No information available.

**Other adverse effects**

No information available.

**13. DISPOSAL CONSIDERATIONS****Waste treatment methods**

**Disposal of wastes** Dispose in accordance with applicable federal, state, and local regulations.

**Contaminated packaging** Since emptied containers may retain product residue, follow label warnings even after container is emptied.

**14. TRANSPORT INFORMATION**

**DOT** Not regulated as a hazardous material by DOT.

**IATA** Not regulated as a dangerous good.

**IMDG** Not regulated as a dangerous good.

**15. REGULATORY INFORMATION****International Inventories**

|               |                |
|---------------|----------------|
| TSCA          | Does not apply |
| DSL/NDSL      | Does not apply |
| EINECS/ELINCS | Complies       |
| ENCS          | Does not apply |
| IECSC         | Does not apply |
| KECL          | Does not apply |
| PICCS         | Does not apply |
| AICS          | Does not apply |

**Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances  
IECSC - China Inventory of Existing Chemical Substances  
KECL - Korean Existing and Evaluated Chemical Substances  
PICCS - Philippines Inventory of Chemicals and Chemical Substances  
AICS - Australian Inventory of Chemical Substances

## **US Federal Regulations**

### **US OSHA Specifically regulated Substances (29 CFR 1910.1001-1050)**

Not listed

### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

### **SARA 311/312 Hazard Categories**

|                                   |    |
|-----------------------------------|----|
| Acute health hazard               | No |
| Chronic Health Hazard             | No |
| Fire hazard                       | No |
| Sudden release of pressure hazard | No |
| Reactive Hazard                   | No |

### **Drug Enforcement Administration (DEA) List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))**

Not regulated

### **DEA Exempt Chemical Mixtures Code Number**

Not regulated

### **Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPS) List**

Not regulated

### **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated

### **CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

### **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

## **US State Regulations**

### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

### **U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated by state right-to-know regulations.

### **U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not available.

## **16. OTHER INFORMATION**

**Revision Date**

15-Jul-2015

**Revision Note**

Not available.

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**