



# SAFETY DATA SHEET

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

Issuing Date 30-Mar-2016

Revision Date 30-Mar-2016

Revision Number 1

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

**Product Name** CINQAIR®  
**CAS** -  
**EINECS** No information available  
**Index No** No information available  
**Reach Registration Number** No information available

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Identified Use** Pharmaceutical  
**Uses advised against** No information available

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

**Manufacturer, Supplier** TEVA  
1090 Horsham Road  
North Wales, PA 19454  
BUSINESS PHONE: 215-591-3000 [08:00 AM --> 05:00 PM]

For further information, please contact

**E-mail Address** TevaSDSRequest@tevapharm.com

### 1.4. Emergency Telephone Number

**Emergency Telephone Number** United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs]

## SECTION 2: Hazards identification

### 2.1. - Classification of the substance or mixture

**Classification according to Regulation (EC) No. 1272/2008**  
Exempt from requirements - regulated as a medicinal product.

### 2.2. Label Elements

Exempt from requirements - regulated as a medicinal product

### 2.3. Other hazards

None known

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

N.A.

### 3.2. Mixtures

Chemical Name	EC No.	REACH Reg. No.	CAS-No	Weight %	CLP/GHS classification
Reslizumab	-	Not available	241473-69-8	<1	Skin Sens. 1 H317

Full text of phrases reported in section 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

<b>Eye Contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Skin Contact</b>	Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes.
<b>Ingestion</b>	Clean mouth with water, only if the person is conscious. Get medical attention.
<b>Inhalation</b>	If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Remove from exposure, lie down.

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

<b>Irritation</b>	No information available.
<b>Corrosivity</b>	No information available.
<b>Eyes</b>	May cause: irritation, Watering, Redness.
<b>Skin</b>	May cause: irritation, allergic skin reaction, Dermatitis.
<b>Inhalation</b>	May cause: Irritation of the nose, Upper respiratory tract irritation, Sneezing, cough.
<b>Ingestion</b>	May cause: nausea, vomiting, diarrhea.

### 4.3. Indication of immediate medical attention and special treatment needed

<b>Notes to Physician</b>	Treat symptomatically.
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## SECTION 5: Fire-fighting measures

### 5.1. Extinguishing media

#### **Suitable Extinguishing Media**

Water spray. Carbon dioxide (CO<sub>2</sub>). Foam. Dry powder.

#### **Unsuitable extinguishing media**

No information available.

### 5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors. Combustible material.

### 5.3. Advice for firefighters

#### **Special protective equipment for firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid contact with dusts/fumes/mists/vapors.

#### **6.1.1. For non-emergency personnel**

**Protective equipment** See section 8

**Emergency procedures** Evacuate the danger area and alert emergency team

#### **6.1.2. For emergency responders**

See section 8

### 6.2. Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas. Prevent further leakage or spillage if safe to do so.

### 6.3. Methods and materials for containment and cleaning up

#### **6.3.1. Methods for Containment**

No information available.

#### **6.3.2. For cleaning up**

Take up mechanically and collect in suitable container for disposal.

#### **6.3.3. Other information**

No information available

### 6.4. Reference to other sections

See Sections 8 & 13 for additional information.

## SECTION 7: Handling and storage

### 7.1. Precautions for Safe Handling

#### Handling

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Do not breathe vapors/dust. Provide appropriate exhaust ventilation at places where dust is formed.

#### Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep in properly labeled containers. Keep away from direct sunlight. Avoid excessive heat. Keep at temperatures between 2 °C and 8 °C.

### 7.3. Specific end use(s)

#### Exposure Scenario

No information available.

#### Other Guidelines

No information available.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Exposure Limits

No occupational exposure limit values have been defined by authorities in production Country.

#### Biological occupational exposure limits

No information available.

#### Derived No Effect Level (DNEL)

No information available.

#### Predicted No Effect Concentration (PNEC)

No information available.

### 8.2. Exposure controls

#### Engineering Measures

Appropriate Engineering Controls.

#### Personal protective equipment

##### Eye/face protection

Use eye protection appropriate for the task.

##### Skin protection:

- Body protection

Use protective clothing appropriate for the task.

- Hand protection

Use appropriate protective gloves.

##### Respiratory Protection

Use appropriate respiratory protection.

#### Environmental exposure controls

No information available.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

<b>Appearance</b>	
<b>Color</b>	Colorless to light yellow
<b>Physical State</b>	Clear Liquid
<b>Odor</b>	No information available
<b>Odour Threshold</b>	No information available
<b>pH</b>	No information available
<b>Melting Point/Range</b>	No information available
<b>Boiling Point/Range</b>	No information available
<b>Flash Point</b>	No information available
<b>Evaporation Rate</b>	No information available
<b>Flammability (solid, gas)</b>	No information available
<b>Flammability Limits in Air</b>	
<b>Upper</b>	No information available
<b>Lower</b>	No information available
<b>Vapor Pressure</b>	No information available
<b>Vapor Density</b>	No information available
<b>Relative Density</b>	No information available
<b>Solubility</b>	No information available
<b>Autoignition Temperature</b>	No information available
<b>Decomposition Temperature</b>	No information available
<b>Viscosity</b>	No information available
<b>Explosive Properties</b>	No information available
<b>Oxidizing Properties</b>	No information available

### 9.2. Other information

No information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No information available.

### 10.2. Chemical Stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

None under normal processing.

### 10.4. Conditions to avoid

Extremes of temperature and direct sunlight.

### 10.5. Incompatible materials.

Strong acids. Strong bases.

### 10.6. Hazardous decomposition products

Toxic fumes of: carbon oxides, Nitrogen oxides (NOx).

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

#### For Reslizumab:

<b>acute toxicity</b>	No information available.
<b>skin corrosion/irritation</b>	No information available.
<b>serious eye damage/irritation</b>	No information available.
<b>respiratory or skin sensitization</b>	No information available.
<b>germ cell mutagenicity</b>	No evidence of mutagenicity in non-clinical studies.
<b>carcinogenicity</b>	No information available.
<b>reproductive toxicity</b>	No evidence of teratogenicity in animal studies. No evidence of effects on fertility in animal studies.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposures</b>	No information available.
<b>aspiration hazard</b>	No information available.

#### Other Information

**Central nervous system** May cause: headache.

## SECTION 12: Ecological information

### 12.1. Toxicity

#### **Ecotoxicity effects**

No information available.

### 12.2. Persistence and degradability

No information available.

### 12.3. Bioaccumulative potential

No information available.

### 12.4. Mobility in soil

It is expected to be mobile in soil.

### 12.5. Results of PBT and vPvB assessment

No information available.

### 12.6. Other adverse effects

#### **Endocrine Disruptor Information**

Not available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### **Waste from Residues/Unused Products**

Dispose of in accordance with local regulations.

#### **Contaminated Packaging**

Empty containers should be taken for local recycling, recovery or waste disposal.

## SECTION 14: Transport information

**14.1.**  
**UN-No** Not hazardous for transport

**14.2.**  
**Proper Shipping Name** Not hazardous for transport

**14.3. Transport hazard class(es)**  
**ADR / RID / ADN (land transport)** Not hazardous for transport  
**IMDG (sea transport)** Not hazardous for transport  
**IATA / ICAO (air transport)** Not hazardous for transport

**14.4.**  
**Packing Group** Not hazardous for transport

**14.5. Environmental hazards**  
**Marine Pollutant** No information available

**14.6. Special precautions for user**  
**Emergency No.** No information available  
**ADR/RID-Labels** No information available

**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**  
**Technical name** No information available  
**Ship type** No information available  
**Annex II** No information available

## SECTION 15: Regulatory information

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**  
- Regulation 1907/2006/EC (REACH) and successive modifications  
- Regulation 1272/2008 (CLP) and successive modifications  
- D.Lgs. 81/2008 and successive modifications and Dir. 2009/161/EU  
- REGULATION (EU) 2015/830

**15.2. Chemical Safety Assessment**  
No information available

**SECTION 16: Other information**

**CLP/GHS - Regulation**

**Hazard Statements**

Training appropriate for workers is required to ensure protection of human health and environment.

Application/Drug Class                      Treatment of eosinophilic asthma, hypereosinophilic syndrome (HES) and other eosinophil-mediated diseases.

**Source of data**

R.T.E.C.S. - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES  
A.C.G.I.H. - AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS  
H.S.D.B. - HAZARDOUS SUBSTANCES DATA BANK  
N.I.O.S.H. - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH  
N.T.P. - NATIONAL TOXICOLOGY PROGRAM  
I.A.R.C. - INTERNATIONAL AGENCY FOR RESEARCH ON CANCER  
ECHA (European chemicals agency) databases  
FDA (Food & Drug administration) database  
EMA (European Medicines agency) documents  
ChemAdvisor  
Chemspider database

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**Revision Note**

Not applicable

**Disclaimer**

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**End of Safety Data Sheet**