

## 1. Identification

### 1.1. Product identifier

**Product Identity** HAEGARDA®  
**Alternate Names** C1 Esterase Inhibitor Subcutaneous (Human)

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

**Intended use** See Technical Data Sheet.  
**Application Method** See Technical Data Sheet.

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

**Company Name** CSL Behring L.L.C.  
1020 First Avenue  
PO Box 61501  
King of Prussia, PA

### Emergency

**24 hour Emergency Telephone No.** Emergency Response: (800) 424-9300  
Emergency Product Information: (800) 504-5434  
**Customer Service: CSL Behring L.L.C.** (610) 878-4000

## 2. Hazard(s) identification

### 2.1. Classification of the substance or mixture

No applicable GHS categories.

### 2.2. Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.

No applicable GHS categories.

**[Prevention]:**

No GHS prevention statements

**[Response]:**

No GHS response statements

**[Storage]:**

No GHS storage statements

**[Disposal]:**

No GHS disposal statements

## 3. Composition/information on ingredients

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

Non-Hazardous Ingredients:

Material: Medicinal product derived from human plasma.

Active ingredient: C1 esterase inhibitor, human (C1-INH) (non hazardous component)

Other components: Aminoacetic acid, sodium chloride, sodium citrate (non hazardous components)

Content: 2000 or 3000 IU per vial

## 4. First aid measures

### 4.1. Description of first aid measures

|                   |  |
|-------------------|--|
| <b>General</b>    | Take off and remove dirty clothes  |
| <b>Inhalation</b> | Not applicable   |
| <b>Eyes</b>       | Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention. |
| <b>Skin</b>       | Wash with water  |
| <b>Ingestion</b>  | Drink water. Obtain medical attention if feeling ill.  |

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

|                 |   |
|-----------------|---|
| <b>Overview</b> | No specific symptom data available.<br>See section 2 for further details. |
|-----------------|---|

## 5. Fire-fighting measures

### 5.1. Extinguishing media

Water or any medium suitable for extinguishing.

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

Hazardous decomposition: No hazardous decomposition data available.

### 5.3. Advice for fire-fighters

None

**ERG Guide No.** ----

## 6. Accidental release measures

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

Put on appropriate personal protective equipment (see section 8).

### 6.2. Environmental precautions

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

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

Collect/absorb spilled material and dispose of properly.

## 7. Handling and storage

### 7.1. Precautions for safe handling

General precautions for handling of pharmaceuticals are to be considered. Protect from light when handling.

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

Handle containers carefully to prevent damage and spillage.

Store and transport at 2C to 25C. Do not freeze.

Incompatible materials: No data available.

Keep container closed tightly.

Store locked up or accessible to authorized persons or their representatives only.

### 7.3. Specific end use(s)

No data available.

## 8. Exposure controls and personal protection

### 8.1. Control parameters

**There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.**

### 8.2. Exposure controls

**Respiratory** Not Applicable

**Eyes** Not Applicable

**Skin** Not Applicable

**Engineering Controls** Provide adequate ventilation.

**Other Work Practices** Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

See section 2 for further details. - [Prevention]:

## 9. Physical and chemical properties

|   |  |
|---|--|
| <b>Appearance</b>                                   | White Solid  |
| <b>Odor</b>   | None   |
| <b>Odor threshold</b>                               | Not Measured   |
| <b>pH</b>   | 6.5-7.5  |
| <b>Melting point / freezing point</b>               | Not Measured   |
| <b>Initial boiling point and boiling range</b>      | Not Measured   |
| <b>Flash Point</b>                                  | Not Measured   |
| <b>Evaporation rate (Ether = 1)</b>                 | Not Measured   |
| <b>Flammability (solid, gas)</b>                    | Not Applicable   |
| <b>Upper/lower flammability or explosive limits</b> | <b>Lower Explosive Limit:</b> Not Measured<br><b>Upper Explosive Limit:</b> Not Measured |

|  |                 |
|--|-----------------|
| <b>Vapor pressure (Pa)</b>                             | Not Measured    |
| <b>Vapor Density</b>                                   | Not Measured    |
| <b>Specific Gravity</b>                                | Not Measured    |
| <b>Solubility in Water</b>                             | Readily Soluble |
| <b>Partition coefficient n-octanol/water (Log Kow)</b> | Not Measured    |
| <b>Auto-ignition temperature</b>                       | Not Measured    |
| <b>Decomposition temperature</b>                       | Not Measured    |
| <b>Viscosity (cSt)</b>                                 | Not Measured    |
| <b>Molecular Weight</b>                                | 105 KD          |

**9.2. Other information**

No other relevant information.

## 10. Stability and reactivity

**10.1. Reactivity**

Hazardous Polymerization will not occur.

**10.2. Chemical stability**

Stable under normal circumstances.

**10.3. Possibility of hazardous reactions**

No data available.

**10.4. Conditions to avoid**

Store and transport at 2°C to 30°C. Do not freeze. Protect from light.

**10.5. Incompatible materials**

No data available.

**10.6. Hazardous decomposition products**

No hazardous decomposition data available.

## 11. Toxicological information

**Acute toxicity**

Single dose studies:

Single subcutaneous administration of HAEGARDA in rabbits at dose levels up to approximately 670 IU/kg did not result in adverse findings.

No animal studies have been conducted to evaluate the effects of C1-INH on carcinogenesis, mutagenesis, and impairment of fertility.

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

| Classification                | Category | Hazard Description |
|-------------------------------|----------|--------------------|
| Acute toxicity (oral)         | ---      | Not Applicable     |
| Acute toxicity (dermal)       | ---      | Not Applicable     |
| Acute toxicity (inhalation)   | ---      | Not Applicable     |
| Skin corrosion/irritation     | ---      | Not Applicable     |
| Serious eye damage/irritation | ---      | Not Applicable     |
| Respiratory sensitization     | ---      | Not Applicable     |
| Skin sensitization            | ---      | Not Applicable     |
| Germ cell mutagenicity        | ---      | Not Applicable     |
| Carcinogenicity               | ---      | Not Applicable     |
| Reproductive toxicity         | ---      | Not Applicable     |
| STOT-single exposure          | ---      | Not Applicable     |
| STOT-repeated exposure        | ---      | Not Applicable     |
| Aspiration hazard             | ---      | Not Applicable     |

## 12. Ecological information

### 12.1. Toxicity

No additional information provided for this product. See Section 3 for chemical specific data.

### Aquatic Ecotoxicity

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

### 12.2. Persistence and degradability

There is no data available on the preparation itself.

### 12.3. Bioaccumulative potential

Not Measured

### 12.4. Mobility in soil

No data available.

### 12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

### 12.6. Other adverse effects

No data available.

## 13. Disposal considerations

**13.1. Waste treatment methods**

Observe all federal, state and local regulations when disposing of this substance.

**14. Transport information**

|   | <b>DOT (Domestic Surface Transportation)</b> | <b>IMO / IMDG (Ocean Transportation)</b>                        | <b>ICAO/IATA</b>                 |
|---|--|---|----------------------------------|
| <b>14.1. UN number</b>                    | Not Applicable                               | Not Regulated   | Not Regulated                    |
| <b>14.2. UN proper shipping name</b>      | Not Regulated                                | Not Regulated   | Not Regulated                    |
| <b>14.3. Transport hazard class(es)</b>   | <b>DOT Hazard Class:</b> Not Applicable      | <b>IMDG:</b> Not Applicable<br><b>Sub Class:</b> Not Applicable | <b>Air Class:</b> Not Applicable |
| <b>14.4. Packing group</b>                | Not Applicable                               | Not Applicable  | Not Applicable                   |
| <b>14.5. Environmental hazards</b>        |  |   |                                  |
| <b>IMDG</b>                               | Marine Pollutant: No                         |   |                                  |
| <b>14.6. Special precautions for user</b> |  |   |                                  |
|   | No further information                       |   |                                  |

**15. Regulatory information**

**Regulatory Overview**     The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.

**Toxic Substance Control Act ( TSCA)**     All components of this material are either listed or exempt from listing on the TSCA Inventory.

**WHMIS Classification**     Not Regulated

**US EPA Tier II Hazards**

**Fire:** No

**Sudden Release of Pressure:** No

**Reactive:** No

**Immediate (Acute):** No

**Delayed (Chronic):** No

**EPCRA 311/312 Chemicals and RQs:**  
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**EPCRA 302 Extremely Hazardous:**  
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**EPCRA 313 Toxic Chemicals:**  
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Carcinogens (>0.0%):**  
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Developmental Toxins (>0.0%):**  
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Female Repro Toxins (>0.0%):**  
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Male Repro Toxins (>0.0%):**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**New Jersey RTK Substances (>1%) :**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Pennsylvania RTK Substances (>1%) :**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

## 16. Other information

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

Not Applicable

The information contained herein is based upon data considered true and accurate. CSL Behring 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.

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