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

1.1. Product identifier

<table>
<thead>
<tr>
<th>Product form</th>
<th>Substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade name</td>
<td>CEFTRIAXONE IMPURITY A CRS</td>
</tr>
<tr>
<td>Chemical name</td>
<td>(6R,7R)-7-[(2E)-(2-aminothiazol-4-yl)(methoxyimino)acetyl]amino]-3-[[2-methyl-5,6-dioxo-1,2,5,6-tetrahydro-1,2,4-triazin-3-yl]sulphanyl[methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid ((E)-isomer)</td>
</tr>
<tr>
<td>Product code</td>
<td>C0692000</td>
</tr>
<tr>
<td>Other means of identification</td>
<td>RTECS No : XI0368800 (ceftriaxone sodium)</td>
</tr>
</tbody>
</table>

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

1.2.1. Relevant identified uses

| Main use category | The product is intended for research, analysis and scientific education. |
| Use of the substance/mixture | For professional use only |
| Function or use category | Laboratory chemicals |

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe
F-67081 Strasbourg
T +33(0)388412035 - F +33(0)388412771

1.4. Emergency telephone number

Emergency number : +44(0)1235239670

**SECTION 2: Hazards identification**

2.1. Classification of the substance or mixture

**Classification according to Regulation (EC) No. 1272/2008 [CLP]**

| Resp. Sens. 1 | H334 |
| Eye Irrit. 2  | H319 |
| Skin Irrit. 2 | H315 |
| STOT SE 3     | H335 |
| Skin Sens. 1  | H317 |
| Aquatic Chronic 4 | H413 |

Full text of H-phrases: see section 16

**Classification according to Directive 67/548/EEC or 1999/45/EC**

Xn: R42
Xi; R36/37/38
Xi: R43
R53

Full text of R-phrases: see section 16

**Adverse physicochemical, human health and environmental effects**

Impurities with unknown properties. No information available on this specific product, however by analogy, the product is considered to be: See Heading 2.2.
CEFTRIAXONE IMPURITY A CRS
Safety Data Sheet

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]
Hazard pictograms (CLP):
- GHS08
- GHS07

Signal word (CLP): Danger
Hazard statements (CLP):
- H315 - Causes skin irritation
- H317 - May cause an allergic skin reaction
- H319 - Causes serious eye irritation
- H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
- H335 - May cause respiratory irritation
- H413 - May cause long lasting harmful effects to aquatic life

Precautionary statements (CLP):
- P261 - Avoid breathing dust/fume/gas/mist/vapours/spray
- P264 - Wash hands and other exposed areas thoroughly after handling
- P272 - Contaminated work clothing should not be allowed out of the workplace
- P273 - Avoid release to the environment
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P285 - In case of inadequate ventilation wear respiratory protection
- P302+P352 - IF ON SKIN: Wash with plenty of soap and water
- P304+P340 - IF INHALED: remove victim to fresh air and keep at rest in a position comfortable for breathing
- P304+P341 - IF INHALED: if breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing
- P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
- P332+P313 - If skin irritation occurs: Get medical advice/attention
- P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
- P337+P313 - If eye irritation persists: Get medical advice/attention
- P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician
- P403+P352 - IF INHALED: if exposed to dust/fume/gas/mist/vapours/spray,
- P501 - Dispose of contents/container to: Hazardous waste. Comply with applicable regulations

2.3. Other hazards

Other hazards not contributing to the classification: Exposure may produce an allergic reaction.

SECTION 3: Composition/information on ingredients

3.1. Substances

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification according to Directive 67/548/EEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEFTRIAXONE IMPURITY A</td>
<td></td>
<td>≤ 100</td>
<td>Xn; R42</td>
</tr>
<tr>
<td>(Main constituent)</td>
<td></td>
<td></td>
<td>Xi; R36/37/38</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Xi; R43</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>R53</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEFTRIAXONE IMPURITY A</td>
<td></td>
<td>≤ 100</td>
<td>Resp. Sens. 1, H334</td>
</tr>
<tr>
<td>(Main constituent)</td>
<td></td>
<td></td>
<td>Eye Irrit. 2, H319</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Irrit. 2, H315</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT SE 3, H335</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Sens. 1, H317</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 4, H413</td>
</tr>
</tbody>
</table>

Full text of R-, H- and EUH-phrases: see section 16

3.2. Mixture

Not applicable
SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general: If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation: Move to fresh air in case of accidental inhalation. Assure fresh air breathing. Obtain medical attention if breathing difficulty persists.
First-aid measures after skin contact: Rinse skin with water/shower. Wash with plenty of soap and water.
First-aid measures after eye contact: Rinse with water while holding the eyes wide open. Contact lenses should be removed. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion: Rinse mouth out with water. The following symptoms may occur: (see section(s) : 2). If you feel unwell, seek medical advice.

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

Symptoms/injuries: See Heading 2.

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

No data available. Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: Small amounts: Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Dry powder. Large amounts: Not applicable.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Precautionary measures fire: Small amounts: Use normal individual fire protective equipment. Large amounts: Not applicable.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures: Wear suitable protective clothing, gloves and eye or face protection. Large amounts: Not applicable.

6.1.1. For non-emergency personnel

Protective equipment: See Headings 7 and 8.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Ensure waste is collected and contained. Clean thoroughly.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed: Small amounts: See Heading 1. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

Precautions for safe handling: Handle and open container with care. See Heading 8.

Hygiene measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures: Comply with applicable regulations.

Storage conditions: To guarantee the quality and properties of the product, keep : dry. Keep in a cool, well-ventilated place away from heat. Store in original container.

Incompatible products: Strong oxidizing agents.

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available
8.2. Exposure controls
Appropriate engineering controls: Material should be handled in a laboratory hood whenever possible.

Hand protection: Gloves. Chemical resistant PVC gloves (to European standard EN 374 or equivalent).
Eye protection: Wear eye protection. DIN EN 166.
Skin and body protection: Lab coat. Wear suitable protective clothing. DIN EN 13034.
Respiratory protection: Quarter mask (DIN EN 140). Wear appropriate breathing apparatus if air renewal not sufficient to maintain dust/vapour under TLV.

SECTION 9: Physical and chemical properties
9.1. Information on basic physical and chemical properties
Physical state: Solid
Colour: No data available
Odour: Not applicable. See Heading 2, 4.2, 8.
Odour threshold: No data available
pH: No data available
Relative evaporation rate (butylacetate=1): No data available
Melting point: No data available
Freezing point: No data available
Boiling point: No data available
Flash point: No data available
Self ignition temperature: No data available
Decomposition temperature: No data available
Flammability (solid, gas): No data available
Vapour pressure: No data available
Relative vapour density at 20 °C: No data available
Relative density: No data available
Solubility: No data available
Log Pow: No data available
Log Kow: No data available
Viscosity, kinematic: No data available
Viscosity, dynamic: No data available
Explosive properties: No data available
Oxidising properties: No data available
Explosive limits: No data available

9.2. Other information
No additional information available

SECTION 10: Stability and reactivity
10.1. Reactivity
No additional information available

10.2. Chemical stability
No additional information available

10.3. Possibility of hazardous reactions
Small amounts: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us. Large amounts: No data available.

10.4. Conditions to avoid
No additional information available

10.5. Incompatible materials
Small amounts: None under normal use. Large amounts: Not applicable.

10.6. Hazardous decomposition products
When heated to decomposition, emits dangerous fumes.
SECTION 11: Toxicological information
11.1. Information on toxicological effects

Acute toxicity : Not classified
Skin corrosion/irritation : Causes skin irritation.
Serious eye damage/irritation : Causes serious eye irritation.
Respiratory or skin sensitisation : May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
Specific target organ toxicity (single exposure) : May cause respiratory irritation.
Specific target organ toxicity (repeated exposure) : Not classified
Aspiration hazard : Not classified
Potential Adverse human health effects and symptoms : No appropriate human or animal health effects data are known to exist.

SECTION 12: Ecological information
12.1. Toxicity
Ecology - general : Small amounts: See Heading 2. Large amounts: Not applicable.

12.2. Persistence and degradability
No additional information available

12.3. Bioaccumulative potential
No additional information available

12.4. Mobility in soil
No additional information available

12.5. Results of PBT and vPvB assessment
No additional information available

12.6. Other adverse effects : The statement is derived from products of similar structure or composition.
:(No data available specific to the product)

SECTION 13: Disposal considerations
13.1. Waste treatment methods
Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.
Waste disposal recommendations : Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.

SECTION 14: Transport information
In accordance with ADR / RID / ADNR / IMDG / ICAO / IATA
14.1. UN number
No dangerous good in sense of transport regulations

14.2. UN proper shipping name
Not applicable

14.3. Transport hazard class(es)
Not applicable

14.4. Packing group
Not applicable

14.5. Environmental hazards
Other information : No supplementary information available.

14.6. Special precautions for user
14.6.1. Overland transport
No additional information available
14.6.2. **Transport by sea**
No additional information available

14.6.3. **Air transport**
No additional information available

14.7. **Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable

### SECTION 15: Regulatory information

15.1. **Safety, health and environmental regulations/legislation specific for the substance or mixture**

15.1.1. **EU-Regulations**
No REACH Annex XVII restrictions

15.1.2. **National regulations**
No additional information available

15.2. **Chemical safety assessment**
No additional information available

### SECTION 16: Other information

Full text of R-, H- and EUH-phrases::

<table>
<thead>
<tr>
<th>Aquatic Chronic 4</th>
<th>Hazardous to the aquatic environment — Chronic Hazard, Category 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Irrit. 2</td>
<td>Serious eye damage/eye irritation, Category 2</td>
</tr>
<tr>
<td>Resp. Sens. 1</td>
<td>Sensitisation — Respiratory, category 1</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>Skin corrosion/irritation, Category 2</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>Sensitisation — Skin, category 1</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation</td>
</tr>
<tr>
<td>H315</td>
<td>Causes skin irritation</td>
</tr>
<tr>
<td>H317</td>
<td>May cause an allergic skin reaction</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation</td>
</tr>
<tr>
<td>H334</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled</td>
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<tr>
<td>H335</td>
<td>May cause respiratory irritation</td>
</tr>
<tr>
<td>H413</td>
<td>May cause long lasting harmful effects to aquatic life</td>
</tr>
<tr>
<td>R36/37/38</td>
<td>Irritating to eyes, respiratory system and skin</td>
</tr>
<tr>
<td>R42</td>
<td>May cause sensitization by inhalation</td>
</tr>
<tr>
<td>R43</td>
<td>May cause sensitisation by skin contact</td>
</tr>
<tr>
<td>R53</td>
<td>May cause long-term adverse effects in the aquatic environment</td>
</tr>
<tr>
<td>Xi</td>
<td>Irritant</td>
</tr>
<tr>
<td>Xn</td>
<td>Harmful</td>
</tr>
</tbody>
</table>

**SDS EU (REACH Annex II)**

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.