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### **1** Identification of the substance/mixture and of the company/undertaking

#### · Product identifier

- · Trade name: Zonisamide
- CAS Number: 68291-97-4
- Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the preparation -
- · Details of the supplier of the safety data sheet
- Manufacturer/Supplier: Fagron UK Ltd First Floor, 1 Pink Lane Newcastle upon Tyne England NE1 5DW
- Further information obtainable from: Tel.: +44 (0) 845 652 2525
   Emergency telephone number: Emergency response telephone number:
- +44 (0) 845 652 2525

## 2 Hazards identification

Classification of the substance or mixture
 Classification according to Regulation (EC) No 1272/2008



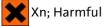
GHS08 health hazard

Repr. 2 H361 Suspected of damaging fertility or the unborn child.



Acute Tox. 4 H302 Harmful if swallowed.

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



R22-62-63: Harmful if swallowed. Possible risk of impaired fertility. Possible risk of harm to the unborn child. • Information concerning particular hazards for human and environment: Not applicable.

### · Label elements

- · Labelling according to Regulation (EC) No 1272/2008
- The substance is classified and labelled according to the CLP regulation.
- · Hazard pictograms GHS07, GHS08
- · Signal word Warning
- Hazard statements
- H302 Harmful if swallowed.

H361 Suspected of damaging fertility or the unborn child.

### · Precautionary statements

P281 Use personal protective equipment as required.

P264 Wash thoroughly after handling.

P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

- P308+P313 IF exposed or concerned: Get medical advice/attention.
- P405 Store locked up.

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P501 Dispose of contents/container in accordance with local/regional/national/international regulations. • Additional information: Void

- · Other hazards
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.

### 3 Composition/information on ingredients

- · Chemical characterization: Substances
- · CAS No. Description
- 68291-97-4 Zonisamide
- Identification number(s) -

### 4 First aid measures

- · Description of first aid measures
- · General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
- After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: Call for a doctor immediately.
- · Information for doctor:
- Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed No further relevant information available.

# **5 Firefighting measures**

- · Extinguishing media
- Suitable extinguishing agents:
- CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- · Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
- · Protective equipment: No special measures required.

# 6 Accidental release measures

- $\cdot$  Personal precautions, protective equipment and emergency procedures  $\mathsf{Not}$  required.
- · Environmental precautions:

Do not allow product to reach sewage system or any water course.

- Inform respective authorities in case of seepage into water course or sewage system.
- Methods and material for containment and cleaning up: Dispose contaminated material as waste according to item 13.
- **Reference to other sections** See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

## 7 Handling and storage

- · Handling:
- Precautions for safe handling No special precautions are necessary if used correctly.
- · Information about fire and explosion protection: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Not required.
- Further information about storage conditions: Store in cool, dry conditions in well sealed receptacles.
- **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- · Control parameters
- Ingredients with limit values that require monitoring at the workplace: Not required.
- Additional information: The lists valid during the making were used as basis.
- · Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures: Keep away from foodstuffs, beverages and feed.
- · Respiratory protection: Fresh air mask
- Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation • Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed. • **Eye protection:** Not required.

# 9 Physical and chemical properties

- Information on basic physical and chemical properties
- General Information • Appearance: Form: Colour:

Crystalline White

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		(Contd. of page 3)
· Odour: · Odour threshold:	Characteristic Not determined.	
· pH-value:	Not applicable.	
<ul> <li>Change in condition Melting point/Melting range: Boiling point/Boiling range:</li> </ul>	Undetermined. Undetermined.	
· Flash point:	Not applicable.	
· Flammability (solid, gaseous):	Product is not flammable.	
· Ignition temperature:		
Decomposition temperature:	Not determined.	
· Self-igniting:	Not determined.	
· Danger of explosion:	Product does not present an explosion hazard.	
<ul> <li>Explosion limits: Lower: Upper:</li> </ul>	Not determined. Not determined.	
· Vapour pressure:	Not applicable.	
<ul> <li>Density:</li> <li>Relative density</li> <li>Vapour density</li> <li>Evaporation rate</li> </ul>	Not determined. Not determined. Not applicable. Not applicable.	
<ul> <li>Solubility in / Miscibility with water:</li> </ul>	Not determined.	
· Partition coefficient (n-octanol/water	): Not determined.	
<ul> <li>Viscosity:</li> <li>Dynamic:</li> <li>Kinematic:</li> <li>Other information</li> </ul>	Not applicable. Not applicable. No further relevant information available.	

# **10 Stability and reactivity**

- · Reactivity
- · Chemical stability

• Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

- Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

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## **11** Toxicological information

- Information on toxicological effects
- Acute toxicity:
- · Primary irritant effect:
- on the skin: No irritant effect.
- **on the eye:** May have an irritating effect.
- Sensitization: No sensitizing effects known.
- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction) Repr. 2

# **12** Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- Persistence and degradability No further relevant information available.
- Behaviour in environmental systems:
- **Bioaccumulative potential** No further relevant information available.
- Mobility in soil No further relevant information available.
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- Other adverse effects No further relevant information available.

## **13 Disposal considerations**

- Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

UN-Number ADR	-	
UN proper shipping name ADR	-	
Transport hazard class(es)	-	
Packing group	-	
Environmental hazards: Marine pollutant:	No	
Special precautions for user	Not applicable.	



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#### Trade name: Zonisamide

 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not a

Not applicable.

### **15 Regulatory information**

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

### **16 Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing MSDS:** Fagron UK Quality Assurance
- · Contact: kathryn.mason@fagron.co.uk
- · Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

CAS: Chemical Abstracts Service (division of the American Chemical Society)

### •\* Data compared to the previous version altered.

FAGRON