according to 1907/2006/EC, Article 31

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

· 1.1 Product identifier

· Trade name: <u>Bumetanide</u> Bumetanidum

· Article number: 101871

• CAS Number: 28395-03-1 • EC number: 249-004-6

- 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Pharma Active ingredients
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Fagron UK Ltd 4B Coquet St Newcastle upon Tyne England NE1 2QB Tel. 0845 6522525

· Further information obtainable from:

Emergency response telephone number:

+44 (0) 845 652 2525

· 1.4 Emergency telephone number:

Emergency response telephone number:

+44 (0) 845 652 2525

SECTION 2: Hazards identification

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

Acute Tox. 4 H302 Harmful if swallowed.

Acute Tox. 4 H312 Harmful in contact with skin.

Acute Tox. 4 H332 Harmful if inhaled.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation. STOT SE 3 H335 May cause respiratory irritation.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the GB CLP regulation.

· Hazard pictograms



Signal word Warning



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· Hazard statements

H302+H312+H332 Harmful if swallowed, in contact with skin or if inhaled.

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/

international regulations.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

PBT: Not applicable.vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.1 Substances

· CAS No. Description

CAS: 28395-03-1 Bumetanide

Bumetanidum

· Identification number(s)

· EC number: 249-004-6

SECTION 4: First aid measures

· 4.1 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.

Immediately remove any clothing soiled by the product.

· After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Immediately rinse with water.

If skin irritation continues, consult a doctor.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· After swallowing: Seek immediate medical advice.

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

No further relevant information available.

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 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:

Use fire extinguishing methods suitable to surrounding conditions.

Water spray

Fire-extinguishing powder

Carbon dioxide

Foam

· 5.2 Special hazards arising from the substance or mixture

During heating or in case of fire poisonous gases are produced.

In case of fire, the following can be released:

Carbon monoxide (CO)

Nitrogen oxides (NOx)

Sulphur dioxide (SO2)

- 5.3 Advice for firefighters
- · Protective equipment:

Mouth respiratory protective device.

Wear self-contained respiratory protective device.

Wear fully protective suit.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Ensure adequate ventilation

Wear protective equipment. Keep unprotected persons away.

Mount respiratory protective device.

- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up:

Pick up mechanically.

Ensure adequate ventilation.

Dispose of the material collected according to regulations.

Dispose contaminated material as waste according to section 13.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Thorough dedusting.

Prevent formation of dust.

Ensure good ventilation/exhaustion at the workplace.

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- · Information about fire and explosion protection: No special measures required.
- · 7.2 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:

Keep container tightly sealed.

Protect from exposure to the light.

Protect from heat and direct sunlight.

Store in cool, dry conditions in well sealed receptacles.

Store receptacle in a well ventilated area.

· 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 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.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- Individual protection measures, such as personal protective equipment
- General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Do not eat, drink, smoke or sniff while working.

Do not inhale dust / smoke / mist.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Hand protection



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.

Rubber gloves

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· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye/face protection



Tightly sealed goggles

Body protection: Protective work clothing

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

Physical state
Colour:
Odour:
Odourless
Odour threshold:
Melting point/freezing point:

Solid
Whitish
Odourless
Not determined.
231–233°C

· Boiling point or initial boiling point and boiling

range Undetermined.

· Flammability Product is not flammable.

· Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.
Decomposition temperature: Not determined.
pH
Not applicable.

· Viscosity:

Kinematic viscosityDynamic:Not applicable.Not applicable.

· Solubility

· water: Not determined.

· Partition coefficient n-octanol/water (log

value) Not determined.

Vapour pressure: Not applicable.

· Density and/or relative density

Density: Not determined.
Relative density Not determined.
Vapour density Not applicable.

· 9.2 Other information

· Appearance:

· Form: Crystalline powder

 Important information on protection of health and environment, and on safety.

· **Ignition temperature:** Not determined.

• Explosive properties: Product does not present an explosion hazard.

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· Change in condition		
Evaporation rate	Not applicable.	
Information with regard to physical hazard classes		
· Explosives	Void	
· Flammable gases	Void	
· Aerosols	Void	
· Oxidising gases	Void	
· Gases under pressure	Void	
· Flammable liquids	Void	
Flammable solids	Void	
Self-reactive substances and mixtures	Void	
· Pyrophoric liquids	Void	
· Pyrophoric solids	Void	
Self-heating substances and mixtures	Void	
· Substances and mixtures, which emit		
flammable gases in contact with water	Void	
· Oxidising liquids	Void	
· Oxidising solids	Void	
· Organic peroxides	Void	
· Corrosive to metals	Void	
· Desensitised explosives	Void	

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

Risk of dust explosion if enriched with fine dust in the presence of air.

- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products:

Poisonous gases/vapours

Carbon monoxide and carbon dioxide

Nitrogen oxides (NOx)

Sulphur oxides (SOx)

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Harmful if swallowed, in contact with skin or if inhaled.
- · LD/LC50 values relevant for classification:

Oral LD50 4624 mg/kg (mouse)

· Skin corrosion/irritation Causes skin irritation.

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- · Serious eye damage/irritation Causes serious eye irritation.
- STOT-single exposure May cause respiratory irritation.
- · 11.2 Information on other hazards
- Endocrine disrupting properties Substance is not listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- 12.7 Other adverse effects
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- · 13.1 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.

SECTION 14: Transport information

· 14.1 UN number or ID number · ADR, IMDG, IATA	not regulated	
· 14.2 UN proper shipping name · ADR, IMDG, IATA	not regulated	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	not regulated	
· 14.4 Packing group · ADR, IMDG, IATA	not regulated	
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· 14.5 Environmental hazards:	Not applicable.	
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Maritime transport in bulk accord	ing to	
IMO instruments	Not applicable.	
· UN "Model Regulation":	not regulated	

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I Substance is not listed.
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 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 SDS:

Fagron UK

Quality Assurance

- · Contact: quality@fagron.co.uk
- Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity - Category 4

Skin Irrit. 2: Skin corrosion/irritation - Category 2

Eye Irrit. 2: Serious eye damage/eye irritation - Category 2

STOT SE 3: Specific target organ toxicity (single exposure) - Category 3

