



CONSEIL DE L'EUROPI

Bumetanide

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 03/04/2023 Version: 1.0

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

1.1. Product identifier Product form : Substance Substance name : Bumetanide : 201600982 Product code : Bumetanide, salts, hydrates, isomers and impurities where applicable Synonyms 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 Restrictions on use : Do not use : Ingestion, Inhalation, Dermal 1.3. Details of the supplier of the safety data sheet European Directorate for the Quality of Medicines & Healthcare EDQM, Council of Europe 7, Allée Kastner, CS30026 F- 67081 Strasbourg France T +33(0)388412035 - F +33(0)388412771 sds@edqm.eu - www.edqm.eu 1.4. Emergency telephone number Emergency number : +33(0)390215608 **SECTION 2: Hazards identification** 2.1. Classification of the substance or mixture Classification according to Regulation (EC) No. 1272/2008 [CLP] H373 Specific target organ toxicity - Repeated exposure, Category 2 Full text of H- and EUH-statements: see section 16 Adverse physicochemical, human health and environmental effects Expert judgement and weight of evidence determination. 2.2. Label elements Labelling according to Regulation (EC) No. 1272/2008 [CLP] Hazard pictograms (CLP) GHS08 Signal word (CLP) : Warning Hazard statements (CLP) : H373 - May cause damage to organs through prolonged or repeated exposure. Precautionary statements (CLP) P260 - Do not breathe dust. P314 - Get medical advice/attention if you feel unwell. Labelling according to: exemption for inner packaging where the contents do not exceed 10ml Hazard pictograms (CLP)



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GHS08

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier		Classification according to Regulation (EC) No. 1272/2008 [CLP]
Bumetanide	-	≤ 100	STOT RE 2, H373

Full text of H- and EUH-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after skin contact First-aid measures after eye contact Wipe off as much as possible (using a clean, soft, absorbent material).Rinse eyes with water as a precaution.

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

No additional information available

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

No additional information available

SECTION 5: Firefighting measures		
5.1. Extinguishing media		
Suitable extinguishing media	: Extinguishing blanket.	
5.2. Special hazards arising from the sub	ostance or mixture	
Fire hazard	: See Heading 2.2.	
5.3. Advice for firefighters		
Firefighting instructions	: Use extinguishing media appropriate for surrounding fire.	

SECTION 6: Accidental release measures		
6.1. Personal precautions, protective equip	ment and emergency procedures	
6.1.1. For non-emergency personnel		
Emergency procedures	: Avoid all unnecessary exposure.	

6.1.2. For emergency responders

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6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

No additional information available

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

No additional information available

7.2. Conditions for safe storage, including any incompatibilities

No additional information available

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Keep in a well-ventilated room. Both local exhaust and general room ventilation are usually required.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

No additional information available

8.2.2.2. Skin protection

Skin and body protection: Lab coat

Hand protection: Protective gloves

8.2.2.3. Respiratory protection

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8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

	_	Calid
Physical state	:	Solid
Colour	:	Not available
Appearance	:	Powder.
Odour	:	Not available
Odour threshold	:	Not available
Melting point	:	Not available
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Not available
Explosive limits	:	Not applicable
Lower explosion limit	:	Not applicable
Upper explosion limit	:	Not applicable
Flash point	:	Not applicable
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	Not available
рН	:	Not available
pH solution	:	Not available
Viscosity, kinematic	:	Not applicable
Solubility	:	Water: < 0.1 g/l
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20°C	:	Not applicable
Particle size	:	Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

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10.5. Incompatible materials

None under normal use. See Section 7.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

SECTION 11: Toxicological information		
11.1. Information on hazard classes as de	efined	d in Regulation (EC) No 1272/2008
Acute toxicity (oral) Acute toxicity (dermal) Acute toxicity (inhalation)	:	Not classified (Lack of data) Not classified (Lack of data) Not classified (Lack of data)
Bumetanide		
LD50 oral rat		> 2000 mg/kg
Skin corrosion/irritation	:	Not classified (Lack of data)
Serious eye damage/irritation	:	Not classified (Lack of data)
Respiratory or skin sensitisation	:	Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	:	Not classified (Lack of data)
Carcinogenicity	:	Not classified (Lack of data)
Reproductive toxicity	:	Not classified (Further details: STOT-repeated exposure)
STOT-single exposure	:	Not classified
STOT-repeated exposure	:	May cause damage to organs through prolonged or repeated exposure.
Aspiration hazard	:	Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

SECTION 12: Ecological information
12.1. Toxicity
Ecology - general : Presents no specific risk for the environment. Hazardous to the aquatic environment, short-term (acute) : Not classified Hazardous to the aquatic environment, long-term (chronic) : Not classified
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. Endocrine disrupting properties
No additional information available
12.7. Other adverse effects
No additional information available

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13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA		
ADR	IMDG	ΙΑΤΑ
14.1. UN number or ID number		
Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name		
Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)		·
Not applicable	Not applicable	Not applicable
14.4. Packing group		
Not applicable	Not applicable	Not applicable
14.5. Environmental hazards		
Not applicable	Not applicable	Not applicable
No supplementary information available		-

14.6. Special precautions for user

Overland transport Not applicable

Transport by sea Not applicable

Air transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

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

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not applicable.

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POP Regulation (Persistent Organic Pollutants)

Not applicable.

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

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 H- and EUH-statements:		
H373	May cause damage to organs through prolonged or repeated exposure.	
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2	

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.