

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

1.1. Product identifier

Product form : Mixture
Product name : Gentian Cystatin C Calibrator
Product code : 1012/1051
Other means of identification : Gentian Cystatin C Calibrator (product codes: 1012, 1012A, 1012USA, 8012, 8012A, 8012A-CN, 8012N, 8012NA, 8012R), Gentian Cystatin C Calibrator Kit (product codes 1051A-1, 1051A-2, 1051A-3, 1051A-4, 1051A-5, 1051A-6, 1051B, 1051USA, 8051, 8051-1, 8051-2, 8051-3, 8051-4, 8051-5, 8051-6, A52763)

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

Relevant identified uses

Industrial/Professional use spec : For professional use only
Use of the substance/mixture : Laboratory chemicals
For in vitro diagnostic use.

Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Gentian AS
Bjørnåsveien 5
1596 Moss - Norway
T +47 993 39 905
info@gentian.no - www.gentian.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Australia	NSW Poisons Information Centre	Childrens Hospital Westmead Hawkesbury Road, Sydney	+61 2 9845 3969 131126	Hours of operation: 24hrs
Bangladesh	Bangladesh National Poison Information Centre		16801	
Canada	Centre Antipoison du Québec	Pavillon Jeffery Hale Québec	+1 418 654 2731 1 800 463 5060	24 hrs
Cyprus	The CYPRUS POISON CENTER Number	Nikosia	1401	
Estonia	Mürgistusteabekeskus Terviseamet	Paldiski mnt 81 10614	16662 +372 7943 794	Calling the hotline is anonymous and at the cost of a local call.
Hong Kong	Hong Kong Poison Information Centre	Room 2A, Block K, United Christian Hospital 130 Hip Wo Street, Kwun Tong Kowloon	+852 2772 2211	24hrs
India	CEARCH (Center for Education, Awareness and Research on Chemicals and Health)	Supath II Vadaj, Ashram Road 380013 Ahmedabad	+91 982 404 7400	24hrs
Indonesia	National Poisons Information Centre (NPIC)	Sentra Informasi Keracunan, Badan POM, Jl Percetakan Negara No. 23 Jakarta	+62 813 1082 6879 +62 21 425 99 45	Available to the public 24hrs
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Israel	Israel Poison Information Center Rambam Health Care Campus	6 Ha'Aliya Street 31096	+972 4 854 1900	

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Malaysia	National Poisons Centre / WHO Collaborating Centre for drug	c/o Universiti Sains Malaysia, Penang	+604 567 0099 1 800 88 90 99	Hours of operation: 24hrs
Malta	Medicines & Poisons Info Office	Mater Dei Hospital Msida MSD 2090 Msida	+356 2545 6508	
Pakistan	National Poisons Control Centre	Jinnah Postgraduate Medical Centre Rafique Shaheed Road 75510 Karachi	+92 21 9920509/35686535	24hrs
Qatar	Qatar Poison Center	PO Box 26999 Al Gharrafa 26999 Doha	+974 4003 1111	9.00-1.00, every day
Saudi Arabia	Drug and Poison Information Center	Pharmaceutical Care Division King Faisal Specialist Hospital & Research Centre 11211 Riyadh	+966 11 442 7604	7:30-17:00 Sunday to Thursday
Singapore	Drug & Poison Information Centre		+65 6423 9119 Ambulance Service: 995	
South Africa	Tygerberg Poison Information Centre	Division of Pharmacology, Department of Medicine Faculty of Health Sciences, Tygerberg Campus, Stellenbosch University 7505 Tygerberg	+27 (0)861 555 777	
Thailand	Ramathibodi Poison Center Faculty of Medicine Ramathibodi Hospital	Mahidol University 10400 Bangkok	1367, Line ID poisrequest (national callers)	
United Arab Emirates	Health Poison and Drug Information Center	Airport Road Abu Dhabi	800 424	7:00-15:00 Sunday-Thursday
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+44 191 2606182 +44 191 2606180	Hours of operation: 24hrs
United Kingdom	National Poisons Information Service (Newcastle Centre) Regional Drugs and Therapeutics Centre	16/17 Framlington Place Newcastle-upon-Tyne NE2 4AB	0344 892 0111	Only for healthcare professionals
USA	National Capital Poison Center	3201 New Mexico Ave Ste 310 Washington, DC 20016 Washington DC	+1 202 362 3867 1 800 222 1222	24hrs

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: No particular/specific measures required. Allow affected person to breathe fresh air. Allow the patient to rest.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: If swallowed, rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Drink a few glasses of water or milk. Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after skin contact	: May cause skin irritation.
Symptoms/effects after eye contact	: Liquid splashes in the eye may cause irritation.
Symptoms/effects after ingestion	: Ingestion may cause nausea, vomiting and diarrhea.

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

In all cases of doubt, or when symptoms persist, seek medical attention.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: None to our knowledge. Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Non flammable.
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5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not enter fire area without proper personal protective equipment, including respiratory protection (EN137).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Concerning personal protective equipment to use, see section 8.
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6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment	: Equip cleanup and emergency crew with proper protection.
Emergency procedures	: Ventilate area.

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6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment : Collect all waste in suitable and labelled containers and dispose according to local legislation.
Methods for cleaning up : Take up liquid spill into absorbent material. The contaminated area should be cleaned up immediately with a suitable decontaminant. Collect spillage. Store away from other materials.

6.4. Reference to other sections

See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin and eyes. Wear appropriate personal protective equipment - see Section 8. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.
Hygiene measures : Wash hands thoroughly after use. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations.
Storage conditions : Store in a well-ventilated place. Keep container tightly closed.
Incompatible materials : Refer to Section 10 on Incompatible Materials.
Heat and ignition sources : Keep away from sources of ignition - No smoking.

7.3. Specific end use(s)

For in vitro diagnostic use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Gentian Cystatin C Calibrator	
Cyprus - Occupational Exposure Limits	
Local name	Αζίδιο του νατρίου
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Remark	δέρμα
Regulatory reference	Κανονισμοί του 2007 (Κ.Δ.Π. 295/2007)
Estonia - Occupational Exposure Limits	
Local name	Naatriumasiid
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Remark	A (Naha kaudu kergesti imenduv aine), S (Sensibiliseeriv aine)
Regulatory reference	Vabariigi Valitsuse 20. märtsi 2001. a määruse nr 105 (RT I, 21.12.2022, 3)
Ireland - Occupational Exposure Limits	
Local name	Sodium azide (as NaN ₃)
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Remark	IOELV (Indicative Occupational Exposure Limit Values), Skin (Substances which have the capacity to penetrate intact skin when they come in contact with it and be absorbed into the body. A substantial contribution to the total body burden via dermal exposure is possible)
Regulatory reference	Chemical Agents Code of Practice 2024

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Malta - Occupational Exposure Limits	
Local name	Sodium azide
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Remark	Skin # Ġilda
Regulatory reference	S.L. 424.24 - Chemical Agents at Work Regulations (L.N. 356 of 2021) # L.S. 424.24 - Regolamenti dwar Agenti Kimiċi fuq il-Post tax-Xogħol (A.L. 356 tal-2021)
United Kingdom - Occupational Exposure Limits	
Local name	Sodium azide
WEL TWA (OEL TWA)	0.1 mg/m ³ (as NaN ₃)
WEL STEL (OEL STEL)	0.3 mg/m ³ (as NaN ₃)
Remark	Sk (Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity)
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

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

No additional information available

8.2.2. Personal protection equipment

Personal protective equipment:

Avoid all unnecessary exposure.

8.2.2.1. Eye and face protection

Eye protection:

Protective goggles. STANDARD EN 166:2001

8.2.2.2. Skin protection

Skin and body protection:

Wear appropriate clothing to prevent any possibility of skin contact.

Hand protection:

Wear protective gloves. Nitril. Neoprene. Breakthrough time : 6 (> 480 minutes). Layer thickness : 0,11 mm. STANDARD EN ISO 374-1:2016/A1:2018, EN ISO 374-2:2019, EN ISO 374-4:2019

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Wear appropriate mask. Type A - High-boiling (>65 °C) organic compounds. Standard EN 143:2021

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Do not eat, drink or smoke during use.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: light brown.
Appearance	: Cloudy.
Odour	: Not available
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Non flammable.
Explosive limits	: Not available
Lower explosive limit (LEL)	: Not available
Upper explosive limit (UEL)	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
Solubility	: Not available
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 available
Particle size	: Not applicable
Particle size distribution	: Not applicable
Particle shape	: Not applicable
Particle aspect ratio	: Not applicable
Particle aggregation state	: Not applicable
Particle agglomeration state	: Not applicable
Particle specific surface area	: Not applicable
Particle dustiness	: Not applicable

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

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under normal conditions of use.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizers.

10.6. Hazardous decomposition products

May liberate toxic gases. Carbon monoxide. Carbon dioxide.

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SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met) (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met) (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met) (Based on available data, the classification criteria are not met)

Ethanol; ethyl alcohol (64-17-5)	
LD50 oral rat	6200 mg/kg (IUCLID)
LC50 Inhalation - Rat (Vapours)	124.7 mg/l/4h (IUCLID)

SODIUM AZIDE (26628-22-8)	
LD50 oral rat	27 mg/kg
LD50 dermal rabbit	20 mg/kg (ECHA)
LC50 Inhalation - Rat (Vapours)	0.054 – 0.52 mg/l/4h

Ethylenediaminetetraacetic acid disodium salt dihydrate (EDTA) (6381-92-6)	
LD50 oral rat	4500 mg/kg OECD Test-Guide 401

Skin corrosion/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-single exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met

SODIUM AZIDE (26628-22-8)	
STOT-repeated exposure	May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %
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11.2.2 Other information

Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met
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SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met) (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic) : Not classified (Based on available data, the classification criteria are not met) (Based on available data, the classification criteria are not met)

Ethanol; ethyl alcohol (64-17-5)	
LC50 - Fish [1]	8140 mg/l 48 h <i>Leuciscus idus</i> (golden orfe)
EC50 - Crustacea [1]	9268 – 14221 mg/l (48 hours - <i>Daphnia magna</i>)
EC50 - Other aquatic organisms [1]	6500 mg/l (48 hours - <i>Pseudomonas putida</i>)
EC50 72h - Algae [1]	5000 mg/l <i>Scenedesmus subspicatus</i>

SODIUM AZIDE (26628-22-8)	
LC50 - Fish [1]	2.75 mg/l <i>Oncorhynchus mykiss</i> (Rainbow trout)
EC50 96h - Algae [1]	0.35 mg/l (96 hours - <i>Pseudokirchneriella subcapitata</i>)

Ethylenediaminetetraacetic acid disodium salt dihydrate (EDTA) (6381-92-6)	
LC50 - Fish [1]	41 mg/l (96 hours - <i>Lepomis macrochirus</i>)

12.2. Persistence and degradability

Gentian Cystatin C Calibrator	
Persistence and degradability	Not established.

Ethanol; ethyl alcohol (64-17-5)	
Biodegradation	94 %

12.3. Bioaccumulative potential

Gentian Cystatin C Calibrator	
Bioaccumulative potential	Not established.

SODIUM AZIDE (26628-22-8)	
Partition coefficient n-octanol/water (Log Pow)	0.3 OECD TG117

12.4. Mobility in soil

Gentian Cystatin C Calibrator	
Ecology - soil	No data available.

12.5. Results of PBT and vPvB assessment

Gentian Cystatin C Calibrator	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : Based on available data, the classification criteria are not met

12.7. Other adverse effects

Other adverse effects : None to our knowledge.

Additional information : Avoid release to the environment.

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Product/Packaging disposal recommendations	: Avoid release to the environment. Dispose in a safe manner in accordance with local/national regulations.
Additional information	: The given LoW-code is a guiding, and the code depends on how the waste is formed. User must evaluate the choice of correct code.
Ecological waste information	: Avoid release to the environment.
European List of Waste (LoW, EC 2000/532)	: 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection 18 01 06* - chemicals consisting of or containing dangerous substances

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID /

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	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

Inland waterway transport

Not applicable

Rail 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

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

Contains no substance(s) listed on the REACH Candidate List

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

15.1.2. National regulations

No additional information available

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15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

Section	Changed item	Change	Comments
1.4	Emergency telephone number	Modified	

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

The information in this safety data sheet is based on information from the manufacturer/supplier, present european and national legislation, and presupposes that the product is used within the specified area of application.