

Safety Data Sheet



Product Information

Analyte: Cystatin C

Components covered by MSDS:

Name	Product codes
Gentian Cystatin C Calibrator	1012, 8012
Gentian Cystatin C Calibrator Kit	1051, 8051, A52763

Standard Used

EC 1272/2008 (CLP/GHS)

Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Revision Changes

Updated to GHS

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Section 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product identifier

Product name: Gentian Cystatin C Calibrator, Gentian Cystatin C Calibrator Kit

Part number:

Name	Product codes
Gentian Cystatin C Calibrator	1012, 8012
Gentian Cystatin C Calibrator Kit	1051, 8051, A52763

1.2 Relevant identified uses of the substance or mixture and uses advised against
Product for *In Vitro* diagnostic use.

1.3 Details of the supplier of the safety data sheet

Manufacturer: Gentian AS
Bjørnåsveien 5
N-1596 MOSS
NORWAY

Telephone: + 47 99 33 99 05

Fax: + 47 69 24 09 62

E-mail address: email@gentian.no

1.4 Emergency telephone number

Giftinformasjonssentralen + 47 22 59 13 00

Section 2: Hazards Identification

2.1 Classification of substance or mixture

Product description: *In vitro* diagnostic reagent, White; Liquid; Mild

Classification according to EC 1272/2008 (CLP/GHS): Not classified as hazardous per EC 1272/2008 (CLP/GHS)

Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS: Skin Irritation Category 3

2.2 Label Elements According to EC 1272/2008 (CLP/GHS) US-OSHA and UN GHS

Hazardous Ingredients: Methyl 4-hydroxybenzoate
Sodium Azide
Ethanol

Pictogram: None

Signal Word: None

Hazard Statements: H316 Causes mild skin irritation
EUH208 May produce an allergic reaction.

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Precautionary Statements: P332+P313 If skin irritation occurs get medical advice/attention

2.3 Other Hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

The concentration of NaN_3 within the product is below the level considered hazardous. However, accumulated NaN_3 in lead and copper pipes may cause generation of explosive metal azides.

This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.

See 'Section 11: Toxicological Information' for more detailed health information.

Section 3: Composition and Information on Ingredients

3.2 Mixtures

Hazardous Ingredients	CAS no.	% by weight in <i>End Product</i>	Hazard Classification of <i>Pure Ingredients</i> EU 1272/2008 CLP/GHS
Sodium Azide	26628-22-8	<0.1%	Acute Tox. Oral 2 Aquatic Acute 1 Aquatic Longterm 1 H300; H400; H410
Methyl 4-hydroxybenzoate	99-76-3	<0.0001%	Chronic aquatic tox. 3, H412
Ethanol	64-17-5	<0.1%	Flam. Liq. 2; H225

Section 4 First Aid Measures

4.1 Description of first aid measures

Inhalation: If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

Eye Contact: If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.

Skin Contact: In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical attention.

Ingestion: If ingested, wash mouth out with water. If irritation or discomfort occurs, seek medical attention.

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4.2 Most important symptoms and effects, both acute and delayed

Exposure may result in irritation of skin and eyes. This product contains a sensitizing substance below concentration limit that may produce an allergic reaction in some people. Refer to Section 3 for composition and Section 11 for more detailed health information.

4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

Section 5: Fire Fighting Measures

Flammable Properties: Non-flammable aqueous solution. This product contains one flammable constituent, however the concentration of this is <0.1% and therefore the mixture is considered as non-flammable

5.1 Extinguishing Media

No product specific requirements

5.2 Special hazards arising from the substance or mixture

No special hazards determined

5.3 Advice for fire fighters

No product specific requirements

5.4 Additional information

No further relevant information applicable.

Section 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions: This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.

Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of contents/container in accordance with local regulations

6.3 Methods and material for containment and cleaning up

As a precautionary measure dilute with water and absorb with an inert dry material and place in an appropriate waste disposal container.

6.4 Reference to other sections

Refer sections 8 and 13.

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Section 7: Handling and Storage

7.1 Precautions for safe handling

This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Keep the product in a cool, well-ventilated area. Store between 2-8°C. Do not use past expiration date stated on the label.

Store at 2 to 8°C, as directed on the product label. To maintain product quality, store according to the instructions in the product labeling.

Store away from strong acids, strong bases, strong oxidizers and incompatible materials.

7.3 Specific end uses

No further relevant information available.

Section 8: Exposure Controls and Personal Protection

8.1 Control parameters

Exposure Limits

Hazardous Ingredients	CAS no.	US OSHA	Occupational exposure limits EU directive 2000/39/EC
Sodium Azide	26628-22-8	None established	0.1 mg/m ³ TWA; 0.3 mg/m ³ STEL; Potential for cutaneous absorption

8.2 Exposure controls

Engineering Controls: No special engineering controls are required. Use with good general ventilation. Eye Protection Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

Skin Protection: Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

Respiratory Protection: Under normal conditions, the use of this product should not require respiratory protection.

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Section 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Appearance Form:	Liquid
Colour:	Translucent yellow
Odour:	Mild
Odour Threshold:	No data available
pH:	Not determined
Melting point/freezing point:	Similar to water, approximately 0 °C
Initial boiling point and boiling range:	Similar to water, approximately 100 °C
Flash point:	>60 °C
Evaporation rate:	No data available
Flammability (solid, gas):	Not applicable
Upper/lower flammability or explosive limits:	Not determined
Vapour pressure:	Similar to water, approximately 23 hPa
Vapour density:	no data available
Relative density:	no data available
Water solubility:	Not determined
Partition coefficient octanol/water:	Not determined
Auto-ignition temperature:	Product is not self-igniting
Decomposition temperature:	Not determined
Viscosity:	Not determined
Explosive properties:	Not determined
Oxidizing properties:	Not determined

9.2 Other Information

No further relevant information available.

Section 10: Stability and Reactivity

10.1 Reactivity

No further relevant information available.

10.2 Chemical stability

The product is stable in accordance with recommended storage conditions as stated on product labelling.

10.3 Possibility of hazardous reactions

Sodium azide forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds.

10.4 Conditions to avoid

Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.

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10.5 Incompatible materials

Metals and metallic compounds. Strong acids.

10.6 Hazardous decomposition products

No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

Section 11: Toxicological Information

11.1 Information on toxicological effects

Toxicity Data for Hazardous Ingredients

Ingredient	CAS no.	Information for pure ingredient
Sodium Azide	26628-22-8	Inhalation LD50 - Rat 37 mg/m ³ Dermal LD50 - Rabbit 20 mg/kg Oral LD50 - Rabbit 10mg/kg
Methyl 4-hydroxybenzoate	99-76-3	LD50 Oral - Rat 2.100 mg/kg
Ethanol	64-17-5	LD50 Oral - Rat 7.060 mg/kg LC50 Inhalation - Rat 10 h 20000 ppm

Primary Routes of Exposure: Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Skin Corrosion/Irritation: May cause skin irritation.

Serious eye damage/eye irritation: May cause eye irritation.

Respiratory/skin sensitization: This product contains a sensitizing substance below concentration limit, may produce an allergic reaction in some people. Refer Section 3.

Carcinogenicity: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

Germ cell mutagenicity: No data available.

Reproductive Toxicity: No component of this product present at levels greater than or equal to 0.1% is identified as contributing to reproductive toxicity.

Specific target organ toxicity (single exposure): This product contains a sensitizing substance below concentration limit, If inhaled may cause respiratory irritation. Refer to Section 3.

Specific target organ toxicity (repeated exposure): No data available.

Aspiration hazard: No data available.

Other Information: This product contains material of human and animal origin and should be considered as potentially capable of transmitting infectious diseases.

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Section 12: Ecological Information

12.1 Ecotoxicity

Ingredient	CAS no.	Information for pure ingredient
Sodium Azide	26628-22-8	EC50 Daphnia pulex (water flea) 4.2 mg/L (48 hrs)
Methyl 4-hydroxybenzoate	99-76-3	LC50 - Oryzias latipes - 59,5 mg/l - 96 h EC50 - Daphnia magna (Water flea) - 41,1 mg/l - 48 h EC50 - Pseudokirchneriella subcapitata - 91 mg/l - 72 h
Ethanol	64-17-5	No data available

12.2 Persistence and degradability

Not determined for the product.

12.3 Bioaccumulation

Not determined for the product.

12.4 Mobility in soil

Not determined for the product.

12.5 Results of PBT and vPvB assessment

Not determined for the product.

PBT: Not applicable

vPvB: Not applicable.

12.6 Other Adverse Effects

This product contains an environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

Section 13: Disposal Considerations

13.1 Waste treatment methods

Product Waste Disposal: Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76). To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations. Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

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Package disposal: Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

Section 14: Transport Information

Transportation of this product is not regulated under ICAO, IMDG, US DOT, European ADR or Canadian TDG.

Section 15: Regulatory Information

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

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization: No ingredients listed.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out.

Section 16: Other Information

Hazard Class, hazard statements and risk phrase description from section 3

Aquatic Acute 1 - Aquatic Hazard Acute, Category 1

Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1

Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2

Chronic aquatic tox. 3 - Chronic aquatic toxicity, Category 3

Eye Irrit. 2 - Eye Irritation Category 2

Flam. Liq. 2 – Flammable liquid, Category 2

H300 - Fatal if swallowed.

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.

H400 - Very toxic to aquatic life.

H410 - Very toxic to aquatic life with long lasting effects.

H412 - Harmful to aquatic life with long lasting effects

H225 - Highly flammable liquid and vapour

Resp. Sens. 1 - Respiratory Sensitization Category 1

Skin Irrit. 2 - Skin Irritation Category 2

Skin Sens. 1 - Skin Sensitization Category 1

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Abbreviations and Acronyms

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road

CLP - Classification, Labeling and Packaging

EC50 – Environmental Lethal Concentration, 50%

GHS - Globally Harmonized System

IARC - International Agency for Research on Cancer

ICAO - International Civil Aviation Organization

IMDG - International Maritime Dangerous Goods

IOELVs - European Unions' Indicative Occupational Exposure Limit Values

LC50 – Lethal Concentration, 50%

LD50 – Lethal Dose, 50%

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PBT - Persistent bioaccumulative and toxic substances

TDG - Canadian Transportation Of Dangerous Goods Regulations.

UN GHS - United Nations Globally Harmonized System

US DOT - United States Department of Transportation

vPvB - Very persistent and very bioaccumulative substances