

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

#### 1.1. Product identifier

Product form : Mixture  
Product name : Gentian Cystatin C Immunoparticles  
Product code : 1101  
Other means of identification : Gentian Cystatin C Immunoparticles (product codes 1014A, 1014A-CN, 8014A, 8014A-CN) and available as part of kits 1100, 1101, 1101USA, 1103, A52761 and B08179

#### 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](mailto:info@gentian.no) - [www.gentian.com](http://www.gentian.com)

#### 1.4. Emergency telephone number

Country	Official advisory body	Address	Emergency number	Comment
Australia	NSW Poisons Information Centre	Childrens Hospital Westmead Hawkesbury Road, Sydney	+61 2 9845 3969 131126	Hours of operation: 24hrs
Canada	Centre Antipoison du Québec	Pavillon Jeffery Hale Québec	+1 418 654 2731 1 800 463 5060	24 hrs
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
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 Haifa	+972 4 854 1900	
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	

# Safety Data Sheet

## Gentian Cystatin C Immunoparticles

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

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
USA	National Capital Poison Center	3201 New Mexico Ave Ste 310 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 is 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

## 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. 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.

# Safety Data Sheet

## Gentian Cystatin C Immunoparticles

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

### 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.
-------------	------------------

### 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.
------------------	---

#### 6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
----------------------	-----------------------------------

#### 6.1.2. For emergency responders

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

### 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. 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. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Wear appropriate personal protective equipment - see Section 8. 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.

# Safety Data Sheet

## Gentian Cystatin C Immunoparticles

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

### 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 Immunoparticles	
<b>Ireland - Occupational Exposure Limits</b>	
Local name	Sodium azide (as NaN <sub>3</sub> )
OEL TWA [1]	0.1 mg/m <sup>3</sup>
OEL STEL	0.3 mg/m <sup>3</sup>
Remark	Sk (Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body), IOELV (Indicative Occupational Exposure Limit Values)
Regulatory reference	Chemical Agents Code of Practice 2021
<b>United Kingdom - Occupational Exposure Limits</b>	
Local name	Sodium azide
WEL TWA (OEL TWA) [1]	0.1 mg/m <sup>3</sup> (as NaN <sub>3</sub> )
WEL STEL (OEL STEL)	0.3 mg/m <sup>3</sup> (as NaN <sub>3</sub> )
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

# Safety Data Sheet

## Gentian Cystatin C Immunoparticles

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

### 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.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: White.
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	: 8.6 – 8.9
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.

# Safety Data Sheet

## Gentian Cystatin C Immunoparticles

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

### 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.

## 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)  
Acute toxicity (dermal) : Not classified (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)

#### hydrochloric acid (7647-01-0)

LC50 Inhalation - Rat	4726 mg/l/4h
-----------------------	--------------

#### 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

#### Methyl 4-hydroxybenzoate (99-76-3)

LD50 oral rat	> 5000 mg/kg OECD Guideline 401
---------------	---------------------------------

#### sodium hydroxide; caustic soda (1310-73-2)

LD50 oral	> 500 mg/kg rabbit
-----------	--------------------

Skin corrosion/irritation : Not classified  
pH: 8.6 – 8.9  
Additional information : Based on available data, the classification criteria are not met  
Serious eye damage/irritation : Not classified  
pH: 8.6 – 8.9  
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

#### hydrochloric acid (7647-01-0)

STOT-single exposure	May cause respiratory irritation.
----------------------	-----------------------------------

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.
------------------------	--

# Safety Data Sheet

## Gentian Cystatin C Immunoparticles

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

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 is 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

#### 11.2.2 Other information

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

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

hydrochloric acid (7647-01-0)	
LC50 - Fish [1]	232 mg/l (96 hours - Gambusia affinis - Mosquito fish)
EC50 - Crustacea [1]	> 56 mg/l (48 hours - Daphnia magna)

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

Methyl 4-hydroxybenzoate (99-76-3)	
LC50 - Fish [1]	59.5 mg/l Oryzias latipes (Ricefish)
EC50 - Crustacea [1]	11.2 mg/l (48 hours - Daphnia magna)
ErC50 algae	91 mg/l 72 hours - Pseudokirchnerella subcapitata

sodium hydroxide; caustic soda (1310-73-2)	
LC50 - Fish [1]	45 mg/l (96 hours - Rainbow trout)
EC50 - Crustacea [1]	30 mg/l Daphnia magna, 48 hours

### 12.2. Persistence and degradability

Gentian Cystatin C Immunoparticles	
Persistence and degradability	Not established.

### 12.3. Bioaccumulative potential

Gentian Cystatin C Immunoparticles	
Bioaccumulative potential	Not established.

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

Methyl 4-hydroxybenzoate (99-76-3)	
Bioconcentration factor (BCF REACH)	6.46
Partition coefficient n-octanol/water (Log Pow)	1.96

# Safety Data Sheet

## Gentian Cystatin C Immunoparticles

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

sodium hydroxide; caustic soda (1310-73-2)	
Partition coefficient n-octanol/water (Log Pow)	< 0

### 12.4. Mobility in soil

Gentian Cystatin C Immunoparticles	
Ecology - soil	No data available.

### 12.5. Results of PBT and vPvB assessment

Gentian Cystatin C Immunoparticles	
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.

## 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 : Dispose in a safe manner in accordance with local/national regulations. Avoid release to the environment.  
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.  
Ecology - waste materials : Avoid release to the environment.  
European List of Waste (LoW) code : 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
<b>14.1. UN number or ID number</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

### 14.6. Special precautions for user

Overland transport  
Not applicable



# Safety Data Sheet

## Gentian Cystatin C Immunoparticles

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

### 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 REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

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.