

Gentian SARS-CoV-2 Total Antibody

Immunoparticles

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Issue date: 10/01/2022 Revision date: 10/01/2022 Version: 1.0 EN

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

1.1. Product identifier

Product form
Product name
Product code
Other means of identification

: Mixture

: Gentian SARS-CoV-2 Total Antibody Immunoparticles

: 1814

: Available as part of Gentian SARS-CoV-2 Total Antibody Reagent Kit (1801)

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

Relevant identified uses

Industrial/Professional use spec Use of the substance/mixture For professional use onlyLaboratory chemicalsFor 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	Official advisory body	Address	Emergency number	Comment
United Kingdom		Claremont Place		Hours of operation: 24hrs
	(Newcastle Unit)	Newcastle-upon-Tyne, Newcastle	+44 191 2606180	

H317

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin Sens. 1

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP)

Signal word (CLP) Contains Hazard statements (CLP) Precautionary statements (CLP)



- : Warning
- 2-methylisothiazol-3(2H)-one
- : H317 May cause an allergic skin reaction.
- : P280 Wear eye protection, protective gloves, protective clothing.
 - P302+P352 IF ON SKIN: Wash with plenty of soap and water.
 - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - P337+P313 If eye irritation persists: Get medical advice/attention.
 - P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 - P362+P364 Take off contaminated clothing and wash it before reuse.



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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

Name	Product identifier	Conc. (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-methylisothiazol-3(2H)-one	(CAS-No.) 2682-20-4 (EC-No.) 220-239-6 (EC Index-No.) 613-326-00-9	≥ 0.005 - < 0.01	Acute Tox. 2 (Inhalation), H330 (ATE=0.5 mg/l/4h) Acute Tox. 3 (Dermal), H311 (ATE=300 mg/kg bodyweight) Acute Tox. 3 (Oral), H301 (ATE=100 mg/kg bodyweight) Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410

Specific concentration limits:				
Name	Product identifier	Specific concentration limits		
2-methylisothiazol-3(2H)-one	(CAS-No.) 2682-20-4 (EC-No.) 220-239-6 (EC Index-No.) 613-326-00-9	(0.0015 ≤C ≤ 100) Skin Sens. 1A, H317		

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Symptoms/effects after eye contact

: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
 Allow affected person to breathe fresh air. Allow the patient to rest. If experiencing respiratory symptoms: Call a poison center or a doctor.
Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. In all cases of doubt, or when symptoms persist, seek medical attention.
 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. If swallowed, rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Drink a few glasses of water or milk. Get medical advice/attention.

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

Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: May cause skin irritation.

- lay cause skin irritation.
- : Liquid splashes in the eye may cause irritation.

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

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



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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 Hazardous decomposition products in case of fire	Non flammable.Carbon oxides (CO, CO2). nitrogen oxides (NOx) and sulphur oxides.			
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. Avoid contact with skin and eyes.		
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.

6.3. Methods and material for containment and cleaning up

For containment Methods for cleaning up Collect all waste in suitable and labelled containers and dispose according to local legislation.
 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.

Avoid contact with skin and eyes. Wear appropriate personal protective equipment - see Section 8. Was 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.
Wash hands thoroughly after use. Wash contaminated clothing before reuse.
ompatibilities
Comply with applicable regulations.
Store in a well-ventilated place. Keep container tightly closed.
Refer to Section 10 on Incompatible Materials.

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

No additional information available



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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.

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	:	8.8 - 9.2
Viscosity, kinematic	:	Not available
Solubility	:	Not available



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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 oxidizers. Strong reducing agents. Amines.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO2). nitrogen oxides (NOx) and sulphur oxides.

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)		
Skin corrosion/irritation	: Not classified		
	pH: 8.8 – 9.2		
Additional information	: Based on available data, the classification criteria are not met		
Serious eye damage/irritation	: Not classified		
	pH: 8.8 – 9.2		
Additional information	: Based on available data, the classification criteria are not met		
Respiratory or skin sensitisation	: May cause an allergic skin reaction.		
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		



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STOT-single exposure Additional information	: Not classified : Based on available data, the classification criteria are not met
STOT-repeated exposure Additional information	 Not classified Based on available data, the classification criteria are not met
Aspiration hazard Additional information	 Not classified 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)

12.2. Persistence and degradability

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Persistence and degradability	Not established.
12.3. Bioaccumulative potential	

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Bioaccumulative potential	Not established.

12.4. Mobility in soil

available.

12.5. Results of PBT and vPvB assessment

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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	:	Based on available data, the classification criteria are not met
disrupting properties		
12.7. Other adverse effects		

Other adverse effects	:	None to our knowledge.
Additional information	:	Avoid release to the environment.

SECTION 13: Disposal consideratio	ns
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.



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- Ecology waste materials
- European List of Waste (LoW) code
- : Avoid release to the environment.

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

ADR	IMDG	ΙΑΤΑ	ADN	RID
14.1. UN number or ID nu	mber			
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 cla	ass(es)			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group	I		!	
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental haza	rds			ł
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

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 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



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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. Full text of H- and EUH-statements: Acute Tox. 2 (Inhalation) Acute toxicity (inhal.), Category 2 Acute Tox. 3 (Dermal) Acute toxicity (dermal), Category 3 Acute Tox. 3 (Oral) Acute toxicity (oral), Category 3 Hazardous to the aquatic environment - Acute Hazard, Category 1 Aquatic Acute 1 Aquatic Chronic 1 Hazardous to the aquatic environment - Chronic Hazard, Category 1 Eye Dam. 1 Serious eye damage/eye irritation, Category 1 H301 Toxic if swallowed. H311 Toxic in contact with skin. H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction H318 Causes serious eye damage. Fatal if inhaled. H330 H400 Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects. H410 Skin Corr. 1B Skin corrosion/irritation, Category 1, Sub-Category 1B Skin Sens. 1 Skin sensitisation, Category 1 Skin Sens. 1A Skin sensitisation, category 1A

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.

