

SAFETY DATA SHEET

Latex Cryptococcus Antigen Detection System – CR1004

Component Ref#	Description
CB0010	Crypto Antigen Positive Control
CG0010	Cryptococcal Latex
EI0010	Pronase Inhibitor
R20000	Pronase Control
DE0010	Pronase
GB0020	Specimen Diluent (10X)
N80110	Negative Control



Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Issue date: 2023-04-28

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

1.1. Product identifier

Product form : Mixture

Trade name Crypto Antigen Positive Control, Cryptococcal Latex, Pronase Inhibitor, Pronase Control

CB0010, CG0010, El0010, R20000 Product code

Product group Trade product

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

1.2.1. Relevant identified uses

Use of the substance/mixture : For In Vitro Diagnostic Use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

IMMY (Immuno-Mycologics, Inc.) 2701 Corporate Centre Dr. Norman, OK 73069 - USA T 405-360-4669

sds@immy.com - www.immy.com

1.4. Emergency telephone number

Emergency number : +1-800-654-3639

8:30 AM - 5:00 PM, Monday - Friday

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

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 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

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

Contains no hazardous ingredients at levels requiring disclosure by Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

SECTION 4: First Aid measures

4.1. Description of first aid measures

First-aid measures general	If exposed or concerned, get medical attention/advice. Show this safety data sheet to the
	doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an

unconscious person.

First-aid measures after inhalation : IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing.

Get medical attention if breathing is affected. If breathing is difficult, supply oxygen.

First-aid measures after skin contact : IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water for at least 15 minutes. If irritation develops or persists, get medical attention.

First-aid measures after eye contact : IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Remove contact

lenses if present and easy to do so. Continue rinsing if pain, blinking, or irritation develops

or persists, get medical attention. Continue rinsing.

First-aid measures after ingestion : IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from

poison control center. Get medical attention if you feel unwell.

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

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/effects after inhalation : May cause respiratory irritation.

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

Symptoms/effects after eye contact : Direct contact with eyes is likely to be irritating.

Symptoms/effects after ingestion : May cause gastrointestinal irritation.

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 : Foam. Carbon dioxide. Dry powder. Water spray.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Not expected to be a fire/explosion hazard under normal conditions of use.

Explosion hazard : Product is not explosive.

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Reactivity in case of fire : None known.

Hazardous decomposition products in case of fire : No information available.

5.3. Advice for firefighters

Precautionary measures fire : Eliminate all ignition sources if safe to do so.

Firefighting instructions : Exercise caution when fighting any chemical fire. Use water spray or fog for cooling

exposed containers. Do not dispose of fire-fighting water in the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

Self-contained breathing apparatus.

Other information : Under fire conditions closed containers may rupture or explode.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Evacuate area. Ventilate area. Keep upwind. Spill should be handled by trained cleaning

personnel properly equipped with respiratory and eye protection.

6.1.1. For non-emergency personnel

Protective equipment : Wear Protective equipment as described in Section 8.

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Wear suitable protective clothing, gloves and eye or face protection. Approved supplied-air

respirator, in case of emergency.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or

streams. Prevent entry to sewers and public waters.

Methods for cleaning up : Use only non-sparking tools. Small quantities of liquid spill: take up in non-combustible

absorbent material and shovel into container for disposal. This material and its container

must be disposed of in a safe way, and as per local legislation.

6.4. Reference to other sections

See Sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not handle until all safety precautions have been read and understood. Keep away from

heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container closed when not in use. Avoid contact with skin and eyes. Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid contact during

pregnancy/while nursing.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in original container. Keep container closed when not in use. Containers which are

opened should be properly resealed and kept upright to prevent leakage. Store in a dry,

cool and well-ventilated place.

Incompatible materials : No data available.

Heat and ignition sources : Avoid ignition sources.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. National occupational exposure and biological limit values

Polystyrene (9003-53-6)		
Czech Republic - Occupational Exposure Limits		
PEL (OEL TWA)	5 mg/m³ (dust)	
Sodium azide (26628-22-8)		
EU - Indicative Occupational Exposure Limit (IOEL)		
IOEL TWA	0.1 mg/m³	
IOEL STEL	0.3 mg/m³	
Notes	Possibility of significant uptake through the skin	
Austria - Occupational Exposure Limits		
MAK (OEL TWA)	0.1 mg/m³	
MAK (OEL STEL)	0.3 mg/m³	
Chemical category	Skin notation	
Belgium - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
Chemical category	Skin, Skin notation	
Bulgaria - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Croatia - Occupational Exposure Limits		
GVI (OEL TWA) [1]	0.1 mg/m³	
KGVI (OEL STEL)	0.3 mg/m³	
Chemical category	Skin notation	
Cyprus - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	

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Sodium azide (26628-22-8)		
OEL STEL	0.3 mg/m³	
Chemical category	Skin-potential for cutaneous absorption	
Czech Republic - Occupational Exposure Limits		
PEL (OEL TWA)	0.1 mg/m³	
Chemical category	Potential for cutaneous absorption	
Denmark - Occupational Exposure Limits		
OEL TWA [1]	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Potential for cutaneous absorption	
Estonia - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Skin notation, Sensitizer	
Finland - Occupational Exposure Limits		
HTP (OEL TWA) [1]	0.1 mg/m³	
HTP (OEL STEL)	0.3 mg/m³	
Chemical category	Potential for cutaneous absorption	
France - Occupational Exposure Limits		
VME (OEL TWA)	0.1 mg/m³ (restrictive limit)	
VLE (OEL C/STEL)	0.3 mg/m³ (restrictive limit)	
Chemical category	Risk of cutaneous absorption	
Germany - Occupational Exposure Limits (TRGS 900)		
AGW (OEL TWA) [1]	0.2 mg/m³	
Gibraltar - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Skin notation	
Greece - Occupational Exposure Limits		
OEL TWA	0.3 mg/m³	
OEL TWA [ppm]	0.1 ppm	
OEL STEL	0.3 mg/m³	
OEL STEL [ppm]	0.1 ppm	
Hungary - Occupational Exposure Limits		
AK (OEL TWA)	0.1 mg/m³	

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Sodium azide (26628-22-8)		
CK (OEL STEL)	0.3 mg/m³	
Ireland - Occupational Exposure Limits		
OEL TWA [1]	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Potential for cutaneous absorption	
Italy - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	skin - potential for cutaneous absorption	
Latvia - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
Chemical category	skin - potential for cutaneous exposure	
Lithuania - Occupational Exposure Limits		
IPRV (OEL TWA)	0.1 mg/m³	
TPRV (OEL STEL)	0.3 mg/m³	
Chemical category	Skin notation	
Luxembourg - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Possibility of significant uptake through the skin	
Malta - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Possibility of significant uptake through the skin	
Netherlands - Occupational Exposure Limits		
TGG-8u (OEL TWA)	0.1 mg/m³	
TGG-15min (OEL STEL)	0.3 mg/m³	
MAC chemical category	Skin notation	
Poland - Occupational Exposure Limits		
NDS (OEL TWA)	0.1 mg/m³	
NDSCh (OEL STEL)	0.3 mg/m³	
Portugal - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³ (indicative limit value)	
OEL STEL	0.3 mg/m³ (indicative limit value)	

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Sodium azide (26628-22-8)			
OEL C	0.29 mg/m³		
OEL C [ppm]	0.11 ppm (vapor)		
Chemical category	A4 - Not Classifiable as a Human Carcinogen, skin - potential for cutaneous exposure indicative limit value		
Romania - Occupational Exposure Limits			
OEL TWA	0.1 mg/m³		
OEL STEL	0.3 mg/m³		
Chemical category	Skin notation		
Slovakia - Occupational Exposure Limits			
NPHV (OEL TWA) [1]	0.1 mg/m³ (Sodium azide)		
NPHV (OEL C)	0.3 mg/m³		
Chemical category	Potential for cutaneous absorption		
Slovenia - Occupational Exposure Limits			
OEL TWA	0.1 mg/m³		
OEL STEL	0.3 mg/m³		
Chemical category	Potential for cutaneous absorption		
Spain - Occupational Exposure Limits			
VLA-ED (OEL TWA) [1]	0.1 mg/m³ (indicative limit value)		
VLA-EC (OEL STEL)	0.3 mg/m³		
Chemical category	skin - potential for cutaneous absorption		
Sweden - Occupational Exposure Limits			
NGV (OEL TWA)	0.1 mg/m³		
KTV (OEL STEL)	0.3 mg/m³		
United Kingdom - Occupational Exposure Limits			
WEL TWA (OEL TWA) [1]	0.1 mg/m³		
WEL STEL (OEL STEL)	0.3 mg/m³		
WEL chemical category	Potential for cutaneous absorption		
Norway - Occupational Exposure Limits			
Grenseverdi (OEL TWA) [1]	0.1 mg/m³		
Korttidsverdi (OEL STEL)	0.3 mg/m³ (value from the regulation)		
Switzerland - Occupational Exposure Limits			
MAK (OEL TWA) [1]	0.2 mg/m³ (inhalable dust)		
KZGW (OEL STEL)	0.4 mg/m³ (inhalable dust)		
Turkey - Occupational Exposure Limits	Turkey - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³		

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Sodium azide (26628-22-8)		
OEL STEL	0.3 mg/m³	
Chemical category	Skin notation	
USA - ACGIH - Occupational Exposure Limits		
Local name	Sodium azide	
ACGIH OEL C	0.29 mg/m³	
ACGIH OEL C [ppm]	0.11 ppm	
Remark (ACGIH)	TLV® Basis: Card impair; lung dam. Notations: A4 (Not classifiable as a Human Carcinogen)	
ACGIH chemical category	Not Classifiable as a Human Carcinogen	
Regulatory reference	ACGIH 2023	
Glycine (56-40-6)		
Latvia - Occupational Exposure Limits		
OEL TWA	5 mg/m³ (Aminoacids)	
Sodium chloride (7647-14-5)		
Latvia - Occupational Exposure Limits		
OEL TWA	5 mg/m³	
Lithuania - Occupational Exposure Limits		
IPRV (OEL TWA)	5 mg/m³	
Lithuania - Occupational Exposure Limits		
IPRV (OEL TWA)	5 mg/m³	

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:

Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Use explosion-proof equipment with flammable materials. Ensure adequate ventilation, especially in confined areas.

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8.2.2. Personal protection equipment

Personal protective equipment:

Gloves. Protective goggles. Protective clothing.

Personal protective equipment symbol(s):







8.2.2.1. Eye and face protection

Eye protection:

Wear eye protection, including chemical splash goggles and a face shield when possibility exists for eye contact due to spraying liquid or airborne particles [EN 166]

8.2.2.2. Skin protection

Skin and body protection:

Wear long sleeves, and chemically impervious PPE/coveralls to minimize bodily exposure. [EN 14605:2005 and EN 13034:2005]

Hand protection:

Use gloves chemically resistant to this material when prolonged or repeated contact could occur. Gloves should be classified under Standard EN 374 or ASTM F1296. Suggested glove materials are: Neoprene, Nitrile/butadiene rubber, Polyethylene, Ethyl vinyl alcohol laminate, PVC or vinyl. Suitable gloves for this specific application can be recommended by the glove supplier.

8.2.2.3. Respiratory protection

Respiratory protection:

Where vapour, mist, or dust exceed PELs or other applicable OELs, use European Standard EN 529:2005 approved dust/particulate respiratory protective equipment

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

Physical state : Liquid

Colour No data available. Odour No data available : Not available Odour threshold Melting point : Not available Freezing point : Not available Boiling point Not available Flammability : Not available **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 : Not available

: Not applicable

Viscosity, kinematic

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Not available Solubility 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 Not applicable Particle aggregation state 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 recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions

None under normal use.

10.4. Conditions to avoid

None under normal use.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified
Skin corrosion/irritation : Not classified

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Not classified Serious eye damage/irritation Respiratory or skin sensitisation Not classified Germ cell mutagenicity Not classified Carcinogenicity Not classified Reproductive toxicity Not classified STOT-single exposure : Not classified STOT-repeated exposure : Not classified Aspiration hazard Not classified

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

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No data available. Hazardous to the aquatic environment, short-term 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

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

12.7. Other adverse effects

Other adverse effects : No data available

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Do not discharge to public wastewater systems without permit of pollution control

authorities. No discharge to surface waters is allowed without a permit.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Do not allow the

product to be released into the environment.

SECTION 14: Transport information

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

14.1. UN number or ID number

UN-No. (ADR) : Not applicable
UN-No. (IMDG) : Not applicable
UN-No. (IATA) : Not applicable
UN-No. (ADN) : Not applicable
UN-No. (RID) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

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Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea (IMDG)

Not applicable

Air transport (IATA)

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 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

All chemical substances in this product are listed as "Active" in the EPA (Environmental Protection Agency) "TSCA Inventory Notification (Active-Inactive) Requirements Rule" ("the Final Rule") of Feb. 2019, as amended Feb. 2021, or are otherwise exempt or regulated by other agencies such as FDA or FIFRA

Germany

Water hazard class (WGK) : WGK nwg, Non-hazardous to water (Classification according to AwSV, Annex 1)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : Albumins, blood serum is listed SZW-lijst van mutagene stoffen : Albumins, blood serum is listed : Albumins, blood serum is listed : None of the components are listed SZW-lijst van reprotoxische stoffen - : None of the components are listed

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

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15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Abbreviations and acronyms		
ACGIH	American Conference of Governement Industrial Hygienists	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways	
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road	
CAS-No.	Chemical Abstract Service number	
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008	
DNEL	Derived-No Effect Level	
EC50	Median effective concentration	
EC-No.	European Community number	
ED	Endocrine disrupting properties	
EN	European Standard	
IATA	International Air Transport Association	
IMDG	International Maritime Dangerous Goods	
LD50	Median lethal dose	
OEL	Occupational Exposure Limit	
OSHA	Occupational Safety and Health Administration	
PBT	Persistent Bioaccumulative Toxic	
PNEC	Predicted No-Effect Concentration	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006	
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail	
SDS	Safety Data Sheet	
STOT	Specific target organ toxicity	
TRGS	Technical Rules for Hazardous Substances	
vPvB	Very Persistent and Very Bioaccumulative	
WGK	Water Hazard Class	

Data sources :	Globally Harmonized System of Classification and Labelling of Chemicals (GHS).
	Classification for the USA in accordance with 29 CFR 1910.1200 (2012).
	Classification for the EU in accordance with 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.
	ECHA (European Chemicals Agency).
Training advice :	Normal use of this product shall imply use in accordance with the instructions for use and corresponding product packaging.

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

Indication of changes:

Pace's Revision 1.0: New SDS Created.

Other information : Author: AK

SDS Prepared for IMMY (Immuno-Mycologics, Inc.) by:
Pace Analytical Services, Inc.
Product Regulatory Services Group
1800 Elm Street
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Classification according to Regulation (EC) No. 1272/2008

Classification procedure

Calculation method

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.



Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Issue date: 2023-04-27

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

1.1. Product identifier

Product form Mixture Trade name Pronase Product code DE0010 Product group : Trade product

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

1.2.1. Relevant identified uses

Use of the substance/mixture : For in vitro diagnostic use only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

IMMY (Immuno-Mycologics, Inc.) 2701 Corporate Centre Dr. Norman, OK 73069 - USA T 405-360-4669

sds@immy.com - www.immy.com

1.4. Emergency telephone number

Emergency number : +1-800-654-3639

8:30 AM - 5:00 PM, Monday - Friday

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

H315 Skin corrosion/irritation, Category 2 Serious eye damage/eye irritation, Category 2 H319 Respiratory sensitisation, Category 1 H334 Specific target organ toxicity - Single exposure, Category 3, Respiratory H335

tract irritation

Full text of 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)



GHS07



GHS08

Signal word (CLP)

: Danger

Hazard statements (CLP) : H315 - Causes skin irritation.

H319 - Causes serious eye irritation.

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H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 - May cause respiratory irritation.

Precautionary statements (CLP) : P261 - Avoid breathing mist/vapours/spray.

P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing

protection.

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

P332+P337+P313 - If skin or eye irritation persists: Get medical advice/attention.

P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor.

2.3. Other hazards

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 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Proteinase, Streptomyces griseus	CAS-No.: 9036-06-0 EC-No.: 232-909-5	80 – 100	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Resp. Sens., H334 STOT SE 3, H335

SECTION 4: First Aid measures

4.1. Description of first aid measures

First-aid measures after eye contact

First-aid measures after ingestion

First-aid measures general : If exposed or concerned, get medical attention/advice. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an

unconscious person.
First-aid measures after inhalation : IF INHALED: Remov.

: IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention. If breathing is difficult, supply oxygen. If breathing has stopped, give

artificial respiration.

First-aid measures after skin contact : IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water for at least 15 minutes. If irritation develops or persists, get medical attention immediately.

: IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Remove contact lenses if present and easy to do so. Get medical attention immediately. Continue rinsing.

: IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from

poison control center or medical professional. Get medical attention immediately.

·

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

Symptoms/effects : Causes skin irritation. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory irritation.

Symptoms/effects after inhalation : May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause

respiratory irritation.

Symptoms/effects after skin contact : Causes skin irritation.

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Symptoms/effects after eye contact : Causes serious eye irritation.
Symptoms/effects after ingestion : May cause gastrointestinal irritation.

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 : Foam. Carbon dioxide. Dry powder. Water spray.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Not flammable.

Explosion hazard : Product is not explosive.

Reactivity in case of fire : None known.

Hazardous decomposition products in case of fire : Thermal decomposition is highly dependent on conditions. A complex mixture of airborne

solids, liquids and gases, including carbon oxides and other organic compounds will be

evolved when this material undergoes thermal degradation.

5.3. Advice for firefighters

Precautionary measures fire : Eliminate all ignition sources if safe to do so.

Firefighting instructions : Exercise caution when fighting any chemical fire. Use water spray or fog for cooling

exposed containers. Do not dispose of fire-fighting water in the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

Self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Evacuate area. Ventilate area. Keep upwind. Spill should be handled by trained cleaning

personnel properly equipped with respiratory and eye protection.

6.1.1. For non-emergency personnel

Protective equipment : Wear Protective equipment as described in Section 8.

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Wear suitable protective clothing, gloves and eye or face protection. Approved supplied-air

respirator, in case of emergency.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or

streams. Prevent entry to sewers and public waters.

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible.

This material and its container must be disposed of in a safe way, and as per local

legislation.

6.4. Reference to other sections

See Sections 8 and 13.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not handle until all safety precautions have been read and understood. Keep container

closed when not in use. Avoid contact with skin and eyes. Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before

eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in original container. Keep container closed when not in use. Containers which are

opened should be properly resealed and kept upright to prevent leakage. Store in a dry,

cool and well-ventilated place.

Incompatible materials : No data available.

7.3. Specific end use(s)

No additional information available

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:

Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Ensure adequate ventilation, especially in confined areas.

8.2.2. Personal protection equipment

Personal protective equipment:

Gloves. Protective goggles. Wear chemically impervious apron over labcoat and full coverage clothing.

Personal protective equipment symbol(s):







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8.2.2.1. Eye and face protection

Eye protection:

Wear eye protection, including chemical splash goggles and a face shield when possibility exists for eye contact due to spraying liquid or airborne particles.

8.2.2.2. Skin protection

Skin and body protection:

Wear long sleeves, and chemically impervious PPE/coveralls to minimize bodily exposure.

Hand protection:

Use gloves chemically resistant to this material when prolonged or repeated contact could occur. Be aware that the chemical may penetrate the gloves. Frequent changes are advisable. Gloves should be classified under Standard EN 374 or ASTM F1296. Suggested glove materials are: Neoprene, Nitrile/butadiene rubber, Polyethylene, Ethyl vinyl alcohol laminate, PVC or vinyl. Suitable gloves for this specific application can be recommended by the glove supplier.

8.2.2.3. Respiratory protection

Respiratory protection:

Use NIOSH (or other equivalent national standard) -approved dust/particulate respirator. Where vapour, mist, or dust exceed PELs or other applicable OELs, use NIOSH-approved respiratory protective equipment.

8.2.2.4. Thermal hazards

Particle aspect ratio

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

Physical state : Liquid

Colour No data available. Odour No data available. Not available Odour threshold : Not available Melting point Freezing point : Not available Boiling point Not available Flammability Not available **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 Not available рΗ Viscosity, kinematic Not applicable 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

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Not applicable

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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 recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions

None under normal use.

10.4. Conditions to avoid

None under normal use.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Proteinase, Streptomyces griseus (9036-06-0)

LD50 oral rat 3290 mg/kg LOLI

 Skin corrosion/irritation
 : Causes skin irritation.

 Serious eye damage/irritation
 : Causes serious eye irritation.

Respiratory or skin sensitisation : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Germ cell mutagenicity : Not classified Carcinogenicity : Not classified Reproductive toxicity : Not classified

STOT-single exposure : May cause respiratory irritation.

STOT-repeated exposure : Not classified Aspiration hazard : Not classified

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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

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general No data available. Hazardous to the aquatic environment, short-term Not classified

(acute)

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

12.6.1 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

12.7. Other adverse effects

Other adverse effects : No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Do not discharge to public wastewater systems without permit of pollution control

authorities. No discharge to surface waters is allowed without a permit.

Dispose in a safe manner in accordance with local/national regulations. Do not allow the

Product/Packaging disposal recommendations product to be released into the environment.

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SECTION 14: Transport information

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

14.1. UN number or ID number

UN-No. (ADR) : Not regulated UN-No. (IMDG) : Not regulated UN-No. (IATA) : Not regulated UN-No. (ADN) : Not regulated UN-No. (RID) : Not regulated UN-No. (RID)

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not regulated Proper Shipping Name (IMDG) : Not regulated Proper Shipping Name (IATA) : Not regulated Proper Shipping Name (ADN) : Not regulated Proper Shipping Name (RID) : Not regulated

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not regulated

IMDG

Transport hazard class(es) (IMDG) : Not regulated

IATA

Transport hazard class(es) (IATA) : Not regulated

ADN

Transport hazard class(es) (ADN) : Not regulated

RID

Transport hazard class(es) (RID) : Not regulated

14.4. Packing group

Packing group (ADR) : Not regulated Packing group (IMDG) : Not regulated Packing group (IATA) : Not regulated Packing group (ADN) : Not regulated Packing group (RID) : Not regulated Packing group (RID) : Not regulated

14.5. Environmental hazards

Dangerous for the environment : No Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea (IMDG)

Not regulated

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Air transport (IATA)

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

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 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

All chemical substances in this product are listed as "Active" in the EPA (Environmental Protection Agency) "TSCA Inventory Notification (Active-Inactive) Requirements Rule" ("the Final Rule") of Feb. 2019, as amended Feb. 2021, or are otherwise exempt or regulated by other agencies such as FDA or FIFRA

Germany

Water hazard class (WGK) : WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : Proteinase, Streptomyces griseus is listed SZW-lijst van mutagene stoffen : Proteinase, Streptomyces griseus is listed

SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed SZW-lijst van reprotoxische stoffen – : None of the components are listed

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

Switzerland

Storage class (LK) : LK 6.1 - Toxic materials

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Abbreviations and acronyms	
ACGIH American Conference of Government Industrial Hygienists	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

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Abbreviations and acronyms		
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road	
CAS-No.	Chemical Abstract Service number	
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008	
DNEL	Derived-No Effect Level	
EC50	Median effective concentration	
EC-No.	European Community number	
ED	Endocrine disrupting properties	
EN	European Standard	
IATA	International Air Transport Association	
IMDG	International Maritime Dangerous Goods	
LD50	Median lethal dose	
OEL	Occupational Exposure Limit	
OSHA	Occupational Safety and Health Administration	
PBT	Persistent Bioaccumulative Toxic	
PNEC	Predicted No-Effect Concentration	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006	
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail	
SDS	Safety Data Sheet	
STOT	Specific target organ toxicity	
TRGS	Technical Rules for Hazardous Substances	
vPvB	Very Persistent and Very Bioaccumulative	
WGK	Water Hazard Class	

Full text of H- and EUH-statements	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Resp. Sens. 1	Respiratory sensitisation, category 1
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.

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Data sources : Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Classification for the USA in accordance with 29 CFR 1910.1200 (2012).

Classification for the EU in accordance with 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.

ECHA (European Chemicals Agency).

Training advice : Normal use of this product shall imply use in accordance with the instructions for use and

corresponding product packaging.

Indication of changes:

Pace's Revision 1.0: New SDS Created.

Other information : Author: AK

SDS Prepared for IMMY (Immuno-Mycologics, Inc.) by: Pace Analytical Services, Inc. Product Regulatory Services Group 1800 Elm Street Minneapolis, MN 55414 United States 612-656-1175

paceSDS@pacelabs.com

Classification according to Regulation (EC) No. 1272/2008	Classification procedure
Skin corrosion/irritation, Category 2	Specific concentration limit
Serious eye damage/eye irritation, Category 2	Specific concentration limit
Respiratory sensitisation, Category 1	Specific concentration limit
Specific target organ toxicity – Single exposure, Category 3	Specific concentration limit

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.



Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Issue date: 2023-04-28

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

1.1. Product identifier

Product form : Mixture

Trade name : Specimen Diluent (10X)

Product code : GB0020
Product group : Trade product

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

1.2.1. Relevant identified uses

Use of the substance/mixture : For In Vitro Diagnostic Use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

IMMY (Immuno-Mycologics, Inc.) 2701 Corporate Centre Dr. Norman, OK 73069 - USA T 405-360-4669

sds@immy.com - www.immy.com

1.4. Emergency telephone number

Emergency number : +1-800-654-3639

8:30 AM - 5:00 PM, Monday - Friday

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Hazardous to the aquatic environment – Chronic Hazard, Category 3 H412

Full text of 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]

Signal word (CLP) : -

Hazard statements (CLP) : H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP) : P273 - Avoid release to the environment.

P501 - Dispose of contents/container to hazardous or special waste collection point, in

accordance with local, regional, national and/or international regulation.

2.3. Other hazards

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 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

Name	Product identifier		Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sodium azide	CAS-No.: 26628-22-8 EC-No.: 247-852-1 EC Index-No.: 011-004-00-7	0.1 – 1.5	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

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

SECTION 4: First Aid measures

4.1. Description of first aid measures

First-aid measures general	: If exposed or concerned, get medical attention/advice. Show this safety data sheet to the	

doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an unconscious person.

First-aid measures after inhalation : IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if breathing is affected. If breathing is difficult, supply oxygen.

IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water

First-aid measures after skin contact for at least 15 minutes. If irritation develops or persists, get medical attention.

First-aid measures after eye contact IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Remove contact

lenses if present and easy to do so. Continue rinsing if pain, blinking, or irritation develops

or persists, get medical attention. Continue rinsing.

First-aid measures after ingestion : IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from

poison control center. Get medical attention if you feel unwell.

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

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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

Symptoms/effects after eye contact Direct contact with eyes is likely to be irritating.

Symptoms/effects after ingestion : May cause gastrointestinal irritation.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

: Foam. Carbon dioxide. Dry powder. Water spray. Suitable extinguishing media

5.2. Special hazards arising from the substance or mixture

: Not expected to be a fire/explosion hazard under normal conditions of use. Fire hazard

Explosion hazard : Product is not explosive.

Reactivity in case of fire : None known.

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Hazardous decomposition products in case of fire : No information available.

5.3. Advice for firefighters

Precautionary measures fire : Eliminate all ignition sources if safe to do so.

Firefighting instructions : Exercise caution when fighting any chemical fire. Use water spray or fog for cooling

exposed containers. Do not dispose of fire-fighting water in the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

Self-contained breathing apparatus.

Other information : Under fire conditions closed containers may rupture or explode.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Evacuate area. Ventilate area. Keep upwind. Spill should be handled by trained cleaning

personnel properly equipped with respiratory and eye protection.

6.1.1. For non-emergency personnel

Protective equipment : Wear Protective equipment as described in Section 8.

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Wear suitable protective clothing, gloves and eye or face protection. Approved supplied-air

respirator, in case of emergency.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or

streams. Prevent entry to sewers and public waters.

Methods for cleaning up : Use only non-sparking tools. Small quantities of liquid spill: take up in non-combustible

absorbent material and shovel into container for disposal. This material and its container

must be disposed of in a safe way, and as per local legislation.

6.4. Reference to other sections

See Sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not handle until all safety precautions have been read and understood. Keep away from

heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container closed when not in use. Avoid contact with skin and eyes. Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid contact during

pregnancy/while nursing.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in original container. Keep container closed when not in use. Containers which are

opened should be properly resealed and kept upright to prevent leakage. Store in a dry,

cool and well-ventilated place.

Incompatible materials : No data available.
Heat and ignition sources : Avoid ignition sources.

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7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. National occupational exposure and biological limit values

Glycine (56-40-6)		
Germany - Occupational Exposure Limits (TRGS 900)		
AGW (OEL TWA) [1]	OELs not established	
Latvia - Occupational Exposure Limits		
OEL TWA	5 mg/m³ (Aminoacids)	
Sodium chloride (7647-14-5)		
Latvia - Occupational Exposure Limits		
OEL TWA	5 mg/m³	
Lithuania - Occupational Exposure Limits		
IPRV (OEL TWA)	5 mg/m³	
USA - ACGIH - Occupational Exposure Limits		
Remark (ACGIH)	OELs not established	
Sodium azide (26628-22-8)		
EU - Indicative Occupational Exposure Limit (IOEL)		
IOEL TWA	0.1 mg/m³	
IOEL STEL	0.3 mg/m³	
Notes	Possibility of significant uptake through the skin	
Austria - Occupational Exposure Limits		
MAK (OEL TWA)	0.1 mg/m³	
MAK (OEL STEL)	0.3 mg/m³	
Chemical category	Skin notation	
Belgium - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
Chemical category	Skin, Skin notation	
Bulgaria - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Croatia - Occupational Exposure Limits		
GVI (OEL TWA) [1]	0.1 mg/m³	
KGVI (OEL STEL)	0.3 mg/m³	

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Sodium azide (26628-22-8)			
Chemical category	Skin notation		
Cyprus - Occupational Exposure Limits			
OEL TWA	0.1 mg/m³		
OEL STEL	0.3 mg/m³		
Chemical category	Skin-potential for cutaneous absorption		
Czech Republic - Occupational Exposure Limits			
PEL (OEL TWA)	0.1 mg/m³		
Chemical category	Potential for cutaneous absorption		
Denmark - Occupational Exposure Limits			
OEL TWA [1]	0.1 mg/m³		
OEL STEL	0.3 mg/m³		
Chemical category	Potential for cutaneous absorption		
Estonia - Occupational Exposure Limits			
OEL TWA	0.1 mg/m³		
OEL STEL	0.3 mg/m³		
Chemical category	Skin notation, Sensitizer		
Finland - Occupational Exposure Limits			
HTP (OEL TWA) [1]	0.1 mg/m³		
HTP (OEL STEL)	0.3 mg/m³		
Chemical category	Potential for cutaneous absorption		
France - Occupational Exposure Limits			
VME (OEL TWA)	0.1 mg/m³ (restrictive limit)		
VLE (OEL C/STEL)	0.3 mg/m³ (restrictive limit)		
Chemical category	Risk of cutaneous absorption		
Germany - Occupational Exposure Limits (TRGS 90	0)		
AGW (OEL TWA) [1]	0.2 mg/m³		
Gibraltar - Occupational Exposure Limits			
OEL TWA	0.1 mg/m³		
OEL STEL	0.3 mg/m³		
Chemical category	Skin notation		
Greece - Occupational Exposure Limits	Greece - Occupational Exposure Limits		
OEL TWA	0.3 mg/m³		
OEL TWA [ppm]	0.1 ppm		
OEL STEL	0.3 mg/m³		
OEL STEL [ppm]	0.1 ppm		

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Sodium azide (26628-22-8)		
Hungary - Occupational Exposure Limits		
AK (OEL TWA)	0.1 mg/m³	
CK (OEL STEL)	0.3 mg/m³	
Ireland - Occupational Exposure Limits		
OEL TWA [1]	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Potential for cutaneous absorption	
Italy - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	skin - potential for cutaneous absorption	
Latvia - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
Chemical category	skin - potential for cutaneous exposure	
Lithuania - Occupational Exposure Limits		
IPRV (OEL TWA)	0.1 mg/m³	
TPRV (OEL STEL)	0.3 mg/m³	
Chemical category	Skin notation	
Luxembourg - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Possibility of significant uptake through the skin	
Malta - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Possibility of significant uptake through the skin	
Netherlands - Occupational Exposure Limits		
TGG-8u (OEL TWA)	0.1 mg/m³	
TGG-15min (OEL STEL)	0.3 mg/m³	
MAC chemical category	Skin notation	
Poland - Occupational Exposure Limits		
NDS (OEL TWA)	0.1 mg/m³	
NDSCh (OEL STEL)	0.3 mg/m³	
Portugal - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³ (indicative limit value)	
OEL STEL	0.3 mg/m³ (indicative limit value)	

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Sodium azide (26628-22-8)		
OEL C	0.29 mg/m³	
OEL C [ppm]	0.11 ppm (vapor)	
Chemical category	A4 - Not Classifiable as a Human Carcinogen, skin - potential for cutaneous exposure indicative limit value	
Romania - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Skin notation	
Slovakia - Occupational Exposure Limits		
NPHV (OEL TWA) [1]	0.1 mg/m³ (Sodium azide)	
NPHV (OEL C)	0.3 mg/m³	
Chemical category	Potential for cutaneous absorption	
Slovenia - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Potential for cutaneous absorption	
Spain - Occupational Exposure Limits		
VLA-ED (OEL TWA) [1]	0.1 mg/m³ (indicative limit value)	
VLA-EC (OEL STEL)	0.3 mg/m³	
Chemical category	skin - potential for cutaneous absorption	
Sweden - Occupational Exposure Limits		
NGV (OEL TWA)	0.1 mg/m³	
KTV (OEL STEL)	0.3 mg/m³	
United Kingdom - Occupational Exposure Limits		
WEL TWA (OEL TWA) [1]	0.1 mg/m³	
WEL STEL (OEL STEL)	0.3 mg/m³	
WEL chemical category	Potential for cutaneous absorption	
Norway - Occupational Exposure Limits		
Grenseverdi (OEL TWA) [1]	0.1 mg/m³	
Korttidsverdi (OEL STEL)	0.3 mg/m³ (value from the regulation)	
Switzerland - Occupational Exposure Limits		
MAK (OEL TWA) [1]	0.2 mg/m³ (inhalable dust)	
KZGW (OEL STEL)	0.4 mg/m³ (inhalable dust)	
Turkey - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	

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Sodium azide (26628-22-8)		
Chemical category	Skin notation	
USA - ACGIH - Occupational Exposure Limits		
Local name	Sodium azide	
ACGIH OEL C	0.29 mg/m³	
ACGIH OEL C [ppm]	0.11 ppm	
Remark (ACGIH)	TLV® Basis: Card impair; lung dam. Notations: A4 (Not classifiable as a Human Carcinogen)	
ACGIH chemical category	Not Classifiable as a Human Carcinogen	
Regulatory reference	ACGIH 2023	

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:

Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Use explosion-proof equipment with flammable materials. Ensure adequate ventilation, especially in confined areas.

8.2.2. Personal protection equipment

Personal protective equipment:

Gloves. Protective goggles. Protective clothing.

Personal protective equipment symbol(s):







8.2.2.1. Eye and face protection

Eye protection:

Wear eye protection, including chemical splash goggles and a face shield when possibility exists for eye contact due to spraying liquid or airborne particles [EN 166]

8.2.2.2. Skin protection

Skin and body protection:

Wear long sleeves, and chemically impervious PPE/coveralls to minimize bodily exposure. [EN 14605:2005 and EN 13034:2005]

Hand protection:

Use gloves chemically resistant to this material when prolonged or repeated contact could occur. Gloves should be classified under Standard EN 374 or ASTM F1296. Suggested glove materials are: Neoprene, Nitrile/butadiene rubber, Polyethylene, Ethyl vinyl alcohol laminate, PVC or vinyl. Suitable gloves for this specific application can be recommended by the glove supplier.

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8.2.2.3. Respiratory protection

Respiratory protection:

Where vapour, mist, or dust exceed PELs or other applicable OELs, use European Standard EN 529:2005 approved dust/particulate respiratory protective equipment

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

Physical state : Liquid

Colour : No data available. Odour : No data available. Odour threshold Not available Melting point Not available Freezing point Not available Boiling point Not available Flammability Not available Explosive limits Not available Lower explosive limit (LEL) Not available Upper explosive limit (UEL) Not available : Not available Flash point : Not available Auto-ignition temperature Decomposition temperature : Not available Not available рΗ Viscosity, kinematic Not applicable Not available Solubility Partition coefficient n-octanol/water (Log Kow) Not available Not available Vapour pressure 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 Not applicable Particle aggregation state

9.2. Other information

Particle dustiness

Particle agglomeration state Particle specific surface area

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

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Not applicable

Not applicable

Not applicable

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SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions

None under normal use.

10.4. Conditions to avoid

None under normal use.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Sodium azide (26628-22-8)	
LD50 oral rat	27 mg/kg
LD50 dermal rabbit	20 mg/kg Source: HSDB
LC50 Inhalation - Rat	0.054 – 0.52 mg/l/4h
Skin corrosion/irritation :	Not classified

: Not classified Serious eye damage/irritation Respiratory or skin sensitisation Not classified Germ cell mutagenicity Not classified Carcinogenicity Not classified : Not classified Reproductive toxicity STOT-single exposure : Not classified STOT-repeated exposure Not classified Aspiration hazard : Not classified

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

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SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No data available. Hazardous to the aquatic environment, short–term : Not classified

(acute)

Hazardous to the aquatic environment, long-term

(chronic)

: Harmful to aquatic life with long lasting effects.

Sodium azide (26628-22-8)	
LC50 - Fish [1]	0.8 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss)
LC50 - Fish [2]	0.7 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus)

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

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

12.7. Other adverse effects

Other adverse effects : No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Do not discharge to public wastewater systems without permit of pollution control

authorities. No discharge to surface waters is allowed without a permit.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Do not allow the

product to be released into the environment.

SECTION 14: Transport information

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

14.1. UN number or ID number

UN-No. (ADR) : Not applicable UN-No. (IMDG) : Not applicable

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UN-No. (IATA) : Not applicable
UN-No. (ADN) : Not applicable
UN-No. (RID) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea (IMDG)

Not applicable

Air transport (IATA)

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

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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 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

All chemical substances in this product are listed as "Active" in the EPA (Environmental Protection Agency) "TSCA Inventory Notification (Active-Inactive) Requirements Rule" ("the Final Rule") of Feb. 2019, as amended Feb. 2021, or are otherwise exempt or regulated by other agencies such as FDA or FIFRA

Germany

Water hazard class (WGK) : WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : Albumins, blood serum is listed SZW-lijst van mutagene stoffen : Albumins, blood serum is listed SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed SZW-lijst van reprotoxische stoffen – : None of the components are listed

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

Switzerland

Storage class (LK) : LK 10/12 - Liquids

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Abbreviations and acronyms		
ACGIH	American Conference of Government Industrial Hygienists	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways	
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road	
CAS-No.	Chemical Abstract Service number	
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008	
DNEL	Derived-No Effect Level	
EC50	Median effective concentration	
EC-No.	European Community number	
ED	Endocrine disrupting properties	

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Abbreviations and acronyms		
EN	European Standard	
IATA	International Air Transport Association	
IMDG	International Maritime Dangerous Goods	
LD50	Median lethal dose	
OEL	Occupational Exposure Limit	
OSHA	Occupational Safety and Health Administration	
PBT	Persistent Bioaccumulative Toxic	
PNEC	Predicted No-Effect Concentration	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006	
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail	
SDS	Safety Data Sheet	
STOT	Specific target organ toxicity	
TRGS	Technical Rules for Hazardous Substances	
vPvB	Very Persistent and Very Bioaccumulative	
WGK	Water Hazard Class	

Full text of H- and EUH-statements	
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
H300	Fatal if swallowed.
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.

Data sources

: Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Classification for the USA in accordance with 29 CFR 1910.1200 (2012). Classification for the EU in accordance with 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. ECHA (European Chemicals Agency).

Training advice

: Normal use of this product shall imply use in accordance with the instructions for use and corresponding product packaging.

Indication of changes:

Pace's Revision 1.0: New SDS Created.

Other information : Author: AK

SDS Prepared for IMMY (Immuno-Mycologics, Inc.) by: Pace Analytical Services, Inc. Product Regulatory Services Group

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1800 Elm Street Minneapolis, MN 55414 United States 612-656-1175 paceSDS@pacelabs.com

Classification according to Regulation (EC) No. 1272/2008	Classification procedure
Hazardous to the aquatic environment — Chronic Hazard, Category 3	Calculation method

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.



according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Issue date: 2023-04-28

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

1.1. Product identifier

Product form Mixture **Negative Control** Trade name Product code : NB0110 Product group : Trade product

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

1.2.1. Relevant identified uses

Use of the substance/mixture : For in vitro diagnostic use only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

IMMY (Immuno-Mycologics, Inc.) 2701 Corporate Centre Dr. Norman, OK 73069 - USA T 405-360-4669

sds@immy.com - www.immy.com

1.4. Emergency telephone number

: +1-800-654-3639 **Emergency number**

8:30 AM - 5:00 PM, Monday - Friday

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

H334 Respiratory sensitisation, Category 1 Hazardous to the aquatic environment - Chronic Hazard, Category 3 H412

Full text of 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) : Danger

Hazard statements (CLP) : H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP) : P261 - Avoid breathing mist/vapours/spray.

P273 - Avoid release to the environment.

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P284 - Wear respiratory protection.

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

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 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sterile Filtered Goat Serum	Proprietary	3 – 7	Resp. Sens. 1, H334
Sodium azide	CAS-No.: 26628-22-8 EC-No.: 247-852-1 EC Index-No.: 011-004-00-7	0.1 – 1.5	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

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

SECTION 4: First Aid measures

4.1. Description of first aid measures

First-aid measures general	: If exposed or concerned, get medical attention/advice. Show this safety data sheet to the
	doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an
	unconscious person.
First aid massures ofter inhalation	· IF INHALED: Pamaya to frosh air and keep at root in a position comfortable for breathing

First-aid measures after inhalation : IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing.

Get medical attention. If breathing is difficult, supply oxygen. If breathing has stopped, give artificial respiration.

First-aid measures after skin contact : IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water for at least 15 minutes. If irritation develops or persists, get medical attention immediately.

First-aid measures after eye contact : IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Remove contact lenses if present and easy to do so. Get medical attention immediately. Continue rinsing.

First-aid measures after ingestion : IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from poison control center or medical professional. Get medical attention immediately.

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

Symptoms/effects : May cause allergy or asthma symptoms or breathing difficulties if inhaled. Symptoms/effects after inhalation : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Symptoms/effects after skin contact : May cause skin irritation. Symptoms/effects after eye contact : May cause eye irritation.

Symptoms/effects after ingestion : May cause gastrointestinal irritation.

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

No additional information available

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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Carbon dioxide. Dry powder. Water spray.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Not flammable.

Explosion hazard : Product is not explosive.

Reactivity in case of fire : None known.

Hazardous decomposition products in case of fire : Thermal decomposition is highly dependent on conditions. A complex mixture of airborne

solids, liquids and gases, including carbon oxides and other organic compounds will be

evolved when this material undergoes thermal degradation.

5.3. Advice for firefighters

Precautionary measures fire : Eliminate all ignition sources if safe to do so.

Firefighting instructions : Exercise caution when fighting any chemical fire. Use water spray or fog for cooling

exposed containers. Do not dispose of fire-fighting water in the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

Self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Evacuate area. Ventilate area. Keep upwind. Spill should be handled by trained cleaning

personnel properly equipped with respiratory and eye protection.

6.1.1. For non-emergency personnel

Protective equipment : Wear Protective equipment as described in Section 8.

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Wear suitable protective clothing, gloves and eye or face protection. Approved supplied-air

respirator, in case of emergency.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or

streams. Prevent entry to sewers and public waters.

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible.

This material and its container must be disposed of in a safe way, and as per local

legislation.

6.4. Reference to other sections

See Sections 8 and 13.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not handle until all safety precautions have been read and understood. Keep container

closed when not in use. Avoid contact with skin and eyes. Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before

eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in original container. Keep container closed when not in use. Containers which are

opened should be properly resealed and kept upright to prevent leakage. Store in a dry,

cool and well-ventilated place.

Incompatible materials : No data available.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. National occupational exposure and biological limit values

Sodium chloride (7647-14-5)		
Latvia - Occupational Exposure Limits		
OEL TWA	5 mg/m³	
Lithuania - Occupational Exposure Limits		
IPRV (OEL TWA)	5 mg/m³	
Glycine (56-40-6)	Glycine (56-40-6)	
Latvia - Occupational Exposure Limits		
OEL TWA	5 mg/m³ (Aminoacids)	
Sodium azide (26628-22-8)		
EU - Indicative Occupational Exposure Limit (IOEL)		
IOEL TWA	0.1 mg/m³	
IOEL STEL	0.3 mg/m³	
Notes	Possibility of significant uptake through the skin	
Austria - Occupational Exposure Limits		
MAK (OEL TWA)	0.1 mg/m³	
MAK (OEL STEL)	0.3 mg/m³	
Chemical category	Skin notation	
Belgium - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
Chemical category	Skin, Skin notation	

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Sodium azide (26628-22-8)		
Bulgaria - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Croatia - Occupational Exposure Limits		
GVI (OEL TWA) [1]	0.1 mg/m³	
KGVI (OEL STEL)	0.3 mg/m³	
Chemical category	Skin notation	
Cyprus - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Skin-potential for cutaneous absorption	
Czech Republic - Occupational Exposure Limits		
PEL (OEL TWA)	0.1 mg/m³	
Chemical category	Potential for cutaneous absorption	
Denmark - Occupational Exposure Limits		
OEL TWA [1]	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Potential for cutaneous absorption	
Estonia - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Skin notation, Sensitizer	
Finland - Occupational Exposure Limits		
HTP (OEL TWA) [1]	0.1 mg/m³	
HTP (OEL STEL)	0.3 mg/m³	
Chemical category	Potential for cutaneous absorption	
France - Occupational Exposure Limits		
VME (OEL TWA)	0.1 mg/m³ (restrictive limit)	
VLE (OEL C/STEL)	0.3 mg/m³ (restrictive limit)	
Chemical category	Risk of cutaneous absorption	
Germany - Occupational Exposure Limits (TRGS 90	0)	
AGW (OEL TWA) [1]	0.2 mg/m³	
Gibraltar - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Skin notation	

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Sodium azide (26628-22-8)		
Greece - Occupational Exposure Limits		
OEL TWA	0.3 mg/m³	
OEL TWA [ppm]	0.1 ppm	
OEL STEL	0.3 mg/m³	
OEL STEL [ppm]	0.1 ppm	
Hungary - Occupational Exposure Limits		
AK (OEL TWA)	0.1 mg/m³	
CK (OEL STEL)	0.3 mg/m³	
Ireland - Occupational Exposure Limits		
OEL TWA [1]	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Potential for cutaneous absorption	
Italy - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	skin - potential for cutaneous absorption	
Latvia - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
Chemical category	skin - potential for cutaneous exposure	
Lithuania - Occupational Exposure Limits		
IPRV (OEL TWA)	0.1 mg/m³	
TPRV (OEL STEL)	0.3 mg/m³	
Chemical category	Skin notation	
Luxembourg - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Possibility of significant uptake through the skin	
Malta - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Possibility of significant uptake through the skin	
Netherlands - Occupational Exposure Limits		
TGG-8u (OEL TWA)	0.1 mg/m³	
TGG-15min (OEL STEL)	0.3 mg/m³	
MAC chemical category	Skin notation	

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Sodium azide (26628-22-8)		
Poland - Occupational Exposure Limits		
NDS (OEL TWA)	0.1 mg/m³	
NDSCh (OEL STEL)	0.3 mg/m³	
Portugal - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³ (indicative limit value)	
OEL STEL	0.3 mg/m³ (indicative limit value)	
OEL C	0.29 mg/m³	
OEL C [ppm]	0.11 ppm (vapor)	
Chemical category	A4 - Not Classifiable as a Human Carcinogen, skin - potential for cutaneous exposure indicative limit value	
Romania - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Skin notation	
Slovakia - Occupational Exposure Limits		
NPHV (OEL TWA) [1]	0.1 mg/m³ (Sodium azide)	
NPHV (OEL C)	0.3 mg/m³	
Chemical category	Potential for cutaneous absorption	
Slovenia - Occupational Exposure Limits		
OEL TWA	0.1 mg/m³	
OEL STEL	0.3 mg/m³	
Chemical category	Potential for cutaneous absorption	
Spain - Occupational Exposure Limits		
VLA-ED (OEL TWA) [1]	0.1 mg/m³ (indicative limit value)	
VLA-EC (OEL STEL)	0.3 mg/m³	
Chemical category	skin - potential for cutaneous absorption	
Sweden - Occupational Exposure Limits		
NGV (OEL TWA)	0.1 mg/m³	
KTV (OEL STEL)	0.3 mg/m³	
United Kingdom - Occupational Exposure Limits		
WEL TWA (OEL TWA) [1]	0.1 mg/m³	
WEL STEL (OEL STEL)	0.3 mg/m³	
WEL chemical category	Potential for cutaneous absorption	
Norway - Occupational Exposure Limits		
Grenseverdi (OEL TWA) [1]	0.1 mg/m³	
Korttidsverdi (OEL STEL)	0.3 mg/m³ (value from the regulation)	

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Sodium azide (26628-22-8)			
Switzerland - Occupational Exposure Limits			
MAK (OEL TWA) [1]	0.2 mg/m³ (inhalable dust)		
KZGW (OEL STEL)	0.4 mg/m³ (inhalable dust)		
Turkey - Occupational Exposure Limits			
OEL TWA	0.1 mg/m³		
OEL STEL	0.3 mg/m³		
Chemical category	Skin notation		
USA - ACGIH - Occupational Exposure Limits			
Local name	Sodium azide		
ACGIH OEL C	0.29 mg/m³		
ACGIH OEL C [ppm]	0.11 ppm		
Remark (ACGIH)	TLV® Basis: Card impair; lung dam. Notations: A4 (Not classifiable as a Human Carcinogen)		
ACGIH chemical category	Not Classifiable as a Human Carcinogen		
Regulatory reference	ACGIH 2023		

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:

Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Ensure adequate ventilation, especially in confined areas.

8.2.2. Personal protection equipment

Personal protective equipment:

Gloves. Protective goggles. Wear chemically impervious apron over labcoat and full coverage clothing.

Personal protective equipment symbol(s):







8.2.2.1. Eye and face protection

Eye protection:

Use eye protection suitable to the environment. Avoid direct contact with eyes. Eye protection should be classified under EN 167(EU).

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8.2.2.2. Skin protection

Skin and body protection:

Wear long sleeves, and chemically impervious PPE/coveralls to minimize bodily exposure. [EN 14605:2005 and EN 13034:2005]

Hand protection

Use gloves chemically resistant to this material when prolonged or repeated contact could occur. Be aware that the chemical may penetrate the gloves. Frequent changes are advisable. Suggested glove materials is Nitrile/butadiene rubber. Gloves should be classified under Standard EN 374 or ASTM F1296. Suitable gloves for this specific application can be recommended by the glove supplier.

8.2.2.3. Respiratory protection

Respiratory protection:

Where vapour, mist, or dust exceed PELs or other applicable OELs, use the European Standard EN 529:2005 approved dust/particulate respiratory protective equipment.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

No additional information available

Particle agglomeration state

Particle specific surface area

Particle dustiness

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour No data available. Odour No data available. Odour threshold Not available Melting point Not available Freezing point Not available Boiling point Not available Flammability Not available **Explosive limits** Not available : Not available Lower explosive limit (LEL) : Not available Upper explosive limit (UEL) Flash point : Not available Auto-ignition temperature : Not available Decomposition temperature : Not available рΗ Not available Viscosity, kinematic Not applicable 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 Not applicable Particle aspect ratio Particle aggregation state Not applicable

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Not applicable Not applicable

Not applicable

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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 recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions

None under normal use.

10.4. Conditions to avoid

None under normal use.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Sodium azide (26628-22-8)		
LD50 oral rat	27 mg/kg	
LD50 dermal rabbit	20 mg/kg Source: HSDB	
LC50 Inhalation - Rat	0.054 – 0.52 mg/l/4h	

Skin corrosion/irritation : Not classified Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified
Aspiration hazard : Not classified

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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

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No data available. Hazardous to the aquatic environment, short–term : Not classified

(acute)

Hazardous to the aquatic environment, long-term

(chronic)

: Harmful to aquatic life with long lasting effects.

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

12.6.1 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

12.7. Other adverse effects

Other adverse effects : No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Do not discharge to public wastewater systems without permit of pollution control

authorities. No discharge to surface waters is allowed without a permit.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Do not allow the product to be released into the environment.

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SECTION 14: Transport information

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

14.1. UN number or ID number

UN-No. (ADR) : Not applicable
UN-No. (IMDG) : Not applicable
UN-No. (IATA) : Not applicable
UN-No. (ADN) : Not applicable
UN-No. (RID) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea (IMDG)

Not applicable

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Air transport (IATA)

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 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

All chemical substances in this product are listed as "Active" in the EPA (Environmental Protection Agency) "TSCA Inventory Notification (Active-Inactive) Requirements Rule" ("the Final Rule") of Feb. 2019, as amended Feb. 2021, or are otherwise exempt or regulated by other agencies such as FDA or FIFRA

Germany

Water hazard class (WGK) : WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : Albumins, blood serum is listed SZW-lijst van mutagene stoffen : Albumins, blood serum is listed SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed SZW-lijst van reprotoxische stoffen – : None of the components are listed

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

Switzerland

Storage class (LK) : LK 6.1 - Toxic materials

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Abbreviations and acronyms		
ACGIH	American Conference of Government Industrial Hygienists	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways	

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Abbreviations and acronyms		
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road	
CAS-No.	Chemical Abstract Service number	
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008	
DNEL	Derived-No Effect Level	
EC50	Median effective concentration	
EC-No.	European Community number	
ED	Endocrine disrupting properties	
EN	European Standard	
IATA	International Air Transport Association	
IMDG	International Maritime Dangerous Goods	
LD50	Median lethal dose	
OEL	Occupational Exposure Limit	
OSHA	Occupational Safety and Health Administration	
PBT	Persistent Bioaccumulative Toxic	
PNEC	Predicted No-Effect Concentration	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006	
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail	
SDS	Safety Data Sheet	
STOT	Specific target organ toxicity	
TRGS	Technical Rules for Hazardous Substances	
vPvB	Very Persistent and Very Bioaccumulative	
WGK	Water Hazard Class	

Full text of H- and EUH-statements		
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2	
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1	
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1	
H300	Fatal if swallowed.	
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
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.	

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Data sources : Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Classification for the USA in accordance with 29 CFR 1910.1200 (2012).

Classification for the EU in accordance with 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.

ECHA (European Chemicals Agency).

Training advice : Normal use of this product shall imply use in accordance with the instructions for use and

corresponding product packaging.

Indication of changes:

Pace's Revision 1.0: New SDS Created.

Other information : Author: AK

SDS Prepared for IMMY (Immuno-Mycologics, Inc.) by: Pace Analytical Services, Inc. Product Regulatory Services Group 1800 Elm Street Minneapolis, MN 55414 United States 612-656-1175

paceSDS@pacelabs.com

Classification according to Regulation (EC) No. 1272/2008	Classification procedure
Respiratory sensitisation, Category 1	Specific concentration limit
Hazardous to the aquatic environment – Chronic Hazard, Category 3	Calculation method

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.