



SAFETY DATA SHEET

Latex Cryptococcus Antigen Detection System – CR1003

Component Ref #	Description
CB0010	Crypto Antigen Positive Control
CG0020	Cryptococcal Latex
EI0010	Pronase Inhibitor
R20000	Pronase Control
GB0020	Specimen Diluent (10X)
N80110	Negative Control
DE0010	Pronase



Crypto Antigen Positive Control; Cryptococcal Latex; Pronase Inhibitor; Pronase Control

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Issue date: 2023-04-14

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
Product code : CB0010, CG0020, EI0010, R20000
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.
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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/m ³ (dust)
Sodium azide (26628-22-8)	
EU - Indicative Occupational Exposure Limit (IOEL)	
IOEL TWA	0.1 mg/m ³
IOEL STEL	0.3 mg/m ³
Notes	Possibility of significant uptake through the skin
Austria - Occupational Exposure Limits	
MAK (OEL TWA)	0.1 mg/m ³
MAK (OEL STEL)	0.3 mg/m ³
Chemical category	Skin notation
Belgium - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
Chemical category	Skin, Skin notation
Bulgaria - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Croatia - Occupational Exposure Limits	
GVI (OEL TWA) [1]	0.1 mg/m ³
KGVI (OEL STEL)	0.3 mg/m ³
Chemical category	Skin notation
Cyprus - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³

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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/m ³
Ireland - Occupational Exposure Limits	
OEL TWA [1]	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Potential for cutaneous absorption
Italy - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Chemical category	skin - potential for cutaneous absorption
Latvia - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
Chemical category	skin - potential for cutaneous exposure
Lithuania - Occupational Exposure Limits	
IPRV (OEL TWA)	0.1 mg/m ³
TPRV (OEL STEL)	0.3 mg/m ³
Chemical category	Skin notation
Luxembourg - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Possibility of significant uptake through the skin
Malta - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Possibility of significant uptake through the skin
Netherlands - Occupational Exposure Limits	
TGG-8u (OEL TWA)	0.1 mg/m ³
TGG-15min (OEL STEL)	0.3 mg/m ³
MAC chemical category	Skin notation
Poland - Occupational Exposure Limits	
NDS (OEL TWA)	0.1 mg/m ³
NDSCh (OEL STEL)	0.3 mg/m ³
Portugal - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³ (indicative limit value)
OEL STEL	0.3 mg/m ³ (indicative limit value)

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Sodium azide (26628-22-8)	
OEL C	0.29 mg/m ³
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/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Skin notation
Slovakia - Occupational Exposure Limits	
NPHV (OEL TWA) [1]	0.1 mg/m ³ (Sodium azide)
NPHV (OEL C)	0.3 mg/m ³
Chemical category	Potential for cutaneous absorption
Slovenia - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Potential for cutaneous absorption
Spain - Occupational Exposure Limits	
VLA-ED (OEL TWA) [1]	0.1 mg/m ³ (indicative limit value)
VLA-EC (OEL STEL)	0.3 mg/m ³
Chemical category	skin - potential for cutaneous absorption
Sweden - Occupational Exposure Limits	
NGV (OEL TWA)	0.1 mg/m ³
KTV (OEL STEL)	0.3 mg/m ³
United Kingdom - Occupational Exposure Limits	
WEL TWA (OEL TWA) [1]	0.1 mg/m ³
WEL STEL (OEL STEL)	0.3 mg/m ³
WEL chemical category	Potential for cutaneous absorption
Norway - Occupational Exposure Limits	
Grenseverdi (OEL TWA) [1]	0.1 mg/m ³
Korttidsverdi (OEL STEL)	0.3 mg/m ³ (value from the regulation)
Switzerland - Occupational Exposure Limits	
MAK (OEL TWA) [1]	0.2 mg/m ³ (inhalable dust)
KZGW (OEL STEL)	0.4 mg/m ³ (inhalable dust)
Turkey - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³

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Sodium azide (26628-22-8)	
OEL STEL	0.3 mg/m ³
Chemical category	Skin notation
USA - ACGIH - Occupational Exposure Limits	
Local name	Sodium azide
ACGIH OEL C	0.29 mg/m ³
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/m ³ (Aminoacids)
Sodium chloride (7647-14-5)	
Latvia - Occupational Exposure Limits	
OEL TWA	5 mg/m ³
Lithuania - Occupational Exposure Limits	
IPRV (OEL TWA)	5 mg/m ³

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.

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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.
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
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available

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Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle size	: Not applicable
Particle size distribution	: Not applicable
Particle shape	: Not applicable
Particle aspect ratio	: Not applicable
Particle aggregation state	: Not applicable
Particle agglomeration state	: Not applicable
Particle specific surface area	: Not applicable
Particle dustiness	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under 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
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified

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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
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SECTION 12: Ecological information

12.1. Toxicity

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

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

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

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

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

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

15.2. Chemical safety assessment

No additional information available

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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
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.

Indication of changes:

Pace's Revision 1.0: New SDS Created.

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Other information : Author: JAD

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
Not hazardous	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.



Specimen Diluent (10X)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Issue date: 2023-04-14

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.
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.
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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.
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/m ³ (Aminoacids)
Sodium chloride (7647-14-5)	
Latvia - Occupational Exposure Limits	
OEL TWA	5 mg/m ³
Lithuania - Occupational Exposure Limits	
IPRV (OEL TWA)	5 mg/m ³
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/m ³
IOEL STEL	0.3 mg/m ³
Notes	Possibility of significant uptake through the skin
Austria - Occupational Exposure Limits	
MAK (OEL TWA)	0.1 mg/m ³
MAK (OEL STEL)	0.3 mg/m ³
Chemical category	Skin notation
Belgium - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
Chemical category	Skin, Skin notation
Bulgaria - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Croatia - Occupational Exposure Limits	
GVI (OEL TWA) [1]	0.1 mg/m ³
KGVI (OEL STEL)	0.3 mg/m ³

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Sodium azide (26628-22-8)	
Chemical category	Skin notation
Cyprus - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Skin-potential for cutaneous absorption
Czech Republic - Occupational Exposure Limits	
PEL (OEL TWA)	0.1 mg/m ³
Chemical category	Potential for cutaneous absorption
Denmark - Occupational Exposure Limits	
OEL TWA [1]	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Potential for cutaneous absorption
Estonia - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Skin notation, Sensitizer
Finland - Occupational Exposure Limits	
HTP (OEL TWA) [1]	0.1 mg/m ³
HTP (OEL STEL)	0.3 mg/m ³
Chemical category	Potential for cutaneous absorption
France - Occupational Exposure Limits	
VME (OEL TWA)	0.1 mg/m ³ (restrictive limit)
VLE (OEL C/STEL)	0.3 mg/m ³ (restrictive limit)
Chemical category	Risk of cutaneous absorption
Germany - Occupational Exposure Limits (TRGS 900)	
AGW (OEL TWA) [1]	0.2 mg/m ³
Gibraltar - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Skin notation
Greece - Occupational Exposure Limits	
OEL TWA	0.3 mg/m ³
OEL TWA [ppm]	0.1 ppm
OEL STEL	0.3 mg/m ³
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/m ³
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CK (OEL STEL)	0.3 mg/m ³
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Ireland - Occupational Exposure Limits

OEL TWA [1]	0.1 mg/m ³
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OEL STEL	0.3 mg/m ³
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Chemical category	Potential for cutaneous absorption
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Italy - Occupational Exposure Limits

OEL TWA	0.1 mg/m ³
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OEL STEL	0.3 mg/m ³
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Chemical category	skin - potential for cutaneous absorption
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Latvia - Occupational Exposure Limits

OEL TWA	0.1 mg/m ³
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Chemical category	skin - potential for cutaneous exposure
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Lithuania - Occupational Exposure Limits

IPRV (OEL TWA)	0.1 mg/m ³
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TPRV (OEL STEL)	0.3 mg/m ³
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Chemical category	Skin notation
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Luxembourg - Occupational Exposure Limits

OEL TWA	0.1 mg/m ³
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OEL STEL	0.3 mg/m ³
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Chemical category	Possibility of significant uptake through the skin
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Malta - Occupational Exposure Limits

OEL TWA	0.1 mg/m ³
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OEL STEL	0.3 mg/m ³
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Chemical category	Possibility of significant uptake through the skin
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Netherlands - Occupational Exposure Limits

TGG-8u (OEL TWA)	0.1 mg/m ³
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TGG-15min (OEL STEL)	0.3 mg/m ³
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MAC chemical category	Skin notation
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Poland - Occupational Exposure Limits

NDS (OEL TWA)	0.1 mg/m ³
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NDSCh (OEL STEL)	0.3 mg/m ³
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Portugal - Occupational Exposure Limits

OEL TWA	0.1 mg/m ³ (indicative limit value)
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OEL STEL	0.3 mg/m ³ (indicative limit value)
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Sodium azide (26628-22-8)	
OEL C	0.29 mg/m ³
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/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Skin notation
Slovakia - Occupational Exposure Limits	
NPHV (OEL TWA) [1]	0.1 mg/m ³ (Sodium azide)
NPHV (OEL C)	0.3 mg/m ³
Chemical category	Potential for cutaneous absorption
Slovenia - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Potential for cutaneous absorption
Spain - Occupational Exposure Limits	
VLA-ED (OEL TWA) [1]	0.1 mg/m ³ (indicative limit value)
VLA-EC (OEL STEL)	0.3 mg/m ³
Chemical category	skin - potential for cutaneous absorption
Sweden - Occupational Exposure Limits	
NGV (OEL TWA)	0.1 mg/m ³
KTV (OEL STEL)	0.3 mg/m ³
United Kingdom - Occupational Exposure Limits	
WEL TWA (OEL TWA) [1]	0.1 mg/m ³
WEL STEL (OEL STEL)	0.3 mg/m ³
WEL chemical category	Potential for cutaneous absorption
Norway - Occupational Exposure Limits	
Grenseverdi (OEL TWA) [1]	0.1 mg/m ³
Korttidsverdi (OEL STEL)	0.3 mg/m ³ (value from the regulation)
Switzerland - Occupational Exposure Limits	
MAK (OEL TWA) [1]	0.2 mg/m ³ (inhalable dust)
KZGW (OEL STEL)	0.4 mg/m ³ (inhalable dust)
Turkey - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³

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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/m ³
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
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 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
Particle aspect ratio	: Not applicable
Particle aggregation state	: Not applicable
Particle agglomeration state	: Not applicable
Particle specific surface area	: Not applicable
Particle dustiness	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

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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
Serious eye damage/irritation : Not classified
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

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SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No data available.
Hazardous to the aquatic environment, short-term (acute) : Not classified
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: JAD

SDS Prepared for IMMY (Immuno-Mycologics, Inc.) by:
Pace Analytical Services, Inc.
Product Regulatory Services Group
1800 Elm Street

Specimen Diluent (10X)

Safety Data Sheet

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

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.

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

1.1. Product identifier

Product form : Mixture
Trade name : Negative Control
Product code : N80110
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]

Respiratory sensitisation, Category 1 H334
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) :



GHS08

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.
P284 - Wear respiratory protection.

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

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/m ³
Lithuania - Occupational Exposure Limits	
IPRV (OEL TWA)	5 mg/m ³
Glycine (56-40-6)	
Latvia - Occupational Exposure Limits	
OEL TWA	5 mg/m ³ (Aminoacids)
Sodium azide (26628-22-8)	
EU - Indicative Occupational Exposure Limit (IOEL)	
IOEL TWA	0.1 mg/m ³
IOEL STEL	0.3 mg/m ³
Notes	Possibility of significant uptake through the skin
Austria - Occupational Exposure Limits	
MAK (OEL TWA)	0.1 mg/m ³
MAK (OEL STEL)	0.3 mg/m ³
Chemical category	Skin notation
Belgium - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
Chemical category	Skin, Skin notation

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Sodium azide (26628-22-8)	
Bulgaria - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Croatia - Occupational Exposure Limits	
GVI (OEL TWA) [1]	0.1 mg/m ³
KGVI (OEL STEL)	0.3 mg/m ³
Chemical category	Skin notation
Cyprus - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Skin-potential for cutaneous absorption
Czech Republic - Occupational Exposure Limits	
PEL (OEL TWA)	0.1 mg/m ³
Chemical category	Potential for cutaneous absorption
Denmark - Occupational Exposure Limits	
OEL TWA [1]	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Potential for cutaneous absorption
Estonia - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Skin notation, Sensitizer
Finland - Occupational Exposure Limits	
HTP (OEL TWA) [1]	0.1 mg/m ³
HTP (OEL STEL)	0.3 mg/m ³
Chemical category	Potential for cutaneous absorption
France - Occupational Exposure Limits	
VME (OEL TWA)	0.1 mg/m ³ (restrictive limit)
VLE (OEL C/STEL)	0.3 mg/m ³ (restrictive limit)
Chemical category	Risk of cutaneous absorption
Germany - Occupational Exposure Limits (TRGS 900)	
AGW (OEL TWA) [1]	0.2 mg/m ³
Gibraltar - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
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/m ³
NDSCh (OEL STEL)	0.3 mg/m ³

Portugal - Occupational Exposure Limits

OEL TWA	0.1 mg/m ³ (indicative limit value)
OEL STEL	0.3 mg/m ³ (indicative limit value)
OEL C	0.29 mg/m ³
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/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Skin notation

Slovakia - Occupational Exposure Limits

NPHV (OEL TWA) [1]	0.1 mg/m ³ (Sodium azide)
NPHV (OEL C)	0.3 mg/m ³
Chemical category	Potential for cutaneous absorption

Slovenia - Occupational Exposure Limits

OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Potential for cutaneous absorption

Spain - Occupational Exposure Limits

VLA-ED (OEL TWA) [1]	0.1 mg/m ³ (indicative limit value)
VLA-EC (OEL STEL)	0.3 mg/m ³
Chemical category	skin - potential for cutaneous absorption

Sweden - Occupational Exposure Limits

NGV (OEL TWA)	0.1 mg/m ³
KTV (OEL STEL)	0.3 mg/m ³

United Kingdom - Occupational Exposure Limits

WEL TWA (OEL TWA) [1]	0.1 mg/m ³
WEL STEL (OEL STEL)	0.3 mg/m ³
WEL chemical category	Potential for cutaneous absorption

Norway - Occupational Exposure Limits

Grenseverdi (OEL TWA) [1]	0.1 mg/m ³
Korttidsverdi (OEL STEL)	0.3 mg/m ³ (value from the regulation)

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Sodium azide (26628-22-8)	
Switzerland - Occupational Exposure Limits	
MAK (OEL TWA) [1]	0.2 mg/m ³ (inhalable dust)
KZGW (OEL STEL)	0.4 mg/m ³ (inhalable dust)
Turkey - Occupational Exposure Limits	
OEL TWA	0.1 mg/m ³
OEL STEL	0.3 mg/m ³
Chemical category	Skin notation
USA - ACGIH - Occupational Exposure Limits	
Local name	Sodium azide
ACGIH OEL C	0.29 mg/m ³
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

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
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 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
Particle aspect ratio	: Not applicable
Particle aggregation state	: Not applicable
Particle agglomeration state	: Not applicable
Particle specific surface area	: Not applicable
Particle dustiness	: Not applicable

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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 (acute) : Not classified
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
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IMDG

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

IATA

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

Resp. Sens. 1	Respiratory sensitisation, category 1
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.

Negative Control

Safety Data Sheet

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

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: JAD

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.

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

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]

Skin corrosion/irritation, Category 2 H315
Serious eye damage/eye irritation, Category 2 H319
Respiratory sensitisation, Category 1 H334
Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation H335
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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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Precautionary statements (CLP)

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 - May cause respiratory irritation.
: 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 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 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 : 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.

Pronase

Safety Data Sheet

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

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.
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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.
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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.
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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.

Pronase

Safety Data Sheet

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

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

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

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
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 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
Particle aspect ratio	: Not applicable

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

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 LOI
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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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Safety Data Sheet

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

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 (acute) : 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

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.

Pronase

Safety Data Sheet

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

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

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
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IMDG

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

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

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

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

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

Pronase

Safety Data Sheet

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

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

Pronase

Safety Data Sheet

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

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.

Pronase

Safety Data Sheet

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

- 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: JAD

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Product Regulatory Services Group
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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.