

SAFETY DATA SHEET

Latex Cryptococcus Antigen Detection System – CR1003

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



Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Issue date: 2023-04-13

SECTION 1: Identification

1.1. Identification

Product form : Mixture

Trade name : Crypto Antigen Positive Control; Cryptococcal Latex; Pronase Inhibitor; Specimen Diluent

(10X); Pronase Control

Product code : CB0010, CG0020, El0010, GB0020, R20000

1.2. Recommended use and restrictions on use

Recommended use : For In Vitro Diagnostic Use

1.3. Supplier

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: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Not classified

2.2. GHS Label elements, including precautionary statements

GHS US labeling

No labeling applicable

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%
Contains no hazardous ingredients at levels requiring disclosure by the OSHA Hazard Commun	nication Standard (29 CFR 191	0.1200)

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.

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according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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 (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 the eyes is likely to be irritating.

Symptoms/effects after ingestion : May cause gastrointestinal irritation.

4.3. Immediate medical attention and special treatment, if necessary

No additional information available

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

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

5.2. Specific hazards arising from the chemical

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

Explosion hazard : Product is not explosive.

Reactivity : No dangerous reactions known under normal conditions of use.

5.3. Special protective equipment and precautions for fire-fighters

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.

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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 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.

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-ignition : Avoid ignition sources.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. 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.

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment symbol(s):







Personal protective equipment:

Gloves. Protective goggles. Protective clothing.

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.

Eve 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.

Skin and body protection:

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

Respiratory protection:

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Color : No data available
Odor : No data available

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Odor threshold No data available : No data available pН Melting point : No data available Freezing point No data available : No data available Boiling point Flash point : No data available : No data available Relative evaporation rate (butyl acetate=1) Flammability (solid, gas) : No data available Vapor pressure No data available Relative vapor density at 20°C : No data available Relative density : No data available : No data available Solubility Partition coefficient n-octanol/water (Log Pow) : No data available Auto-ignition temperature No data available : No data available Decomposition temperature : Not applicable Viscosity, kinematic Viscosity, dynamic No data available **Explosion limits** : No data available : No data available Explosive properties Oxidizing properties · No data available

9.2. Other information

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 toxicological effects

Acute toxicity (oral) : Not classified : Not classified Acute toxicity (dermal) Acute toxicity (inhalation) Not classified Skin corrosion/irritation Not classified Serious eye damage/irritation : Not classified Respiratory or skin sensitization : Not classified Germ cell mutagenicity : Not classified Carcinogenicity : Not classified Reproductive toxicity Not classified STOT-single exposure Not classified STOT-repeated exposure : Not classified

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according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Aspiration hazard : Not classified Viscosity, kinematic : Not applicable

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 the eyes is likely to be irritating.

Symptoms/effects after ingestion : May cause gastrointestinal irritation.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No data available.

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. Other adverse effects

Other adverse effects : No data available.

SECTION 13: Disposal considerations

13.1. Disposal 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 an NPDES 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

Department of Transportation (DOT)

In accordance with DOT

Not regulated for transport

Transport by sea (IMDG)

Not regulated for transport

Air transport (IATA)

Not regulated for transport

SECTION 15: Regulatory information

15.1. US Federal regulations

Crypto Antigen Positive Control; Cryptococcal Latex; Pronase Inhibitor; Specimen Diluent (10X); Pronase Control

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

15.2. International regulations

No additional information available

15.3. US State regulations

This product does not contain any substances known to the state of California to cause cancer and/or reproductive harm

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Component	State or local regulations
Sodium azide (26628-22-8)	U.S Massachusetts - Right To Know List; U.S New Jersey - Right to Know Hazardous Substance List; U.S Pennsylvania - RTK (Right to Know) List; U.S Pennsylvania - RTK (Right to Know) - Environmental Hazard List

SECTION 16: Other information

Other information : Author: JAD.

NFPA health hazard : 0 - Materials that, under emergency conditions, would offer

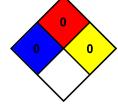
no hazard beyond that of ordinary combustible materials.

 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as

concrete, stone, and sand.

: 0 - Material that in themselves are normally stable, even

under fire conditions.



HMIS Hazard Rating

NFPA fire hazard

NFPA reactivity

Health : 0 Flammability : 0 Physical : 0

Indication of changes:

Pace's Revision 1.0: New SDS Created.

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



Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Issue date: 2023-04-14

SECTION 1: Identification

1.1. Identification

Product form : Mixture

Trade name : Negative Control

Product code : N80110

1.2. Recommended use and restrictions on use

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

1.3. Supplier

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: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Resp. Sens. 1 H334

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Hazard pictograms (GHS US)



Signal word (GHS US) : Danger

Hazard statements (GHS US) : H334 - May cause an allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary statements (GHS US) : P261 - Avoid breathing mist/vapors/spray.

P284 - [In case of inadequate ventilation] wear respiratory protection.

P304+P341 - If inhaled: If breathing is difficult, 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 which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%
Sterile Filtered Goat Serum	Proprietary	3 - 7

*In accordance with paragraph (i) of the OSHA Hazard Communication Standard (29 CFR §1910.1200), the specific chemical identity or exact weight % has been withheld as a trade secret

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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 (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. Immediate medical attention and special treatment, if necessary

No additional information available

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

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

5.2. Specific hazards arising from the chemical

Fire hazard : Not flammable.

Explosion hazard : Product is not explosive.

Reactivity : No dangerous reactions known under normal conditions of use.

5.3. Special protective equipment and precautions for fire-fighters

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.

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according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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 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.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sterile Filtered Goat Serum		
ACGIH	Remark (ACGIH)	OELs not established
OSHA	Remark (OSHA)	OELs not established

8.2. 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.

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment symbol(s):







Personal protective equipment:

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

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.

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.

Skin and body protection:

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

Respiratory protection:

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Color : No data available

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Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Odor : No data available Odor threshold : No data available рΗ No data available : No data available Melting point No data available Freezing point Boiling point : No data available : No data available Flash point Relative evaporation rate (butyl acetate=1) : No data available Flammability (solid, gas) : No data available No data available Vapor pressure : No data available Relative vapor density at 20°C : No data available Relative density : No data available Solubility Partition coefficient n-octanol/water (Log Pow) : No data available : No data available Auto-ignition temperature : No data available Decomposition temperature Viscosity, kinematic : Not applicable Viscosity, dynamic No data available : No data available **Explosion limits** Explosive properties No data available Oxidizing properties No data available

9.2. Other information

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 toxicological effects

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 sensitization : 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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Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Viscosity, kinematic : Not applicable

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.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No data available.

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. Other adverse effects

Other adverse effects : No data available.

SECTION 13: Disposal considerations

13.1. Disposal 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 an NPDES 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

Department of Transportation (DOT)

In accordance with DOT

Not regulated for transport

Transport by sea (IMDG)

Not regulated for transport

Air transport (IATA)

Not regulated for transport

SECTION 15: Regulatory information

15.1. US Federal regulations

Negative Control

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

SARA Section 311/312 Hazard Classes

Health hazard - Respiratory or skin sensitization

15.2. International regulations

No additional information available

15.3. US State regulations

This product does not contain any substances known to the state of California to cause cancer and/or reproductive harm

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Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Component	State or local regulations
Sodium azide (26628-22-8)	U.S Massachusetts - Right To Know List; U.S New Jersey - Right to Know Hazardous Substance List; U.S Pennsylvania - RTK (Right to Know) List; U.S Pennsylvania - RTK (Right to Know) - Environmental Hazard List

SECTION 16: Other information

Other information : Author: JAD.

NFPA health hazard : 2 - Materials that, under emergency conditions, can cause

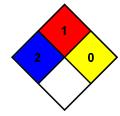
temporary incapacitation or residual injury.

NFPA fire hazard : 1 - Materials that must be preheated before ignition can

occur.

NFPA reactivity : 0 - Material that in themselves are normally stable, even

under fire conditions.



HMIS Hazard Rating

Health : 2

* - Chronic (long-term) health effects may result from repeated overexposure

Flammability : 1 Physical : 0

Indication of changes:

Pace's Revision 1.0: New SDS Created.

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.

 PIS-00136 Rev. 3
 Negative Control
 13/19



Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Issue date: 2023-04-14

SECTION 1: Identification

1.1. Identification

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

1.2. Recommended use and restrictions on use

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

1.3. Supplier

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: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Skin Irrit. 2 H315 Eye Irrit. 2 H319 Resp. Sens. 1 H334 STOT SE 3 H335

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Hazard pictograms (GHS US)





Signal word (GHS US) : Danger

Hazard statements (GHS US) : H315 - Causes skin irritation

H319 - Causes serious eye irritation

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

H335 - May cause respiratory irritation

Precautionary statements (GHS US) : P261 - Avoid breathing mist/vapors/spray.

P264 - Wash hands, forearms and face thoroughly after handling.

P271 - Use only outdoors or in a well-ventilated area.

P280 - Wear protective gloves, protective clothing, chemical goggles, & face protection.

P284 - [In case of inadequate ventilation] wear respiratory protection.

P302+P352 - If on skin: Wash with plenty of water.

P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing. P304+P341 - If inhaled: If breathing is difficult, 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 P312 - Call a poison center or doctor if you feel unwell.

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

P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.

P362+P364 - Take off contaminated clothing and wash it before reuse. P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

P405 - Store locked up.

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 which do not result in classification

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Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%
Proteinase, Streptomyces griseus	(CAS-No.) 9036-06-0	80 – 100

^{*}In accordance with paragraph (i) of the OSHA Hazard Communication Standard (29 CFR §1910.1200), the specific chemical identity or exact weight % has been withheld as a trade secret

SECTION 4: First-aid measures

First-aid measures after ingestion

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.

: 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 (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.

Symptoms/effects after eye contact : Causes serious eye irritation.

Symptoms/effects after ingestion : May cause gastrointestinal irritation.

4.3. Immediate medical attention and special treatment, if necessary

No additional information available

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

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

5.2. Specific hazards arising from the chemical

Fire hazard : Not flammable.

Explosion hazard : Product is not explosive.

Reactivity : No dangerous reactions known under normal conditions of use.

5.3. Special protective equipment and precautions for fire-fighters

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.

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.

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.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Proteinase, Streptomyces griseus (9036-06-0)		
ACGIH	Remark (ACGIH)	OELs not established
OSHA	Remark (OSHA)	OELs not established

8.2. 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.

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment symbol(s):







Personal protective equipment:

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

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.

Eye protection:

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

Skin and body protection:

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

Respiratory protection:

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid (rehydrated to liquid)

: Clear liquid Color Odor No data available Odor threshold No data available : No data available pН Melting point No data available : No data available Freezing point : No data available Boiling point Flash point : No data available Relative evaporation rate (butyl acetate=1) : No data available Flammability (solid, gas) No data available : No data available Vapor pressure Relative vapor density at 20°C : No data available Relative density No data available Solubility : No data available : No data available Partition coefficient n-octanol/water (Log Pow) : No data available Auto-ignition temperature Decomposition temperature : No data available Viscosity, kinematic No data available Viscosity, dynamic : No data available : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Explosion limits
Explosive properties

Oxidizing properties

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.

· No data available

: No data available

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

Proteinase, Streptomyces griseus (9036-06-0)

LD50 oral rat 3290 mg/kg LOLI

Skin corrosion/irritation : Causes skin irritation.

Serious eye damage/irritation : Causes serious eye irritation.

Respiratory or skin sensitization : 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
Viscosity, kinematic : Not applicable

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.

Symptoms/effects after eye contact : Causes serious eye irritation.

Symptoms/effects after ingestion : May cause gastrointestinal irritation.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No data available.

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. Other adverse effects

Other adverse effects : No data available.

SECTION 13: Disposal considerations

13.1. Disposal 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 an NPDES 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

Department of Transportation (DOT)

In accordance with DOT

Not regulated for transport

Transport by sea (IMDG)

Not regulated for transport

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Air transport (IATA)

Not regulated for transport

SECTION 15: Regulatory information

15.1. US Federal regulations

Pronase	
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	
SARA Section 311/312 Hazard Classes	Health hazard - Respiratory or skin sensitization Health hazard - Serious eye damage or eye irritation Health hazard - Skin corrosion or Irritation Health hazard - Specific target organ toxicity (single or repeated exposure)

15.2. International regulations

No additional information available

15.3. US State regulations

This product does not contain any substances known to the state of California to cause cancer and/or reproductive harm

SECTION 16: Other information

Other information : Author: JAD.

NFPA health hazard : 2 - Materials that, under emergency conditions, can cause

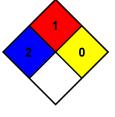
temporary incapacitation or residual injury.

NFPA fire hazard : 1 - Materials that must be preheated before ignition can

occur.

NFPA reactivity : 0 - Material that in themselves are normally stable, even

under fire conditions.



HMIS Hazard Rating

Health : 2

* - Chronic (long-term) health effects may result from repeated overexposure

Flammability : 1 Physical : 0

Indication of changes:

Pace's Revision 1.0: New SDS Created.

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.

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