

Material Safety Data Sheet

Procleix Enzyme Reagent

1. Product and company identification

Product name	: Procleix Enzyme Reagent
Used in	: BS0476, Procleix HIV-1/HCV Assay 301117,301118,301030,301031, Procleix Ultrio Assay 301102, 301103C, 301104, 301105C, Procleix Ultrio ABD 301165, Procleix WNV Assay 302181, 301187, Procleix Ultrio Plus 302573, 302574.
Material uses	: In vitro diagnostic.
Supplier/Manufacturer	: Gen-Probe Incorporated 10210 Genetic Center Drive San Diego, CA 92121-4362
MSDS #	: 0024P
In case of emergency	: CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887

2. Hazards identification

Emergency overview

Color	: Colorless.
Physical state	: Liquid. [Frozen Liquid]
Signal word	: WARNING!
Hazard statements	: CAUSES EYE IRRITATION. MAY CAUSE SKIN IRRITATION. CONTAINS MATERIAL THAT MAY CAUSE TARGET ORGAN DAMAGE, BASED ON ANIMAL DATA.
Precautions	: Do not get in eyes. Avoid breathing vapor or mist. Avoid contact with skin and clothing. Wash thoroughly after handling.

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Routes of entry : Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

Inhalation	: Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
Ingestion	: No known significant effects or critical hazards.
Skin	: Slightly irritating to the skin.
Eyes	: Severely irritating to eyes. Risk of serious damage to eyes.

Potential chronic health effects

Chronic effects	: Contains material that can cause target organ damage.
Carcinogenicity	: No known significant effects or critical hazards.
Mutagenicity	: No known significant effects or critical hazards.
Teratogenicity	: No known significant effects or critical hazards.
Developmental effects	: No known significant effects or critical hazards.
Fertility effects	: No known significant effects or critical hazards.
Target organs	: Contains material which may cause damage to the following organs: kidneys, upper respiratory tract, skin, eyes.

Over-exposure signs/symptoms

Inhalation	: No specific data.
Ingestion	: No specific data.
Skin	: Adverse symptoms may include the following: irritation redness

2. Hazards identification

- Eyes** : Adverse symptoms may include the following:
pain or irritation
watering
redness
- Medical conditions aggravated by over-exposure** : Pre-existing disorders involving any target organs mentioned in this MSDS as being at risk may be aggravated by over-exposure to this product.

See toxicological information (section 11)

3. Composition/information on ingredients

United States

Name	CAS number	%
Glycerin	56-81-5	10 - 30
Triton X-100	9002-93-1	10 - 30
N-Acetyl-L-Cysteine	616-91-1	1 - 5

Canada

Name	CAS number	%
Glycerin	56-81-5	10 - 30
Triton X-100	9002-93-1	10 - 30

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Hazardous materials listed are the same in each part number in " Used In " section, however due to differing non-hazardous components, the use of these products are not interchangeable. See package insert for product use.

4. First aid measures

- Eye contact** : Immediately flush eyes with plenty of water for at least 20 minutes, occasionally lifting the upper and lower eyelids. Get medical attention.
- Skin contact** : In case of contact, immediately flush skin with plenty of water for at least 20 minutes. Get medical attention.
- Inhalation** : Move exposed person to fresh air. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. Get medical attention.
- Ingestion** : Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention immediately.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.
- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

5. Fire-fighting measures

- Flammability of the product** : No specific fire or explosion hazard.
- Extinguishing media**
- Suitable** : Use an extinguishing agent suitable for the surrounding fire.
- Not suitable** : None known.

5. Fire-fighting measures

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
 carbon dioxide
 carbon monoxide
 nitrogen oxides
 sulfur oxides
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

6. Accidental release measures

- Personal precautions** : Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment (see section 8).
- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).
- Methods for cleaning up**
- Spill** : Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see section 1 for emergency contact information and section 13 for waste disposal.

7. Handling and storage

- Handling** : Put on appropriate personal protective equipment (see section 8). Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Do not get in eyes or on skin or clothing. Do not breathe vapor or mist. Do not ingest. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Storage** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

8. Exposure controls/personal protection

United States

Ingredient	Exposure limits
Glycerin	ACGIH TLV (United States, 1/2009). TWA: 10 mg/m ³ 8 hour(s). Form: Mist OSHA PEL (United States, 11/2006). TWA: 5 mg/m ³ 8 hour(s). Form: Respirable fraction TWA: 15 mg/m ³ 8 hour(s). Form: Total dust

Canada

Occupational exposure limits		TWA (8 hours)			STEL (15 mins)			Ceiling			
Ingredient	List name	ppm	mg/m ³	Other	ppm	mg/m ³	Other	ppm	mg/m ³	Other	Notations

8. Exposure controls/personal protection

Glycerin	US ACGIH 1/2009	-	10	-	-	-	-	-	-	-	[a]
	AB 4/2009	-	10	-	-	-	-	-	-	-	[3] [a]
	BC 9/2009	-	10	-	-	-	-	-	-	-	[a]
		-	3	-	-	-	-	-	-	-	[b]
	ON 8/2008	-	10	-	-	-	-	-	-	-	[c]
	QC 6/2008	-	10	-	-	-	-	-	-	-	[c]

[3]Skin sensitization

Form: [a]Mist [b]Respirable mist [c]mist

Consult local authorities for acceptable exposure limits.

Recommended monitoring procedures : Personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment.

Engineering measures : Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits.

Hygiene measures : Ensure that eyewash stations and safety showers are close to the workstation location. Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period.

Personal protection

Respiratory : Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator. Recommended: Wear an appropriate NIOSH approved respirator if concentration levels exceed the safe exposure limits.

Hands : Compatible chemical resistant gloves.

Eyes : Safety eyewear should be used when there is a likelihood of exposure. Recommended: Safety glasses with side shields.

Skin : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Recommended: Lab coat.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

9. Physical and chemical properties

Physical state : Liquid. [Frozen Liquid]

Color : Colorless.

pH : 7

Solubility : Easily soluble in the following materials: cold water, hot water, Methanol and acetone.

10. Stability and reactivity

Chemical stability : The product is stable.

Conditions to avoid : No specific data.

Materials to avoid : Reactive or incompatible with the following materials: oxidizing materials and reducing materials.

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

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Hazardous polymerization : Under normal conditions of storage and use, hazardous polymerization will not occur.

11. Toxicological information

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Glycerin	LD50 Oral	Rat	12600 mg/kg	-

Chronic toxicity : No specific data.

12. Ecological information

Environmental effects : Not established

Aquatic ecotoxicity

Product/ingredient name	Result	Species	Exposure
Triton X-100	Acute LC50 11.2 mg/L Fresh water	Daphnia - Daphnia magna - Neonate - 24 hours	48 hours
Glycerin	Acute LC50 2800 to 3200 ug/L Fresh water Acute LC50 54 to 57 ml/L Fresh water	Fish - Lepomis macrochirus - 1 g Fish - Oncorhynchus mykiss - 0.9 g	96 hours 96 hours

Other adverse effects : No known significant effects or critical hazards.

13. Disposal considerations

Waste disposal : The generation of waste should be avoided or minimized wherever possible. This material and its container must be disposed of in a safe way. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Empty containers or liners may retain some product residues. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor.

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Refer to Section 7: HANDLING AND STORAGE and Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION for additional handling information and protection of employees.

14 . Transport information

DOT/TDG/IMDG/IATA : Not regulated.

15 . Regulatory information

United States

HCS Classification : Irritating material
Target organ effects

U.S. Federal regulations : TSCA 8(a) PAIR: Triton X-100
United States inventory (TSCA 8b): All components listed.

SARA 302/304/311/312 extremely hazardous substances: No products were found.

SARA 302/304 emergency planning and notification: No products were found.

SARA 302/304/311/312 hazardous chemicals: N-Acetyl-L-Cysteine; Glycerin; Triton X-100

SARA 311/312 MSDS distribution - chemical inventory - hazard identification: N-Acetyl-L-Cysteine: Delayed (chronic) health hazard; Glycerin: Immediate (acute) health hazard, Delayed (chronic) health hazard; Triton X-100: Immediate (acute) health hazard, Delayed (chronic) health hazard

Clean Water Act (CWA) 307: No products were found.

Clean Water Act (CWA) 311: EDTA Calibration Sample; Sodium hydroxide

Clean Air Act (CAA) 112 accidental release prevention: No products were found.

Clean Air Act (CAA) 112 regulated flammable substances: No products were found.

Clean Air Act (CAA) 112 regulated toxic substances: No products were found.

Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs) : Not listed

15 . Regulatory information

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

State regulations :

- Connecticut Carcinogen Reporting:** None of the components are listed.
- Connecticut Hazardous Material Survey:** None of the components are listed.
- Florida substances:** None of the components are listed.
- Illinois Chemical Safety Act:** None of the components are listed.
- Illinois Toxic Substances Disclosure to Employee Act:** None of the components are listed.
- Louisiana Reporting:** None of the components are listed.
- Louisiana Spill:** None of the components are listed.
- Massachusetts Spill:** None of the components are listed.
- Massachusetts Substances:** The following components are listed: Glycerin
- Michigan Critical Material:** None of the components are listed.
- Minnesota Hazardous Substances:** None of the components are listed.
- New Jersey Hazardous Substances:** The following components are listed: Glycerin
- New Jersey Spill:** None of the components are listed.
- New Jersey Toxic Catastrophe Prevention Act:** None of the components are listed.
- New York Acutely Hazardous Substances:** None of the components are listed.
- New York Toxic Chemical Release Reporting:** None of the components are listed.
- Pennsylvania RTK Hazardous Substances:** The following components are listed: Glycerin
- Rhode Island Hazardous Substances:** None of the components are listed.

California Prop. 65

California prop. 65: No products were found.

Canada

WHMIS (Canada) : Class D-2B: Material causing other toxic effects (Toxic).

Canadian lists :

- CEPA Toxic substances:** None of the components are listed.
- Canadian ARET:** None of the components are listed.
- Canadian NPRI:** The following components are listed: Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy-
- Alberta Designated Substances:** None of the components are listed.
- Ontario Designated Substances:** None of the components are listed.
- Quebec Designated Substances:** None of the components are listed.

Canada inventory : **Canada inventory:** All components listed.

This product has been classified in accordance with the hazard criteria of the **Controlled Products Regulations** and the MSDS contains all the information required by the **Controlled Products Regulations**.

International regulations

International lists :

- Australia inventory (AICS):** All components are listed or exempted.
- China inventory (IECSC):** All components are listed or exempted.
- Japan inventory:** Not determined.
- Korea inventory:** Not determined.
- New Zealand Inventory of Chemicals (NZIoC):** All components are listed or exempted.
- Philippines inventory (PICCS):** All components are listed or exempted.

16 . Other information

United States

Label requirements : CAUSES EYE IRRITATION. MAY CAUSE SKIN IRRITATION. CONTAINS MATERIAL THAT CAN CAUSE TARGET ORGAN DAMAGE.

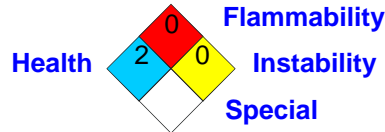
Hazardous Material Information System (U.S.A.) :

Health	*	2
Flammability		0
Physical hazards		0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings are not required on MSDSs under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.

The customer is responsible for determining the PPE code for this material.

National Fire Protection Association (U.S.A.) :



Canada

WHMIS (Canada) :



Date of issue : 07/15/2010

Date of previous issue : 06/15/2010

Version : 4.2

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.