

# Enzymatic Cleaner

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

Date of issue : 11/15/2018 Revision: 2

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

#### 1.1. Product identifier

Product form : Mixture  
Product name : REPROCHEM Enzymatic and Equipment Cleaner  
Product code : GX0-LA883  
Synonyms : Enzyme Cleaner

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

##### 1.2.1. Relevant identified uses

Main use category : A concentrated enzymatic preparation for effective cleaning and breakdown of proteinaceous and organic material from the surfaces of surgical instruments, endoscopes and medical devices.

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

Manufactured by: Medimark Scientific  
PO Box 237  
Sevenoaks  
Kent  
TN15 0ZJ  
Phone: + 44 (0)8452 22 33 44  
Fax: +44 (0) 1732 763530

Supplied by: ADS Biotec Inc.  
7409 Irvington Road  
Omaha, NE 68122 - USA  
[support@adsbiotec.com](mailto:support@adsbiotec.com)

#### 1.4. Emergency telephone number

Emergency Contact Number : USA: 1-800-255-3924 (CHEMTEL 24hr); International: +1-813-248-0585 (CHEMTEL 24hr)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

Not classified

##### Classification according to Directive 67/548/EEC or 1999/45/EC

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

This substance/mixture does not meet the PBT criteria of REACH, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH, annex XIII.

### SECTION 3: Composition/information on ingredients

#### 3.1. Substance

Liquid cleaning mixture.

#### 3.2. Mixture

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Protease Enzyme	(CAS No) 9014-01-1 (EC no) 232-565-6	1-5 %	Not classified

# Safety Data Sheet for Enzymatic Cleaner GX0-LA883

according to Regulation (EC) No. 453/2010

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Amylase enzyme	(CAS No) 9000-90-2 (EC no) 232-565-6	1-5%	Not classified
Lipase enzyme	(CAS No) 9001-62-2 (EC no) 232-619-9	1-5%	Not classified

Full text of R- and H-phrases: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Remove to fresh air, keep the patient warm and at rest. If symptoms develop obtain medical attention.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. If symptoms develop obtain medical attention.
First-aid measures after eye contact	: Rinse immediately with plenty of water for 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If symptoms develop obtain medical attention.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Give 100 - 200 ml of water to drink. If symptoms develop obtain medical attention.

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

Symptoms/injuries	: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/injuries after ingestion	: Ingestion may cause nausea, vomiting and diarrhea.

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: This product is not flammable. Use fire extinguishing media appropriate for surround materials.
Unsuitable extinguishing media	: None.

### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: None known.
--------------------------------------------------	---------------

### 5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting	: As in any fire, wear self-contained breathing apparatus and full protective gear.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

Emergency procedures	: Use with care, avoid eye contact and prolonged skin contact. Gloves and safety glasses recommended if available. External use only. Not for ingestion..
----------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------

#### 6.1.2. For emergency responders

Protective equipment	: Wear suitable protective clothing and eye or face protection.
Emergency procedures	: Ensure adequate ventilation.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials. Wash spill area with soapy water.
-------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

### 6.4. Reference to other sections

SECTION 8: Exposure controls/personal protection. SECTION 13: Disposal considerations.

# Safety Data Sheet for Enzymatic Cleaner GX0-LA883

according to Regulation (EC) No. 453/2010

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid contact with skin, eyes and clothing.
- Hygiene measures : Do not eat, drink or smoke when using this product.

### 7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep only in the original container in a cool, well ventilated place away from : Oxidizing agents. Keep container closed when not in use.
- Incompatible products : Strong oxidizing agents.
- Storage temperature : Room temperature

### 7.3. Specific end use(s)

A concentrated enzymatic preparation for effective cleaning and breakdown of proteinaceous and organic material from the surfaces of surgical instruments, endoscopes and medical devices..

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Ingredient comments  
No exposure limits noted for ingredient(s).

### 8.2. Exposure controls

- Appropriate engineering controls : Engineering measures, not relevant.
- Personal protective equipment : Protect eyes when handling product concentrate as enzymes may irritate the eyes and skin.
- Hand protection : Standard EN 374 - Protective gloves against chemicals.
- Eye protection : Standard EN 166 - Personal eye-protection. Safety glasses with face shield.
- Skin and body protection : Wear suitable protective clothing.
- Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment.
- Thermal hazard protection : Not required for normal conditions of use.
- Environmental exposure controls : Avoid release to the environment.
- Other information : Do not eat, drink or smoke during use.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

- Physical state : Liquid
- Colour : Green
- Odour : No data available
- Odour threshold : No data available
- pH : 7-8
- Relative evaporation rate (butylacetate=1) : No data available
- Melting point : No data available
- Freezing point : No data available
- Boiling point : No data available
- Flash point : No data available
- Self ignition temperature : No data available
- Decomposition temperature : No data available
- Flammability (solid, gas) : Non flammable
- Vapour pressure : No data available
- Relative vapour density at 20 °C : 1.03 g/cm<sup>3</sup>
- Relative density : No data available
- Solubility : Miscible with water.
- Log Pow : 0
- Log Kow : No data available
- Viscosity, kinematic : No data available
- Viscosity, dynamic : No data available

# Safety Data Sheet for Enzymatic Cleaner GX0-LA883

according to Regulation (EC) No. 453/2010

Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

## 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Stable under normal conditions.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

None known.

### 10.4. Conditions to avoid

There are no known conditions that are likely to result in a hazardous situation.

### 10.5. Incompatible Materials

No incompatible groups noted.

### 10.6. Hazardous decomposition products

No hazardous decomposition products.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential Adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

## SECTION 12: Ecological information

### 12.1. Toxicity

We have not carried out any Aquatic testing, therefore we have no aquatic toxicity data specifically for this product.

### 12.2. Persistence and degradability

The preparation is readily biodegradable.

### 12.3. Bioaccumulative potential

The product does not contain any substances expected to bio-accumulate.

# Safety Data Sheet for Enzymatic Cleaner GX0-LA883

according to Regulation (EC) No. 453/2010

## 12.4. Mobility in soil

This preparation is highly dispersible in water. It is highly likely to distribute predominantly to the aqueous environment.

## 12.5. Results of PBT and vPvB assessment

This product does not contain any PBT or vPvB substances.

## 12.6. Other adverse effects

: None known.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Empty containers should be taken to an approved waste handling site for recycling or disposal.

Ecology - waste materials : Avoid release to the environment.

## SECTION 14: Transport information

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

### 14.1. UN number

Not dangerous good in sense of transport regulations

### 14.2. UN proper shipping name

Proper Shipping Name (ADR/RID) : Not applicable

Proper Shipping Name (IATA) : Not applicable

Proper Shipping Name (IMDG) : Not applicable

:

### 14.3. Transport hazard class(es)

Not applicable

### 14.4. Packing group

Not applicable

### 14.5. Environmental hazards

Other information : No supplementary information available.

### 14.6. Special precautions for user

#### 14.6.1. Overland transport

No additional information available

#### 14.6.2. Transport by sea

No additional information available

#### 14.6.3. Air transport

No additional information available

### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

No REACH Annex XVII restrictions

Contains no REACH candidate substance

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

# Safety Data Sheet for Enzymatic Cleaner GX0-LA883

according to Regulation (EC) No. 453/2010

## SECTION 16: Other information

Data sources	: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Abbreviations and acronyms	: ADR (Accord européen relatif au transport international des marchandises Dangereuses par Route). CAS (Chemical Abstracts Service) number. IARC (International Agency for Research on Cancer). IATA (International Air Transport Association). IMDG (International Maritime Dangerous Goods Code). RID (Règlement concernant le transport international ferroviaire de marchandises).
Other information	: None.

NCEC SDS EU (REACH ANNEX II)

*The information and recommendations contained herein are based upon data believed to be up-to-date and correct. However, no guarantee or warranty of any kind, express or implied, is made with respect to the information and recommendations contained herein. We accept no responsibility and disclaim all liability for any harmful effects that may be caused by (incorrect) use, handling, purchase, resale, or exposure to our product. Customers and users of our product must comply with all applicable health and safety laws, regulations, and orders. In particular, they are under an obligation to carry out a risk assessment for the particular work places and to take adequate risk management measures in accordance with the national implementation legislation of EU Directives 89/391 and 98/24.*