

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

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 |

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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.

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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/cm³
- 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

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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.

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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

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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)

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