



Instrument cleaning



PLURAZYME[®] extra

tri-enzymatic cleaner for surgical instruments and endoscope reprocessing

- strong cleaning power
- concentrate for economical use
- ideal for ultrasonic cleaning
- excellent material compatibility

Product Properties

PLURAZYME[®] extra offers an excellent material compatibility and is therefore the ideal cleaning concentrate for manual reprocessing of surgical instruments and flexible endoscopes. It is economic in use and recommended for use in ultrasonic baths.

PLURAZYME[®] extra offers an excellent cleaning performance due to the combination of highly surface active nonionic surfactants and a stabilised triple enzyme complex. The self-acting formula counteracts, penetrates and effectively removes all kinds of organic contaminations such as proteins, coagulated blood, mucus, vomit, fat and fecal matter even in hard-to-reach areas.

Application area

PLURAZYME[®] extra is especially suitable for the manual cleaning without protein fixation of:

- all kinds of medical instruments
- rigid and flexible endoscopes
- endoscopic accessories
- ideal for use in ultrasonic baths

Application

Prepare working solution of 0,4 % PLURAZYME[®] extra by using 4 ml of concentrate per 1 liter of warm water. The use of warm water (temperature = 30 – 40 °C) is recommended. Immerse instruments and endoscopes into the cleaning solution and ensure a complete wetting of all instrument surfaces and cavities. Completely remove air from lumens. Brush instruments if necessary. Clean endoscope channels mechanically.

Remove cleaned instruments and rinse thoroughly with clear water prior to further reprocessing steps.

Dosage

Concentration	Temperature	Soaking time
0.25 % (2.5 ml /L) recommended for ultrasonic baths	30 – 40 °C	minimum 5 min.
0.4 % (4 ml /L)	30 – 40 °C	minimum 5 min.

Composition

5 – 15 % non-ionic surfactants; preservatives: 2-methyl-2H-isothiazol-3-one, 1,2-benzylisothiazol-3(2H)-one; enzymes: Protease, amylase, lipase

Chemical Properties

Appearance: Clear blue solution
pH concentrate: 8.0
pH solution 0.4%: 7.0 – 7.5

Delivery units

Single unit	Delivery unit	REF
1 liter bottle	12	00-138-010EXP
5 liter container	3	00-138-050EXP



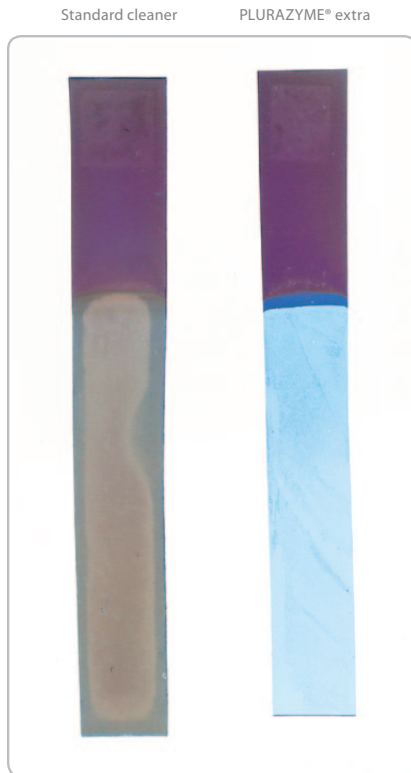
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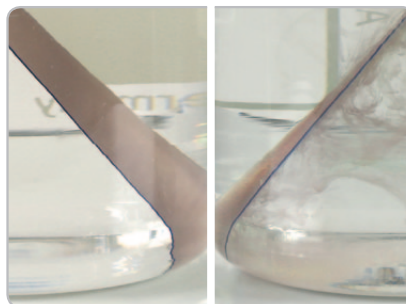
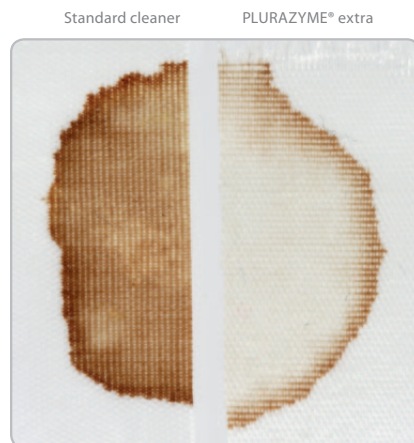
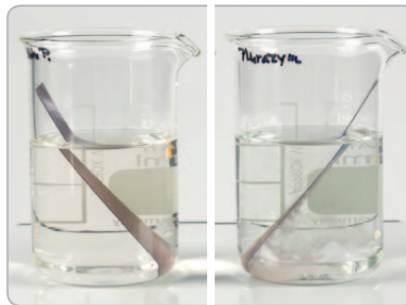
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Examples:



Cleaning performance in comparison to standard cleaners at 40 °C



Additional Information

Causes serious eye damage. Wear protective gloves/protective clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician. Contains amylase, alpha-; subtilisin; lipase. May produce an allergic reaction.

Material Compatibility

PLURAZYME® extra offers an excellent material compatibility and has been tested to be suitable for the following materials.

Recommended usage:

Metals

- Stainless Steel (V2A, V4A)
- Copper
- Aluminum

Plastics

- Polymethylmethacrylate (PMMA)
- Polyoxymethylene (POM)
- Acrylonitrile-butadiene-styrene (ABS)
- Polycarbonate (PC)
- Polyurethane (PU)
- Polyethylene (PE)
- Polyamide (PA6, PA12)
- Polystyrene (PS)
- Polyester (PES)

Elastomers

- Nitrile Butadiene Rubber (NBR)
- Neoprene, Polychloroprene
- Silicone
- Latex

Not recommended for the use on

- Brass
- Ethylene Propylene Diene Monomer Rubber (EPDM)

Product Status

PLURAZYME® extra conforms to the EU-guideline 93/42/EC for medical devices. Product for professional use only.

Environmental Information

The products of Dr. Schumacher GmbH are manufactured according to modern, safe and environmentally friendly processes in compliance with high quality standards.



Dr. Schumacher GmbH is certified according to DIN EN 13485, DIN EN ISO 9001, DIN EN ISO 14001 & BS OHSAS 18001 and has a validated eco management system (according to EMAS).

We are members of IHO, VCI, BAH, DGSV and DGKH.

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

1.1. Product identifier

PLURAZYME extra

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

Use of the substance/mixture

Enzymatic cleaner.

1.3. Details of the supplier of the safety data sheet

Company name: Dr. Schumacher GmbH
Street: Postfach 11 62
Place: D-34201 Melsungen
Telephone: +49 (0) 5664/9496-0
Responsible Department: Responsible for the safety data sheet: sds@gbk-ingelheim.de
Telefax: +49 (0) 5664/8444

1.4. Emergency telephone number:

INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a)
England and Wales: NHS Direct - 0845 4647; Scotland: NHS 24 - 08454 24 24
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Indications of danger: Xi - Irritant

R phrases:

Irritating to eyes.

GHS classification

Hazard categories:

Serious eye damage/eye irritation: Eye Dam. 1

Hazard Statements:

Causes serious eye damage.

2.2. Label elements

Hazardous components which must be listed on the label

Alcohol ethoxylate C9-C11

Signal word: Danger

Pictograms: GHS05



Hazard statements

H318 Causes serious eye damage.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

Special labelling of certain mixtures

EUH208 Contains Amylase, alpha, Subtilisin, Lipase, triacylglycerol. May produce an allergic reaction.

2.3. Other hazards

Not known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mixture of the following substances with non-hazardous admixtures

Hazardous components

EC No	Chemical name	Quantity
CAS No	Classification	
Index No	GHS classification	
REACH No		
	Alcohol ethoxylate C9-C11	< 10 %
68439-46-3	Xn - Harmful, Xi - Irritant R22-41	
	Acute Tox. 4, Eye Dam. 1; H302 H318	
201-069-1	Citric acid, monohydrate	< 5 %
5949-29-1	Xi - Irritant R36	
	Eye Irrit. 2; H319	
01-2119457026-42		
233-139-2	boric acid	< 5 %
10043-35-3	Repr. Cat. 2 R60-61	
005-007-00-2	Repr. 1B; H360FD	
01-2119486683-25		
232-752-2	Subtilisin	< 1 %
9014-01-1	Xi - Irritant R37/38-41-42	
647-012-00-8	Skin Irrit. 2, Eye Dam. 1, Resp. Sens. 1, STOT SE 3, Aquatic Acute 1; H315 H318 H334 H335 H400	
01-2119480434-38		
232-565-6	Amylase, alpha	< 1 %
9000-90-2	R42	
647-015-00-4	Resp. Sens. 1; H334	
01-2119938627-26		
232-619-9	Lipase, triacylglycerol	< 1 %
9001-62-1	R42	
	Resp. Sens. 1; H334	
01-2119972939-13		

Full text of R and H phrases: see Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

After inhalation

Move to fresh air in case of accidental inhalation of vapours or decomposition products.

In the event of symptoms refer for medical treatment.

After contact with skin

In case of contact with skin wash off with soap and water.

Consult a doctor if skin irritation persists.

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After contact with eyes

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Seek medical treatment by eye specialist.

After ingestion

Do not induce vomiting.
Rinse out mouth and give plenty of water to drink.
Never give anything by mouth to an unconscious person.
Consult a physician.
Induce vomiting only upon the advice of a physician.

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

Causes serious eye damage.
Watch out. Beware, hazard of foam aspiration.

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

Treat symptoms.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Alcohol-resistant foam, dry chemical, carbon dioxide (CO₂), water-spray.
Product does not burn, fire-extinguishing activities according to surrounding.

Unsuitable extinguishing media

Full water jet.

5.2. Special hazards arising from the substance or mixture

Fire may produce:
Carbon monoxide and carbon dioxide.

5.3. Advice for firefighters

Use breathing apparatus with independent air supply.
Protective suit.

Additional information

Cool containers at risk with water spray jet.
Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

In case of vapour formation use respirator.
Ensure adequate ventilation.
Use personal protective clothing.

6.2. Environmental precautions

Do not discharge into the drains/surface waters/ground water.

6.3. Methods and material for containment and cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder).
Shovel into suitable container for disposal.

6.4. Reference to other sections

Observe protective instructions (see Sections 7 and 8).
Information for disposal see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Keep container tightly closed.

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Use only in thoroughly ventilated areas.

Avoid contact with skin, eyes and clothing.

Advice on protection against fire and explosion

No special protective measures against fire required.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep containers tightly closed in a dry, well-ventilated place.

Advice on storage compatibility

Incompatible with oxidizing agents.

Further information on storage conditions

Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

Enzymatic cleaner.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
57-55-6	Propane-1,2-diol, particulates	-	10		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL
9014-01-1	Subtilisins (Bacillus subtilis Carlsberg)	-	0.00004		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL

8.2. Exposure controls

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas.

Protective and hygiene measures

Wash hands before breaks and after work.

When using, do not eat, drink or smoke.

Avoid contact with eyes and skin.

Remove and wash contaminated clothes before re-use.

Eye/face protection

Tightly fitting goggles (EN 166).

Eye wash bottle with pure water (EN 15154).

Hand protection

Suitable are gloves made of following materials (breakthrough time \geq 8 hours):

Natural rubber/latex - NR (0,5 mm) (use powder free and allergene-free products)

Polychloropren - CR (0,5 mm)

Nitrile rubber/nitrile latex - NBR (0,35 mm)

Butyl rubber - Butyl (0,5 mm)

Fluoro-rubber - FKM (0.4 mm)

Polyvinyl chloride - PVC (0.5 mm)

Skin protection

Long sleeved clothing (EN 368).

Respiratory protection

No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Liquid
Colour: Blue
Odour: Mild

pH-Value (at 20 °C): 8,03 **Test method**

Changes in the physical state

Flash point: n.d.
Lower explosion limits: n.d.
Upper explosion limits:
Ignition temperature: n.d.
Density (at 20 °C): 1,0203 g/cm³
Water solubility: Miscible
(at 20 °C)

9.2. Other information

No data available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No decomposition if stored and applied as directed.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Reactions with oxidizing agents.

10.4. Conditions to avoid

To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials

Strong oxidizing agents

10.6. Hazardous decomposition products

Carbon monoxide and carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.

No toxicological data available.

CAS No	Chemical name	Exposure routes	Method	Dose	Species	Source
68439-46-3	Alcohol ethoxylate C9-C11	oral	LD50 mg/kg	300 - 2000	Rat	
5949-29-1	Citric acid, monohydrate	oral	LD50	3000 mg/kg	Rat	

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Irritation and corrosivity

Causes serious eye damage.
Skin irritation: Not classified.

Sensitising effects

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

Severe effects after repeated or prolonged exposure

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.
Carcinogenicity: Not classified.
Mutagenicity: Not classified.
Reproductive toxicity: Not classified.

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information on tests

Classification in compliance with the assessment procedure specified in the Regulation (EC) no 1272/2008.

Practical experience

Other observations

Repeated or long-term contact with enzymes will lead to allergic reactions of skin and respiratory tract
Watch out. Beware, hazard of foam aspiration.

SECTION 12: Ecological information

12.1. Toxicity

Ecological data are not available.

12.2. Persistence and degradability

The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

According to Regulation (EC) No 1907/2006 (REACH) none of the substances, contained in this product are a PBT / vPvB substance.

12.6. Other adverse effects

Hazardous water pollutant.

Further information

This concentrate is not allowed to be released into the sewerage, surface water or groundwater.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Where possible recycling is preferred to disposal.
Can be incinerated, when in compliance with local regulations.

Waste disposal number of waste from residues/unused products

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070699 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics; wastes not otherwise specified

Contaminated packaging

Empty containers should be taken for local recycling, recovery or waste disposal.

Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse.

Packaging that cannot be cleaned should be disposed of like the product.

SECTION 14: Transport information

Other applicable information

No hazardous material as defined by the transport regulations.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

1999/13/EC (VOC): 0 %

Additional information

Regulation (EC) No 648/2004 (Regulation on detergents):

5 - 15% Non-ionic surfactants, 2-methyl-2H-isothiazol-3-one, 1,2-benzisothiazol-3(2H)-one,

1,2-benzisothiazolin-3-one,

Enzymes Protease, amylase, lipase

National regulatory information

Employment restrictions: Observe employment restrictions for young people. Observe employment restrictions for child bearing mothers and nursing.

Water contaminating class (D): 2 - water contaminating

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

Abbreviations and acronyms

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route

RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses

ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure

IMDG = International Maritime Code for Dangerous Goods

IATA/ICAO = International Air Transport Association / International Civil Aviation Organization

MARPOL = International Convention for the Prevention of Pollution from Ships

IBC = Code International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

REACH = Registration, Evaluation, Authorization and Restriction of Chemicals

CAS = Chemical Abstract Service

EN = European norm

ISO = International Organization for Standardization

VOC = Volatile organic compound

STOT SE = Specific target organ toxicity single exposure

STOT RE = Specific target organ toxicity repeated exposure

PBT = Persistent Bioaccumulative and Toxic

vPvB = Very Persistent and very Bio-accumulative

bw = body weight

LD = Lethal dose

LC = Lethal concentration

EC = Effect concentration

IC = Median immobilisation concentration or median inhibitory concentration

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Full text of R phrases referred to under Sections 2 and 3

- 22 Harmful if swallowed.
- 36 Irritating to eyes.
- 37/38 Irritating to respiratory system and skin.
- 41 Risk of serious damage to eyes.
- 42 May cause sensitisation by inhalation.
- 60 May impair fertility.
- 61 May cause harm to the unborn child.

Full text of H statements referred to under Sections 2 and 3

- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H335 May cause respiratory irritation.
- H360FD May damage fertility. May damage the unborn child.
- H400 Very toxic to aquatic life.

Further Information

Data of items 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities.

The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge.

The delivery specifications are contained in the corresponding product sheet.

This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

(n.a. = not applicable; n.d. = not determined)

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)