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Safety Data Sheet

according to Regulation (EC) No 1907/2006

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

1.1. Product identifier

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

Use of the substance/mixture

Ready-to-use solution disinfection of dental impression material

1.3. Details of the supplier of the safety data sheet

Company name: AMPri Handelsgesellschaft mbH

 Street:
 Benzstraße 16

 Place:
 21423 Winsen (Luhe)

 Telephone:
 +49 (0) 4171-84 80-0

e-mail: info@ampri.de

Responsible Department: Responsible for the safety data sheet: sds@gbk-ingelheim.de

1.4. Emergency telephone INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a)

number: In England and Wales: NHS 111 In Scotland: NHS 24 - dial 111

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

This mixture is not classified as hazardous in accordance with GB CLP Regulation.

2.2. Label elements

Regulation (EC) No. 1272/2008

Special labelling of certain mixtures

EUH208 Contains Glyoxal, Glutaraldehyde. May produce an allergic reaction.

EUH210 Safety data sheet available on request.

2.3. Other hazards

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

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Aqueous solution



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Hazardous components

CAS No	Chemical name			
	EC No	Index No	REACH No	
	GHS Classification		•	
107-22-2	Glyoxal			
	203-474-9	605-016-00-7	01-2119461733-37	
	Muta. 2, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H341 H332 H315 H319 H317 H335			
111-30-8	Glutaraldehyde			< 0.1 %
	203-856-5	605-022-00-X	01-2119455549-26	
	Met. Corr. 1, Acute Tox. 2, Acute Tox. 3, Skin Corr. 1B, Resp. Sens. 1, Skin Sens. 1A, STOT SE 3, Aquatic Acute 1, Aquatic Chronic 1; H290 H330 H301 H314 H334 H317 H335 H400 H410 EUH071			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc.	Specific Conc. Limits, M-factors and ATE	
107-22-2	203-474-9	Glyoxal	< 1 %
	inhalation: LC50 = 2,41 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); dermal: LD50 = 12700 mg/kg		
111-30-8	203-856-5	Glutaraldehyde	< 0.1 %
		E = 0.5 mg/l (vapours); inhalation: ATE = 0.05 mg/l (dusts or mists); oral: ATE = 100 $E = 0.5 = 0.5 = 0.5 = 0.5 = 0.5$; M=1	

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 fumes from overheating or combustion.

After contact with skin

Wash off with soap and plenty of water.

Consult a doctor if skin irritation persists.

After contact with eyes

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

If eye irritation persists, consult a specialist.

After ingestion

Do not provoke vomiting. Consult physician. Attention in case of vomiting - acute danger of suffocating, produced by foaming ingredients. Rinse mouth. Make drink some glasses of water. The decision whether to provoke vomiting is to be taken by a physician.

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

Contact with eyes may cause irritation.

Prolonged skin contact may cause skin irritation.

May cause sensitization of susceptible persons by skin contact.

Watch out. Beware, hazard of foam aspiration.

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

Treat symptoms.



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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

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 (CO), carbon dioxide (CO2) and nitrogen oxides (NOx)

Chlorine compounds

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

General advice

Attention. Hazard of skidding.

Ensure adequate ventilation.

For non-emergency personnel

Avoid contact with skin, eyes and clothing.

For emergency responders

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

For containment

Prevent spread over a wide area (e.g. by containment or oil barriers).

For 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.

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



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Requirements for storage rooms and vessels

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

Keep at temperatures between 5°C and 25°C.

Further information on storage conditions

Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

Ready-to-use solution disinfection of dental impression material

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
111-30-8	Glutaraldehyde	0.05	0.2		TWA (8 h)	WEL
		0.05	0.2		STEL (15 min)	WEL

Additional advice on limit values

No data available

8.2. Exposure controls

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas.

Protective and hygiene measures

Wash hands before breaks and immediately after handling the product.

When using do not eat or drink.

Avoid contact with skin, eyes and clothing.

Remove and wash contaminated clothes before re-use.

Eye/face protection

Safety goggles with side protection (EN 166).

Hand protection

Rubber gloves

This recommendation refers exclusively to the chemical compatibility and the lab test conforming to EN 374 carried out under lab conditions.

Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves.

Skin protection

Long sleeved clothing (DIN EN ISO 6530)

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: Light blue

Odour: Perfumed (scented)

Test method

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pH-Value (at 20 °C): 4 - 6,5 Concentrate

Changes in the physical state



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Melting point/freezing point:	n.d.		
Boiling point or initial boiling point and boiling range:	approx. 100 °C		
Sublimation point:	n.a.		
Softening point:	n.d.		
Flash point:	n.a.		
Sustaining combustion:	Not sustaining combustion		
Flammability Solid/liquid:	n.a.		
Gas:	n.a.		
Explosive properties			
The product is not explosive.			
Lower explosion limits:	n.a.		
Upper explosion limits:	n.a.		
Auto-ignition temperature:	n.a.		
Self-ignition temperature			
Solid:	n.a.		
Gas:	n.a.		
Decomposition temperature:	n.d.		
Oxidizing properties Not oxidising.			
Vapour pressure:	n.d.		
Density (at 20 °C):	approx. 1,01 g/cm³		
Bulk density:	n.a.		
Water solubility: (at 20 °C)	Miscible		
Solubility in other solvents n.d.			
Partition coefficient n-octanol/water:	n.d.		
Viscosity / dynamic:	ca. 9 mPa⋅s		
Viscosity / kinematic:	n.d.		
Flow time:	n.d.		
Relative vapour density:	n.d.		
Evaporation rate:	n.d.		
Solvent separation test:	0 %		
Solvent content:	0 %		
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



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No hazardous reactions known.

10.4. Conditions to avoid

To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials

No materials to be especially mentioned.

10.6. Hazardous decomposition products

No hazardous decomposition products known.

Fire may produce:

carbon monoxide (CO), carbon dioxide (CO2) and nitrogen oxides (NOx)

Chlorine compounds

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No. 1272/2008

Acute toxicity

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

No toxicological data available.

Irritation and corrosivity

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

Sensitising effects

Contains Glyoxal, Glutaraldehyde. May produce an allergic reaction.

Carcinogenic/mutagenic/toxic effects for reproduction

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

STOT-single exposure

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

STOT-repeated exposure

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

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.

11.2. Information on other hazards

Endocrine disrupting properties

No data available

Other information

Contact with eyes may cause irritation.

Prolonged skin contact may cause skin irritation.

May cause sensitization of susceptible persons by skin contact.

Watch out. Beware, hazard of foam aspiration.

If appropriately handled and if in accordance with the general hygienic rules, no damages to health have become known.

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.



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12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

Hazardous water pollutant.

Further information

Do not discharge into surface waters/groundwater.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Where possible recycling is preferred to disposal.

Can be incinerated, when in compliance with local regulations.

List of Wastes Code - residues/unused products

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

Land transport (ADR/RID)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number: No dangerous good in sense of this transport regulation.



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14.2. UN proper shipping name:
 14.3. Transport hazard class(es):
 14.4. Packing group:
 No dangerous good in sense of this transport regulation.
 No dangerous good in sense of this transport regulation.
 No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

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

EU regulatory information

Authorisations (REACH, annex XIV):

-

Restrictions on use (REACH, annex XVII):

Entry 75

2004/42/EC (VOC): < 1 %

Information according to 2012/18/EU

(SEVESO III):

Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Water hazard class (D): 2 - obviously hazardous to water

15.2. Chemical safety assessment

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

SECTION 16: Other information

Changes

Changes in section: 2, 6, 9, 10, 11, 12, 15, 16

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

DIN = Deutsche Industrie Norm

PBT = Persistent Bioaccumulative and Toxic

vPvB = Very Persistent and very Bio-accumulative



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LD = Lethal dose

LC = Lethal concentration

EC = Effect concentration

IC = Median immobilisation concentration or median inhibitory concentration

Relevant H and EUH statements (number and full text)

H290	May be corrosive to metals.
H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH071	Corrosive to the respiratory tract.
EUH208	Contains Glyoxal, Glutaraldehyde. May produce an allergic reaction.
EUH210	Safety data sheet available on request.

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.

The provision of the safety data sheet does not automatically guarantee the marketability of the product.

(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.)