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Safety data sheet - according to Regulation (EC) No 1907/2006

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. PRODUCT IDENTIFIER

Trade name

BePro suction CM

UFI

3FJD-X5FD-700S-USTG

1.2. RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

Relevant identified uses:

Cleaning and preservative agent.

Intended purpose:

Liquid concentrate for the weekly acid contra-cleaning and maintenance of dental aspiration systems with and without amalgam separator.

Uses advised against:

None at intended use.

Note:

The product is intended for professional users.

1.3. DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Manufacturer/Supplier:

W&H Sterilization Srl

Via Bolgara 2

24060 Brusaporto (BG) - Italy

Telephone: +39 035 66 63 000

E-mail: office.sterilization@wh.com

Internet: www.wh.com

E-mail address for the competent person responsible for the safety data sheet:

doku@alpro-medical.de

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1.4. EMERGENCY TELEPHONE NUMBER

In-house emergency telephone number:

+49 7725 9392-0

Monday – Friday from 08:00 am to 04:30 pm (UTC+1); for chemical information and legal information on hazardous substances only

Poison centre:

+49 761 19240

Poisoning information centre, Freiburg, Germany (24 h / 7 d), English is spoken

SECTION 2: HAZARDS IDENTIFICATION

2.1. CLASSIFICATION OF THE SUBSTANCE OR MIXTURE;

CLASSIFICATION IN ACCORDANCE WITH REGULATION (EC) NO 1272/2008 [CLP]

<i>Classification</i>	<i>Classification procedure</i>
Eye Irrit. 2; H319	Calculation method
Skin Irrit. 2; H315	Calculation method

Full text of hazard classes as well as H-phrases: see under SECTION 16.1.

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2.2. LABEL ELEMENTS

LABEL ELEMENTS IN ACCORDANCE WITH REGULATION (EC) NO 1272/2008 [CLP]

Hazard pictograms:



Signal word:

Warning

Hazard components for labelling:

-

H-phrases

H315: Causes skin irritation.

H319: Causes serious eye irritation.

P-phrases

P280: Wear protective gloves /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.

P337+P313: If eye irritation persists: Get medical advice/attention.

2.3. OTHER HAZARDS

The substances in the mixture do not meet the PBT/vPvB criteria according to Regulation (EC) No 1907/2006, Annex XIII.

No further hazards known.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. MIXTURES

Chemical characterization

Mixture of substances listed below with non-hazardous additions in aqueous solution.

Hazardous ingredients

Chemical name	Identification numbers	Classification in accordance with Regulation (EC) No 1272/2008	Weight %
Sulphamidic acid	CAS No: 5329-14-6 EC No: 226-218-8 Index No: 016-026-00-0 REACH Registration No: 0-2119488633-28-XXXX	Eye Irrit. 2; H319 Skin Irrit. 2; H315 Aquatic Chronic 3; H412	≥ 1 - < 5

Full text of hazard classes and H-phrases: see SECTION 16.1.

SECTION 4: FIRST AID MEASURES

4.1. DESCRIPTION OF FIRST AID MEASURES

General information:

First aider: Pay attention to self-protection!

Following inhalation:

Move affected person into fresh air and keep still and warm. Seek medical advice. In case of continued complaints seek medical advice

Following skin contact:

Wash skin immediately with plenty of water and soap. In case of skin reactions, consult a physician.

Following eye contact:

Flush eyes immediately with flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Consult an ophthalmologist.

Following ingestion:

Rinse mouth with water. Let drink plenty of water. Do not induce vomiting (risk of perforation). Consult a physician immediately.

4.2. MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Causes skin irritation. Causes serious eye irritation.

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4.3. INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No information available.

SECTION 5: FIREFIGHTING MEASURES

5.1. EXTINGUISHING MEDIA

Suitable extinguishing media:

Water spray jet, alcohol resistant foam, extinguishing powder, carbon dioxide (CO₂)

Unsuitable extinguishing media:

Full water jet

5.2. SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

Hazardous combustion products:

Carbon monoxide (CO), carbon dioxide (CO₂), nitrogen oxides (NO_x), sulfur oxides (S O).

5.3. ADVICE FOR FIREFIGHTERS

Special protective equipment:

Wear self-contained breathing apparatus.

Further information:

Cool endangered containers with water spray jet

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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

For non-emergency personnel

Use personal protective equipment. See SECTION 8.2. Avoid skin and eye contact. Special danger of slipping by leaked/spilled product

For emergency responders

Use personal protective equipment. See SECTION 8.2.

6.2. ENVIRONMENTAL PRECAUTIONS

Do not discharge into drains or rivers

6.3. METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Containment

For large spills, dyke spilled material or otherwise contain material to ensure runoff does not reach a waterway. Cover or seal drains.

Cleaning up

Wipe up small amounts with absorbent material (e.g. cloth, fleece). Absorb large amounts with liquid binding material (sand, diatomaceous earth, universal binder, sawdust). Collect in suitable, closed containers for disposal. Clean contaminated surfaces thoroughly.

Other information

Inappropriate containment and cleaning methods are not known.

6.4. REFERENCE TO OTHER SECTIONS

Information on safe handling see SECTION 7.1.

Information on personal protective equipment see SECTION 8.2.

Information on disposal see SECTION 13.

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SECTION 7: HANDLING AND STORAGE

7.1. PRECAUTIONS FOR SAFE HANDLING

Precautions

Avoid contact with skin and eyes. Fill refill packages only in labelled original bottles.

Advice on general occupational hygiene

When using do not eat, drink or smoke. Wash hands before breaks and at end of work. Keep away from food and drink.

7.2. CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Requirements for storage rooms and vessels:

Keep only in the original container. Keep container tightly closed and kept upright to prevent any leakage.

Advice on common storage:

Not necessary.

Further information on storage conditions:

Not necessary.

Storage class ([DE] TRGS 510):

LGK 12 Non-combustible liquids that are not assigned to any of the aforementioned LGK.

7.3. SPECIFIC END USE(S)

Apart from the uses mentioned in section 1.2 no other specific end uses are stipulated.

Industry and sector specific guidance

[DE]

TRGS 525 – Hazardous substances in medical care facilities (Section 7 Activities with disinfectants); Issue: September 2014;

Source: GMBI 2014 page 1294-1307 of 13.10.2014 [No 63]; www.baua.de

[DE]

DGUV rules 107-002 (former BGR 206) - Disinfection works in health service

Issue: July 1999; Source: www.dguv.de/publikationen

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. CONTROL PARAMETERS

Occupational exposure limits

Does not contain substances above concentration limits fixing an occupational exposure limit

Biological limit values

Does not contain substances above concentration limits fixing an occupational exposure limit.

Information on monitoring procedures

BS EN 482:2012-04-30; Title: Workplace exposure - General requirements for the performance of procedures for the measurement of chemical agents;

British version of EN 482:2012

BS EN 689:1996-04-15; Title: Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy;

British version of EN 689:1995

BS EN 14042:2003-04-24; Title: Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents;

British version of EN 14042:2003

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8.2. EXPOSURE CONTROLS

Appropriate engineering controls

Technical and organisational protective measures

The eyewash station (or eyewash bottle) and emergency shower must be located near the workplace.

Personal protective equipment

Eye/face protection:

Safety glasses with side protection according to EN 166.

Skin protection:

Hand protection:

Protective gloves according to EN 374.

Splash guard:

Disposable gloves made of nitrile rubber (thickness 0.11 mm).

Permanent contact (> 480 min):

Protective gloves made of nitrile rubber (thickness 0.40 mm).

Other skin protection:

Not necessary when used as intended.

Respiratory protection:

Not necessary when used as intended.

Thermal hazards:

No special protective measures necessary.

Environmental exposure controls

Do not discharge into drains.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	clear, orange liquid	
Odour:	slightly aromatic	
Odour threshold:	no data available	
pH (50 g/l H ₂ O):	1.5 –2.5	(20 °C)
Melting point/freezing point:	no data available	
Initial boiling point and boiling range:	no data available	
Flash point:	> 60 °C	
Evaporation rate:	no data available	
Flammability (solid, gas):	not applicable	
Lower explosive limit:	not applicable	
Upper explosive limit:	not applicable	
Vapour pressure:	no data available	(... °C)
Vapour density:	no data available	
Relative density:	1.050 – 1.060	(20 °C)
Solubility in water:	completely soluble	
Partition coefficient:		
n-octanol/water	not applicable	
Auto-ignition temperature:	not applicable	
Decomposition temperature:	no data available	
Viscosity:	no data available	
Explosive properties:	none	
Oxidising properties:	none	

9.2. OTHER INFORMATION

Refractive index nD:	1.3418-1.3448	(20 °C)
Electrical conductivity (50 g/l H ₂ O):	6000-7000 µS/cm	(20 °C)

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SECTION 10: STABILITY AND REACTIVITY

10.1. REACTIVITY

No hazardous reactions when handled and stored as intended.

10.2. CHEMICAL STABILITY

The product is stable when handled and stored as intended.

10.3. POSSIBILITY OF HAZARDOUS REACTIONS

None known.

10.4. CONDITIONS TO AVOID

None known.

10.5. INCOMPATIBLE MATERIALS

None known.

10.6. HAZARDOUS DECOMPOSITION PRODUCTS

Does not decompose when used as intended.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1. INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity

Product

Acute toxicity - oral:

Acute Toxicity Estimate $ATE_{mix} > 2000$ mg/kg

=> no classification

Acute toxicity - dermal:

Acute Toxicity Estimate $ATE_{mix} > 2000$ mg/kg

> no classification

Acute toxicity - inhalation:

Acute Toxicity Estimate $ATE_{mix} > 20$ mg/l

=> no classification

Skin corrosion/irritation

Product

Causes severe skin burns. [calculation method]

Serious eye damage/irritation

Product

Causes serious eye damage. [calculation method]

Respiratory or skin sensitization

Product

No data available.

Germ cell mutagenicity

Product

No data available.

Carcinogenicity

Product

No classification. [calculation method]

Reproductive toxicity

Product

No data available

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STOT-single exposure

Product

No classification. [calculation method]

STOT-repeated exposure

Product

No data available.

Aspiration hazard

Product

No data available.

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SECTION 12: ECOLOGICAL INFORMATION

12.1. TOXICITY

No classification. [calculation method].

12.2. PERSISTENCE AND DEGRADABILITY

Biodegradability

The product is biodegradable according to OECD criteria. The statement has been derived from the properties of the ingredients.

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 Regulation (EC) No 1907/2006, Annex XIII.

12.6. OTHER ADVERSE EFFECTS

No data available.

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SECTION 13: DISPOSAL CONSIDERATIONS

13.1. WASTE TREATMENT METHODS

Disposal of the product

Product residues must be disposed of as hazardous waste in compliance with the Directive 2008/98/EC on waste as well as national and regional regulations. Do not dispose of via the waste water. Leave product in the original container as possible. Do not mix with other waste materials.

Waste codes / waste designations according to EWC

Product residues:

16 10 03* aqueous concentrates containing hazardous substances

Disposal of the packaging

Packaging contaminated with product is considered as hazardous waste and must be disposed of accordingly.

Waste codes / waste designations according to EWC

Contaminated packaging:

15 01 10* packaging containing residues of or contaminated by hazardous substances

Recommendation

Contaminated packaging must be emptied optimally and can be recycled after appropriate cleaning (rinse with water).

SECTION 14: TRANSPORT INFORMATION

14.1. TRANSPORT CLASSIFICATION

Dangerous good in sense of the transport regulations in road traffic (ADR), railway traffic (RID), inland waterway traffic (ADN), maritime traffic (IMDG-Code) and air traffic (ICAO-TI/IATA-DGR).

14.2. UN NUMBER

-

14.3. UN PROPER SHIPPING NAME

-

14.4. TRANSPORT HAZARD CLASS(ES)

-

14.5. PACKING GROUP

-

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14.6. ENVIRONMENTAL HAZARDS

-

14.7. SPECIAL PRECAUTIONS FOR USER

-

14.8. TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE

-

14.9. FURTHER INFORMATION

-

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SECTION 15: REGULATORY INFORMATION

15.1. SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE EU-REGULATIONS

REGULATION (EC) No 1005/2009 on substances that deplete the ozone layer
not applicable.

REGULATION (EC) No 850/2004 on persistent organic pollutants and amending Directive 79/117/EEC
not applicable.

REGULATION (EU) No 649/2012 concerning the export and import of hazardous chemicals
not applicable.

DIRECTIVE 2012/18/EU (Seveso III Directive) on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC
not applicable.

DIRECTIVE 2010/75/EU on industrial emissions (integrated pollution prevention and control)
not applicable.

REACH – List of substances subject to authorisation (Annex XIV)
not applicable.

REACH – Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)
not applicable.

COUNCIL DIRECTIVE 94/33/EC on the protection of young people at work
Observe employment restrictions for juveniles.

COUNCIL DIRECTIVE 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding.
Not applicable.

15.2. CHEMICAL SAFETY ASSESSMENT

For this mixture no chemical safety assessment has been carried out.

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SECTION 16: OTHER INFORMATION

16.1. FULL TEXT OF HAZARD CLASSES AND H-PHRASES

Hazard classes

Aquatic Chronic

Long term aquatic hazard

Eye Irrit.

Eye irritation

Skin Irrit.

Skin irritation

H-phrases (Hazard statements)

H315

Causes skin irritation.

H319

Causes serious eye irritation.

H412

Harmful to aquatic life with long lasting effects.

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16.2. ABBREVIATIONS AND ACRONYMS

ADN

Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)

ADR

Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

BGR

Berufsgenossenschaftliche Regeln (English: Employers' liability insurance association rules)

BS

British Standards

CAS

Chemical Abstracts Service

CLP

Regulation on Classification, Labelling and Packaging of Substances and Mixtures

[DE]

National German regulations

DGUV

Deutsche Gesetzliche Unfallversicherung (English: German statutory accident insurance)

EC

European Community

EEC

European Economic Community

EN

European Standard

EU

European Union

EWC

European Waste Catalogue

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GHS

Globally Harmonized System of Classification, Labelling and Packaging of Chemicals

GMBI

Gemeinsames Ministerialblatt (English: Joint Ministerial Gazette)

IATA-DGR

International Air Transport Association - Dangerous Goods Regulations

IBC-Code

International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk

ICAO-TI

Technical Instructions For The Safe Transport of Dangerous Goods by Air

IMDG-Code

International Maritime Code for Dangerous Goods

LGK

Lagerklasse (English: Storage class)

MARPOL

International Convention for the Prevention of Marine Pollution from Ships

OECD

Organization for Economic Co-operation and Development

PBT

Persistent, bioaccumulative and toxic

REACH

Registration, Evaluation, Authorisation and Restriction of Chemicals

RID

Règlement concernant le transport International ferroviaire de marchandises Dangereuses (Regulations Concerning the International Carriage of Dangerous Goods by Rail)

TRGS

Technische Regeln für Gefahrstoffe (English: Technical Rules for Hazardous Substances)

UN

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United Nations

UTC

Coordinated Universal Time (French: Temps Universel Coordonné)

vPvB

Very persistent and very bioaccumulative

16.3. KEY LITERATURE REFERENCES AND SOURCES FOR DATA

Regulation (EC) No 1907/2006 (REACH), Annex II

European Chemicals Agency (ECHA) – Guidance on the compilation of safety data sheets; Version 2.1 (February 2014);
http://echa.europa.eu/documents/10162/13643/sds_en.pdf

GISBAU (Hazardous substances information system of the BG BAU) – course „safety data sheet“;
<http://www.bgbau.de/gisbau/SDB/lehrgang/lehrgang.htm>

Regulation (EC) No 1272/2008 (CLP regulation)

European Chemicals Agency (ECHA) – Guidance on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 (04/2011);
http://echa.europa.eu/documents/10162/13562/clp_labelling_en.pdf

European Chemicals Agency (ECHA), Registered substances;
<http://echa.europa.eu/information-on-chemicals/registered-substances>

European Chemicals Agency (ECHA), C&L Classification and Labelling Inventory;
<http://echa.europa.eu/information-on-chemicals/cl-inventory-database>

Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA):
GESTIS database on hazardous substances and GESTIS - International limit values for chemical agents;
<http://www.dguv.de/dguv/ifa/index.jsp>

German Environmental Agency (Umweltbundesamt), Section IV 2.4: Office of Documentation and Information on Substances Hazardous to Waters RIGOLETTO (catalogue of Substances Hazardous to Waters);
<http://webriigoletto.uba.de/rigoletto>

16.4. TRAINING ADVICE

Provide adequate information, instructions and training for users.

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16.5. INDICATION OF CHANGES

New safety data sheet. No changes so far.

The information given in the safety data sheet only applies to the described product in connection with its intended use. This information is based on the latest state of our knowledge at the time of revision. In particular, it describes our product under the aspect of its hazards and safety measures to be taken. It does not constitute any guarantee of product properties and quality features.