

schülke -†



Mildly alkaline high performance cleaner
for the automated reprocessing of medical
devices

thermosept® X·tra

Our Plus

- excellent cleaning performance achieved by the synergistic combination of active substances of enzymes and surfactants
- low foaming formular
- optimized material compatibility, also suitable for anodized aluminium
- high economic efficiency due to low working concentration
- pH of >10 in the cleaning solution - risk reduction in the case of vCJK according to the recommendation of the German RKI (Robert-Koch Institute)
- silicate-free

Application areas

thermosept® X·tra is designed for the automated cleaning of medical devices and accessories e.g. surgical instruments, minimally invasive surgical instruments, including robotic instruments, materials used in anaesthesia, ophthalmological instruments, rigid endoscopes, containers and other instruments commonly used in the Central Sterile Supply Department. Product can be used in all common types of washer/disinfectors (WD) and tunnel/washers. The outstanding cleaning performance is based on the combination of an innovative system of detergents combined with high-performance enzymes. The activity of the special enzyme variant develops initially in the application solution - in this way, powerful performance is achieved directly in the cleaning phase in WD. Even at low doses, thermosept® X·tra removes organic contaminants such as blood, proteins, tissue residues as well as mucus and fatty impurities. The synergistic combination of active ingredients allow excellent compatibility with materials, even with sensitive materials such as anodized aluminum and non-ferrous metal. With a pH-value of >10, a ten-minute cleaning time and an elevated, non-protein-fixing process temperature during the cleaning phase, thermosept® X·tra contributes to risk reduction with regard to vCJK according to the German RKI recommendation. Released for the manual pretreatment and

automated reprocessing of Intuitive Surgical® da Vinci robotic instruments.

Instructions for use

Dosage:

Standard concentration: 0.5 % (5 ml/l)

Depending on the degree of soiling: 0.3 - 1.0 % (3 - 10 ml/l)

Cleaning temperature standard: approx. 55°C (30 - 65 °C),
cleaning time approx. 5 - 10 minutes

Cleaning indicators: All common indicators can be used.

Do not use thermosept® X·tra in combination with other products. The use of purified water is recommended. The neutralisation step required for classical alkaline cleaning agents is not necessary. When preparing ocular instruments, two interim rinsing steps with purified water before thermal disinfection are recommended or use neutraliser thermosept® NKZ. Dosing is performed by machine-integrated dosing pumps. Please note recommendations of machine and instrument manufacturers.

CE



Product data

Composition:

Labelling according to Regulation (EC) No. 648/2004: 5 - 15 % anionic surfactants, < 5 % nonionic surfactants, < 5 % polycarboxylate, enzymes.

Other ingredients: Solubiliser, corrosion inhibitors.

Chemical-physical data

Color	yellow
Density	ca. 1,1 g/cm ³ / 20 °C / 1.013 hPa
Flash point	> 100 °C / Method : DIN 51755 Part 1
Form	liquid
pH	ca. 11 / 20 °C / concentrate
Viscosity, dynamic	ca. 9 mPa*s / Method : ISO 3219

Special advice

Keep container tightly closed. Store at room temperature in the original container. Protect from frost, heat and sunlight. (Storage temperature: 5 - 25 °C).

Information for order

Item	Delivery form	Item no.
thermosept X-tra 200 I FA	1/drum(s)	on request
thermosept X-tra 5 I KA	1/Canister	on request
thermosept X-tra 10 I KA	1/Canister	on request
thermosept Xtra 20 I KA	1/Canister	on request
thermosept X-tra SOKA 5 I KA	1/Canister	on request

These products are not available in every country. For more information please contact our local subsidiary or distributor.

Accessories

Accessories	Item no.
Can key for 5 + 10 l	135810

Environmental information

schülke manufactures products economically and with advanced, safe and environmentally friendly production processes while at the same time maintaining out high quality standards.

Expert opinion and information

Please visit our website for an overview of all available literature/reports on the product: <http://www.schuelke.com/>.
For individual questions: Customer Care Phone: +49 40 52100-666 E-Mail: info@schuelke.com



Schülke & Mayr GmbH holds a Manufacturer's Authorisation according to sect 13 para 1 German Drug Law and Certificates of GMP Compliance for medicinal products.



A company of the Air Liquide-Group

schülke Headquarters
Schülke & Mayr GmbH
Robert-Koch-Str. 2
22851 Norderstedt, Germany
Phone +49 (0) 40 - 52100 - 0
Fax +49 (0) 40 - 52100 - 318
www.schuelke.com
mail@schuelke.com

Schülke & Mayr UK Ltd.
1 Jenkin Road
GB-Sheffield S9 1 AT
Phone +44 (0) 1142 - 5435 - 00
Fax +44 (0) 1142 - 5435 - 01
www.schulke.co.uk
mail.uk@schuelke.com

Schülke & Mayr Ges.m.b.H.
Seidengasse 9
1070 Wien, Austria
Phone +43 (0) 1 - 5232501-0
Fax +43 (0) 1 - 5232501-60
www.schuelke.at
office.austria@schuelke.com