SteelcoXide

SteelcoXide-DT is a modern and effective concentrated synthetic detergent substance, which is totally hydro-soluble, for the cleaning of flexible endoscopes and other medical devices.

SteelcoXide-DT performs an exclusive synergic action combining the proteolytic properties of ADAMAVIR COMPLEX® with an enzymatic complex and with ionic surfactants.

- It does not modify the chemical and physical properties of materials, leaving the surface of the treated device totally clean, without any residual or captured chemical elements.

- SteelcoXide-DT prepares the materials for subsequent disinfection/sterilization, leaving the surface of the treated device totally clean \( \text{UFC}=0 \), without any residual or captured chemical elements. It performs a synergic action of an enzymatic complex with Adamavir Complex®, acts rapidly in the short time of 5 minutes against fungal species.

- SteelcoXide-DT, and all its components are stable/valid for 24 months in its unopened and correctly stored pack.
Classification: High-performance detergent to use as a preliminary treatment to the disinfection / sterilization process for automatic endoscope washing machines or for manual use

Composition: SteelcoXide-DT contains an active formula consisting of a proteolytic ADAMAVIR COMPLEX® element, ionic surfactant and enzymatic surfactant. Other components: basic water-soluble coformulants.

Exclusive synergetic mechanism: SteelcoXide-DT is indicated for combined use with SteelcoXide (SteelcoXide-A + SteelcoXide-B) chemical sterilant. It can be used in manual and automatic washing procedures in order to remove protein dirt from surgical instruments and accessories. It is not a common detergent for the cleaning of instruments but a product able to prepare the surface of any material for a better penetration of the following sterilising treatment. It is able to effectively remove any impurities which may be present in the porous lamellar structure of the materials composing flexible and/or heat sensitive devices.

Instructions: SteelcoXide-DT is for cleaning of medical devices.

Compatibility: SteelcoXide-DT has shown excellent compatibility with materials composing all the devices and systems used in medical surgical applications. It has been specifically tested on and is suitable for all optical fibre flexible devices, including new generation devices made from plastic materials. Tested materials: metals, aluminium, brass, copper, stainless steel, carbon steel.

Plastics: polyurethane, polythene, PVC, polyacetate, polypropylene, PTFE, nylon, ABS.

Rubbers: silicon, viton, neoprene, latex, EPDM rubber.
Study:

- **University of Perugia, Perugia - Dip. Ing. Civile e Ambientale:** Morphological study of electron microscopy SEM Spectrophotometric and FT-IR on the components of fiber optics instrument.

Testing methods: a morphologic study with scanning electron microscopy VP SEM (CNR Department of Physical Chemistry, Rome) was carried out.

Results of the study: changes in weight or impregnation causing a variation in the initial colours were not detected.

Mode of use:

**SteelcoXide DT** is a concentrated product that has been tested and validated for use in Steelco AER’s and in the automatic device to support the manual cleaning phase Steelco EPW 100. In AER’s it is used at a dilution of 1:100 (1%), in EPW 100 system efficacy of cleaning has been tested and validated in conformity to ISO / TS 15883: 5 to 1:50 dilution (0.5%).

The cleaning effectiveness of the cleaning concentrate SteelcoXide DT, in combination automatic device to support the manual cleaning phase Steelco EPW 100, has been tested and validated for use at ambient temperature at a concentration of 0.5% and a contact time of 5 minutes. The cleaning must be carried out for not less than 10 minutes followed by 1 minute of rinse time.

**SteelcoXide** is automatically dosed by the integrated dosing system of the AER. **Contact time 10 minutes**.

Use only from the original container. Any other dilution compared to the original container solution is not acceptable. Do not mix with organic materials (eg. Oil, grease, rubber, paper, ..) or rust.

Warnings:

The product must be handled by specialised staff according to appropriate safety standards and correct hygienic practices. Keep out of reach of children. Do not add bleaches or other chemical substances. Preliminary cleaning of devices with brushes is necessary. **SteelcoXide-DT** detergent must not be used as a means of preserving instruments. Keep in a dry place at room temperature and far from heat sources (a
range from +5°C to +25°C). The expiry date refers to the unopened and correctly stored product.

**Precautions:**

The product does not require particular precautionary measures for persons or the environment as substances are at a concentration below the minimum danger threshold.

**Stability and Validity:**

If unopened and correctly stored at room temperature, **SteelcoXide-DT** is stable for 24 months.

**Study:**

- **Laboratorio interno FIS&DM:** Analysis on the stability of the product according to the scheme “Tripartide ICH Guideline” and the UNI EN ISO 175:2010.

**Pharmacology:**

The analytical method was validated by the study:


**Toxicity:**

**SISTEMA SteelcoXide** is not toxic.

**Studies:**

- **HERA – Human & Environmental Risk Assessment on ingredients of household cleaning products**
- **ECHA**

Ecotoxicological and Toxicological Informations.

**Biodegradability:**

After use the solutions that such should be disposed of as hazardous waste. The high dilutions in service conditions, make that these solutions do not generate harmful or dangerous products.

**Traceability:**

The complete traceability of batches from raw material acceptance to the distribution of the finished product is carried out according to internal quality system procedures.
Proteolytic activity:
The proteolytic activity of SteelcoXide-DT was determined through the studies carried out at Pisa University.

- Pisa University, Department for Experimental Pathology, Medical Biotechnologies, Infectious Diseases and Epidemiology - Retrovirus Centre – Director: Prof. Mauro Pistello – 27 October 2006- Studies on microbiologic efficiency and viral activity. Test of Exjum’s capacity to denature viral RNAs.

The study demonstrated the ability of Adamavir Complex to denature proteins either as a single substance or in combination with the co-formulants of the product.

The efficacy of the washing has been widely evaluated. The results have shown that when the product is used according to its instructions, the cleaning action is effective. The percentage of removal of organic residual is equal to 98,5% with rinses at 30° and equal to 85,5% with rinses at room temperature (drying test at room temperature).

(H) Risk phrases:
The risk phrases mentioned below are to be referred exclusively to the product as is. Are not considered valid by the percentages of use to which the product is intended as the substances are present at a concentration below the minimum danger threshold.

SteelcoXide-DT

Acute Tox.4: H302 - Harmful if swallowed
Flam Liq 3: H226 – Flammable liquid and vapour
Skin Irrit. 2: H315 – Causes skin irritation
Eye Dam. 2: H320 – Causes eye irritation
STOT SE 3: H335 – Causes eye irritation
Aquatic Acute 4: H413 – May cause long lasting harmful effects to aquatic life

(P) Precautionary advice:
The precautionary advice phrases mentioned below are to be referred exclusively to the product as is. Are not considered valid by the percentages of use to which the product is intended as the substances are present at a concentration that does not require any precautionary advice.
SteelcoXide-DT

P261 – Avoid breathing dust/fume/gas/mist/vapours/spray.
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
P342 + P311 – If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician

Packaging

5 liter tank SteelcoXide-DT - Code 9992068
Packed in boxes of 2 tanks

N.B. Further information, literature and safety sheets are available from the company only upon request. The company reserves the right to modify or update the information at any time.