EC 15

ALKALINE-ENZYMATIC CLEANING AND PRE-DISINFECTION GRANULATE for the treatment of medical and dental instruments, rotating precision instruments and endoscopes.

Description

Alkaline-enzymatic cleaning and pre-disinfection granulate for the treatment of medical and dental instruments, rotating precision instruments and endoscopes in ultrasonic and immersion baths and washer disinfectors. Removes blood, proteins, residues of tissues and biofilms. EC certificate: 004804MR2, notified body: **(**€ 0297.

Medical certificates: SMP, Tübingen, cleaning capacity according to ISO/TC 198/WG13, chapter 6.2, 2010-09; HygCen Germany GmbH, Schwerin, Prof. Dr. H.-P. Werner, high level virucidal acc. to DVV-guideline 2012, 2016-06; HygCen Germany GmbH, Schwerin, Prof. Dr. H.-P. Werner, test of virucidal efficacy with ultrasonics, 2016-06.

Application and dosage

0.5-1% (1 to 2 bags in 2 liter water), Exposure time: 5-15 min in ultrasonic bath at 20-40 $^{\circ}$ C or choose cleaning program "Enzymatic cleaner" on Denta Pro device, 60 min in immersion bath at 20-40 $^{\circ}$ C.

<u>Cleaning</u>: In ultrasonic bath or in immersion bath mix 1 bag (10g *EC 15*) with 2 liters of warm water (20-40 $^{\circ}$ C), e.g. in Denta Pro device or Elmasonic S 30. If ultrasonic starts, the enzyme is released, causing clouding of the solution. This does not have a negative effect on the cleaning performance. After cleaning, rinse instruments thoroughly with warm water. Prepare a new cleaning solution at least daily or sooner if the bath is visibly contaminated.

<u>Pre-Disinfection</u>: (Caution: EC 15 is virucidal. For a bactericidal efficacy a disinfection or sterilization process must be carried out!) High personal protection (TRBA 250), with an application concentration of 0.5% virucidal against enveloped viruses (e.g. HBV, HCV, HIV, influenza) and non-enveloped adeno- and noroviruses, efficacy extendible to parvovirus at 1% concentration (DVV-guideline 2012, see medical certificates above). Optimal pre-treatment, in combination with *EC 55* comprehensively bactericidal and virucidal.

Safety recommendations

EC 15 is classified as hazardous according to the regulation (EC) No 1272/2008 [GHS] (skin corrosive and serious eye damage, respiratory irritant effect). Observe also with respect to this the hints indicated in the Safety Data Sheet and always handle chemicals with care.

Physical-chemical characterisation

Bulk density: ~900 g/l, pH (0,5% solution): 11.5-12.5.

Ingredients according to Annex VII A, EC-Regulation 648/2004 (detergents): 5-15% phosphates, <5% non-ionic surfactants, enzymes (coated).

Disposal

The surfactants in our product meet the criteria for biodegradation as laid down in Annex III of the Regulation (EC) No 648/2004 on detergents.

The cleaning bath can be fed into the public sewage system after neutralisation; observe the local pH limit values and make sure that the contamination contained complies with the local sewage regulations. Recommendation: use acetic acid or citric acid for neutralisation in the ultrasonic bath but not hydrochloric or sulphuric acid. European waste code: 07 06 99*, "wastes not otherwise specified". / 20 01 29*, "detergents containing dangerous substances". / 15 01 10*, "packaging containing residues of or contaminated by hazardous substances".

Delivery form, storage and transport

Delivery form: Surgery package (70 bags a 10 g), order number: 8000632.

Store in closed original container at a temperature between -5 $^{\circ}$ C and +30 $^{\circ}$ C, keep container dry, protected from heat and direct solar radiation. Do not store with acids.

Shelf life: 3 years from date of production (see stamp on label).

Classification for all means of transport: class 8, UN 3253. Regulations concerning free quantities are to be observed.

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