

Klorsept 17 Technical Data Sheet

1. Name of the Product

Klorsept 17.

2. Product Type

Klorsept 17 tablets are effervescent disinfectant tablets.

Strength/Potency:

Klorsept 17 contains 1.67gm NaDCC (Sodium Dichloroisocyanurate/Troclosene Sodium)

3. Dosage & Usage

Klorsept 17 Tablets Dosage Form: White/off white, flat bevelled edged, effervescent tablets.

Klorsept 17 Tablets Usage instructions & Dilution Chart

Clean the surface then apply Klorsept 17 solution with mop, cloth, sponge, brush, wipe, foaming equipment or coarse trigger sprayer. Allow surface to remain wet for 5-15 minutes. Wipe with a brush, sponge or cloth and allow to air dry. Prepare a fresh solution weekly when using closed containers (spray bottles). Prepare a fresh solution daily when using open containers (buckets) or if solution becomes diluted.

Application	Dilution
General disinfection for cleaned non-critical areas, e.g. walls, floors, food handling surfaces, trolleys.	200 ppm 1 tablet in 5 L
Disinfection of cleaned critical areas e.g. operating theatres, post-mortem rooms.	1000 ppm 1 tablet in 1 L
Disinfection of dirty surfaces potentially contaminated with blood or other bodily fluid spillages.	5000 ppm 1 tablet in 0.2 L

4. Qualitative & Quantitative Composition

Klorsept 17 Tablets Active Ingredient:

Active Substance: Troclosen Sodium (CAS No. 2893 - 78 - 9)

Excipients:

Each Klorsept 17 tablet contains the following excipients:

Adipic acid

Sodium bicarbonate

Sodium sulphate

5. Klorsept 17 Physiochemical Properties

Klorsept 17:

Appearance : White/off white, flat bevelled edged, effervescent tablet

Odour : Slight chlorine odour

Average weight : 3.34gm (target)

Hardness : $\geq 49N$

Disintegration : ≤ 7 minutes (in 500mls water)

NaDCC content : 1.67gm NaDCC per tablet (target)

Available chlorine content : 1.08gm available chlorine per tablet (target)

Solubility : Soluble in water

pH : 5 – 6

6. Packaging

Klorsept 17 tablets are packaged into polypropylene/polyethylene tubs with 200 tablets per tub. Six tubs are packaged per each cardboard outer carton.

7. Shelf-life

Klorsept 17 tablets when tub-packed have a shelf life of 3 years.

8. Certificates

To assure that Klorsept 17 tablets are manufactured to appropriate Quality Control standards, Medentech manufactures to standards of Good Manufacturing Practice (GMP) and is also an ISO9001 & ISO13485 Quality-Assured Company.

Inspections are undertaken on a regular basis by the Health Products Regulatory Authority (HPRA), which is the responsible Authority in Ireland, for GMP conformance to European Standards. This ensures that all appropriate testing is undertaken to assure that the product meets specification, that the processes have been validated to produce a consistent product, that stability studies have been undertaken to International standards, that materials are selected and tested to meet specified standards and specifications etc.

Inspections to meet ISO9001 & ISO13485 requirements are undertaken biannually by NSAI (National Standards Authority of Ireland).