Technical Data Sheet

1. Name of the Product

Klorkleen

2. Product Type

Klorkleen White is an effervescent disinfectant and cleaning tablet incorporating a compatible detergent.
Strength/Potency: 1.67gm NaDCC (Sodium Dichloroisocyanurate/Troclosene Sodium) per tablet.

3. Dosage & Usage

Dosage Form: White, flat bevelled edged, effervescent tablets.

Usage Instructions:

- Add 1 tablet to 5 litres of warm water (up to 40°C) for a solution strength of 200ppm available chlorine.
- For critical care areas use 1 tablet per litre for a solution strength of 1000ppm.
- For use on food handling and processing surfaces and equipment add 1 tablet to 10 litres to give 100ppm available chlorine.
- User category: Industrial, Professional, Non-professional (general public)
  Kills 99.999% of bacteria in < 10 minutes.

4. Qualitative & Quantitative Composition

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

Excipients:
Each Klorkleen tablet contains the following excipients:
Adipic acid
Sodium bicarbonate
Sodium carbonate
SDBS detergent

5. Klorkleen Physiochemical Properties

Physical and Chemical Properties:

Appearance	: White, flat bevelled edged, effervescent tablet
Odour	: Slight chlorine odour
Average weight	: 3.91 – 4.15g (Target: 4.03g)

Hardness	: ≥ 49N
Disintegration	: ≤ 12 minutes (in 1000mls water @ 40°C)
NaDCC content	: 1.50g – 1.84g/tablet (Target:1.67g/tablet)
Available chlorine content	: 0.97g – 1.19g/tablet (Target:1.08g/tablet)
Solubility	: Soluble in water
pH	: 5 – 6

6. Packaging

Klorkleen tablets are tub-packaged into polypropylene/polyethylene tubs.

7. Shelf-life

Klorkleen tablets when tub-packed have a shelf life of 2 years.

8. Certificates

To assure that Klorkleen 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).