AMUCHINA TABLETS

Medical-Surgical Device (Presidential Decree No. 392 of 6 October 1998) Registration no. 18026 of the Ministry of Health

ACRAF Codes: 419584, 419309, 419308, 419224

1. Composition

100 g of product contain: troclosene sodium (sodium salt of dichloroisocyanuric acid) 50%, adipic acid 27.5%, sodium bicarbonate 22.5%.

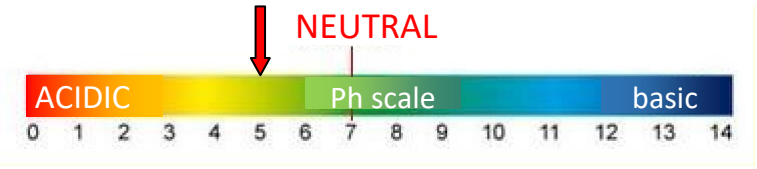
EACH 5 G TABLET CONTAINS:
Sodium salt of dichloroisocyanuric acid (anhydrous) 2.5 g equal to 1.562 g (62.5%) of available chlorine.

EACH 2 G TABLET CONTAINS:
Sodium salt of dichloroisocyanuric acid (anhydrous) 1 g equal to 0.625 g (62.5%) of available chlorine.

EACH 1 G TABLET CONTAINS :
Sodium salt of dichloroisocyanuric acid (anhydrous) 0.5 g equal to 0.312 g (62.5%) of available chlorine.

2. Chemical-physical characteristics

Appearance	Flat tablets, with rounded edge
Color	White
Odor	Characteristic chlorine smell
pH	4-6



3. Indicated use

Amuchina Tablets is indicated for antiseptic washing of fruit and vegetables, for disinfecting rubber objects (teats), plastic and glass objects (feeding bottles, utensils, kitchenware) and in case of emergency, for reducing the bacterial load of drinking water.

4. Mechanism of action

The active ingredient of AMUCHINA TABLETS, the sodium salt of dichloroisocyanuric acid (troclosene sodium), releases hypochlorous acid in aqueous solution.

Hypochlorous acid is the active part, mainly responsible for the disinfectant action, the so-called ACTIVE OR AVAILABLE CHLORINE.
The hypochlorous acid is mainly responsible for the disinfectant action, the reason is due to its extremely small molecular structure with no electrical charge and fully assimilable to that of water. Because of this molecular structure, the hypochlorous acid penetrates easily through the cell membrane of the bacterial cell, thus becoming an agent with high microbial activity.

In water, hypochlorous acid dissociates according to the following reaction:

$HOCl \leftrightarrow H^+ + OCl^-$

Chlorine-active compounds in aqueous solution give rise to hypochlorous acid (HOCl), which has a high oxidising power and is capable of damaging microbial cells, and hypochlorous ions (OCl), which originate from each other depending on the pH of the solution. The mechanism of action is mainly related to the oxidation of cellular protoplasmic components and enzymatic systems that regulate the energy metabolism of microorganisms.

5. Spectrum of action

Efficacy	**Tested strains**	**Concentrations**	**Contact times (min)**	**Conditions**	**Reference standard**
Bactericide	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538	62.5-125-250 ppm	5	N.A.	EN1040
Bactericide	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 10536 *Enterococcus faecium* ATCC 10541	125-250-500 ppm	5	clean	EN 1276
		125-250-500 ppm	5	dirty	
Bactericide	*Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 10536 *Enterococcus faecium* ATCC 10541	500 ppm 250 ppm	5 15	surface test	CEN prEN 13697

The results of the microbiological efficacy evaluation tests summarized in the table above demonstrate the disinfectant activity of the preparation, to be used as is, as a ready-to-use product, in relation to

- Gram+ and Gram- bacteria

6. How to use

- For antiseptic washing of fruit and vegetables and to disinfect rubber, plastic and glass objects or kitchenware:
  - One 5 g tablet in 12.5 l of water
  - One 2 g tablet in 5 l of water
  - One 1 g tablet in 2.5 l of water

After dissolving, leave the disinfectant to act for 15 minutes. Rinse thoroughly with drinking water.

- To reduce the bacterial load of drinking water in an emergency:
  - One 5 g tablet in 150 l of water
  - One 2 g tablet in 60 l of water
  - One 1 g tablet in 30 l of water

7. Safety/ Warnings/ Disposal Methods

See Safety Data Sheet.

This material and its container must be disposed of as hazardous waste. Refer to the special instructions/safety information sheets.

8. Storage and shelf-life

Shelf-life 36 months.

9. Packages available

2 g and 5 g tablets in 0.5 kg bottle for professional use, 1 g tablets in box with blister of 24 tablets.

10. Marketing Authorization

Registration no. 18026 of the Ministry of Health

11. Marketing Authorization holder

Amuchina S.r.l. - Via Pontasso, 13 - 16015 Casella, Genoa, ITALY - Tel. 010/968761

12. Sales dealer

Aziende Chimiche Riunite Angelini Francesco – A.C.R.A.F. S.p.A. – Viale Amelia, 70 – 00181 Rome

13. Bibliographical references

1. **Basic bactericide efficacy evaluation - Biolab SpA Test Centre - Vimodrone (MI): Report No 01/3132-1 of 20/03/2001.**
2. **Evaluation of bactericidal efficacy in the presence of interfering substances under clean conditions - Biolab SpA Test Centre - Vimodrone (MI): Report No 01/3132-2 of 20/03/2001.**
3. **Evaluation of bactericidal effectiveness in the presence of interfering substances in dirty conditions - Biolab SpA Test Centre - Vimodrone (MI): Report No 01/3132-3 of 20/03/2001.**
4. **Evaluation of bactericidal activity: surface test - Biolab SpA Test Centre - Vimodrone (MI): Report No 01/3132-4 of 20/03/2001.**
5. **Evaluation of bactericidal activity: surface test - Biolab SpA Test Centre - Vimodrone (MI): Report No 01/3132-5 of 18/04/2001.**
6. **Chemical disinfectants surface method - Biolab SpA test centre - Vimodrone (MI): Report No 95/4551 of 11/05/1995.**