

ProClin® 950 Preservative for Diagnostic Reagents

Directions for Use



ProClin 950 preservative for diagnostic reagents is a precise formulation of 9.5% active ingredient in water. The active ingredient in ProClin 950 is methylisothiazolinone and it is totally miscible in water, lower alcohols and glycols.

General Directions for Use

The recommended use level for ProClin 950 is 0.05% - 0.1% (48-95 ppm of active ingredient) of ProClin 950 as supplied. ProClin 950 preservative should be added as the last ingredient and at the lowest temperature (<45 °C if possible). Because the components of *in vitro* diagnostic kits vary considerably and may impact on the effect of preservatives, we encourage confirming the efficacy and stability of ProClin 950 for each formulation.

The use of ProClin 950 at the recommended use level is considered to be safe and does not present a mutagenic, teratogenic, reproductive or carcinogenic risk to humans.

Conversion of % Active Ingredient to % Product

Active Ingredient PPM	%	% Product Proclin 950
50	0.0050	0.053
75	0.0075	0.079
100	0.0100	0.105

Microbiological Efficacy

ProClin 950 preservative exhibits outstanding antimicrobial activity, inhibiting a wide variety of gram-negative bacteria,

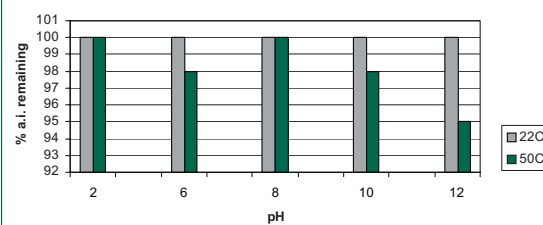
yeast and molds. The table below gives the minimum inhibitory concentration (MIC) in ppm active ingredients (methylisothiazolinone) that inhibited the growth of various microorganisms in broth tests.

Minimal inhibitory concentration test parameters: nutrient broth, 30 °C/pH 7, 24 hour contact time, ProClin 950 at test levels, microorganisms - ATCC and product isolate; 7 bacteria, 1 yeast, 2 molds.

Chemical Stability

ProClin 950 Preservative is stable over a wide range of pH and temperature conditions.

Figure 1. Effect of pH and Temperature in Buffered Water (methylisothiazolinone stability after 3 weeks)



Analytical Procedures

High Performance Liquid Chromatography (HPLC) analysis is the preferred method for determining low levels of ProClin 950.

Organism	ATCC No.	MIC (ppm a.i.)
Bacteria		
Enterobacter aerogenes	15038	30
Pseudomonas aeruginosa	15442	40
Burkholderia cepacia	17765	20
Pseudomonas oleovorans	8062	30
Pseudomonas putida	795	20
Staphylococcus aureus	6538	40
Serratia marcescens	Lab Isolate	30
Fungi		
Aspergillus niger	6275	3
Penicillium oxalicum	24784	80
Candida albicans	11651	40

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