ProClin™ Biocidal Preservatives

An eco-friendly alternative to sodium azide for diagnostic assays

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Introduction

ProClin™ preservatives are among the most widely used biocides in the IVD industry, used in over 1,000 FDA registered IVD kits from industry leading manufacturers. At low working concentrations, ProClin™ preservatives can help extend the shelf life of IVD reagents by effectively and immediately inhibiting a broad spectrum of microbes (**Figure 1 and Figure 2**). ProClin™ preservatives attack the Krebs cycle at four key points: the enzymes pyruvate dehydrogenase, α-ketoglutarate dehydrogenase, succinate dehydrogenase, and NADH dehydrogenase (**Figure 3**). Because all bacteria and fungi possess at least part of the Krebs cycle, ProClin™ preservatives are broad spectrum in their activity.

Biocide Selection

All four ProClin™ formulations are safe to use and environmentally friendly at recommended usage levels. Unlike other biocides, ProClin™ products present a reduction in health hazards, toxicology problems, or disposal issues. Despite the enhanced safety profile for users, a study conducted by an independent laboratory shows comparable efficacy to traditional preservatives thimerosal and sodium azide (**Table 1**).

This study indicates that ProClin™ 150 and ProClin™ 300 preservatives may be effective replacements for thimerosal and offer better protection than sodium azide, without the handling and disposal concerns associated with either traditional preservative. For full study methodology, please visit sigmaaldrich.com/proclin.

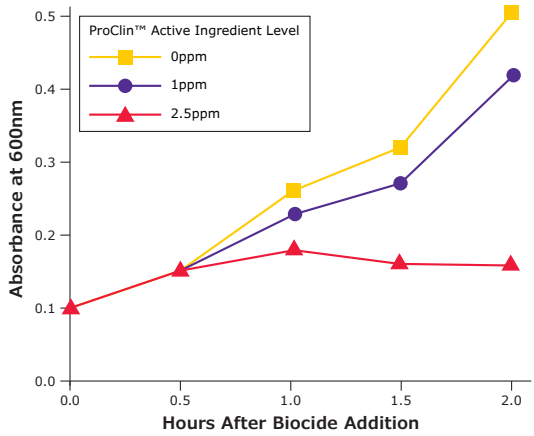

Figure 1. Rapid Inhibition of Growth

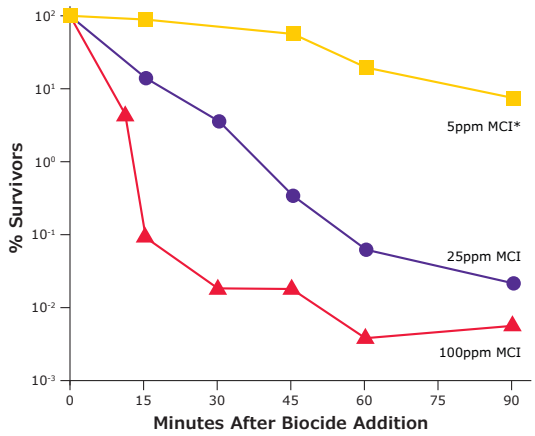

Figure 2. Cidal Activity of ProClin™ Preservatives (Cell Death)

Results of microbial challenge

Table 1. ProClin™ Preservatives, Thimerosal Pass Microbial Challenge (All values in CFU/mL).

Test Solution	First Inoculation	14-Day Count	Second Inoculation	14-Day Count	Third Inoculation	14-Day Count	Fourth Inoculation	14-Day Count
Unpreserved mPBS								
Tryptic Soy Broth Agar	3.38 x 10^6	4.2 x 10^6	3.30 x 10^6	6.5 x 10^6	a			
Potato Dextrose Agar	1.93 x 10^6	2.1 x 10^6	3.56 x 10^6	1.31 x 10^7	a			
Sodium Azide								
Tryptic Soy Broth Agar	3.38 x 10^6	b	3.30 x 10^6	d	a			
Potato Dextrose Agar	1.93 x 10^6	c	3.56 x 10^6	e	a			
0.005% Thimerosal								
Tryptic Soy Broth Agar	3.38 x 10^6	<10	3.30 x 10^6	<10	1.88 x 10^6	<10	4.50 x 10^6	<10
Potato Dextrose Agar	1.93 x 10^6	<10	3.56 x 10^6	<10	1.16 x 10^6	<10	2.75 x 10^6	<10
15 ppm ProClin™ 150								
Tryptic Soy Broth Agar	3.38 x 10^6	<10	3.30 x 10^6	<10	1.88 x 10^6	<10	4.50 x 10^6	<10
Potato Dextrose Agar	1.93 x 10^6	<10	3.56 x 10^6	<10	1.16 x 10^6	<10	2.75 x 10^6	<10
15 ppm ProClin™ 300								
Tryptic Soy Broth Agar	3.38 x 10^6	<10	3.30 x 10^6	<10	1.88 x 10^6	<10	4.50 x 10^6	<10
Potato Dextrose Agar	1.93 x 10^6	<10	3.56 x 10^6	<10	1.16 x 10^6	<10	2.75 x 10^6	<10

a Test ended due to growth on plates

b Aerobic bacteria (*C. albicans*) count = 870 (membrane filtration method)

c Yeast/mold (*A. niger*) count = 950 (membrane filtration method)

d Aerobic bacteria (*C. albicans*) count = >3,000 (spread plate method)

e Yeast/mold (*A. niger*) count = 980 (membrane filtration method)

Features of ProClin™ Preservatives

Feature	ProClin™ 150	ProClin™ 200	ProClin™ 300	ProClin™ 950
Active Ingredient (A.I.) %	CMIT/MIT (1.5)	CMIT/MIT (1.5)	CMIT/MIT (3)	MIT (9.5)
Bactericide	++	++	++	++
Fungicide	+	+	+	+/-
Stabilizer	23-25% Mg salts	3% Mg and Cu salts	Alkyl Carboxylate (salt-free)	None
Matrix	Water	Water	Modified glycol	Water
Working pH Range	2.5 - 8.5	2.5 - 8.5	2.5 - 8.5	2 - 12
Temperature Range	< 45 °C	< 45 °C	< 45 °C	< 90 °C
Typical Dosage Levels (W/W)	0.06 - 0.10% (9 – 15 ppm A.I.)	0.06 - 0.10% (9 – 15 ppm A.I.)	0.03 - 0.05% (9 – 15 ppm A.I.)	0.05 - 0.10% (50 – 150 ppm A.I.)
Specific Gravity	1.20	1.02	1.03	1.02
Shelf Life	2 years	18 months	3 years	3 years

When choosing between formulations there are a few key differences to consider, namely salt content, matrix material, shelf life, and in the case of ProClin™ 950, active pH range. While ProClin™ 300 is our most popular product, with its absence of magnesium salts and a three-year shelf life, ProClin™ 950 is most appropriate when working with extreme pHs or temperatures. To determine the appropriate product for your specific application, we offer a ProClin™ Variety Pack. This kit contains 5 mL of each, ProClin™ 150, 200, 300, and 950. For more information, or to order a variety kit, visit sigmaaldrich.com/proclin.

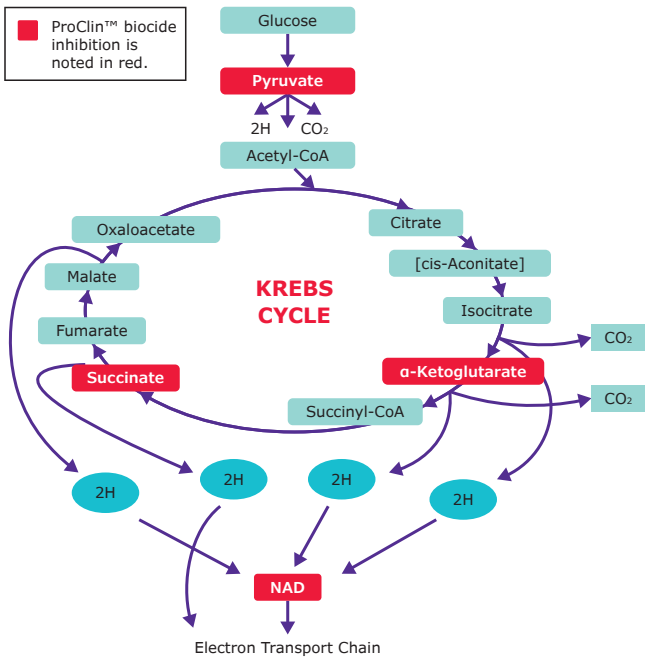

Figure 3. ProClin™ biocide inhibits the Krebs Cycle at four key sites.

Ordering information

Product Description	Cat. No.
ProClin™ Variety Pack	**48119-U**
ProClin™ 150	
50 mL bottle	**49376-U**
400 mL bottle	**49377-U**
3.6 L bottle	**49378-U**
15 L pail	**49379-U**
110 kg drum (91.7 L)	**49380-U**
ProClin™ 200	
50 mL bottle	**48171-U**
400 mL bottle	**500380**
3.6 L bottle	**500399**
15 L pail	**500402**
ProClin™ 300	
5 mL ampule	**48934-U**
50 mL bottle	**48912-U**
400 mL bottle	**48914-U**
2.0 L bottle	**48915-U**
3.6 L bottle	**48917-U**
18 L pail	**48918-U**
110 kg drum (106.8 L)	**48919-U**
ProClin™ 950	
5 mL ampule	**46885-U**
50 mL bottle	**46878-U**
400 mL bottle	**46879-U**
3.6 L bottle	**46883-U**
17 L pail	**46884-U**
110 kg drum (107.8 L)	**799130**

ProClin™ preservatives are restricted to use in IVD assay development. Contact your local regulatory body for specific biocide usage and handling guidelines.

Sigma-Aldrich®

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