

# ProClin® 150 Preservative for Diagnostic Reagents

## Stability and Storage

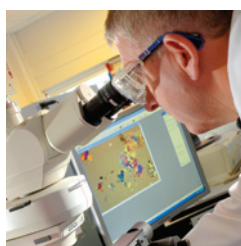


ProClin 150 Preservative, as supplied, is listed with a shelf life of 4 years when stored at 25 °C. To determine the effect of extended storage on the pH and active ingredients (A.I.) levels, a series of studies were conducted, and are summarized here.

Samples of ProClin 150 that had initial pH of 2.1 - 4.8 were selected and stored at 25 °C for 7 months. The results summarized in Table 1 demonstrate that the pH of the ProClin 150 samples declined toward 2, regardless of the initial pH. Importantly, the lower the initial pH, the smaller the pH decline.

The results of the study summarized in Table 2 demonstrate that:

- Over 9 months storage at 25 °C, the pH declined to a minimum of 1.7-1.9.
- There was no appreciable loss of active ingredient (A.I.) or magnesium nitrate over 6 months storage at 25 °C.



An additional study was performed with seven ProClin 150 preservative batches with an initial pH of 2.6-2.8.

Table 1. Effect of Storage at 25 °C on the pH of ProClin 150 Preservative

No. of Samples	Average Initial pH	4 Months		7 Months	
		Average pH	Average pH Drop	Average pH	Average pH Drop
2	2.1	2.0	0.1	--	--
3	2.6	2.2	0.4	2.1	0.5
3	3.1	2.3	0.8	2.2	0.9
3	3.5	2.6	0.9	2.2	1.3
3	4.8	2.9	1.9	2.5	2.3



Table 2. Effects of Storage at 25 °C on pH and A.I. of ProClin 150 Preservative

Time (months)	pH Range	Average % Remaining			
		RH-651 <sup>1</sup>	RH-573 <sup>2</sup>	Total A.I.	Mg(NO <sub>3</sub> ) <sub>2</sub>
0	2.6–2.8	100	100	100	100
3	2.1–2.4	100	100	100	94
6	2.1–2.3	98	103	99	101
9	1.7–1.9	--	--	--	--

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Data for an additional group of six batches of ProClin 150 preservative demonstrate that the pH equilibrated at a low point of 1.7, and did not change over a storage period of 42-54 months

at 25 °C (Table 3). There was no appreciable loss of active ingredient or magnesium nitrate over this storage interval.

Table 3. ProClin 150 Preservative Stability After 42-54 Months Storage at 25 °C

Time (months)	pH Range	Average % Remaining			
		RH-651 <sup>1</sup>	RH-573 <sup>2</sup>	Total A.I.	Mg(NO <sub>3</sub> ) <sub>2</sub>
0	2.0–4.8	100	100	100	100
42-54	1.7–1.9	97	95	97	101

### Storage at 55 °C

Accelerated aging studies also were performed at 55 °C on several lots of ProClin 150 preservative samples. The data summarized in Table 4 show a

downward pH change from the initial pH of 2.0-3.4 to 1.5-2.2 after storage for 1 month at 55 °C. No appreciable loss of active ingredient occurred over this storage interval.

Table 4. Effects of Storage at 55 °C on pH and A.I. of ProClin 150 Preservative

No. of Batches	pH Range	Time (months)	Average % Remaining		
			RH-651 <sup>1</sup>	RH-573 <sup>2</sup>	Total A.I.
10	2.8–3.4	0	100	100	100
	1.9–2.2	1	97	92	96
5	2.0–3.2	0	100	100	100
	2.2	1	100	96	99
2	2.0–3.0	0	100	100	100
	1.5–1.6	1	97	100	98

(1) 5-Chloro-2-methyl-4-isothiazolin-3-one

(2) 2-Methyl-4-isothiazolin-3-one

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