

# Certificate of Stability

## OROLIN® Multisept Plus

### INTRODUCTION

To determine stability during storage and transportation, the product was subjected to the following stability test. Samples were stored in incubators under constant testing conditions. These conditions represent internationally accepted experimental settings and simulate the environment experienced by the product during its life. At pre-defined time points, the samples were analyzed using approved analytical methods and incubation was carried on. At the end of the stability test, the results were summarized and evaluated. The product was considered stable for a given period of time if all product specifications were fulfilled during this time.

### PRODUCT DESCRIPTION

OROLIN® Multisept Plus is a powerful concentrate for the manual disinfection and cleaning of medical and surgical instruments. The solution is bactericidal, tuberculocidal, mycobactericidal, yeasticidal and virucidal in 15 minutes. The unique formulation contains powerful corrosion inhibitors resulting in a solution far less corrosive than water on copper alloys, iron and tin. Tests confirm compatibility with stainless steel and most non-metal materials including acrylic glass, Plexiglas®, polyamides, polyethylene, PVC and silicone. OROLIN® Multisept Plus is free of aldehydes, phenols and chlorine. Suitable for use in ultrasonic cleaning devices.

### RELEVANT PHYSICAL AND CHEMICAL PROPERTIES

Colour:	Blue
Physical state:	Clear, slightly viscous liquid
Scent:	Aromatic

### EVALUATED PRODUCT SPECIFICATIONS

Test criterion:	Test method:
Appearance and odour:	PA.009
Density at 20°C:	PA.057
pH:	PA.007
Surfactants content:	PA.058

### STABILITY TESTS

► <b>Accelerated stability test at 40 °C / 80% air humidity</b>	<b>For the accelerated stability test under moist and warm conditions the samples were stored at a temperature of 40 °C (± 2°C) and a relative air humidity of 80% (± 5%).</b>
Test laboratory:	...
Duration of test:	17 months.
Quantitative specifications:	All samples fulfilled the specification requirements over the entire test period.
Appearance:	No change in colour was observed over the entire test period.
Scent:	No change in odour was perceived over the entire test period.



► **Long term stability test at room temperature**

Test laboratory:

Duration of test:

Quantitative specifications:

Appearance:

Scent:

**For the long term stability test at room temperature the samples were stored at 25 °C (± 2°C) and a relative air humidity of 60% (± 5%).**

...

17 months.

All samples fulfilled the specification requirements over the entire test period.

No change in colour was observed over the entire test period.

No change in odour was perceived over the entire test period.

## CONCLUSIONS

The major tested product characteristics remained within the specifications over the entire test period. Under extreme conditions such as high temperature, slight changes in colour and odour were observed only after several months.

Considering these results, the stated use, the known stability of the biocide agent(s) and the obligation to use the tested original containers, we therefore declare that the product is stable for at least the indicated shelf life in climate zones I to IV:

## EXPIRY OF THE SOLUTION:

Unopened container: 24 months

After first opening:

Unused working solution: 7 days

Working solution in use: 7 days

The shelf life of the product is subject to correct storage and transportation conditions and the use of original containers. Keep containers tightly closed. The shelf life of a working solution in use depends on the degree of contamination. In case of heavy use, a daily change is recommended. Always replace the working solution if it becomes turbid or changes colour.

Fehraltorf, 20.09.2018

**Oro Clean Chemie AG**

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