

Letter of Clarification

Fehraltorf, 13 April 2021

Dear Sir/Madam,

Subject: Letter of Clarification

Oro Clean Chemie AG, the owner of the **OROCLEAN®** brand of hygienic, disinfectants, and cleaning products, hereby clarifies that "ORO CLEAN Plus 2 liter" (CH-071020) with the following Lot numbers have their expiration date extended from 24 months to 36 months:

- 19-16082 – new expiration date is effectively 15.10.2022
- 20-17816 – new expiration date is effectively 07.12.2023

An accelerated stability test and long-term stability test were conducted and presented to our Notified Body. The Notified Body has reviewed the reports and approved our request to extend the product's expiration date. The report is attached together in this letter.

Please contact the undersign should more information is required.

Yours sincerely,

Oro Clean Chemie AG


Vincent Loo
Key Account Manager

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Certificate of Stability

ORO CLEAN® 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

ORO CLEAN® Plus is a broad spectrum concentrate for the disinfection, cleaning and deodorisation of dental suction units and spittoon bowls. ORO CLEAN® Plus removes bad odours and leaves behind a fresh peppermint scent. Perfect for daily disinfection.

RELEVANT PHYSICAL AND CHEMICAL PROPERTIES

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

EVALUATED PRODUCT SPECIFICATIONS

Test criterion:	Test method:
Cationic surfactants content:	PA.005
pH:	PA.007
Appearance and odour:	PA.009

STABILITY TESTS

- | | |
|--|--|
| <p>▶ Accelerated stability test at 40 °C / 80% air humidity</p> <p>Test laboratory:
Duration of test:
Quantitative specifications:
Appearance:
Scent:</p> | <p>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%).</p> <p>Oro Clean Chemie AG, Research & Development, Fehraltorf, Switzerland.
6 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.</p> |
| <p>▶ Long term stability test at room temperature</p> <p>Test laboratory:
Duration of test:
Quantitative specifications:
Appearance:
Scent:</p> | <p>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%).</p> <p>Oro Clean Chemie AG, Research & Development, Fehraltorf, Switzerland.
36 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.</p> |

CONCLUSIONS

All tested product characteristics remained within the specifications over the entire test period. Even under extreme conditions such as high temperature, no changes were observed.

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:	36 months
After first opening:	
Unused working solution:	Not applicable.
Working solution in use:	Not applicable.

The shelf life of the product is subject to correct storage and transportation conditions and the use of original containers. Keep containers tightly closed.

Fehraltorf, 13.04.2021
Oro Clean Chemie AG

A handwritten signature in black ink, appearing to read 'Juerg Suter'.

Juerg Suter
Chief Operating Officer

YOUR LOCAL DISTRIBUTOR



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