

# Shelf Life of Contec® PeridoxRTU®

## Before and After Opening

We are frequently asked “How long can I use product “X” after opening?” For products from Contec®, product “X” may include:

1. Bottles of disinfectant or cleaning solutions
2. Wipes presaturated with disinfectants or solutions such as 70% alcohol
3. Wipes that are saturated by staff at the facility
4. Packages of dry wipes or mops



As described below, the useful life of a disinfectant or cleaning product after opening can be impacted by chemical and physical stability of the solution. For products that have been validated as sterile either through terminal sterilization or aseptic manufacturing, the “use-by” date also must consider how the bioburden of the product is influenced by the surrounding environment.

### Before Opening (Chemical Stability and Sterility)

- A sealed bottle, pouch, canister of alcohol or disinfectant from Contec has an expiration date printed on the container.
- For EPA-registered disinfectants, this date represents the shelf life of the unopened item, which is based on studies of the concentration of the active ingredients in the product using EPA-mandated and defined protocols.
- For Contec products not registered with the EPA (e.g., 70% IPA), the expiration dates are based on chemical and physical stability and were determined using internal analyses.
- For products designated as sterile (including dry wipes or mops), the expiration date also indicates the expected shelf life of the packaging after the sterilization method (usually gamma irradiation) using techniques associated with the ISO sterility validation process.
- Products should not be used after the expiration date, whether they have been opened or not.

**Table 1:** Shelf life of PeridoxRTU based on chemical and physical stability before the products are opened. For sterile products, this unopened shelf life also considers the package integrity after the sterilization process.

Product	Unopened
PeridoxRTU®	2 years

### After Opening (Chemical Stability)

- Contec has conducted numerous studies to understand the chemical and physical stability of our disinfectants or cleaning solutions after the containers (bottles, pouches, canisters) are opened.
- Depending on the solution and type of container, data indicate the products remain within specification for periods ranging from 14 days to 6 months. However, those studies are based on appropriate use of the product, including proper closure of the container after opening and use.

**Table 2:** Shelf life of PeridoxRTU based on chemical and physical stability for products before and after opening. For sterilized products, the unopened shelf life also considers the package integrity after the sterilization process.

Product	Unopened	After Opening
PeridoxRTU®	2 years	6 months

\*As discussed above, the products should not be used beyond the maximum shelf life date as listed for unopened containers, regardless of when they were opened.

**After Opening (Sterility)**

Contec designs containers and guides the use of our sterilized products to minimize the risk of contamination after opening.

- Products that contain solutions with antimicrobial properties, such as disinfectants or alcohol, will exhibit some level of protection against extrinsic contamination. However, the sterility validations described above only apply to unopened packages.
- Contec has conducted several studies to assess the risk of microbial contamination in open containers. Results indicate that proper technique during use dramatically reduces the risk that the solutions and presaturated wipes will become contaminated.
- Contec cannot predict or control the environmental conditions, user technique, and work practices during product use.
- Users should demonstrate and document their approach through specific SOPs that address how these products are used in their facilities, audit the consistency of work practices, make improvements where necessary, and determine and document their “use-by” date.
- Table 3 summarizes the results of studies that measured bioburden in products after opening.
- Appendix A includes details of the studies that assessed shelf life after opening. In most cases, the studies were conducted in unclassified environments with lower requirements for cleanliness than a cleanroom suite.
- Appendix B includes recommendations on procedures to reduce the risk of contamination after opening.

**Table 3:** Results of Contec Studies on the sterility of Products after Opening.

Product	Duration of Study
PeridoxRTU®	6 months

**Appendix A**

**PeridoxRTU® In-Use Shelf life Study**

**Objective**

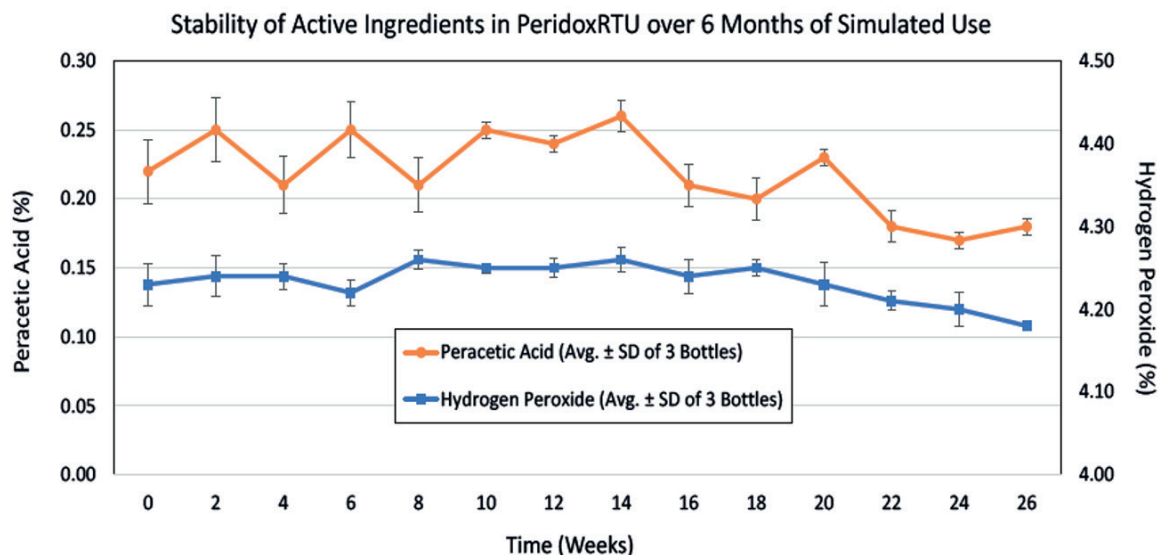
Determine the concentration of active ingredients (peroxyacetic acid and hydrogen peroxide) and hygiene status of sterilized Contec’s PeridoxRTU® in bottles after the product has been opened and used over a period of several months.

**Test Procedures**

Five bottles of sterile PeridoxRTU (CR85335IR) were obtained for testing. All bottles were opened in a nonsterile environment and the reclosable push-pull caps were installed on each bottle. At the initial installation of the cap (T0) and every 2 weeks for 6 months, 20 mL of solution was dispensed from each of the five bottles through the reclosable cap. The caps were then closed properly, and the bottles were stored at room temperature on the benchtop. At each time point, the solution dispensed from three of the bottles were tested for percent peroxyacetic acid and hydrogen peroxide. After 6 months, all five bottles from each product were sent to a third-party laboratory to assess the hygiene of a portion of the remaining solutions.

**Results**

The active ingredients in PeridoxRTU are peroxyacetic acid (nominal concentration of 0.23%) and hydrogen peroxide (nominal concentration of 4.4%). As shown on a typical Certificate of Analysis (COA) for PeridoxRTU, the specification range for peroxyacetic acid is 0.17 – 0.28% and the specification range for hydrogen peroxide is 4.0 – 4.8%. Five bottles of sterilized PeridoxRTU (CR85335IR) were repeatedly opened, sampled and tested for stability of the two active ingredients to simulate real world usage over a 6-month time period. The concentrations of peroxyacetic acid and hydrogen peroxide remained within the specification limits over the 6-month period. Fluctuations in the data can be attributed to normal variability of the test method, but the concentrations of both ingredients trended downward after 16-20 weeks.



After 6 months of simulated use in a non-classified laboratory environment, the sterility of the PeridoxRTU solution (300 mL from each bottle) was tested in an outside lab using a conventional assay. As shown in the snapshot of the sample report, all five samples were negative for bacterial and fungal growth using two types of recovery media (SCD and FTM).

**FINAL TEST REPORT**

**Sample Information:** B00125936002  
Peridox RTU

**Date Received:** September 09, 2021

**Date in Test:** September 21, 2021

**Date Completed:** October 05, 2021

**Test Information:** 122500.2  
USP (2 Media) Sterility Membrane Filtration

**Procedure #:** SOP-00379 / SOP-00380

**STI Reference #:** S0019090-v1

Sample ID	Portion /SIP Tested	Number Tested	Media Type	Media Volume	Incubation Period	Incubation Temperature	Number Negative	Number Positive
GH32090508201	300 mL	5	SCD-T-L	400 mL	14 Days	20 °C to 25 °C	5	0
GH32090508201	300 mL	5	FTM-T-L	400 mL	14 Days	30 °C to 35 °C	5	0

From this study, we can conclude that the concentration of active ingredients in PeridoxRTU remains within specification after opening. Furthermore, sterile PeridoxRTU remains sterile for up to 6 months after opening if proper technique is followed during use.

## Appendix B



### Variables to Consider When Establishing Use-By Dates for Containers After Opening

1. Determine the typical duration of use for containers of sterile disinfectants or cleaning agents.
2. Discuss with your Contec Cleanroom representative to find the container size that best matches your typical duration of use after opening.
3. Examine the results of studies conducted by Contec that measured the chemical and physical stability of the products after opening.
  - When properly resealed, the products are chemically and physically stable for weeks-months.
4. Adopt the best practices to minimize the risk of contamination described below.
5. Base the “use-by” dates for disinfectants and cleaning solutions in bottles and presaturated wipes on:
  - Your current common-use patterns.
  - Results of environmental monitoring and measures to reduce risk of contamination.
  - Results of simulated use shelf life studies from Contec.
6. Consider assessing the hygiene of products at the end of their proposed use-by dates to substantiate the dates for your SOPs.

### Initiate a Best Practice Approach to Reduce the Risk of Contamination after Opening Packages and Record the Approach in SOPs

- Open presaturated wipe packages only in the ISO class environment where they will be used; however, best practice is to open, assemble and close sterile 70% IPA and disinfectant solutions in ISO 5 air only.
- Always use aseptic technique when opening packages.
- Touch and remove only the desired number of wipes.
- Properly close the lid or reseal the pouch immediately after removing the product.
- Never open the container in ISO class conditions worse than where they will be used (e.g., do not open in ISO 7 and later move to and use in ISO 5).
- If an opened product is removed from a lower ISO class area for storage in a higher ISO class area, ensure the product's packaging is wiped with sterile IPA prior to transfer.
- If a package is opened in a room with a higher ISO class (used in ISO 5 then moved and opened in ISO 7), it should now be dedicated for use in ISO 7 or 8.

## Appendix C

Part No.	Description		Size	Packaging
CR85336	PeridoxRTU Single bagged		1 gallon (3.8 L)	4/case
CR85335	PeridoxRTU Single bagged with reclosable cap		32 oz. (0.95 L)	6/case
CRPERTRIGEB	PeridoxRTU Irradiated Foaming trigger		-	6/box
CR85336IR	Sterile PeridoxRTU Double bagged		1 gallon (3.8 L)	4/case
CR85335IR	Sterile PeridoxRTU Double bagged with reclosable cap		32 oz. (0.95 L)	6/case