

Understanding Expiration Dating vs Open Container Data

Many STERIS Instrument Cleaning Chemistries have an expiration date printed on them. In some regions of the world, this is required by regulation, whereas it is provided as a convenience in other regions. Some of our Instrument Cleaning Chemistries are regulated in the US by the FDA as medical devices, and this is also true in Europe and Canada.

Expiration Dates Explained

Expiration dates are established using the product's shelf life as determined through stability studies and its date of manufacture. These stability studies are conducted under controlled laboratory conditions for a length of time that defines the period after production that a product can continue to be sold and used. It is this expiration date that is printed on the bottle and that should be used to determine whether or not the product remains within its expiration date and whether or not to discard a product.

What is Open Container Data?

The term "expiration date" should not be used in conjunction with open container studies. STERIS performs open container studies as a courtesy to our Customers. These studies are not performed to determine product expiration but instead are intended to determine the acceptability of the product, once opened, over a finite timeframe. Open container study intervals can be used to give Customers confidence that the product is acceptable for use for at least the timeframe of the testing period. This information answers the question "How do you know the product is still good once the container is opened?". However, it is not meant to answer the question "How long is the product good once a container is opened?" because that would require an open-ended test with no specified end date.

Always Pay Attention to the Expiration Date

Open container studies provide data for our Customers; they do not take the place of the labeled expiration date nor do they indicate that "after this test interval the product is no longer good". Dates handwritten by Customers on the label may appear to supersede or extend the actual expiration date printed on the container. However, the product will expire on the printed date regardless of when the container was opened.