How Long Does a Product Remain Sterile?

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A common question asked of suppliers of sterile products is how long does a sterile product remain sterile?

Products that are sterilized, whether aseptically processed or terminally sterilized, remain sterile until opened. A common example of this is a band-aid. Once the product is opened in ambient air, there is a chance of contamination. In aseptic environments, the microbial load is monitored, and the chance of contamination is much less. A far greater risk of contamination in aseptic environments comes from the personnel working with the products.

Isn't all alcohol sterile?
Isopropyl alcohol and ethyl alcohol are intermediate level disinfectants, meaning that they kill bacteria and viruses on surfaces. However, poor quality isopropyl alcohol purchased from bulk chemical suppliers or local re-packagers can contain spores, or spore-forming bacteria. In addition, the bottles may be dirty, potentially contaminating the filling areas where it was used. Sterile IPA is usually produced by filtering a solution of USP grade 70% isopropyl alcohol and 30% purified water through a 0.22 micron filter to prevent spores from entering the bottle, then terminally sterilizing to a sterility assurance level of 10^{-6}. This means that there is less than a one in a million probability that there is 1 cfu (colony forming unit) in the bottle. This should be backed up by validation documentation. This same alcohol blend is used in the production of sterile presaturated wipes. These products are terminally sterilized and should be validated to a SAL of 10^{-6}.

Does packaging really matter?
Aerosol cans are a common delivery system for sterile alcohol, and are used to prevent the aspiration of ambient air back into the can, potentially leading to contamination. Bladder packaging technology was also developed to prevent the introduction of ambient air into a traditional trigger spray bottle. When a traditional spray bottle is used, the liquid that is expelled is replaced with ambient air. When a spray bottle with a bladder system is used, the bladder begins to collapse, preventing air from flowing back into the bottle. An aerosol can also prevent the entry of ambient air back into the container.

A study published in *Controlled Environments* demonstrated that there is no contamination due to aspiration of contaminated air back into the trigger spray alcohol bottle. Traditional trigger spray bottles were discharged in controlled environments as well as uncontrolled areas such as warehouses. The conclusion of the study was that "…Sterile 70% Isopropanol trigger-spray bottles in confirmed contaminated environments does not promote or sustain bacterial or mold growth within the bottle."

How long can I leave my product in the aseptic environment?
There is no industry standard regarding protocol for the handling and use of sterile products in an aseptic (or other) environment. In the United States, it is common practice to introduce all new supplies into an environment at the start of each new shift. At the end

"Products that are sterilized remain sterile until opened"

of the shift, all supplies are discarded and replaced with new materials at the beginning of the next shift.

In aseptic environments, it is the responsibility of the user to perform studies to determine how long a product should remain in that area before discarding.

The FDA expects that "Air monitoring samples of critical areas should normally yield no microbiological contaminants."

If a cleanroom product remains in the aseptic environment, the facility must validate their protocol. Their procedure should be documented and followed as part of their Standard Operating Procedure. Sterile products should be noted with date and time when they are introduced into an area and when they are to be discarded. In these environments the FDA may question the validity of the facility's procedure and it is up to the customer to have supporting internal data demonstrating the effectiveness of their protocol. For example, if the FDA questions a facility's protocol of using an open package of sterile saturated wipes for up to 24 hours, it is up to the facility to have their own internal justification demonstrating that the product remains sterile in their environment with their handling techniques. Data from a supplier cannot be used as each environment is different. Testing must be done under working conditions in the cleanroom.

Aseptic techniques (handling of products by technicians) play a key role in the sterility of products. Under the best of conditions, poor techniques can result in contamination of products.

Summary

The FDA requires that the facility has procedures in place for control of products used in aseptic environments. The longer a product is used in an environment, the more likely it will bring greater scrutiny. Using products that are packed in small quantities eliminates waste and minimizes the risk of contamination. Contec offers sterile products packaged in smaller packaging configurations. Typically, sterile dry wipes are packaged 25 pieces per bag, saturated wipes in pouches of 30 wipes per bag, and Sterile Alcohol in 16 oz. bottles. All of these are small enough units that can be consumed in short periods of time. Contec has been supplying sterile products for use in FDA regulated aseptic manufacturing facilities for over twenty years.

Contec offers many dry and presaturated wipes, mops and alcohols all validated sterile for use in aseptic processing and sterile core areas. To learn more, visit our website at www.contecinc.com or contact your regional Contec representative.

"Contec sterile products are packaged in small quantities reducing waste and minimizing the risk of contamination."

References

CFR Title 21

§ 211.113 Control of microbiological Contamination.

(b) Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes.
[43 FR 45077, Sept. 29, 1978, as amended

Guidance for Industry Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice

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Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
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