



Did you know that validated sterile and gamma-irradiated wipes are different?

It can be confusing to choose sterile wipes when you encounter both gamma-irradiated and validated sterile options. You may need to know the difference to be sure whether using gamma-irradiated wipes suits your processes instead of validated sterile wipes. Making the wrong choice could be costly.

What are Gamma Irradiated Wipes?

Gamma Irradiated Wipes are wipes that have been treated with high doses of gamma rays to eliminate microbiological contamination that may be present. This process is known as bioburden destruction and is commonly used in clean rooms where maintaining a sterile environment is crucial. Gamma-irradiated wipes are exposed to a radiation dose the manufacturer assumes will eliminate bioburden. However, no metrics to determine their sterility level after irradiation, known as a Sterility Assurance Level (SAL), exist. It's important to note that continual validation may only sometimes be necessary.

Irradiating at >25 kGy and claiming microbial control (where validated sterile claims are not required) is a viable option for some situations. For example, if the finished product is terminally sterilized, then there may not be a need for a validated sterile wipe.

Although gamma-irradiated wipes are cost-effective, validated sterile wipes are more rigorously produced. If you prioritize cost over regulations, consider the potential costs of incurring contaminated processes. Validated sterile wipes provide assurance to protect your customers and your business.

What are Validated Sterile Wipes?

These wipes, known as Validated Sterile wipes, are sterilized using gamma-ray bombardment. In addition, to confirm their sterility levels, they also undergo testing according to the appropriate Sterility Assurance Level (SAL). Sterility assurance means confidence that a product or unit claimed to be sterile is sterile. This assurance is

achieved through carefully controlled practices and procedures. The irradiation dosage is closely monitored, and its effectiveness is regularly tested to comply with regulatory guidelines.

To satisfy the standards for Validated Sterile wipes, the minimum sterilizing dosage is based on the average bioburden levels of the product. Once the mean bioburden and minimum validated sterilizing dose is established, the product can enter production with a sterile claim. However, regular dose audits are conducted to ensure that the bioburden levels or their sensitivity to gamma irradiation have stayed the same over time. Both bioburden and dose audits are required for continued sterile validated claims.

It's important to note that, unlike gamma-irradiated wipes, customers can be confident that Validated Sterile wipes have a SAL of 10^{-6} and are documented as sterile. Their dosage is carefully monitored, and their effectiveness is consistently tested according to regulatory guidelines.

Most validated sterile wipes that are widely used have a probability of only one non-sterile unit for every one million sterile units. Furthermore, the packaging is strictly controlled to ensure the wipes remain sterile over the shelf life assigned to the product.

Breaking Down Validated Sterile and Gamma-Irradiated Wipes

What's The Difference Between Gamma Irradiated and Validated Sterile Wipes?

Both types of wipes have been exposed to gamma radiation, but they aren't identical. The validated sterile wipes have undergone strict monitoring and testing to ensure sterility. They are guaranteed to be sterile and are the safest option to use in cleanrooms.

On the other hand, gamma-irradiated wipes have been treated with gamma rays, which are known to kill most organisms. However, no tests have been conducted to evaluate the effectiveness of the gamma-ray treatment. Although gamma-irradiated wipes may be very clean, perhaps as clean as validated sterile wipes, there is no way to confirm this because no tests have been performed.

What are the packaging considerations for sterile wipes?

Sterile wipes that have been validated are usually packaged in a way that keeps them sterile. Package validation is a measure of how effective the packaging is in maintaining the sterility of the wipes. Several factors are considered, such as the barrier's performance and the materials' compatibility. If the packaging has not been tampered with, we can be sure that the validated sterile wipes are safe for use in a cleanroom. Packaging for gamma-irradiated wipes is usually not validated and does not assure that the product remains sterile in shipping, handling, or storage.

Should you choose a Validated Sterile or Gamma Irradiated Wipe?

The quality of your final product depends on the type of cleanroom wipes you select. Choosing wipes that meet your specific cleanroom's requirements is crucial. While validated sterile wipes may cost slightly more, you'll have peace of mind knowing that they have been tested and proven sterile. For less critical applications, non-validated gamma-irradiated wipes may suffice. However, always refer to your cleanroom requirements, final product specifications, and any other mandatory standards before deciding.



The **Gamma Wipe**[®] line of nonwoven and knitted polyester wipers is validated sterile. They are gamma-irradiated and sterile validated to a 10⁻⁶ Sterility Assurance Level per ANSI/AAMI/ISO guidelines. Validated sterile wipes are certified to meet the rigorous requirements of the most

demanding aseptic environments where the slightest contamination can lead to disastrous outcomes.



The **Sterile SatPax**[®] line of presaturated IPA nonwoven and knitted polyester wipers are validated sterile. They are gamma-irradiated and sterile validated to a 10⁻⁶ Sterility Assurance Level per ANSI/AAMI/ISO guidelines.



Validated sterile presaturated wipers provide a cost-effective and easy-to-use solution versus traditional bulk handling of solvents, maintenance of squirt bottles, and inconsistent wetting and cleaning associated with wetting a dry wiper.



Do you have questions or want to learn more about our validated sterile wipes?

Berkshire Technical Account manager team is well-trained and knowledgeable about contamination control and cleanroom supplies. And they are ready to help guide you in your product selection. To locate and contact your representative today, please visit <https://berkshire.com/support/customer-service/find-a-technical-account-manager/>.

For additional technical data specifications about our validated sterile wipers, please visit www.berkshire.com to view and download our Product Information Sheets.



CONTAMINATION CONTROL PRODUCTS
FOR CLEANROOMS AND CONTROLLED ENVIRONMENTS