

Sterilization Methods & Considerations

This brief gives advice for:

- Sterilization Methods
- Suitable Evonik Cyro Materials
- Effect of Sterilization on Properties of Evonik Cyro Materials

Sterilization is defined as the total absence of living organisms. The technology required is used in industries as diverse as food processing and space exploration. Generally though, it is most often associated with healthcare. Devices that are required to be sterile are those intended to breach the body's defense mechanism, to come into contact with damaged tissue or to be implanted into the body. Most industries that use sterilization technology are regulated by a federal agency. Medical devices are regulated by the FDA. This brief will cover the most common sterilization methods.

Use of Evonik Cyro Materials in Medical Applications

Evonik Cyro offers materials that may be sterilized using Ethylene Oxide (EtO), gamma radiation, and electron beam (E-beam) radiation. These materials include: transparent CYROLITE® G-20 acrylic based multipolymer compounds, gamma stable CYROLITE® GS-90 and CG-97 compounds and opaque, high impact CYREX® acrylic-polycarbonate alloy.

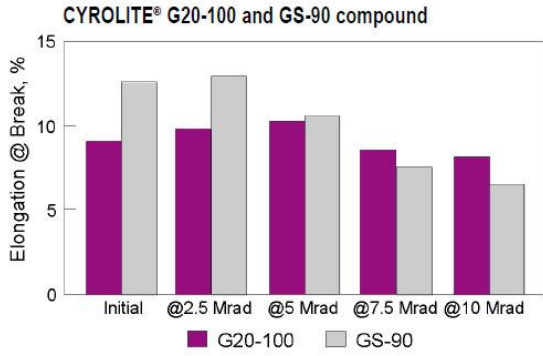
Key physical properties of these materials have been extensively evaluated after typical gamma, E-beam and EtO sterilization.

Under these conditions, the previously mentioned materials suffer little or no physical property deterioration as shown by the change in such key properties as elongation at break and notched Izod impact.

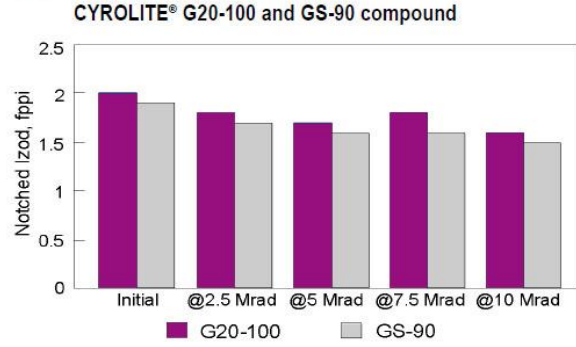
All CYROLITE® compound grades maintain physical properties after exposure. However, CYROLITE® G-20 compound does show some yellowing immediately after gamma and E-beam irradiation which is reduced with time.

CYROLITE® GS-90 and CG-97 compounds have been developed as gamma stable grades. They exhibit minimal yellowing due to irradiation. Some of the key results obtained are presented in the graphs on the following page.

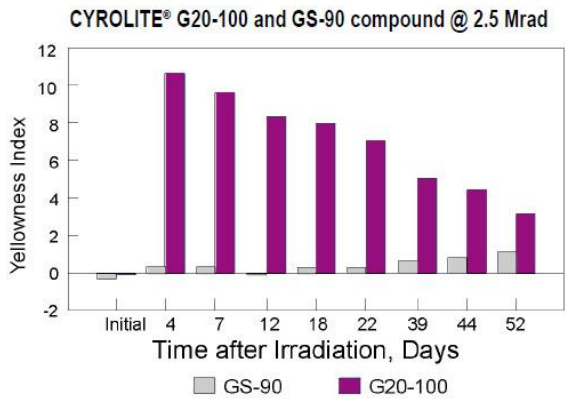
1 Effect of Gamma Irradiation on Elongation



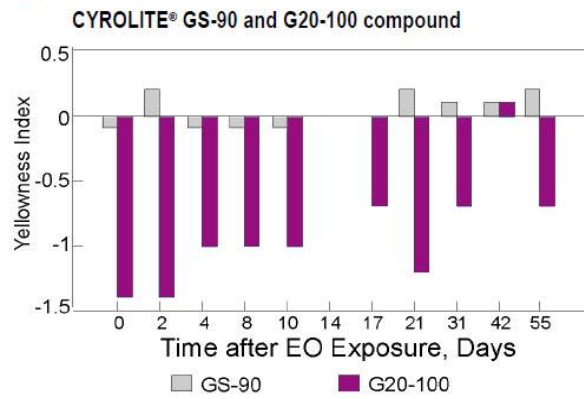
2 Effect of Gamma Irradiation on Impact



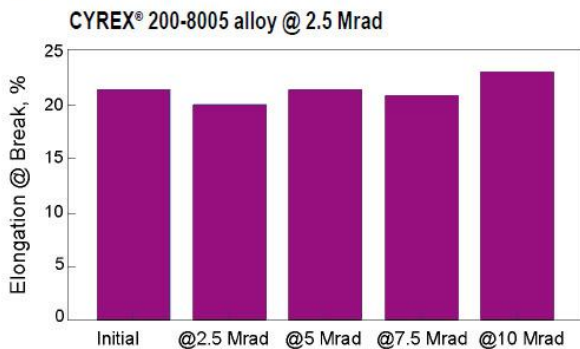
3a Yellowness Index vs Time after Gamma Irradiation



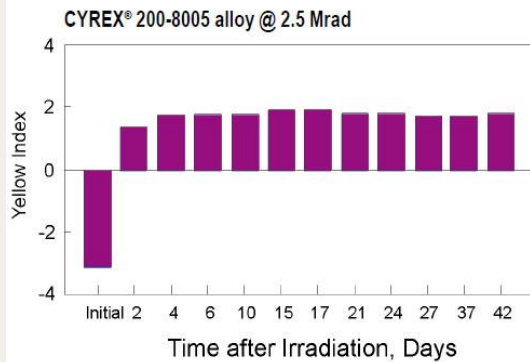
3b Effect of EtO on Y.I.



4 Effect of Gamma Irradiation on Elongation



5 Effect of Gamma Irradiation on Y.I.



The following recommendations and conclusions can be drawn from the information presented in the graphs on the left.

1. CYROLITE® G20, GS-90, and CG-97 compounds as well as CYREX® alloys show no significant loss in physical properties at an exposure level of 5 megarads.
2. CYROLITE® GS-90 compound is recommended for applications requiring minimal yellowing and a high transparency level.
3. CYROLITE® CG-97 compound is recommended for applications requiring minimal yellowing and superior lipid and isopropyl chemical resistance (data not shown).
4. EtO sterilization results in little to no color shift in CYROLITE compounds.
5. CYREX® 200-8005 alloy is recommended for applications where transparency is not required but high impact and color retention are critical.
6. The use of EtO sterilization results in no significant property deterioration or yellowing in CYROLITE compounds or CYREX® alloys.

Ionizing Radiation Sterilization

Ionizing radiation sterilization is a type of “cold” sterilization. It can employ either electron accelerators (E-beam sterilization) or radioisotopes (gamma sterilization). Electrons have relatively low penetration ability, and the use of accelerators requires careful control.

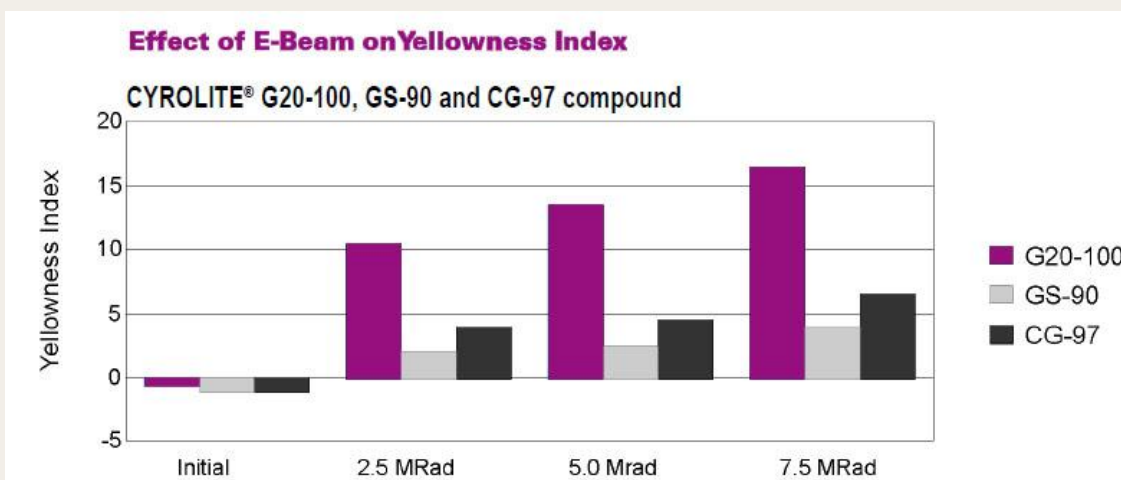
Gamma-radiation sterilization usually employs ⁶⁰Co as the radioisotope source. A wide range of packaging materials can be used because gamma rays possess considerable penetrating ability. A dose of 2.5x10⁴ Gy (2.5 megarad) is generally selected for many articles although higher levels are occasionally used.

Both E-beam and gamma sterilization effectively kill microorganisms because of their ability to break the chemical bonds of organic compounds, producing highly reactive species known as free radicals.

When polymers are used as the packaging or dispensing materials, the above ionizing radiation can result in chain scission which reduces the strength-related properties of the material, cross-linking which results in a stiffer but more brittle material, and color formation (yellowness) due to trapped free radicals. The highest product temperatures reached in gamma sterilization are usually in the range of 30-40°C.

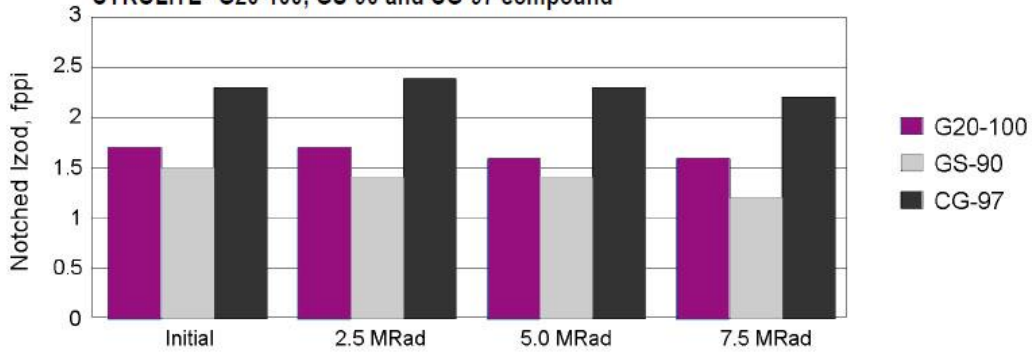
This sterilization method has been extensively evaluated with the Evonik Cyro products listed above and is also recommended.

Some of the key results obtained are presented in the graphs below.



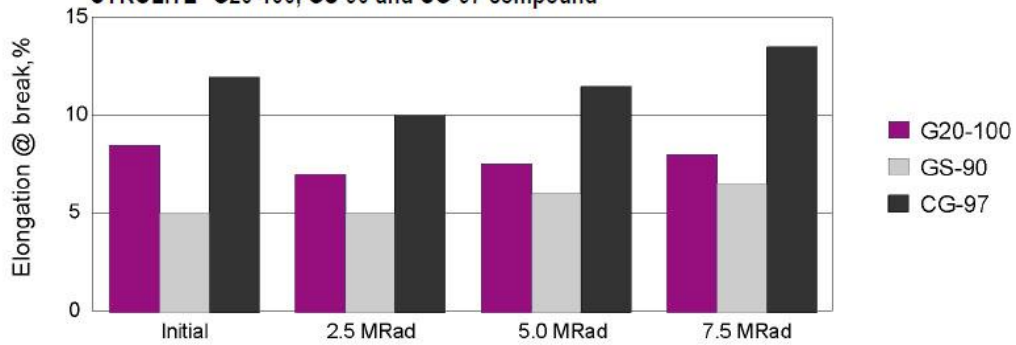
Effect of E-Beam on Impact

CYROLITE® G20-100, GS-90 and CG-97 compound



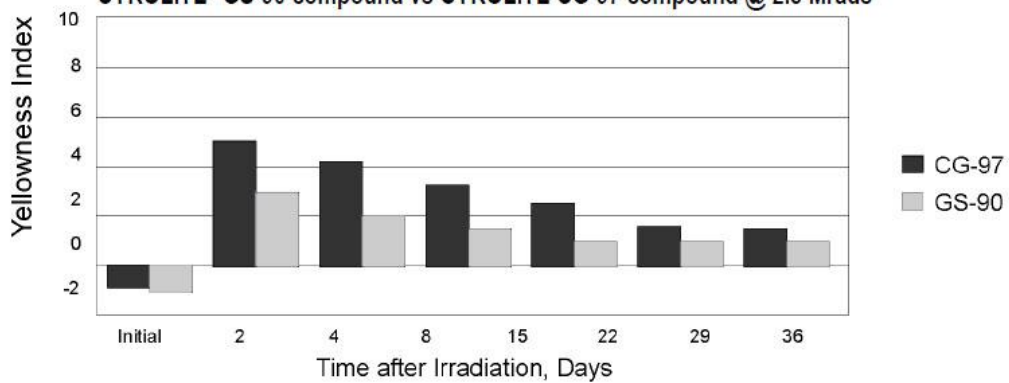
Effect of E-Beam on Elongation

CYROLITE® G20-100, GS-90 and CG-97 compound



Effect of Gamma Irradiation on Yellowness Index

CYROLITE® GS-90 compound vs CYROLITE CG-97 compound @ 2.5 Mrads



Gas Sterilization (EtO)

Materials that cannot withstand the temperatures and moisture of steam sterilization can use gas sterilization as an alternative. Gaseous sterilants can function at relatively low temperatures but need to be safe during handling. Another requirement is that the absorbed gas, if any, should volatilize relatively quickly. Ethylene oxide (EtO) satisfies these requirements and is the most frequent choice. Since it is highly flammable, it must be used in a carefully controlled manner, and is dispensed from a single-use cartridge or diluted with inert gases until no longer flammable. The most frequently used diluents are fluoro-carbon gases or carbon dioxide. The critical parameters are temperature, time, gas concentration, and relative humidity. Temperatures reached in ethylene oxide (EtO) gas sterilization are usually in the 50–60°C range. This method can be used with the Evonik Cyro products listed above without significant property deterioration or change in appearance.

Dry-Heat Sterilization

Dry-heat sterilization is generally conducted at 160–170°C for a minimum of two hours. Specific exposures are dictated by the bioburden concentration and the temperature tolerance of the products. Appropriate conditions must be determined throughout the material being sterilized. The equipment used is forced-air type ovens with temperature-recording. This type of sterilization is not recommended for use with Evonik Cyro materials because of the high temperatures required.

Steam-Sterilization

Steam-sterilization indicates sterilization by moist heat. The process is carried out in autoclaves using saturated steam.

Temperatures range from 115°C to 12°C and higher. Critical parameters are temperature, time, air elimination, steam quality, and absence of superheating. There must be direct steam contact which can be prevented by the presence of air; its absence is therefore considered an absolute

requirement. The selection of an appropriate steam-sterilization cycle must be made after careful study of the nature of the articles being sterilized, the type and number of organisms present, type and size of each package, type of packaging material used, and other factors which may influence the performance in the application. This method is not recommended for use with Evonik Cyro products because of the high temperatures involved.

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