



Gel Warming & Storage

The following is provided in response to requests for information on the bacteriostatic effectiveness of EcoVue® and EcoVue®HV Ultrasound Gel when placed in a warming device commonly used for warming ultrasound gel.

It is important to note that when stored properly (room temperature (15° - 30°C; 59° - 86°F) and away from direct sunlight), unopened bottles of EcoVue® and EcoVue®HV Ultrasound Gel have a shelf life of 36 months from the date of manufacture. The date of expiration is indicated across all packaging options of EcoVue. Once the packaging of any multi-use product has been opened, any unused portion should be discarded in accordance with internal facility guidelines on multi-use products. Single-use packets should be discarded immediately after use.

During the course of a 28-day study, after initial opening, bottles of EcoVue® Ultrasound Gel were stored at 37°- 43°C to simulate conditions in an Acclimate® Gel Warmer. The Acclimate® Gel Warmer has been designed to maintain a temperature of 40°C +/- 2.77°C. Samples evaluated at the conclusion of the 28-day period found no evidence of bacterial or fungal growth. This study supports the effectiveness of the preservative system within the EcoVue formulation while the gel is being warmed during a 28-day period.

Conclusion

EcoVue® Ultrasound Gel complies with USP standards for antimicrobial effectiveness and data supports that the preservation system in EcoVue will function as intended while the gel is warmed (during a 28-day period) so long as proper storage and handling practices are maintained. Since there is no effective way to determine whether an opened bottle of gel placed in a warmer has been contaminated, general industry guidelines are that gel should be marked to expire 28 days after opening (or sooner if internal facility guidelines require multi-use products be discarded in a shorter timeframe). Single-use packets should never be reused.

