

Halocarbon Products Corporation

Does Halocarbon manufacture its own sevoflurane?

Yes, Halocarbon manufactures its sevoflurane in its plant in South Carolina, USA. In addition, unlike other sevoflurane suppliers, Halocarbon is one of the world's largest manufacturers of the key precursor to sevoflurane, hexafluoroisopropanol (HFIP).

Is Halocarbon® Sevoflurane FDA approved as a therapeutic equivalent to the branded drug and is it listed in the “Orange Book”?

Yes, the US FDA has approved Halocarbon's sevoflurane as a therapeutic equivalent to Ultane® and lists Halocarbon's sevoflurane in their “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”).

How is Halocarbon's sevoflurane packaged?

Halocarbon's sevoflurane is packaged in 250 ml USP Type III amber glass containers with a water content of not more than 70 parts per million (ppm). In order to receive FDA approval, a drug's manufacturer must demonstrate its product's stability in the sale container. Data submitted to the FDA showed Halocarbon's sevoflurane in glass bottles was stable under standard accelerated conditions (bottles stored at 40°C and 75% relative humidity for 3 months). Halocarbon also submitted data that showed its sevoflurane in glass bottles was stable under even more stressful hotter and drier conditions (60 °C and less than 5% relative humidity for 3 months). Halocarbon's stability testing and other research has produced no evidence that storing sevoflurane in type III glass results in Lewis Acid formation or otherwise contributes to decomposition of sevoflurane, or that the addition of water is necessary to promote stability.

What is the shelf life of Halocarbon Sevoflurane?

24 months.

Why are there different types of containers for sevoflurane?

Packaging is a matter of patents and/or marketing preference and each container type has its advantages and disadvantages. If a company has a compatible plastic container patented, obviously other manufacturers cannot use that type of packaging. While a glass bottle can break and an aluminum bottle can't, the sevoflurane level in the glass bottle is visible. Sevoflurane in plastic bottles has been recalled due to pinhole leaks in the plastic. As previously noted, in order to receive FDA approval, a drug must be shown to be stable in whatever container it is supplied.

Are there any labeling differences between the branded drug and Halocarbon Sevoflurane?

No, other than company names.

Can Halocarbon Sevoflurane be used the same as the branded drug?

Yes, Halocarbon's sevoflurane is listed by the FDA as a therapeutic equivalent to Ultane®.

What information do I need prior to using Halocarbon Sevoflurane?

As with all inhalation anesthetics, product handling, storage and administration information must be *thoroughly* reviewed *prior* to any use of drug. Please consult both the **product insert** and the **MSDS**.