

Summary of Sterilant Substitutes Listed in SNAP Notice 25

The table below provides additional information on the substitutes listed in Notice 25 for sterilants. “ODP” is the ozone depletion potential of the substitute, relative to a value of 1.0 for CFC-11. “GWP” is the 100-year integrated global warming potential of a chemical or the weighted average of the GWPs of the chemicals in a blend, relative to a value of 1 for CO₂. (Technically, GWP only applies to individual chemicals; however, for a blend, an average weighted by the percentage composition provides a rough approximation of a blend’s impact.) “VOC status” indicates whether the substitute contains any components that are defined as, or are exempt from the definition of, volatile organic compounds under Clean Air Act regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the national ambient air quality standards. Substitutes listed as “exempt” in the column for VOC status in Table 5 contain only compounds that are exempt from the definition of VOC under those regulations. “HAP status” indicates whether the substitute contains any components that are defined as hazardous air pollutants under the Clean Air Act. Note that ethylene oxide itself is a HAP, so any chemical blend containing ethylene oxide will contain a HAP. “Flammable” indicates whether the sterilant is flammable by flashpoint testing using ASTM E 681. Flammable and highly reactive sterilants are hazardous waste when disposed. Sterilants must be registered by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) prior to use. “Registered under FIFRA” indicates whether or not EPA has registered the sterilant.

EPA is not providing information on the acceptable exposure limits for substitutes in this end use, recognizing that the predominant component that is of concern for toxicity in EtO blends is EtO. EtO has a U.S. Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) of 1 ppm on an 8-hour time-weighted average and a short-term excursion limit of 5 ppm over a 15-minute time-weighted average.

Summary of Information on Sterilant Substitutes for Ethylene Oxide Blends Containing HCFC-22

Substitute	Further Identification Information for Substitute	Previous Federal Register Listings	Additional Information	ODP	GWP	VOC status	HAP status	Flammable	Registered under FIFRA
CO ₂ / ethylene oxide	Ethylene oxide (EtO) is also known as oxirane or 1,2-epoxyethane. CAS # 75-21-8. Carbon dioxide has CAS ID # 124-38-9. Common commercial blend contains 91.5% CO ₂ and 8.5% EtO.	March 18, 1994 SNAP rule (58 FR 13044)	CO ₂ /EtO blends can serve as drop-in replacements to 12/88 in some but not in all existing equipment because they require a higher operating pressure.	0	1	one component is VOC	HAP	blend not flammable	yes
hydrogen peroxide gas plasma systems	Uses hydrogen peroxide (H ₂ O ₂), CAS # 7722-84-1. Sterrad™ system.	Notice 3, July 28, 1995; 60 FR 38729	Low toxicity compared to EtO. Hydrogen peroxide is highly reactive.	0	N/A	N/A	none	no	yes
IoGas™ Sterilant Blend 1	blend of CF ₃ I/CO ₂ /EtO	Notice 19, October 1, 2004; 69 FR 58903		< 0.001	<1	some components are VOCs	HAP	blend not flammable	no
IoGas™ Sterilant Blend 3	blend of CF ₃ I/CO ₂ /EtO	Notice 19, October 1, 2004; 69 FR 58903		< 0.001	<1	some components are VOCs	HAP	blend not flammable	no
IoGas™ Sterilant Blend 6	blend of CF ₃ I/CO ₂ /EtO	Notice 19, October 1, 2004; 69 FR 58903		< 0.001	<1	some components are VOCs	HAP	blend not flammable	no
Mini-Max® Cleaner	A device that creates super-heated, high pressure steam vapor.	Notice 21, September 28, 2006; 71 FR 56884	Applicable only to medical equipment resistant to moisture.	0	N/A	N/A	N/A	no	no

Substitute	Further Identification Information for Substitute	Previous Federal Register Listings	Additional Information	ODP	GWP	VOC status	HAP status	Flammable	Registered under FIFRA
peroxyacetic acid / hydrogen peroxide gas plasma systems	Plazlyte™ system. Peroxyacetic acid, also called peracetic acid or ethaneperoxoic acid (CAS # 79-21-0), may be used alone or together with hydrogen peroxide in a system creating an ionized gas (plasma).	Notice 3, July 28, 1995; 60 FR 38729		0	N/A	N/A	none	yes	yes
pure EtO	Ethylene oxide is also known as oxirane or 1,2-epoxyethane. CAS # 75-21-8	March 18, 1994 SNAP rule (58 FR 13044)	EtO is a toxic, carcinogenic substance. Potential exposures of the general population to EtO releases can be limited either through the use of catalytic converters which convert waste EtO into CO ₂ and water, or through the use of acid water scrubbers which convert waste EtO into ethylene glycol. Must be used in accordance with manufacturer recommendations to address flammability concerns. Must be used in accordance with OSHA standards to limit occupational exposures.	0	1	VOC	HAP	yes	yes
Steam		March 18, 1994 SNAP rule (58 FR 13044)	Applicable only to devices resistant to heat and moisture.	0	N/A	N/A	none	no	no