

40 C.F.R. § 152.6

Substances excluded from regulation by FIFRA.

Products and substances listed in this section are excluded from FIFRA regulation if they meet the specified conditions or criteria.

(a) *Liquid chemical sterilants.* A liquid chemical sterilant product is not a pesticide under section 2(u) of FIFRA if it meets all of the following criteria. Excluded products are regulated by the Food and Drug Administration (FDA). Products excluded are those meeting all of the following criteria:

(1) *Composition.* The product must be in liquid form as sold or distributed. Pressurized gases or products in dry or semi-solid form are not excluded by this provision. Ethylene oxide products are not liquid products and are not excluded by this provision.

(2) *Claims.* The product must bear a sterilant claim, or a sterilant plus subordinate level disinfection claim. Products that bear antimicrobial claims solely at a level less than “sterilant” are not excluded and are jointly regulated by EPA and FDA.

(3) *Use site.* (i) The product must be intended and labeled only for use on “critical or semi-critical devices.” A “critical device” is any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body. A *semi-critical device* is any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

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