

**Cosmetic ingredients/material prohibited/restricted by FDA (14 total, through November, 2011).** For the most part, FDA regulatory action to ban use of an ingredient in cosmetics means that ingredient is exempt from CIR review. In the case of Methylene Chloride, CIR's safety assessment that preceded FDA's regulation is now superceded. In the case of Tallow and tallow derivatives, the FDA identification of prohibited cattle material does not ban Tallow and tallow derivatives use in cosmetics. In the case of Trichloroethane, the EPA ban (except for essential uses) and the FDA determination of non-essential use appears to relate to aerosol cosmetic uses only.

Ingredient	No.	CIR Conclusion	FDA Regulation
Bithionol	1	Exempt from CIR review because of FDA regulation.	Cosmetics containing bithionol are deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act (21CFR§700.11)
Chlorofluorocarbon propellants	1	Exempt from CIR review because of FDA regulation.	FDA has prohibited the use of Chlorofluorocarbon propellants in cosmetic products with self-pressurized containers (21CFR§700.23)
Chloroform	1	Exempt from CIR review because of FDA regulation	FDA has prohibited the use of Chloroform, except if present in residual amounts from its use as a processing solvent during manufacture, or as a byproduct from the synthesis of an ingredient (21CFR§700.18)
Halogenated salicylanilides	4	Exempt from CIR review because of FDA regulation	FDA has prohibited (21CFR§700.15) the use of four halogenated salicylanilides: <ul style="list-style-type: none"> <li>• tribromsalan (TBS, 3,4,5-tribromosalicylanilide),</li> <li>• dibromsalan (DBS, 4,5-dibromosalicylanilide),</li> <li>• metabromsalan (MBS, 3,5 – dibromosalicylanilide) and</li> <li>• 3,3,4,4,5,5- tetrachlorosalicylanilide (TCSA)</li> </ul>
Hexachlorophene	1	Exempt from CIR review because of FDA regulation (CIR has reviewed Chlorophene and Dichlorophene - data insufficient to support safety in cosmetics)	Not allowed as a preservative in cosmetics where normal use may be applied to mucous membranes or which are intended to be used on mucous membranes. For all other cosmetic uses, OK at a level that is no higher than necessary to achieve the intended preservative function, and in no event higher than 0.1 percent. Such use of hexachlorophene shall be limited to situations where an alternative preservative has not yet been shown to be as effective or where adequate integrity and stability data for the reformulated product are not yet available.
Mercury	1	Exempt from CIR review because of FDA regulation.	FDA has prohibited Mercury in cosmetic products, except for trace amount below 1 ppm and except for use as a preservative in eye-area cosmetic products at concentrations up to 65 ppm (21CFR§700.13)
Methylene Chloride	1	Safe for brief, discontinuous use only.	FDA has prohibited the use of Methylene Chloride in cosmetic products, action which supercedes the CIR conclusion (21CFR§700.19)
Prohibited cattle material	1	Tallow, Tallow Glyceride, Tallow Glycerides, Hydrogenated Tallow Glyceride, and Hydrogenated Tallow Glycerides are safe as	FDA has prohibited the use in cosmetics of specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed, or MS(Beef). Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexaneinsoluble impurities and tallow derivatives. (21CFR§700.27)

		used in cosmetics.	
Trichloroethane	1	Safe for use as a solvent	The U.S. Environmental Protection Agency has banned the production of Trichloroethane because it is considered a Class I ozone-depleting substance, except for essential uses, medical devices, and aviation safety. FDA has determined that the use of Trichloroethane in an aerosol cosmetic product is not essential.
Vinyl Chloride	1	Exempt from CIR review because of FDA regulation.	Cosmetics containing vinyl chloride (including use as a propellant) are deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act (21CFR§700.14)
Zirconium	1	Exempt from CIR review because of FDA regulation.	Aerosol cosmetics containing zirconium are deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act (21CFR§700.16)
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**In addition, in a GUIDE TO INSPECTIONS OF COSMETIC PRODUCT MANUFACTURERS (available at <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074952.htm>), FDA lists the ingredients above, and then also includes the following:**

- **Acetyl ethyl tetramethyl tetralin (AETT)** - In a subchronic toxicity study in rats conducted in 1977, AETT was found to cause serious neurotoxic disorders and discoloration of internal organs. It was also determined to penetrate human skin. The fragrance industry voluntarily discontinued the use of AETT in 1978.

Investigate and document any use of AETT in fragrance formulations and finished cosmetic products, usually those claiming to be fragrance free.

- **6-Methylcoumarin (6-MC)** - 6-MC, a fragrance ingredient, is a potent photocontact sensitizer which may cause serious skin and systemic disorders in some consumers on contact in the presence of sunlight. Between 1976 & 1978, the FDA received many reports of adverse reactions associated with the use of 6-MC containing suntan preparations. The photocontact allergenicity of 6-MC was subsequently confirmed in clinical studies. In 1978, the FDA asked manufacturers of suntan and sunscreen products to discontinue the use of 6-MC. Two firms voluntarily recalled their 6-MC containing suntan products from the market.

Investigate and document any use of 6-MC in the fragrance of sun exposure products.

- **Musk Ambrette** - Musk ambrette, a fragrance ingredient, may cause photocontact sensitization, i.e., allergic reaction of the skin on exposure to musk ambrette and sunlight. Animal studies demonstrated that musk ambrette may cause neurotoxic effects. The International Fragrance Association has recommended that musk ambrette should not be used in products applied to the skin, particularly in products used on skin that is customarily also exposed to sunlight.

Investigate and document any use of musk ambrette in the fragrance of sun exposure products.

- **Nitrosamines** - Cosmetics containing as ingredients amines and amino derivatives, particularly di- & triethanolamine (DEA & TEA) may form nitrosamines, if they also contain an ingredient which acts as a nitrosating agent as for example, 2-bromo-2-nitropropane-1,3-diol (Bronopol, Onyxide 500), 5-bromo-5-nitro-1,3-dioxane (Bronidox C) or tris(hydroxymethyl)nitro-methane (Tris Nitro); or if they are contaminated with a nitrosating agent, e.g., sodium nitrite. Amines and their derivatives are mostly present in

creams, cream lotions, hair shampoos and cream hair conditioners. The nitrosation may occur during manufacture as well as product storage.

Many nitrosamines have been determined to cause cancer in laboratory animals. They have also been shown to penetrate the skin. Nitrosamine contamination of cosmetics became an issue in early 1977. In a study of 29 cosmetic creams and lotions, N-Nitrosodiethanolamine (NDELA) was determined in 27. The levels of NDELA contamination ranged from less than 10 ppb to 50 ppm. Of the more than 300 cosmetic samples analyzed in 1978, 1979 and early 1980 in FDA laboratories, 7% contained less than 30 ppb NDELA, 26% contained 30 ppb to 2 ppm, and 7% contained between 2 ppm and 150 ppm.

The FDA expressed its concern about the contamination of cosmetics with nitrosamines in a Federal Register notice dated April 10, 1979, which stated that cosmetics containing nitrosamines may be considered adulterated and subject to enforcement action. In surveys of cosmetic products conducted in 1991-92, NDELA was found in 65% of the samples at levels up to 3 ppm.

Investigate whether DEA or TEA containing products contain as ingredients one of the aforementioned nitrosating agents, and report any cosmetic containing these two types of ingredients. When collecting surveillance samples, select such products for chemical analysis.

- **Dioxane** - Cosmetics containing as ingredients ethoxylated surface active agents, i.e., detergents, foaming agents, emulsifiers and certain solvents identifiable by the prefix, word or syllable "PEG," "Polyethylene," "Polyethylene glycol," "Polyoxyethylene," "-eth-," or "-oxynol-," may be contaminated with 1,4-dioxane. It may be removed from ethoxylated compounds by means of vacuum stripping at the end of the polymerization process without an unreasonable increase in raw material cost.

In rodent feeding studies conducted for the National Cancer Institute, 1,4-dioxane was found to produce cancer of the liver and the nasal turbinates. It also caused systemic cancer in a skin painting study. Skin absorption studies demonstrated that dioxane readily penetrates animal and human skin from various types of vehicles. However, it was also determined that most of the dioxane applied to the skin in a vehicle evaporates into the environment and may not be available for skin absorption.

The contamination of ethoxylated surface-active agents with dioxane was first reported in 1978. Many of the raw materials analyzed since then have been found to contain dioxane; some contained as much as, or more than, 100 ppm. In finished cosmetic products containing ethoxylated surface-active agents, the incidence and level of dioxane contamination was significantly lower.

[No instructions to FDA investigators are provided.]