420 Breakspear Road
Syracuse, New York, 13219

March 4, 2000

Re: Docket No. 99P-1340/CP 1

Dockets Management Branch
The Food and Drug Administration
Department of Health & Human Services, RM. 1-23
12420 Parklawn Drive
Rockville, MD 20857

I am requesting that you please place appropriate warning statements on the labeling of Calvin Klein's "Eternity" fragrance products because such products contain toxic fragrance components.

Perfumes and colognes cause my sister to have respiratory infections and rash, and for me, give me headaches and nausea.

Please help in this very serious matter.

Very sincerely,

Theodora Apostolo

Theodora Apostolo

99P-1340

C591

12-19-99

# Too much perfume can get a person a bit choked up

**Dear Ann Landers:** As I sat in the doctor's waiting room today, in walked a woman who smiled pleasantly and took a seat next to me. Within a minute, I thought I'd pass out. She had on enough perfume to asphyxiate an army.

First, I should tell you, I'm a smoker, but I do try to be respectful of others. I obey all no-smoking signs and never light up in a no-smoking area, nor do I smoke in a group without asking permission. My complaint is about women who douse themselves in perfume. After being around them, I get choked up to the point where I can't breathe, and I lose my voice. This is exactly what happened to me in the doctor's waiting room.

I know I can't be the only person in the world with this problem, so please, Ann, print my letter in your column. It would be a tremendous service to millions of readers. — D.P., Somewhere in Texas

**Dear D.P.:** I hope your letter will alert millions of readers to the fact that a dab of perfume behind the ears is fine, but please, don't drown in it.

Readers can write to Ann Landers at 5777 W. Century Blvd., Suite 700, Los Angeles, CA 90045.

# Fragrances: Why Do We Assume They Are Safe?

## Synthetic Chemicals

About 95% of all ingredients used by the fragrance industry are synthetic compounds.

According to the federal Food and Drug Administration (FDA), about 4,000 different chemicals are used in fragrances.

## Untested, But Dangerous Chemicals

84% of the ingredients in fragrances have minimal or no toxicity data, according to the National Academy of Sciences.

The FDA does not test cosmetics for safety. Even when serious adverse health effects are suspected, FDA cannot legally require either ingredient information or safety test data from the manufacturer. (*Potential Health Hazards of Cosmetic Products*, (Serial 99-68). Hearings before the Subcommittee on Regulation and Business Opportunities, U.S. House of Representatives, 8/14/88 and 9/15/88.)

The National Institute of Occupational Safety and Health (NIOSH) found 884 toxic substances in a partial list of 2,983 chemicals used in the fragrance industry. The thousands of cosmetic and fragrance chemicals include chemicals that might cause cancer, birth defects, central nervous system damage, allergic disorders, and other acute toxic effects. (*Potential Health Hazards*)

## Hazardous Waste Chemicals

Methylene chloride, toluene, methyl ethyl ketone, methyl isobutyl ketone, ethanol, and benzal chloride are fragrance chemicals which are also designated as hazardous waste chemicals. (Identified by comparing a list of only 120 fragrance chemicals from a 1991 U.S. EPA study "Identification of Polar Volatile Organic Compounds in Consumer Products and Common Microenvironments" presented at the 84th Annual Meeting of the Air and Waste Management Association in Vancouver, BC, Canada, June 1991, and the EPA's Code 40 of Federal Regulations, Chapter 1, Section 261.33, listing hazardous waste site chemicals.)

## Air Contaminants

Of the EPA's list of just 120 fragrance chemicals, methylene chloride, toluene, methyl ethyl ketone, methyl isobutyl ketone, tert butyl, and sec butyl are fragrance ingredients classified by the California Division of Occupational Safety and Health as airborne contaminants in 1991.

## Cancer-Causing

Methylene chloride, a known carcinogen that also causes autoimmune disease, is listed as one of the 20 most common chemicals found in fragrance products in the 1991 EPA study, even though the FDA banned the chemical in all cosmetic and fragrance products in 1989.

## Toxicity to the Nervous System

The National Academy of Science's 1984 study targeted fragrance raw materials as one of six types of chemicals that should be given high priority for neurotoxicity testing. The other chemicals prioritized were heavy metals, solvents, insecticides, food additives, and certain air pollutants. (*Neurotoxins: At Home and the Workplace*, (Report 99-827), Report by the Committee on Science and Technology, U.S. House of Representatives, 9/16/86. Free from Congressman Robert Roe. (202) 225-4494.)

"Musk AETT and musk ambrette, two tested raw materials of the hundreds [sic] of untested chemicals used in fragrances and flavors, have demonstrated potent neurotoxic effects and the capacity to induce breakdown of nerve cells and myelin sheaths in the brain, spinal cord, and peripheral nerves." [Musk ambrette also caused "marked loss in weight, progressive weakness of hind quarters, leading to complete loss of the use of the legs . . . muscular atrophy, and blood changes" in laboratory animals; musk AETT was withdrawn voluntarily after it was shown to cause permanent brain damage in animals.]

"Countless other substances applied daily to the skin of consumers in the form of soaps, perfumes, aftershaves, and detergents have yet to be tested for their chronic neurotoxic effect." (*Neurotoxins*)

## Asthma-Causing

72% of asthma patients have respiratory symptoms from exposure to perfumes. ("Effects of Odors in Asthma," *American Journal of Medicine* Jan. 1986.)

## Synthetic Scents Are Everywhere

About 80% of the fragrance industry's revenue is from perfuming plastics, fabrics, clothing, tires, automobile interiors, tobacco, soap, cleaning products, medicines, and other objects.

A 1991 U.S. EPA study found toluene in every fragrance sample collected in different public places. It was most abundant in the auto parts store and the fragrance section of the department store. Toluene is used in furniture wax, tires, plastic garbage bags, inks, hairgel, hairspray, and kitty litter. It is known to cause asthma in previously healthy people and is listed on California's Proposition 65 as a birth-defect-causing chemical.

Adapted from several sources: "Making Sense of Scents," Julia Kendall, Citizens for a Toxic-Free Marin, 400 Canal Street, Suite 329, San Rafael, CA 94901. (415) 485-6870. "How Safe Are Perfumes?" by Karen Stevens, *The Human Ecologist*, Fall 1990. Also see "Perfume or Pollutant?" by Irene Wilkenfeld, *Green Alternatives* (Box 28, Annandale-on-Hudson, NY 12504. (914)246-6948), Nov./Dec. 1992.

# Twenty Most Common Chemicals Found in Thirty-One Fragrance Products

1991 EPA Study

Reference: Lance Wallace, Environmental Protection Agency. Phone (703) 349-8970

Excerpts from "Health Hazard Information." Compiled by Julia Kendall, Co-Chair, *Citizens for a Toxic-Free Marin*. Phone (415) 485-6870

References: *Material Safety Data Sheets* (MSDS)

Principal chemicals found in scented products are —

**ACETONE** (in: cologne, dishwashing liquid and detergent, nail enamel remover) — On EPA, RCRA, CERCLA Hazardous Waste lists. "Inhalation can cause dryness of the mouth and throat; dizziness, nausea, incoordination, slurred speech, drowsiness, and, in severe exposures, coma." "Acts primarily as a central nervous system (CNS) depressant."

**BENZALDEHYDE** (in: perfume, cologne, hairspray, laundry bleach, deodorants, detergent, vaseline lotion, shaving cream, shampoo, bar soap, dishwasher detergent) — Narcotic. Sensitizer. "Local anesthetic, CNS depressant"... "irritation to the mouth, throat, eyes, skin, lungs, and GI tract causing nausea and abdominal pain." "May cause kidney damage." "*Do not use with contact lenses.*"

**BENZYL ACETATE** (in: perfume, cologne, shampoo, fabric softener, stickup air freshener, dishwashing liquid and detergent, soap, hairspray, bleach, after shave, deodorants) — Carcinogenic (linked to pancreatic cancer); "From vapors: irritating to eyes and respiratory passages, exciting cough." "In mice: hyperaemia of the lungs." "Can be absorbed through the skin causing systemic effects." "*Do not flush to sewer.*"

**BENZYL ALCOHOL** (in: perfume, cologne, soap, shampoo, nail enamel remover, air freshener, laundry bleach and detergent, vaseline lotion, deodorants, fabric softener) — "irritating to the upper respiratory tract" ... "headache, nausea, vomiting, dizziness, drop in blood pressure, CNS depression, and *death* in severe cases due to respiratory failure."

**CAMPHOR** (in: perfume, shaving cream, nail enamel, fabric softener, dishwasher detergent, nail color, stickup air freshener) — "local irritant and CNS stimulant" ..."readily absorbed through body tissues" ..."irritation of eyes, nose and throat" ..."dizziness, confusion, nausea, twitching muscles and convulsions" "*Avoid inhalation of vapors.*"

**ETHANOL** (in: perfume, hairspray, shampoo, fabric softener, dishwashing liquid and detergent, laundry detergent, shaving cream, soap, vaseline lotion, air fresheners, nail color and remover, paint and varnish remover) — On EPA Hazardous Waste list; symptons: "...fatigue; irritating to eyes and upper respiratory tract *even in low concentrations...*" "*Inhalation of ethanol vapors can have effects similar to those characteristic of ingestion.* These include an initial stimulatory effect followed by drowsiness, impaired vision, ataxia, stupor..." Causes CNS disorder.

**ETHYL ACETATE** (in: after shave, cologne, perfume, shampoo, nail color, nail enamel remover, fabric softener, dishwashing liquid) — Narcotic. On EPA Hazardous Waste list; "...irritating to the eyes and respiratory tract" ..."may cause headache and narcosis (stupor)" ..."defatting effect on skin and may cause drying and cracking" ..."may cause anemia with leukocytosis and damage to liver and kidneys" "*Wash thoroughly after handling.*"

**LIMONENE** (in: perfume, cologne, disinfectant spray, bar soap, shaving cream, deodorants, nail color and remover, fabric softener, dishwashing liquid, air fresheners, after shave, bleach, paint and varnish remover) — Carcinogenic. "*Prevent its contact with skin* or *eyes* because it is an irritant and sensitizer." "*Always wash thoroughly after using this material* and *before eating, drinking, ...applying cosmetics. Do not inhale limonene vapor.*"

**LINALOOL** (in: perfume, cologne, bar soap, shampoo, hand lotion, nail enamel remover, hairspray, laundry detergent, dishwashing liquid, vaseline lotion, air fresheners, bleach powder, fabric softener, shaving cream, after shave, solid deodorant) — Narcotic. ..."respiratory disturbances" ... "Attracts bees." "In animal tests: ataxic gait, reduced spontaneous motor activity and depression ... development of respiratory disturbances leading to death." ..."depressed frog-heart activity." Causes CNS disorder.

**METHYLENE CHLORIDE** (in: shampoo, cologne, paint and varnish remover) — Banned by the FDA in 1988! *No enforcement possible due to trade-secret laws protecting chemical fragrance industry.* On EPA, RCRA, CERCLA Hazardous Waste lists. "Carcinogenic" ..."Absorbed, stored in body fat, it metabolizes to carbon monoxide, reducing oxygen-carrying capacity of the blood." "Headache, giddiness, stupor, irritability, fatigue, tingling in the limbs." Causes CNS disorder.

**a-PINENE** (in: bar and liquid soap, cologne, perfume, shaving cream, deodorants, dishwashing liquid, air freshener) — Sensitizer (*damaging to the immune system*).

**g-TERPINENE** (in: cologne, perfume, soap, shaving cream, deodorant, air freshener) — "Causes asthma and CNS disorders."

**a-TERPINEOL** (in: perfume, cologne, laundry detergent, bleach powder, laundry bleach, fabric softener, stickup air freshener, vaseline lotion, cologne, soap, hairspray, after shave, roll-on deodorant) — ..."highly irritating to mucous membranes"... "Aspiration into the lungs can produce pneumonitis or even fatal edema." Can also cause "excitement, ataxia (loss of muscular coordination), hypothermia, CNS and respiratory depression, and headache." "*Prevent repeated or prolonged skin contact.*"

***Unable to secure MSDS for the following chemicals:***

**1,8-CINEOLE; b-CITRONELLOL; b-MYRCENE; NEROL; OCIMENE; b-PHENETHYL ALCOHOL; a-TERPINOLENE**

- 95% of chemicals used in fragrances are synthetic compounds derived from petroleum. They include benzene derivatives, aldehydes and many other known toxics and sensitizers — capable of causing cancer, birth defects, central nervous system disorders and allergic reactions. *Neurotoxins: At Home and the Workplace*, Report by the Committee on Science & Technology, U.S. House of Representatives, Sept. 16, 1986. (Report 99-827)
- Central Nervous System disorders (brain and spine) include Multiple Sclerosis, Parkinson's Disease, Alzheimer's Disease, Sudden Infant Death Syndrome.
- Chloroform was found in tests of fabric softeners: *EPA's 1991 study.*
- A room containing an air freshener had high levels of p-dichlorobenzene (a carcinogen) and ethanol: *EPA's 1991 study.*
- An FDA analysis (1968-1972) of 138 compounds used in cosmetics that most *frequently involved adverse reactions*, identified five chemicals (alpha-terpineol, benzyl acetate, benzyl alcohol, limonene and linalool) that are among the 20 most commonly used in the 31 fragrance products tested by the EPA in 1991!
- Thirty-three million Americans suffer from sinusitis (inflammation or infection of sinus passages).
- Ten million Americans have asthma. Asthma and asthma deaths have increased over 30% in the past 10 years.
- Headaches cost $50 billion in lost productivity and medical expenses and 157 million lost work days in 1991. "Focus on Fragrance and Health," by Louise Kosta, *The Human Ecologist*, Fall 1992.

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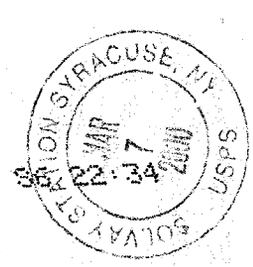


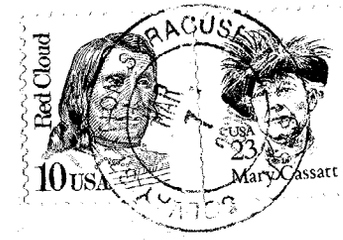


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