

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

06/12/00

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Re: 99P-1340/CP 1 -- Petition to have "Eternity" declared misbranded

Dear Sir or Madam:

In May 1999, the Environmental Health Network submitted the above petition. I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec.740.1, 21CFR Sec.740.2, and 21CFR Sec.740.10.

"Eternity" is just one of many toxic products misbranded. When I am exposed to fragrance products I can experience any of the following symptoms:

breathing difficulty, concentration disruption, dizziness, disorientation, loss of focus, fatigue, coughing, headaches, irritability, anxiety, restlessness, depression, irritated or itchy eyes, ear burning or pain, hypertension, incoherence, incontinence, joint aches, muscle pain/weakness, nasal congestion, lymph nodes swell, nausea, mood swings, short term memory loss, sinusitis, sneezing, sore throat, disruption of digestion, and skin sores and rashes.

Some people think that people who react to fragrances are unhealthy or weak. In contrast, my health practitioner and personal experience assure me of excellent health with a very strong immune system. I have solved food allergies and other sensitivities with a nutritionist and allergy specialist. I avoid those harmful things. However, it is impossible to avoid fragrance toxins in public and my work as an educator. Other than my reactions to fragrances, I have not had a cold or bacterial illness in years. My immune system is so strong, it is able to give me warning signs (the reactions to fragrances). In the enclosed article, Dr. Cynthia Fincher points out that these warning signs indicate poisons present in the environment.

Reacting to irritating, toxic chemicals (fragrances), is not necessarily a sign of weakness. It is analogous to reacting to cigarette smoke. Are people weak because they react to tobacco smoke?

Alcohol, is proof that the human body gains a tolerance to a poison. While the tolerance creates the perception of not being "drunk" so easily, the alcohol or poison is present nonetheless. It's quite possible that most people have generated tolerances to fragrances. Babies in the womb are exposed from the mother's system. Even breast milk has been shown to contain fragrance chemicals. Many baby products are loaded with fragrance. Of course, fragrant homes and society constantly exposes them. This tolerance may explain why many react less easily. Without the perceptual awareness of "being drunk from fragrance", one should wonder about the silent or suppressed reactions that may be taking place. Chronic alcohol drinking creates liver disease. What about chronic fragrance exposure and the degenerative diseases it may be causing. Fragrances might be more toxic than we already know. Those infants with little or no tolerance

99P-1340

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may be trying to tell us something with their sudden deaths, i.e.- (SIDS) Sudden Infant Death Syndrome.

In contrast to fragrance tolerances, fragrance reactions may show a sign of strength from the immune system. At least, it may be a desperate plea to stop the abusive exposure. No perceptual signs may be the indication of overworked, suppressed immune systems. Some people are exposed 24 hours a day, non-stop. The constant barrage of daily fragrances, may leave no choice for the immune system but to succumb, accept and adapt. However, with this apparent tolerance, there may be a hidden price tag such as cancer or other diseases. After all, independent lab tests have identified carcinogenic ingredients in fragrant products. Think about it, just because you can't perceive carbon monoxide, doesn't mean damage is not being done. After enough exposure, finally perception is realized perhaps with death. Maybe this analogy applies to fragrances. I've heard a professional nutritionist and allergy specialist comment about the people who seemingly don't react to fragrances. He suggests that most people's immune systems are weakened from food allergies and environmental toxins, primarily society's onslaught of fragrances. The weakened immune system can't conjure up the energy to send a warning or to give perceptual awareness. However, through determined consistent elimination, one could prove his or her own sensitivity.

"Eternity" is just one of many toxic nuisances. I even react to the fragrances in all the common commercial "fragrance-free" products except for a select handful. The FDA/CFSAN fact sheet titled "Fragrance free and Unscented" revealed why most of these "fragrance free" products still cause problems (they still have fragrance). It also reveals several problems. Non-regulation of "fragrance free" products leaves no reliable protection for sensitive consumers who rely on fragrance free products. Unreliable labeling also denies certainty for sensitive people and those who try to accommodate. This fact sheet states that manufacturers are not required to label the masking fragrance. It states that most manufacturers voluntarily list the masking fragrance. With no certainty, it tries to assure that genuinely fragrance free products can be determined by looking at the ingredient label. Unfortunately, reliable labeling is not the norm. According to personal experience and tests, only 44 out of 161 common commercial "fragrance free" products with masking fragrance list it in the ingredients. Of the sample, that's only about 27%. According to this substantial study, most manufacturers are not voluntarily listing the masking fragrance. That is another issue I hope the FDA can address. Ideally "fragrance free" should mean 100% fragrance free. If not, then there needs to be mandatory labeling of the masking fragrance. Besides the needed regulation changes, the FDA/CFSAN fact sheet should be immediately changed so that it is accurate. A misstatement can breach public trust. Everyone needs reliable labeling and trust in the FDA.

The following is another problem of a self-regulated industry. Some "fragrance free" products are inconsistent. Sometimes they are genuinely fragrance free in one batch but not in another batch. Thankfully there are some companies (very few) that make reliable 100% fragrance free products. Perhaps they understand some of the problems with added fragrances.

Consider the correlation of increased use of fragrances with the increased percentages of asthma, cancer, migraines, ADD, MCS (multiple chemical sensitivities), and SIDS (Sudden Infant Death Syndrome). How

much pain do we all have to go through before change takes place? How long do we have ponder whether it is right or wrong to pollute ourselves with chemicals in fragrances known (or not so known to uninformed masses) to be neurotoxic, carcinogenic, airborne contaminants, and chemicals designated as hazardous waste disposal chemicals?! Sure, the issues and changes are seemingly complex but the logic is simple:

- A neurotoxin is neurotoxic
- A carcinogen is carcinogenic
- An airborne contaminant contaminates the air
- Hazardous waste is waste that is hazardous
- A toxin is toxic
- A poison is poisonous.

Now for some logic review you might remember from algebra:

a=b
 b=c
 If a=b and b=c then a=c

Now lets try that one with this:

- Most fragrances are derived from petrochemicals.
- Petrochemicals are neurotoxic.
- Most fragrances are neurotoxic.

With 80-90% of fragrance materials being petrochemicals, chances are all synthetic fragrances are neurotoxic. Please save us and yourselves from this toxic tragedy!

Misbranding "Eternity" is just one small step in the right direction. Everyone needs reliable labeling, safe products, and trust in the FDA. Just think of how much appreciation there would be from the chemically sensitive, asthmatics, allergic people and the loved ones who try to accommodate. There would be millions of appraisals. So much good could result from the FDA's action to help.

Sincerely,



Timothy Mainka, B.A.

ANN LANDERS**Manufacturers listen to consumers**

Dear Ann: Your column is a great way to educate millions of people, and I hope you think my letter is worth printing.

I have Multiple Chemical Sensitivity. This means I have become so sensitive to so many chemicals that I am like that canary in the coal mine. If I sit next to a person for a minute, I will react to his or her laundry detergent, perfume, antiperspirant, hair-spray, and so on. I am also affected by car-exhaust fumes, and must wear a mask to go for a drive or walk outside. In order to create a livable environment for myself, I had to remove every chemical in my home.

How did this happen? I worked for 10 years in a chemical plant, and had constant daily exposure to perfumes and other chemicals. The company I worked for is extremely safety conscious, and follows all the rules. Even so, the chemical odor was quite noticeable, and my reaction was severe, including joint stiffness, swelling and pain. More recently, I have been getting stroke-like reactions, such as numbness on one side of my body, slurred speech, dizziness and nausea.

The first few doctors I saw insisted I had psychological problems. I am thankful that I now have a competent, well-educated environmental doctor who is helping me. There is a treatment to desensitize the sufferer to those enzymes that cause the problem, but it is obscure and expensive, many doctors do not know about it, and insurance agencies do not always cover the cost. Only specially trained doctors are familiar with this treatment.

My plea is to manufacturers who put toxic chemicals, such as perfumes, in their products when they are not necessary. The only products I use to clean my house are Borax, baking soda and vinegar. Those do the job just as well as those high-priced, brand-name chemical cleaners. Please, Ann, tell them to stop adding all that stuff before more of us become incapacitated.

— Bonita in Brockville, Ontario

Dear Bonita: Your letter will be greatly appreciated by readers who have the same problem. Meanwhile, the sale of Borax, baking soda and vinegar is sure to increase because you wrote. We have been using all of the above in my home for a long time. I learned about their effectiveness from my mother.

Many readers complained about magazines that inserted highly perfumed ads for fragrances, and I see that the practice has decreased. Speak up, Readers. The consumer really is king.

Dear Ann: Like millions of others, I have grown up reading your column, but I never thought I would need to write to you. Today's incident, however, has changed all that.

As I sat in the doctor's waiting room, 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 CANNOT 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.: Here's your letter, and for whatever comfort it may be, you have a lot of company. I have received hundreds of letters from both men and women who cannot tolerate perfume, cologne or men's after-shave lotion. Some have written, "My throat closes up." Others have said, "I break out in hives."



- [Ball Home Page](#)
- [Application Form](#)
- [List of Dances](#)
- [Dance Descriptions](#)
- [Other Associated Activities](#)
- [Maps to All Events](#)
- [Fragrance-free Policy](#)
- [1998 Ball Committee](#)
- [Acknowledgements](#)

Dancing in Clean Air: Our Fragrance-free Policy

The Seattle English country dances are advertised as "fragrance free". This is because about 15% of the general population and about 20% of our English country dance community have adverse health effects from perfume and solvents, and become ill from even small amounts of fragrance products. Reported adverse health effects from perfume range from migraine headaches and asthma attacks to cardiac and neurological symptoms, including permanent brain damage. **This is not a preference issue -- it is a serious health issue for a significant number of people.**

Please refrain from wearing scented versions of the following products to dances:

perfume	shampoo	soap	make-up
cologne	conditioner	deodorant	chapstick
after-shave	hair gel	hand lotion	hair spray

In addition to these products, consider that **even your ball attire** has the potential to cause problems to other dancers, especially if it has been stored in mothballs, if it has been recently dry-cleaned, or if you have worn it with cologne on a previous occasion.

Safe products include:

Deodorant	Tom's of Maine deodorant, or the crystal
Shampoo & conditioner	Pure Essentials, Organic Essence



sponsored by:



Hair gel	make your own from Knox plain gelatin
Shaving cream	Kiss My Face
Laundry soap	Arm and Hammer fragrance-free or the disc
Hand & body lotion	Lubriderm or Kiss My Face

(some of the brands listed above make fragranced products also -- be sure to check the label)

In addition, hair-spray, fabric softeners and dandruff shampoos (whether scented or not) can trigger reactions in chemically sensitive people because of toxic contents.

Start reading the label!

Products called "unscented" may in fact contain fragrances! So, look at the list of ingredients and choose products labelled "fragrance-free" instead. In general, it is helpful to avoid anything with "fragrance" in the list of ingredients. "Fragrance-free" is safer than "natural" fragrances, many of which may contain toxic chemicals as preservatives.

By helping us to stay healthy, you may be healthier too

Because of the large number of people on the dance floor, even small amounts of scent on each person add up quickly to intolerable amounts. Those of us with asthma and chemical sensitivities can only attend if you help by wearing fragrance-free products. Someone who is healthy this year may be tipped over the edge into illness by small accumulations of fragrance, solvents and other chemicals in doses thought to be safe. By changing to safe products, you can help insure that this doesn't happen to you!

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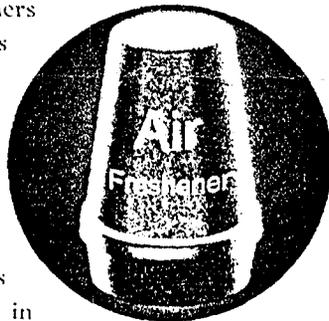
Concentrations of air pollution, specifically volatile organic compounds, are up to 10 times higher indoors than they are outdoors, according to Environmental Protection Agency (EPA) findings.¹

A primary cause of toxic chemical emissions in our homes are the cleaning products we choose.² Making some informed changes in your housecleaning arsenal is an easy and earth-friendly way to begin detoxifying your home. This article will get you started, targeting some of the worst offenders—several of which may be sitting under your kitchen and bathroom sinks right now.

SECRET INGREDIENTS: WHAT NO ONE TELLS YOU

It may surprise you to learn that the manufacturers of air fresheners and other household products are not required to reveal the ingredients they use, even if the product makes people sick.

[In response to health complaints, the EPA tried to identify which chemicals were most commonly used in consumer products that cause symptoms like headaches, fatigue, irritability and dizziness.] First researchers tested 31 consumer products, including several



or benzene can cause “solvent syndrome,” characterized by dizziness, nausea, fatigue, weakness, uncoordination, insomnia, visual disturbances, reduced cognitive functioning, personality changes, irritability, depression and more. Only with early detection can this condition be reversed.⁵

Few studies have addressed the impact of long-term, low-level exposure to these solvents, which is what most of us experience from housecleaning products. We do know that chemicals can accumulate in the body. Chlordane, a pesticide used to kill termites, has been detected in people 10 years after exposure.⁶

The health hazards of neurotoxins extend beyond the nervous system to the systems regulated by the nervous system. These include the immune,⁶ endocrine,⁷ cardiovascular and digestive systems.

FAKE FRAGRANCES: UNREGULATED AND DANGEROUS

“Air-freshening” sprays, solids, electric devices and even candles use synthetic chemicals to create strong, persistent odors that permeate the air. These chemicals, however, affect more than just your nose. A recent study of mothers and their infants, conducted at Bristol University in England, found that air-freshener sprays were associated with headaches and depression in the mothers and ear infections and diarrhea in the babies.

In a study of the effects of air-freshener emissions on mammals, the animals showed behavioral responses indicat-

It may surprise you to learn that manufacturers of household products are not required to reveal use, even if the product makes people sick.

air fresheners and cleaning products, to detect what chemicals they contained. Then they tested the air in 16 locations where these products are heavily used or displayed. The neurotoxins benzene and ethanol were detected in a room following the use of an air freshener. In locations such as a potpourri shop and the detergent aisle of a grocery store, ethanol and benzene were detected as well as the neurotoxic chemicals toluene and tetrachloroethylene.³

A toxic chemical is considered neurotoxic if it is fat-soluble, which means it can cross the blood-brain barrier and the placenta in pregnant women. When the body is exposed to more of these substances than it can detoxify, it stores the excess toxins in fat reserves. These substances can accumulate over time and are suspected of contributing to degenerative neurological diseases such as Parkinson's, Alzheimer's and ALS, or Lou Gehrig's disease.⁴

Long-term, high-level exposures to solvents like toluene

ing neurotoxicity, such as hyperactivity, tremors, loss of balance, loss of grip strength, paralysis and even death.⁸

Asthmatics may be particularly vulnerable to these emissions. The role of pollutants' effects on asthma is suspected but poorly understood.⁹

When you want a pleasant fragrance, use only those derived from natural sources. You can recognize natural fragrances on product labels because the source is usually listed. For example, you might see citrus, lavender, sage or peppermint. If you see natural essential oils listed on the label, these too are derived from plant sources, and they're not only safe but often therapeutic.

DOES MOPPING THE FLOOR GIVE YOU A HEADACHE?

Many people experience symptoms such as irritability and fatigue when using household cleaning products. For some, simply walking down the detergent aisle of the grocery

DON'T FALL FOR ANTIBACTERIAL SOAPS



Antibacterial is the latest buzzword appearing on popular hand soaps and cleaning product labels. Don't be taken in. This is a marketing ploy designed to play on our fears. Rather than protecting us, these soaps and cleaners may even increase the danger of bacterial infections by helping to create

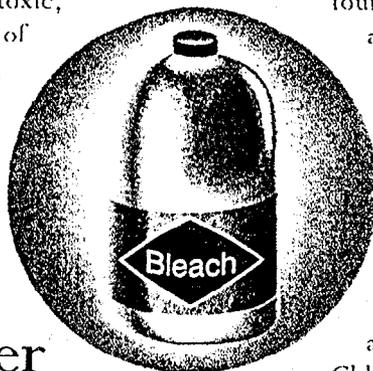
resistant strains of bacteria.

You don't need powerful antibacterial chemicals to clean your hands or your kitchen counter. Cleansing with basic soap and water eliminates the breeding ground for most germs and fungi. If someone is sick and you want to sterilize surfaces, hydrogen per-

oxide (or nonchlorine bleach), tea tree oil or grape seed extract are effective nontoxic antiseptics. If fungi are your worry, borax, tea tree oil and grape seed extract are all effective, nontoxic antifungal agents.

store will trigger a headache. Most of us do not realize that these are signs of neurotoxicity and that they should be taken seriously. They are the body's early warning signals that a poison is present.

Many of us have been trained to associate certain strong odors with cleanliness, but all these odors indicate is the presence of chemicals. Chemicals to avoid in cleaning products are petrochemicals, which are neurotoxic, and chlorine bleach. There are hundreds of petrochemicals used in cleaning products, including ammonia, ammonia chloride, ethanols, alcohols, methanols, benzenes, toluene, hydrocarbon solvent, aliphatic petroleum distillate, petroleum hydrocarbons, dimethyl benzyl ammonium chloride, DEA, TEA, xylene—and the list goes



air fresheners and other the ingredients they

on. Most detergents, fragrances and inert ingredients in cleaning products are petrochemicals.

You will notice an obvious difference in labeling when you compare toxic cleaning products with nontoxic cleaning products. Manufacturers of nontoxic products readily and proudly reveal the natural, safe ingredients in their products. In contrast, mainstream products using toxic chemicals rarely reveal their ingredients. They often hide them behind phrases like "inert ingredients," "quality control agents" or "odor neutralizers."

~Ammonia

Ammonia is used in hundreds of household cleaners for its grease-cutting properties. Unfortunately, it also is an irritant to the eyes, lungs and skin. At a high level of exposure it can be fatal, which is why it is regulated in industrial settings. A nontoxic and effective alternative grease-cutter is vinegar. The good news is that you can find a selection of nontoxic products in most health food stores that use vinegar, citrus oil or tea tree oil instead of ammonia. Most of these products

combine the active cleaner with a natural fragrance. You can find nontoxic glass cleaners, furniture polish and all-purpose cleaners. By switching to these products, you can completely eliminate ammonia fumes from your home.

~Bleach

Chlorine bleach is used to sanitize and whiten. It's found in bathroom cleaners, scouring powders and laundry detergents. By-products of chlorine that contaminate the air in your home include chloroform, trihalomethanes and nonvolatile chlorinated hydrocarbons.¹⁰ Compounding the problem, chlorine combines with other chemicals in your home (and septic tank) to create chlorinated compounds that are even more toxic. The combination of chlorine and ammonia is particularly dangerous.

Chlorine bleach can be easily replaced with a bleach made from hydrogen peroxide. Nonchlorine bleach can be used to whiten laundry, as part of regular cleaning or to sterilize surfaces.

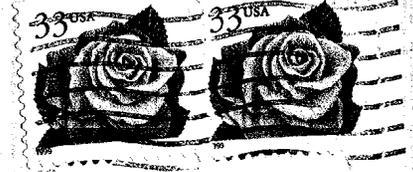
Household products that contain chlorine bleach, such as shower or toilet-bowl cleaners, can be replaced with nontoxic products like those described above. You'll also find chlorine-free scouring powders and creams that effectively clean and whiten sinks, toilets and tubs. For extra tough stains, try nonchlorine bleach or scrub with borax or a pumice stone. You will probably notice that you feel less fatigued after using these nontoxic products.

The air inside your home can have a profound effect on your health and well-being. Don't allow the glitzy advertising of neurotoxic petrochemicals to pressure you into compromising the quality of the air that you and your family breathe. *GL*

Cynthia Fincher, Ph.D., is the author of Healthy Living in a Toxic World (Piñon Press, 1996) and specializes in treating patients with chronic illnesses (fibromyalgia, chronic fatigue syndrome, multiple chemical sensitivities and chronic pain).

FOR REFERENCES CITED IN THIS ARTICLE AND FOR OTHER RESOURCES, PLEASE TURN TO "THE SOURCE" ON PAGE 56.

 **Timothy Mainka**
7755 48th Ave. Apt. 5
Hudsonville, MI 49426-9780



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12420 Parklawn Dr
Rockville, MD 20857

