

# *Beauty Secrets*

*Does A Common Chemical In Nail Polish  
Pose Risks To Human Health?*



*Jane Houlihan  
Richard Wiles*

## Acknowledgments

This report was written by Jane Houlihan and Richard Wiles of the Environmental Working Group.

This report was made possible by grants from the W. Alton Jones Foundation, the Turner Foundation, Inc., the Mitchell Kapor Foundation and the Jenifer Altman Foundation.

Copyright © November 2000 by Environmental Working Group. All rights reserved. Manufactured in the United States of America. *Printed on recycled paper.*

## Environmental Working Group

The Environmental Working Group (EWG) is a nonprofit environmental research organization based in Washington, D.C. Through analysis of government and private sector databases, environmental monitoring programs, and scientifically grounded research, EWG develops high-profile publications, computer databases and Internet resources that consistently create public awareness and concern about high priority environmental problems and solutions.

Kenneth A. Cook, President  
Richard Wiles, Vice President for Research  
Mike Casey, Vice President for Public Affairs

### To order a copy

Copies of this report may be ordered for \$25.00 each (plus 6% sales tax or \$1.50 for Washington, DC residents) and \$3.00 for postage and handling. Payment must accompany all orders. Please make checks payable to:

Environmental Working Group  
1718 Connecticut Avenue, N.W. Suite 600  
Washington, D.C. 20009  
(202) 667-6982 (phone)  
(202) 232-2592 (fax)

**[www.ewg.org](http://www.ewg.org)**

This and many other EWG publications are available on the World Wide Web at **[www.ewg.org](http://www.ewg.org)**.

# **Contents**

Executive Summary .....	1
Chapter 1: Chemical industry systematically defeats health protections .....	7
Chapter 2: Phthalates .....	11
Chapter 3: Phthalates in cosmetics and beauty products .....	19
References .....	25

## Executive Summary

In September 2000, researchers at the Centers for Disease Control and Prevention (CDC) reported that every single one of the 289 persons tested for the plasticizer dibutyl phthalate (DBP) had the compound in their bodies. The finding passed with little public fanfare, but surprised government scientists, who just one month earlier had rated DBP of little health concern based on the scientific assumption, which later turned out to be wrong, that levels in humans were within safe limits. DBP causes a number of birth defects in lab animals, primarily to male offspring, including testicular atrophy, reduced sperm count, and defects in the structure of the penis (CERHR 2000).

The most critical population, women of childbearing age whose fetuses are exposed in the womb, appear to receive the highest exposures. Estimates based on data published by the same CDC researchers in October 2000, indicate that DBP exposures for 3 million women of childbearing age may be up to 20 times greater than for the average person in the population. The highest exposure

estimates for these women were above the federal safety standard (Blount et al 2000, Kohn et al 2000, EPA 1990). EPA rates their overall confidence in the safety standard as “low”, largely because it is based on a study published in 1953 that did not examine the test animals for the birth defects that concern scientists today (EPA 1990).

DBP is just one ingredient in an alphabet soup of pollutants that contaminate every person in the industrialized world. A patchwork of studies from the federal government indicates that everyone in the United States carries more than 100 chemical pollutants, pesticides, and toxic metals in their bodies. No one knows exactly where these exposures come from, and no one has studied the effect of constant exposure to this low-level mixture of poisons. Nor is it possible to do so. To test 100 chemicals in combinations of three for just one health effect (cancer, for example, as opposed to birth defects) would require 162,000 new tests. There are currently 75,000 chemicals licensed for use in the United States. Approximately 15,000 are sold in volumes greater than

**DBP is just one ingredient in an alphabet soup of pollutants that contaminate every person in the industrialized world.**

**No one knows exactly where these exposures come from, and no one has studied the effect of constant exposure to this low-level mixture of poisons.**

10,000 pounds per year. Under the Toxic Substances Control Act the EPA has regulated just five chemicals (Roe et al 1997).

**Table 1. EWG shoppers turned up 37 DBP-containing products from 22 companies.**

Name brand	Nail care product containing DBP
Black Radiance U.S.A.	Black Radiance Nail Color
Bon Bons	Bon Bons (nail polish)
Chanel	Nail Colour
Christian Dior	Nail Enamel
Club Monaco	Nail Color
Cosmar	Cosmar Press&Go Nails Kit
Cover Girl	Cover Girl Nail Slicks
Hard Candy	Nail Enamel
Loud Music	Nail Enamel
M	M Professional Nail Polish
Max Factor	Diamond Hard Nail Enamel
Maybelline	Express Finish Fast-Dry Nail Enamel Ultimate Wear (nail enamel) Salon Finish Nail Enamel)
Nailene	Professional Solutions Acrylic Tough Polish Shield PROfessional Solutions Acrylic Polish Shield PROfessional Solutions Calcium Growth Builder Nail Paints Art Kit
NARS	Nail Polish
Naturistics	90 Second Dry Super Fast Nail Color
Nutra Nail	Nutra Nail Maximum Strengthener Nutra Nail Calcium Nail thickener Nutra Nail Iron Shield Nail Hardener
Oil of Olay	Nail Lacquer
Orly	Orly Salon Nails Nail Color
Tony & Tina	Tony & Tina (nail enamel)
Sally Hansen	Color Fast! One Coat Fast-Dry Enamel Maximum Support Strengthen & Grow No More Breaks Restructurizing Strengthener Hard as Nails with Nylon Triple Strong Advanced Gel Nail Fortifier Thicken Up! Strengthening Nail Thickener Ultimate Shield Fortifyng Base & Top Coat Hard as Nails Instant Strength Calcium Gel Nail Fortifier
Urban Decay	Nail Enamel
Wet 'n' Wild	Wet 'n' Wild Nail Color

Source: Environmental Working Group.

Government researchers speculate that the elevated levels of DBP among women of child-bearing age come from cosmetics and beauty products, but no one has done the studies to test this hypothesis. As a first step in discovering some major sources, the Environmental Working Group (EWG) shopped at a local Rite-Aid, surfed the on-line store Drugstore.com, and searched the U.S. patent office records for products that contain DBP in the patent application. We found:

- DBP in 37 popular nail polishes, top coats, and hardeners, including products by L'Oréal, Maybelline, Oil of Olay, and CoverGirl (Table 1).
- Patents proposing to use DBP in a broad range of beauty and personal care products, including shampoos and conditioners, lotions, hair growth formulations, antiperspirants, and sunscreen. Even patents relating to gum, candy, and pharmaceuticals taken orally propose DBP as an ingredient.
- Many major manufacturers who propose to use DBP in cosmetics and related products. Of more than 100 patents analyzed by EWG, Procter & Gamble holds the most (37) that propose to use DBP in personal care products. Other major companies with multiple patents are L'Oréal (10), Lever Brothers (4), and Maybelline (3) (Table 2).

**Table 2. Major corporations hold patents that propose to use the toxic plasticizer DBP in a broad range of consumer products, from nail polish to hair growth formulations.**

Company holding patent	Products for which DBP is proposed as essential or possible additive
The Procter & Gamble (Cincinnati, OH)	lotion, hairspray, mousse, gel, lotion, cream, pomade, hair spray, conditioner, spritz, hair tonic, facial moisturizers, foundations, lipsticks, mascaras, nail polishes, oral pharmaceuticals, hair loss treatments
L'Oreal (Bureau D. A. Casalonga-Josse)	hair and nail products
Lever Brothers Company (New York, NY)	deodorant, skin and hair cleansers
Maybelline Cosmetics Corporation (Wilmington, DE)	nail enamel
Anheuser-Busch, Incorporated (St. Louis, MO)	gelled antiperspirant
Chesebrough-Pond's USA Co., Division of Conopco, Inc. (Greenwich, CT)	product to treat or prevent baldness
Colgate Palmolive Company (New York, NY)	antiperspirant and deodorant gels
Eastman Chemical Company (Kingsport, TN)	nail products
Elizabeth Arden Co., Division of Conopco, Inc. (New York, NY)	skin products
Kraft General Foods, Inc. (Northfield, IL)	sunscreen
Revlon Consumer Products (NY, NY)	nail enamel
Rhodia Chimie (Courbevoie, FR)	hair and skin care products (sprays, tonic lotions, gels, mousses)
Rhone-Poulenc Chimie (Courbevoie Cedex, FR)	nail varnishes
Unilever Patent Holding B.V. (Vlaardingen, NL)	skin and hair care products, antiperspirants

Source: Environmental Working Group.

### The Spoils of a Rotten System

Contrary to popular belief, industrial chemicals in consumer products are essentially unregulated in the United States. Except for chemicals added directly to food, there is no legal requirement for health and safety testing or human exposure monitoring for any chemical in commerce. The same chemicals, ironically, are often tightly regulated as pollutants.

For example, phthalates are recognized as toxic substances under environmental law, but

companies are free to use unlimited amounts in cosmetics. An environmental release of just 10 pounds of DBP must be reported to environmental authorities under the Superfund law. The cosmetics industry, in contrast, puts hundreds of thousands of pounds of DBP into nail polish each year, with no requirements for safety testing or reporting to anyone.

In the 25 years of the Toxic Substances Control Act, the EPA has regulated exactly one toxic

**Phthalates are recognized as toxic substances under environmental law, but companies are free to use unlimited amounts in cosmetics.**

**Industry can and does put chemicals into widespread commercial use without meaningful testing for toxicity and without any monitoring of people or the environment.**

substance in a consumer product, lead in paint. This is largely because the agency cannot demand the health and safety tests needed to evaluate a chemical's safety and risk. Industry recently agreed to a voluntary testing program for high production volume compounds (chemicals produced annually in amounts of at least one million pounds), but this program has many shortcomings. Many basic tests are not required, such as those for cancer, nervous system damage, and virtually all tests for toxicity to the developing and immature animal including developmental neurotoxicity or effects on the immature immune system. About 80 percent of all high production volume chemicals are *not* covered by the initiative.

Pivotal court decisions implementing the 1976 Toxic Substances Control Act (TSCA) have rendered EPA impotent to control toxic chemicals in commerce. The agency must prove an "unreasonable risk of injury" to human health before it can remove a chemical from the market. But EPA is powerless to make that finding because the law prohibits the agency from requiring safety studies until it proves that "substantial" or "significant" exposures are occurring. The agency can almost never prove that substantial or significant exposures are occurring because exposure data are also extremely difficult to obtain.

In other words, EPA cannot regulate a chemical until it makes

a finding of risk based on data that the law virtually prohibits it from collecting.

The law also allows industry to manufacture and sell new chemicals without conducting any toxicity studies to determine if the chemicals are safe. After a chemical enters the marketplace, there is no requirement for human monitoring, even for those compounds to which people are routinely exposed.

Except for direct food additives, the Federal Food Drug and Cosmetic Act (FDC&A) is no better (FDA 2000). DBP is allowed in food as an indirect additive via food packaging, but this use was grandfathered in and has not been subject to modern food safety standards. The FDC&A does not require pre-market safety testing, review, or approval for cosmetics or the compounds used to make them. While manufacturers might study the short-term effects in lab animals of the substances that they sell, they almost never study long term effects of their products. Industry can and does put chemicals into widespread commercial use without meaningful testing for toxicity and without any monitoring of people or the environment.

### **What You Can Do**

Researchers are just beginning to discover the names of the hundreds of commercial chemicals that contaminate the human body. What those chemicals'

actual health effects might be are just beginning to be understood. In the meantime, scores of new chemicals are introduced into commerce each year, with no requirement that they be shown to be safe.

This situation is the single biggest failure in U.S. environmental law and is not likely to be fixed anytime soon. Until it is, people can do a few simple things to reduce exposure to the contaminants that we do know about.

- Women who are pregnant, nursing or thinking about getting pregnant should look for and avoid all personal care products with the word phthalate on the label. Some common forms of phthalates in personal care products are dibutyl phthalate, diethyl phthalate, and dimethyl phthalate.
- Urge manufacturers to reformulate their products with safer alternative chemicals. Go to [www.ewg.org](http://www.ewg.org) for a list of phone numbers and e-mail addresses for some major personal care products manufacturers.
- If you use nail products, choose those that contain fewer toxins. Use products free of DBP and other common nail polish toxins like toluene and formaldehyde. Types of nail

polish that are DBP-, toluene-, and formaldehyde-free include L'Oréal Paris Jet-Set Quick Dry Nail Enamel, Revlon Nail Enamel, Garden Botanika Natural Color Nail Color, and Kiss Products Kiss Colors, to name a few.

### **Policy Recommendations**

When it comes to the use of potentially toxic chemicals in manufactured consumer products, the official operating principle is use first, test later, or better yet, don't test at all. This situation is disgraceful and completely unacceptable. In the face of growing evidence that the human population is contaminated with hundreds of poorly tested hazardous industrial chemicals, we recommend the following:

- The chemical industry must immediately and completely fund a comprehensive human biomonitoring initiative in conjunction with the Centers for Disease Control and Prevention. The initiative would monitor the human population for all chemicals reasonably likely to be found in human tissue. The study design must include highly exposed and potentially vulnerable sub-populations, and must include enough individuals to support statistically meaningful conclusions and regulatory decisions for all sectors of the population, and all chemicals

**When it comes to the use of potentially toxic chemicals in manufactured consumer products, the official operating principle is use first, test later, or better yet, don't test at all.**



monitored. All of the information gathered must be made available to the public after it is peer reviewed.

- The chemical industry must expand its commitment to screening of high production volume chemicals to include tests for carcinogenicity, neurotoxicity, immunotoxicity, and endocrine system toxicity at all life stages including gestation, infancy, childhood, adolescence and adulthood.
- The chemical industry and the personal care products industry must immediately label all products containing phthalates and any other toxic substance to which there is human exposure. Labels must be improved so that they are legible.
- The current exemption for labeling requirements that applies to non-retail sales of these products to professionals, must be rescinded.

# Chemical industry systematically defeats health protections

No pre-market safety testing or approval is required under any federal law for chemicals in cosmetics, toys, clothing, carpets, or construction materials, to name just a few obvious sources of chemical exposure in everyday life. This little known fact is the premeditated result of an orchestrated campaign by the chemical industry to avoid testing and regulation of their products. It largely explains why products like hair spray, hair dye, pacifiers, stain repellants, glues and children's toys get on the market, only to be found to contain highly toxic compounds at unsafe levels after decades of widespread use. Once these products are on the market, there is no practical legal mechanism by which health authorities can remove them from commerce, short of a public health disaster or consumer uproar.

## OSHA

Since the 1950's, the chemical industry has systematically blocked efforts to require safety studies for the compounds it produces. This strategy first played out with workplace standards adopted under the Occupational Safety and Health

Administration (OSHA), and was repeated with the passage and implementation of the Toxic Substances Control Act (TSCA).

The first chemical health standards in the United States were adopted by OSHA in 1972. Set in theory to protect workers, these standards were initially created in the 1940's by representatives from the chemical industry operating under the auspices of the American Council of Governmental and Industrial Hygienists (ACGIH). At the time the standards were first introduced in 1942, ACGIH issued major caveats regarding their application to human health, stating that: "[they are] not to be construed as recommended safe concentrations" (ACGIH 1942).

Toxicity tests on animals had barely been invented at that time, and the standards themselves were based on rough estimates of acutely hazardous and lethal levels of exposure. In the words of the scientist who devised many of them, the so-called threshold limit values (TLVs) were designed, "to provide a handy yardstick to be used as guidance for the routine control of these health hazards — not that compliance with the figures listed would

**Since the 1950's, the chemical industry has systematically blocked efforts to require safety studies for the compounds it produces.**

**Passed with virtually no regulatory teeth, TSCA has been an unparalleled failure.**

guarantee protection against ill health” (Cook, 1945).

This did not stop the chemical industry from promoting TLVs as legitimate health standards, and in 1972, OSHA adopted TLVs wholesale as the nation’s first set of enforceable health standards for chemicals in the workplace. In the process these “handy yardsticks” took on an aura of respectability that belied the fact that there was essentially no science to support their relevance to human health and safety. The best estimates are that basic toxicological data were available for only five percent of some 600 industrial chemicals for which OSHA had adopted standards by 1988 (Castleman and Ziem 1994, Roach and Rappaport 1990).

### **TSCA**

This process of faux regulation was repeated again when the same chemical industry giants teamed up to write the nation’s major toxic chemical law, the Toxic Substances Control Act (TSCA). Passed with virtually no regulatory teeth, TSCA has been an unparalleled failure. Of the 62,000 chemicals on the market when TSCA was passed in 1976, EPA has successfully requested data for 263 compounds. Of the 15,000 chemicals marketed in quantities exceeding 10,000 pounds per year, EPA has completed regulatory actions to limit use or exposures on just 5, or 0.03 percent (3 one hundredths of one percent). Four of the five were already regulated under other

statutes, and only one, lead in paint, affected a consumer product (Roe et al 1997).

TSCA is best thought of as a self-defeating feedback loop. Under the law, all chemicals are presumed safe, and the burden of proof is on the EPA to demonstrate that a chemical is causing harm before it can take any regulatory action. However, the agency cannot require that industry conduct the tests needed to show that a chemical is causing harm, until the agency has shown that the compound may present an “unreasonable risk,” or that human exposure is “substantial” or “significant”. Substantial exposures can almost never be proven without additional data from industry, and significant exposures cannot be proven without information on the chemical’s toxicity. Of course, compelling toxicity data are almost never available for the compound in question or EPA would not be trying to publish a test rule in the first place.

Even if all these hurdles are cleared, which is extremely unlikely, in order to request basic toxicity data on any single chemical the EPA must issue a test rule through the process of a rulemaking under administrative law. This roadblock is unique to TSCA. Under pesticide law, or food safety law, EPA or FDA can request virtually any test that they need to assess the safety of a compound.

**Of the 15,000 chemicals marketed in quantities exceeding 10,000 pounds per year, EPA has completed regulatory actions to limit use or exposures on just 5, or 0.03 percent.**

A defining moment in the collapse of TSCA occurred in 1990 when EPA attempted to issue test rules for the paint thinner cumene. The proposed test rules were immediately challenged by the Chemical Manufacturers Association on the grounds that EPA had not shown that human exposure was “substantial,” the basic requirement under Section 4 of the Act. The courts upheld the CMA argument that the burden of proving “substantial” exposure and risk was on the EPA and not the manufacturers (Chemical Manufacturers Ass’n v. EPA, 5<sup>th</sup> Cir. 1990).

To date EPA has issued rules requiring toxicity testing for 0.4 percent, or 263, of the 62,000 chemicals on the market when the law was passed. And even when issued, test rules generally do not require comprehensive testing. With barely any data generated via test rules the agency cannot support a finding of substantial risk for any chemical, and indeed the agency has taken only five final actions since passage of the law (Roe et al 1997).

The final nail in the coffin came in 1991. EPA was trying to use TSCA to regulate asbestos, arguing that it presented an “unreasonable risk of injury” to human health. Again the TSCA feedback loop prevailed, and the court ruled that EPA had not met the burden of providing substantial evidence that asbestos presented an unreasonable risk of

injury to human health (Corrosion Proof Fittings v. EPA, 5<sup>th</sup> Cir. 1991). Since this decision, EPA has undertaken no additional major regulatory actions under the Act.

Under pressure from environmentalists and the Clinton administration, in 1999 the chemical industry agreed to conduct basic health screening tests for about 3,000 high production volume compounds out of a universe of more than 75,000 chemicals registered for commercial use today, 15,000 of which are marketed in quantities exceeding 10,000 pounds per year. This tiny step forward is entirely voluntary and, even if it is completed, it will not provide regulators and public health authorities with sufficient information to fully assess the long-term adverse effects of toxic chemical exposure. Tests now recognized as critical to a full understanding of a chemical’s toxicity will not be conducted at all under this initiative. These include cancer bioassays, studies on the developing nervous system, the immune system, the endocrine system, and perhaps most important, human monitoring to determine the extent of human exposure.

This latter element is critical. As discussed below, a string of recent discoveries reveal that human exposure to commercial chemicals used in common consumer products is almost certainly much more pervasive than previously thought. This new strata of contamination is in

**In 1999 the chemical industry agreed to conduct basic health screening tests for about 3,000 high production volume compounds out of universe of more than 75,000 chemicals registered for commercial use today.**

**Tests now recognized as critical to a full understanding of a chemical’s toxicity will not be conducted at all under this initiative.**

addition to the considerable well-known toxic load of pollutants (such as PCBs, dioxin, and DDT) found in the blood and body fat of virtually all people in the industrialized world.

## Phthalates

Invented in the 1930's, the versatile group of common industrial chemicals called phthalates (pronounced tha-lates) are used as ingredients in a diverse range of consumer products from cosmetics to food wraps, toys and building materials. Currently the chemical industry produces *billions* of pounds of phthalates each year. They are used as plasticizers to soften plastic, as skin moisturizers and skin penetration enhancers in cosmetics, and as solvents in a wide range of applications. People are exposed to phthalates daily through their contact with consumer products and via food and indoor air.

In spite of their widespread presence in cosmetics and other common consumer products, industry has only partially studied the health effects of phthalates and has never tested for the presence of phthalates in human bodies. Finally, in April 1999, over six decades after phthalates were first marketed, the federal government's National Institute for Environmental Health Sciences (NIEHS) initiated a study of the effects of phthalates on the human reproductive system through their

new Center for the Evaluation of Risk to Human Reproduction (CERHR).

At the same time, scientists at the Centers for Disease Control and Prevention (CDC) were achieving the first accurate measurements of phthalates in people. Researchers there were surprised to find that people have much higher levels of some phthalates in their bodies than predicted by previous estimates (Blount et al 2000). In October 2000, CDC scientists announced that levels of some phthalates in women of childbearing age, including dibutyl phthalate (DBP) and di(2-ethylhexyl) phthalate (DEHP), exceed the government's safe levels set to protect against birth defects. Estimates based on data from this study indicate that for more than 3 million heavily exposed women of childbearing age, exposures to DBP may be 20 times greater than the average exposures in the rest of the population (Kohn et al 2000).

This report focuses primarily on DBP, a widely used phthalate that produces serious reproductive and developmental effects in laboratory animals. But DBP is not the only toxic phthalate to

**Currently the chemical industry produces *billions* of pounds of phthalates each year.**

**In October 2000, CDC scientists announced that levels of some phthalates in women of childbearing age, including dibutyl phthalate (DBP) and di(2-ethylhexyl) phthalate (DEHP), exceed the government's safe levels set to protect against birth defects.**

**At least two decades ago, scientists began building a body of work indicating that DBP can be a powerful reproductive and developmental toxicant in laboratory animals, particularly for males.**

**Early studies focused on DBP's ability to cause testicular atrophy.**

which people are routinely exposed. Many other phthalates widely detected in human urine by the CDC cause the same birth and developmental defects to the male reproductive system as DBP. Absent evidence to the contrary, it is reasonable to assume that the health effects from exposures to multiple phthalates are additive.

### **Health effects of dibutyl phthalate**

At least two decades ago, scientists began building a body of work indicating that DBP can be a powerful reproductive and developmental toxicant in laboratory animals, particularly for males. Early studies focused on DBP's ability to cause testicular atrophy (e.g., Gray et al 1980), but DBP is now known to cause a broad range of birth defects and lifelong reproductive impairment in male laboratory animals exposed in-utero and shortly after birth (Ema et al 1998, Marsman et al 1995, Mylchreest et al 1998, 1999, and 2000, Gray et al 1999, Wine et al 1997 ).

Scientists believe that the active toxicant of DBP exposure is its first breakdown product, monobutyl phthalate (MBuP), which has been shown to harm the male reproductive system. The precise mechanism of action is not known but the pattern of reproductive harm is consistent with other so-called anti-androgens or chemicals that interfere with the male hormones called androgens.

**Effects in immature male animals:** DBP exposure damages the testes, prostate gland, epididymus, penis, and seminal vesicles in laboratory animals (see, for example, Mylchreest et al, 1998). These effects persist throughout the animal's life, and include, specifically:

- Testicular atrophy (the testes produce sperm and male sex hormones)
- Hypospadias (a defect of the penis in which the opening occurs on the bottom of the penis instead of the tip)
- Undescended testicles – a condition in which the testes fail to descend into the scrotal sac during pregnancy.
- Ectopic testes – a condition in which testes are grown outside the scrotal sac
- Absent testes – testes are not formed at all
- Absent prostate gland (the prostate gland contributes liquid secretions to semen)
- Absent or small seminal vesicles (seminal vesicles, like the prostate gland, contribute liquid secretions to semen)
- Reduced sperm count (reduced fertility of offspring)
- Malformed or absent epididymus (the epididymus

is the structure where sperm mature and are stored)

Potential health effects of DBP continue to be significant for newborn animals who can be exposed to DBP by breathing phthalate-contaminated air, by touching things that contain phthalates, or by drinking their mother's milk, which can contain phthalates as a result of her exposures. In young lab animals, DBP has been shown to cause permanent testicular atrophy and reduced sperm counts (Foster et al 1981, Marsman 1995).

In animal tests DBP is also “embryolethal” — causing loss of pregnancy — and prevents implantation of the fertilized egg. In lab animals it also causes “resorption” of some or all of the fetuses in a litter, where the mother's body essentially dissolves the fetus without miscarriage. DBP also causes a range of skeletal and external birth defects for male and female offspring of animals exposed during pregnancy – including deformity of vertebra and ribs, cleft palate, and fused breastbone (Ema et al 1994 and 1995).

### Relevance to people

Broad and disturbing trends in human male reproductive health include many of the same effects seen in lab animals dosed with phthalates. Although a cause and effect relationship has not been established, the ubiquity of phthalates in the human

population creates a biologically plausible presumption that phthalates may be contributing to these problems. Until proven safe, phthalates should be considered as potential contributors to the following human health effects:

- Declining sperm count: Recent analysis of 101 studies (1934-1996) by Shanna Swan of the University of Missouri confirms results of previous studies: average sperm counts in industrialized countries are declining at a rate of about 1 percent each year (Swan et al 2000).
- Hypospadias: Data from the Centers for Disease Control show that rates of hypospadias in the U.S. began climbing in about 1970, and continued this increase through the 1980s. This condition is a physical deformity of the penis in which the opening of the urethra occurs on the bottom of the penis instead of the tip. (Currently the occurrence of hypospadias appears to be stable, at about 30 to 40 cases per 10,000 births.) (Paulozzi 1999)
- Undescended testicles: This birth defect, where testicles fail to completely descend into the scrotum during pregnancy, occurs in 2-5 percent of full-term boys in Western countries. Rates of the defect increased greatly in the U.S. in the **1970s and**

**In young lab animals, DBP has been shown to cause permanent testicular atrophy and reduced sperm counts.**

**In animal tests DBP is also “embryolethal” – causing loss of pregnancy — and prevents implantation of the fertilized egg.**



**In September 2000, CDC scientists published the results of the first human testing program for phthalates.**

1980s. Men born with this defect are at higher risk for testicular cancer and breast cancer (Paulozzi 1999).

- Testicular cancer: This is the most common cancer of young men in many countries, including the U.S. Its incidence continues to increase at a rate of about 2 to 4 percent each year in industrialized countries, although rates appear to have stabilized in the U.S. after a 20-year increase. Men with hypospadias, infertility, and undescended testicles – the same constellation of conditions seen in lab animals exposed to DBP – are at greater risk for developing testicular cancer (Toppari et al 1996 and Moline 2000).

**They found phthalates in every person tested, and at surprisingly high levels in some individuals.**

### **History of recent government studies of phthalates**

In April 1999, CERHR initiated a review of the reproductive and developmental effects of phthalates in humans. The Center chose seven phthalates for examination, based on consideration of production volume, extent of human exposures, use in children's products, or published evidence of reproductive or developmental toxicity.

They addressed the following three questions for each phthalate based on their current understanding of levels of human exposure to phthalates:

1. Are young children at risk for harm to the reproductive system?

2. Is the fetus at risk for developmental effects when the mother is exposed?

3. Are adults at risk for effects to the reproductive system?

In their June 2000 report draft CERHR assigned low, minimal, or negligible concern to five phthalates, and higher concern for only one, DEHP. ("Concern" refers to whether CERHR believes the chemical is a reproductive or developmental toxicant in people at current levels of exposure.)

In September 2000, Dr. Brock and his team of CDC scientists published the results of the first human testing program for phthalates (Blount et al 2000). The results turned the CERHR conclusions of minimal concern on end. They found phthalates in every person tested, and at surprisingly high levels in some individuals for some phthalates. The scientists concluded that "from a public health perspective, these data provide evidence that phthalate exposure is both higher and more common than previously suspected," adding that, "Exposure data for phthalates is (sic) critically important for human risk assessment, especially among potentially susceptible populations."

**THE PHTHALATE INDUSTRY LEFT IT UP TO THE GOVERNMENT TO FINALLY DEVELOP A TEST METHOD THAT GIVES ACCURATE MEASUREMENTS OF PHTHALATES IN PEOPLE.**

Historically, phthalate exposure has been difficult to measure precisely because the compounds are so widely used. Pervasive background contamination during laboratory analyses commonly produced test results where true contamination in body fluids could not be distinguished from phthalates found in laboratory equipment or in cosmetics worn by technicians. Until the CDC published its research in September 2000, it was generally assumed that phthalates detected in biological samples in large part reflected this background contamination.

As the CERHR study of phthalate risk neared completion, independent work led by Dr. John Brock at the Centers for Disease Control and Prevention (CDC) resulted in a new analytical method that would, for the first time, allow for the accurate analysis of phthalates in biological samples free from concerns of background contamination. Brock's method involves testing urine for human breakdown products, or metabolites, of phthalates. The specific metabolites for which he tests, called the glucuronidated monoesters, are not manufactured by industry. With Brock's innovative method, issues of background contamination disappear.

Brock and his team measured levels of seven phthalate metabolites in the urine of 289 adults. They found metabolites from two of these in 100 percent of those tested – dibutyl phthalate, or DBP, and benzylbutyl phthalate, or BzBP. A metabolite of DBP called monobutyl phthalate (MBuP), a potent reproductive toxin in lab animals, was found at significantly higher levels in women of childbearing age. Six of the eight highest measured levels were in this group. CDC postulates in their paper that high exposures to phthalates in women of childbearing age may arise from the use of cosmetics and beauty products.

These results caught both government and industry off guard. Now, government scientists are beginning a search for answers: Are normal body levels of phthalates safe for infants and pregnant women? How are people exposed to phthalates – through which consumer products and via what pathway?

Government scientists published a letter in the October issue of Environmental Health Perspectives outlining the significance of the CDC urine study. Their analyses showed that the highest exposures measured, in women of childbearing age, were above federal safety levels set to protect against birth defects.

**The results caught both government and industry off guard.**

**If a woman reads the fine print on the back of every cosmetic bottle she purchases, she might discover whether the product contains phthalates. However, she won't know how much phthalates are in the product, or what health effects her use of the product could possibly have on her fetus.**

Estimates based on these data indicate that DBP exposures for up to 3 million women of child-bearing age may be 20 times higher than for the rest of the population.

In an effort to determine key routes of exposure, CDC is beginning work on an extensive survey to find which products are causing the high DBP levels in women of childbearing age.

**Phthalates: regulated as toxic pollutants – but OK in consumer products**

Phthalates are considered a hazardous waste and are regulated as pollutants in air and water. In contrast, phthalates are essentially unregulated in food and cosmetics. (One phthalate, DEHP, which was removed from children's toys more than a decade ago, is regulated in drinking water.)

Under various environmental laws, individual companies are limited with regards to how much DBP they can release to the environment as pollution each year. For example, industries must report any spill or release of DBP over 10 pounds, and industries using phthalates must keep records of their location and transportation. But FDA does not limit the amount of DBP that can be used in cosmetics and other beauty products. And the FD&C Act does not require that cosmetic manufacturers or marketers test their products for safety.

So, by design from the chemical industry, the federal government treats phthalates with a bipolar approach. Phthalates are recognized as toxic substances under environmental law, but companies are free to use unlimited amounts in cosmetics. Moreover, the labeling requirements for cosmetics are riddled with loopholes. If a woman reads the fine print on the back of every cosmetic bottle she purchases, she might discover whether the product contains phthalates. However, she won't know the quantity of phthalates in the product, or what health effects her use of the product could possibly have on her fetus.

Specifically, FDA's labeling requirements state that all cosmetics produced or distributed for retail sale to consumers for their personal care bear a list of ingredients, ordered by prevalence (21 CFR 701.3). Cosmetic labeling requirements apply to all cosmetics marketed in the U.S., whether manufactured here or abroad. But it's simple for industry to hide phthalates in consumer products, as components of fragrances, flavorings — or chemical mixtures that are considered “trade secrets” — all of which are exempt from labeling requirements.

Remarkably, women who work in nail and hair salons and presumably get the highest exposures, are not protected even by labeling regulations. Ingredient labeling requirements

do not apply to products used only by beauty professionals in the workplace. The 1997 U.S. Economic Census shows that over 407,000 people are employed in the more than 81,000 beauty salons across the country. These employees, primarily women including what is likely a large percentage of women of childbearing age, are exposed to DBP in beauty products daily, with no knowledge of it and no option for choosing alternate products.

**The federal government has “low” confidence in their safe daily dose value for DBP**

Ten years ago, using a study published in 1953, the Environmental Protection Agency (EPA) established a “safe” daily dose of DBP, called the Reference Dose, or RfD. Even then, the EPA characterized this pivotal study as weak, and their confidence in the RfD as “low.” Ten years later the agency has not revised the safe dose, nor required new studies to strengthen its knowledge of DBP toxicity.

The CDC found that high-end DBP exposures in women of childbearing age are above the federal safe daily dose (Kohn et al 2000). If the safe daily dose value were brought up to modern standards, even more women in the CDC study group would fall into the zone of concern.

The study supporting the RfD is archaic in design and does not

provide any information on the health effects that concern scientists today – birth defects in male offspring. The study included only adult male rats, and death was the only health effect studied. Irrespective of the fact that the study examined only the most crude endpoint, the results are of marginal relevance to real world human exposures, and do not provide a sufficient scientific basis to establish a safe exposure level under contemporary standards applied to pesticides or food additives regulated under federal law. EPA admits that the study has many deficiencies. In their documentation of the RfD the agency states “The Oral RfD for dibutyl phthalate may change in the near future pending the outcome of a further review now being conducted by the Oral RfD Work Group” (EPA 1990).

Nonetheless, the current RfD is derived from a “safe” dose in this study of 125 mg of chemical ingested per kilogram of body weight (mg/kg) – the dose that was shown to induce no additional deaths relative to the control group. A study published this year (2000) found that exposures at this level, thought previously to produce no effects, in fact cause birth defects in male pups, including extra nipples in a third of the pups (Mylchresst et al 2000). This study found a “safe” dose, called a no observed adverse effect level, or NOAEL, of 50 mg/kg – 60 percent lower than the dose that is currently the basis for the RfD.

**Women who work in nail and hair salons and presumably get the highest exposures, are not protected even by labeling regulations.**



## Phthalates in cosmetics and beauty products

It is remarkable that such a heavily used chemical, with known toxicity, can be so poorly regulated. For example, Procter & Gamble holds a patent which proposes to add 5 milligrams of DBP to each dose of an oral pharmaceutical. A woman of average weight (140 pounds) ingesting this tablet would get a daily dose of DBP that is 80 percent of her current allowable daily dose defined by the RfD. She would get double the dose that would be allowed if the RfD were updated to protect the male fetus from birth defects, assuming no other exposure to DBP in other products.

The Environmental Working Group conducted a web-based analysis to locate consumer products, particularly cosmetics and beauty aids, containing phthalates. We found both dibutyl phthalate (DBP) and diethyl phthalate (DEP) in numerous products, and butylbenzyl phthalate (BBP) in a smaller number of products. Ultimately we limited our search to DBP, because it is a more potent reproductive and developmental toxin than DEP, and is found in a greater number of products than BBP.

Several points became clear during our product search. First, alternatives to phthalates are readily available to industry, as only a fraction of any given type of cosmetic or beauty product contains phthalates.

Second, women have no practical way to choose products that are phthalate-free. Some cosmetics contain ingredient labels on the outside of the product, but the print is so small as to be nearly unreadable, and a typical shopper will not know that “dibutyl phthalate” is the same thing as “butyl ester” or even possibly “plasticizer.” Other products, such as more expensive perfumes, contain ingredient labels inside the packaging where they cannot be read until after the product is purchased. We found still other products on store shelves, particularly imported products, that lacked ingredient labels altogether, in direct violation of federal regulations.

Third, with information currently in the public arena, it is nearly impossible to develop anything approaching a comprehensive list of cosmetic and beauty products that contain

**Women have no practical way to choose products that are phthalate-free.**

**The results of our analysis only scratch the surface of what will be a daunting task for CDC as they try to define exactly where women of childbearing age are being exposed to phthalates.**

phthalates. This would require a product-by-product, label-by-label search of every single cosmetic and personal care box and bottle sold in the United States. The results of our analysis only scratch the surface of what will be a daunting task for CDC as they try to define exactly where women of childbearing age are being exposed to phthalates.

As a first step in discovering some of the beauty and personal care products that contain DBP,

the Environmental Working Group (EWG) shopped at a local Rite-Aid, surfed the on-line store Drugstore.com, and searched the U.S. patent office records for products that contain DBP in the patent application. We found that DBP may be used in a broad range of beauty and personal care products, including shampoos and conditioners, lotions, hair growth formulations, antiperspirants, and sunscreen. It can even be used in gum, candy and pharmaceuticals taken orally.

**Table 3. A limited online drugstore label search by EWG found DBP in 37 nail products from 22 companies, including Cover Girl, Maybelline, and MaxFactor products.**

Name brand	Product	Manufacturer or parent company, and distributor shown in italics	Location
Black Radiance U.S.A.	Black Radiance Nail Color	<i>AM Cosmetics, Inc.</i>	North Arlington, NJ 07031
Bon Bons	Bon Bons (nail polish)	<i>Bari Cosmetics, Ltd</i>	Greenwich, CT 06831
Chanel	Nail Colour	<i>Chanel, Inc.</i>	New York, NY 10019
Christian Dior	Nail Enamel	<i>Parfums Christian Dior</i>	Paris, France
Club Monaco	Nail Color	<i>Club Monaco Cosmetics</i>	Toronto, Canada
Cosmar	Cosmar Press&Go Nails Kit	<i>Cosmar Corporation</i>	Huntington Beach, CA 92647
Cover Girl	Cover Girl Nail Slicks	<i>Procter &amp; Gamble Inc. (Noxell Corp)</i>	Hunt Valley, MD 21030
Hard Candy	Nail Enamel	<i>Hard Candy, Inc.</i>	Beverly Hills, CA 90211
Loud Music	Nail Enamel	<i>Sel-Leb Marketing</i>	Patterson, NJ 07524
M	M Professional Nail Polish	<i>Professional Makeup Company</i>	Hollywood, CA 90028
Max Factor	Diamond Hard Nail Enamel	<i>Procter &amp; Gamble Inc. (Max Factor &amp; Co.)</i>	Hunt Valley, MD 21030
Maybelline	Express Finish Fast-Dry Nail Enamel Ultimate Wear (nail enamel) Salon Finish Nail Enamel)	<i>L'Oréal USA (Maybelline LLC)</i> <i>L'Oréal USA (Maybelline LLC)</i> <i>L'Oréal USA (Maybelline LLC)</i>	New York, NY 10017 New York, NY 10017 New York, NY 10017
Nailene	Professional Solutions Acrylic Tough Polish Shield PROfessional Solutions Acrylic Polish Shield PROfessional Solutions Calcium Growth Builder Nail Paints Art Kit	<i>Pacific World Corp.</i> <i>Pacific World Corp.</i> <i>Pacific World Corp.</i> <i>Pacific World Corp.</i>	Lake Forest, CA 92630 Lake Forest, CA 92630 Lake Forest, CA 92630 Lake Forest, CA 92630
NARS	Nail Polish	<i>Agora Cosmetics, Inc.</i>	New York, NY 10012
Naturistics	90 Second Dry Super Fast Nail Color	<i>Del Laboratories, Inc (Naturistics Div.)</i>	Farmingdale, NY 11735
Nutra Nail	Nutra Nail Maximum Strengthener Nutra Nail Calcium Nail thickener Nutra Nail Iron Shield Nail Hardener	<i>CCA Industries, Inc.</i> <i>CCA Industries, Inc.</i> <i>CCA Industries, Inc.</i>	E Rutherford, NJ 07073 E Rutherford, NJ 07073 E Rutherford, NJ 07073
Oil of Olay	Nail Lacquer	<i>Procter &amp; Gamble Inc.</i>	Hunt Valley, MD 21030
Orly	Orly Salon Nails Nail Color	<i>Orly International Inc.</i>	Los Angeles, CA 91311
Sally Hansen	Color Fast! One Coat Fast-Dry Enamel Maximum Support Strengthen & Grow No More Breaks Restructurizing Strengthener Hard as Nails with Nylon Triple Strong Advanced Gel Nail Fortifier Thicken Up! Strengthening Nail Thickener Ultimate Shield Fortifying Base & Top Coat Hard as Nails Instant Strength Calcium Gel Nail Fortifier	<i>Del Laboratories, Inc (Sally Hansen Div.)</i> <i>Del Laboratories, Inc (Sally Hansen Div.)</i> <i>Del Laboratories, Inc (Sally Hansen Div.)</i> <i>Del Laboratories, Inc (Sally Hansen Div.)</i> <i>Del Laboratories, Inc (Sally Hansen Div.)</i> <i>Del Laboratories, Inc (Sally Hansen Div.)</i> <i>Del Laboratories, Inc (Sally Hansen Div.)</i> <i>Del Laboratories, Inc (Sally Hansen Div.)</i> <i>Del Laboratories, Inc (Sally Hansen Div.)</i>	Farmingdale, NY 11735 Farmingdale, NY 11735 Farmingdale, NY 11735 Farmingdale, NY 11735 Farmingdale, NY 11735 Farmingdale, NY 11735 Farmingdale, NY 11735 Farmingdale, NY 11735 Farmingdale, NY 11735
Tony & Tina	Tony & Tina Nail Enamel	<i>Tony &amp; Tina, Inc.</i>	New York, NY 10012
Urban Decay	Nail Enamel	<i>Urban Decay</i>	Costa Mesa, CA 92627
Wet 'n' Wild	Wet 'n' Wild Nail Color	<i>AM Cosmetics, Inc.</i>	North Arlington, NJ 07031

Source: Environmental Working Group.

Our product label searches in electronic and real-world drug-stores showed that, for the consumer, the products most easily found that contain DBP are nail enamels and hardeners. In a limited label search of nail products on online drugstore web sites, EWG found DBP in a wide variety of name brand items, including Cover Girl and Maybelline nail enamels (Table 3).

The difficulty of compiling comprehensive lists of phthalate-containing cosmetics, from label searches alone, led us to conduct a web-based patent search to discover which companies claimed cosmetic-related inventions that included phthalates as ingredients. As of October 5, 2000, the U.S. Patent and Trademark Office had records of 309 patents related to cosmetics that included DBP as an essential or optional ingredient, or as an ingredient in an example product formulation. Thirty-eight individual companies or inventors hold 105 recent cosmetic-related patents that propose DBP as an additive (Table 4).

In some patents, companies gave information on the percent by weight of DBP proposed to be added to the product. DBP in nail polishes tends to be added at about five percent by weight (for example, Maybelline nail enamel patent 5972095), but DBP in other products ranged up to 20 percent, in a night cream invented by the Japanese

**Table 4. Procter and Gamble holds more phthalate-related cosmetic patents than any other company (37 of 105 patents analyzed).**

Assignee	Number of patents	Products for which DBP is proposed as essential or possible additive
The Procter & Gamble (Cincinnati, OH)	37	lotion, hairspray, mousse, gel, lotion, cream, pomade, hair spray, conditioner, spritz, hair tonic, facial moisturizers, foundations, lipsticks, mascaras, nail polishes, oral pharmaceuticals, hair loss treatments
L'Oréal (Bureau D. A. Casalonga-Josse)	10	hair and nail products
Lever Brothers Company (New York, NY)	4	deodorant, skin and hair cleansers
LVMH Recherche (FR)	4	nail varnish
Shiseido Co., Ltd. (Tokyo, JP)	4	skin cream for pharmaceuticals or night cream
Kirker Enterprises, Inc. (Paterson, NJ)	3	nail enamel
Mansouri; Zari (828 Port Walk Pl., Redwood Shores, CA 94065)	3	skin lotions
Maybelline Cosmetics Corporation (Wilmington, DE)	3	nail enamel
Woodward Laboratories, Inc. (Los Alamitos, CA)	3	nail products
Almell, Ltd. (Dallas, TX)	2	nail products
Astra Aktiebolag (Sodertalje, SE)	2	lotions and skin creams
Bar-Shalom; Daniel (Rypevaenget 213, DK-2980 Kokkedal, DK); Bukh; Niels (Strandvejen 122, DK-2900 Hellerup, DK)	2	product to treat or prevent baldness
Focal, Inc. (Lexington, MA)	2	in creams, gels, powders, etc applied to skin
Perio Products, Ltd. (Jerusalem, IL); Yisum Research Development Company of the Hebrew University of Jerusalem (Jerusalem, IL)	2	product to treat tooth and gum disease
Akzo Nobel NV (Arnhem, NL)	1	fabric softeners and personal care compositions
Anheuser-Busch, Incorporated (St. Louis, MO)	1	gelled antiperspirant
Chesebrough-Pond's USA Co., Division of Conopco, Inc. (Greenwich, CT)	1	product to treat or prevent baldness
Colgate Palmolive Company (New York, NY)	1	antiperspirant and deodorant gels
Digestive Care Inc. (Lebanon, NJ)	1	coating ingredient for oral pharmaceutical
Eastman Chemical Company (Kingsport, TN)	1	nail products
E-L Management Corp. (New York, NY)	1	foundation, blushes, eye shadow, lipstick
Elizabeth Arden Co., Division of Conopco, Inc. (New York, NY)	1	skin products
Goldiner; Arthur (1565 Strand Way, Oceano, CA 93445); Campese; Linda (1565 Strand Way, Oceano, CA 93445)	1	custom fit teeth
Henkel Kommanditgesellschaft auf Aktien (Duesseldorf, DE)	1	skin care and hair care formulations
Kao Corporation (Tokyo, JP)	1	emulsion for general cosmetics
Kao Corporation (Tokyo, JP); Taiyo Kagaku Co., Ltd. (Yokkaichi, JP)	1	hair care products
Kraft General Foods, Inc. (Northfield, IL)	1	sunscreen
Laboratoires Virbac (Carros, FR)	1	added to stabilize drugs
Minnesota Mining and Manufacturing Company (St. Paul, MN)	1	general cosmetics and personal care products
Mitsui Toatsu Chemicals, Inc. (Tokyo, JP)	1	hair care products
Resler; Renee (3046 E. Marlette, Phoenix, AZ 85016)	1	nail products
Revlon Consumer Products (NY, NY)	1	nail enamel
Rhodia Chimie (Courbevoie, FR)	1	hair and skin care products (sprays, tonic lotions, gels, mousses)
Rhone-Poulenc Chimie (Courbevoie Cedex, FR)	1	nail varnishes
Unilever Patent Holding B.V. (Vlaardingen, NL)	1	skin and hair care products, antiperspirants
Wacker-Chemie GmbH (DE)	1	nail varnish
Warner-Lambert Company (Morris Plains, NJ)	1	chewing gum and candy
Witco Corporation (Greenwich, CT)	1	conditioning products for skin and hair

Source: Environmental Working Group.



**Scientists in Hamburg, Germany showed that water-soluble components of the polish, like DBP, are dissolved out of the polish each time they contact water.**

company Shiseido (patent number 5891846) (Table 5).

**Why the cosmetic industry adds phthalates to their products**

Multiple chemical properties of DBP make it a useful additive in many types of cosmetics. These properties include its ability to impart flexibility to thin films for mascara and nail polish, its oily texture that makes skin feel soft, and its ability to make lotions penetrate deeper into the skin (Table 6).

**DBP as a plasticizer in nail enamel**

The plasticizing and film-formation properties of DBP make the chemical particularly

useful for nail polish. After nail polish is applied, some of the ingredients volatilize and leave behind a film that is the coating over the nail. DBP is one of the ingredients left behind, reducing brittleness and cracking in the polish.

If the DBP stayed intact in the polish, women might absorb negligible amounts of the chemical into their bodies. But a group of scientists in Hamburg, Germany showed that water-soluble components of the polish, like DBP, are dissolved out of the polish each time they contact water, a conclusion they reached after measuring the leaching of DBP from nail polish that had dried for three days. In fact, one of the reasons nail

**Table 5. Consumer products ranging from skin cream to oral pharmaceuticals can contain up to 20 percent DBP, according to example product formulations given in company patents.**

Company	Product	DBP in product by weight
Procter & Gamble (Cincinnati, OH)	long wear nail polish	7%
Shiseido Company, Ltd. (Tokyo, JP)	oil essence	10%
Woodward Laboratories, Inc (Los Alamitos, CA)	nail coating	3.4%
L'Oreal (France)	treatment base for nails	3.8%
Procter & Gamble (Cincinnati, OH)	pump hair spray	0.2%
Kirker Enterprises, Inc (Paterson, NJ)	nail enamel	7%
Maybelline Cosmetics Corporation (Wilmington, DE)	nail enamel	5%
Shiseido Company, Ltd. (Tokyo, JP)	night cream	5%
LVMH Recherche (France)	nail enamel	6-8%
Shiseido Company, Ltd. (Tokyo, JP)	skin cream	20%
Wacker-Chemie GmbH (Denmark)	nail varnish	2%
L'Oreal (France)	nail varnish	5%
Digestive Care Inc. (Lebanon, NJ)	coating for oral drugs	2%
Kao Corporation (Tokyo, JP)	cosmetic emulsion	7%
Procter & Gamble (Cincinnati, OH)	oral drugs	5 mg per dosage unit
Anheuser-Busch, Incorporated (St. Louis, MO)	antiperspirant gel	10%

Source: Environmental Working Group.

polish eventually chips is that it becomes brittle as DBP is leached out of the film. This means that every time a woman washes her hands, DBP is washed out of her nail polish and contacts her skin. The scientists conclude that “water-soluble components... attain the skin during extensive but transient contact.” Therefore, a woman wearing nail polish not only can absorb DBP through her nail, but also has multiple opportunities to absorb DBP directly through her skin.

Since the 1940’s scientists have known that nail polish contains allergenic ingredients (Sainio et al 1997). Some companies are beginning to study formulations of nail polish that have reduced quantities of DBP, because of concerns over allergic reactions. The well-known French cosmetics company L’Oréal, in patent number 5,676,935, claims “Nowadays, it is preferable to use plasticizers other than phthalates in varnishes for reasons of allergy...” In fact, allergic responses to DBP can be severe. In a 1999 case study published in the journal *Dermatology*, the authors describe a case of anaphylactic shock, a severe allergic reaction, in a patient exposed to DBP in the coating of an oral pharmaceutical (Gall et al 1999).

The ability of DBP to cause allergic reactions means that the chemical can induce a state of hypersensitivity in the immune system. Environmental antigens

**Table 6. DBP is used in cosmetics most often as a plasticizer, to reduce brittleness and cracking, but is also used to soften and moisturize skin, and as a penetration enhancer.**

Function of DBP in cosmetic product	Percent of patents in which DBP serves that function
Plasticizer	49%
Humectant	24%
Solvent	16%
Coalescent	4%
Penetration enhancer	2%
Emollient	2%
Gastric-acid resistant polymer coating "oily material"	1%
	1%

Source: Environmental Working Group.

such as DBP can cause the immune system to respond to chemical exposures with immunological reactions that are harmful, varying from hives to life-threatening responses such as anaphylactic shock, where low blood pressure and breathing difficulties can result in death.

L’Oréal USA is still using DBP in their nail products – for example, in their Maybelline Express Finish Fast-Dry, Ultimate Wear, and Salon Finish nail enamels that EWG found on the shelves of a Rite-Aid drugstore in Washington DC, in September 2000. Even DBP’s well-recognized effects on the immune system have not been enough to change manufacturers’ practices.

**DBP as a “penetration enhancer”**

Both Elizabeth Arden Company (New York, New York) and Chesebrough Ponds (Greenwich,

**The well-known French cosmetics company L’Oréal, in patent number 5,676,935, claims “Nowadays, it is preferable to use plasticizers other than phthalates in varnishes for reasons of allergy...”**

**Industry continues to use DBP specifically for its ability to absorb deep into the skin.**

Connecticut) hold patents for cosmetics in which DBP is proposed as a penetration enhancer.

Elizabeth Arden proposes DBP as an additive to skin care products, where DBP is used to get more of the product deeper into the skin: “improving [the product’s] delivery through the stratum corneum to its site of action in the epidermis.” Similarly, Chesebrough Ponds proposes that DBP can be added to a hair growth formulation for men to help the formulation penetrate deeper into the scalp to the site of action at the hair follicles.

Research from the chemical giant Zeneca gives more evidence that DBP acts as a penetration enhancer. Their work shows that when DBP is added to products for the skin, allergic reactions are more severe (in this case, to ingredients other than DBP). The scientists postulate that the enhanced allergic reactions stem from DBP’s ability to deliver the chemicals deeper into the skin (Dearman et al 1996).

The use of DBP as a penetration enhancer stands in direct contrast to CERHR’s assertion that “Dermal contact with products containing DBP is possible, but absorption through the skin is most likely minimal.” The Center cites a study of DBP migration through rat skin. CDC, on the other hand, upon discovering

high levels of DBP in women of childbearing age, postulates that dermal absorption is playing a role: “Dermal absorption also occurs at a significant rate for phthalates with short side chains such as ...DBP...,” citing the same rat study as evidence (Blount et al 2000).

Regardless of how various government agencies are interpreting the dermal absorption study in rats, industry continues to use DBP specifically for its ability to absorb deep into the skin.

**DBP as a humectant and emollient**

DBP is listed as a humectant or emollient in patents from Procter & Gamble Company (Cincinnati, OH), Lever Brothers Company Inc (New York, NY), Colgate Palmolive Company (New York, NY), Kraft General Foods (Northfield, IL), Anheuser-Busch, Incorporated (St Louis, MO) and four other companies. Humectants are skin moisturizers; emollients soften the skin. Information in patents from these major companies indicate that DBP is added to skin care products because its oily texture gives the impression that the skin itself is soft and moisturized, when in fact it is the DBP residue that makes the skin feel this way.

## References

Blount BC, MJ Silva, SP Caudill, LL Needham, JL Pirkle, EJ Sampson, GW Lucier, RJ Jackson, JW Brock. October 2000. Levels of seven urinary phthalate metabolites in a human reference population. *Environmental Health Perspectives*. 108(10):979-982.

Castleman, BI, and GE Ziem. 1994. American Conference of Governmental Industrial Hygienists: Low Threshold of Credibility. *American Journal of Industrial Medicine*. 26:133-143.

Center for the Evaluation of Risks to Human Reproduction (CERHR), National Toxicology Program, U.S. Department of Health and Human Services. October 2000. NTP-CERHR Expert Panel Report on Di n Butyl Phthalate. NTP-CERHR-DBP-00.

Dearman RJ, Cumberbatch M, J Hilton, HM Clowes, I Fielding, JR Heylings, I Kimber. 1996. Influence of dibutyl phthalate on dermal sensitization to fluorescein isothiocyanate. *Fundam Appl Toxicol* 1996 Sep;33(1):24-30.

Ema M, Amano H, Ogawa Y. 1994. Characterization of the developmental toxicity of di-n-butyl phthalate in rats. *Toxicology* 86:163-174.

Ema M, Kurosaka R, Amano H, Ogawa Y. 1995. Comparative developmental toxicity of n-butyl benzyl phthalate and di-n-butyl phthalate in rats. *Arch Environ Contam Toxicol* 28:223-228(1995).

Ema M, Miyawaki E, Kawashima K. 1998. Further evaluation of developmental toxicity of di-n-butyl phthalate following administration during late pregnancy in rats. *Toxicol Lett*:87-93(1998).

Environmental Protection Agency (EPA). 1990. Integrated Risk Information System. Dibutyl phthalate, CASRN 84-74-2. October 1990. Available online at <http://www.epa.gov/ngispgm3/iris/>

Foster PM, BG Lake, LV Thomas, MW Cook, SD Gangolli. 1981. Studies on the testicular effects and zinc excretion produced by various isomers of monobutyl-o-phthalate in the rat. *Chem Biol Interact* 1981 Mar 1;34(2):233-8.

Gall H, Kohler A, and Peter RU. 1999. Anaphylactic shock reaction to dibutyl-phthalate-containing capsules. *Dermatology*. 199(2):169-70.

Gray LE, Jr, Wolf C, Lambright C, Mann P, Price M, Cooper RL, Ostby J. 1999. Administration of potentially antiandrogenic pesticides (procymidone, linuron, iprodione, chlozolate, p,p'-DDE, and ketoconazole and toxic substance (dibutyl- and diethylhexyl phthalate, PCB 169, and ethane dimethane sulphonate) during sexual differentiation produces diverse profiles of reproductive malformations in the male rat. *Toxicol Ind Health* 15:94-118(1999).

Kohn MC, Parham F, Masten SA, Portier CJ, Shelby MD, Brock JW, Needham LL. October 2000. Human Exposure Estimates for Phthalates. *Environmental Health Perspectives* 108(10).

Marsman DS. 1995. NTP technical report on toxicity studies of dibutyl phthalate (CAS No. 84-74-2) administered in feed to F344 rats and B6C3F1 mice. NIH Publication 95-3353. Research Triangle Park: National Toxicology Program.

Moline JM, Golden A, Bar-Chama N, Smith E, Rauch M, Chapin R, Perreault S, Schrader S, Suk W, Landrigan P. September 2000. Exposure to hazardous substances and male reproductive health: a research framework. *Environmental Health Perspectives*. 108(9).

Mylchreest E, Cattley RC, Foster PM. 1998. Male reproductive tract malformations in rats following gestational and lactational exposure to di(n-butyl) phthalate: An antiandrogenic mechanism? *Toxicol Sci* 43:47-60(1998).

Mylchreest E, Sar M, Cattley RC, Foster PM. 1999. Disruption of androgen-regulated male reproductive development by di(n-butyl) phthalate during late gestation in rats is different from flutamide. *Toxicol Appl Pharmacol* 156:81-95(1999).

Mylchreest E, Wallace DG, Cattley RC, Foster P. 2000. Dose-dependent alternations in androgen-regulated male reproductive development in rats exposed to di\_n-butyl phthalate during late gestation. *Toxicol Sci*(2000).

Paulozzi LJ. 1999. International trends in rates of hypospadias and cryptorchidism. *Environmental Health Perspectives*. 107(4). April 1999.

Roach, SA and SM Rappaport. 1990. But they are not thresholds: A critical analysis of the documentation of threshold limit values. *American Journal of Industrial Medicine*. 17:727-753.

Roe D, Pease W, Florini K, and. Silbergeld E. 1997. Toxic Ignorance. *Environmental Defense*. Washington DC. Summer 1997.

Sainio EL, Engstrom K, Henriks-Eckerman ML, Kanerva L. 1997. Allergenic ingredients in nail polishes. *Contact Dermatitis* Oct;37(4):155-62.

Swan SH, Elkin EP, Fenster L. 2000. The question of declining sperm density revisited: An analysis of 101 studies published 1934-1996. *Environmental Health Perspectives*. 108(10). October 2000.

Toppari, J, Larsen JC, Christiansen P, Giwercman A, Grandjean P, Guillette Lj Jr, Jegou B, Jensen, TK, Jouannet P, Keiding N, Leffers H, McLachlan JA, Meyer O, Muller J, Meyts, E R-D, Scheike T, Sharpe R, Sumpter J, Skakkebaek NE. August 1996. Male reproductive health and environmental xenoestrogens. *Environmental Health Perspectives*. 104. Supplement 4.

Wine R, Li L\_H, Barnes LH, Gulati DK, Chapin RE. 1997. Reproductive toxicity of di-n-butyl phthalate in a continuous breeding protocol in Sprague-Dawley rats. *Environ Health Perspect* 105:102-107 91997).



**1718 Connecticut Ave., NW Suite 600  
Washington, DC 20009  
tel 202-667-6982 • fax 202-232-2592  
info@ewg.org • www.ewg.org**