

QUESTIONS AND ANSWERS ABOUT U.S. ANIMAL TESTING OF

COSMETICS

What kinds of products are considered to be cosmetics?

Cosmetic products, as defined by U.S. law, include shampoo, soaps, perfumes, makeup, moisturizers, lipsticks, nail polish, hair colors, toothpastes, and deodorants.¹

Who regulates cosmetics in the U.S. and under what laws?

The marketing of cosmetics in the U.S. is regulated by the Office of Cosmetics and Colors within the Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA)² and the Fair Packaging and Labeling Act.³

Does FDA specifically require that cosmetics or their ingredients be tested on animals?

No. In contrast to most other products regulated by FDA, cosmetics and their ingredients are *not* subject to specific testing requirements or pre-market approval by the agency. However, the FFDCA broadly prohibits the marketing of “adulterated” or “misbranded” cosmetics, including any product (other than a hair dye) that “bears or contains any poisonous or deleterious substance which may render it injurious to users....”⁴⁻⁵ In other words, cosmetic manufacturers are responsible for assuring the safety of their products and the ingredients they use, but are not required to use animal tests to do so.

Are there other ways that cosmetics or their ingredients may be subject to animal testing?

Yes. In some cases, a substance used as cosmetic ingredients may also fall within the scope of another regulatory program that does require animal testing (e.g., high production volume chemicals regulated by the U.S. Environmental Protection Agency).⁶ In addition, if a company wishes to export its products to a country that does require animal testing of cosmetic ingredients and/or finished products, the company will have to choose between conducting the testing to satisfy the regulatory requirements of the importing country, or forfeiting a potential market. Examples of emerging markets with specific animal testing requirements for cosmetics include China and Brazil.⁷

¹ <http://www.cfsan.fda.gov/~dms/cos-218.html>

² <http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm>

³ <http://www.fda.gov/opacom/laws/fplact.htm>

⁴ <http://www.fda.gov/opacom/laws/fdcact/fdcact6.htm>

⁵ <http://www.cfsan.fda.gov/~dms/fdahdye.html>

⁶ <http://www.hsus.org/web-files/PDF/ARI/chemicals.pdf>

⁷ http://ec.europa.eu/enterprise/cosmetics/html/cosm_comparative_study.htm

What animal tests may be carried out on cosmetics?

Some or all of the following types of toxicity tests⁸ may be carried out on cosmetic products and/or their raw ingredients:

- Acute systemic toxicity in rodents or rabbits
- Eye and skin irritation *in vitro* and/or in rabbits
- Skin allergy in mice or guinea pigs
- Skin absorption *in vitro* or in rodents
- Phototoxicity *in vitro* or in rodents
- Absorption, distribution, metabolism and elimination studies in rodents
- Repeated-dose (1, 3 and/or 12 month) general toxicity studies in rodents and/or dogs
- Reproductive toxicity in at least two generations of rodents
- Developmental toxicity in rabbits and/or rodents
- Genetic toxicity studies of at least 3 varieties *in vitro* and/or in rodents
- Lifetime (18-24 month) cancer studies in mice and/or rats

How many animals may be used in cosmetics testing?

Some of the tests above consume hundreds or thousands of animals per study. Unfortunately, laboratory-bred rats and mice and non-mammalian species are not covered under the U.S. Animal Welfare Act standards for animals used in experiments, and as such, statistics concerning their use are not recorded or made publicly available.⁹ However, according to European statistics for 2005, the testing of cosmetic ingredients consumed approximately 0.5% of all animals used in toxicological and other safety evaluations that year.¹⁰

Are animal tests accurate predictors of human health hazard?

Not necessarily. Animal tests may under- or over-estimate human health hazards. For example, studies of acute lethality and birth defects in rats have been shown to be poor predictors of similar test results in mice and rabbits—let alone the real-world health risks for people. The same is true for rodent cancer studies and other types of animal tests. For example, both rat and rabbit tests failed to predict the developmental hazards of PCBs, industrial solvents, and many drugs, while cancer tests in rats and mice failed to detect the hazards of asbestos, benzene, cigarette smoke, and many other substances—delaying consumer and worker protection measures by decades in some cases.¹¹

What are some practical alternatives to animal testing?

A number of *in vitro* and other alternative methods germane to cosmetic safety assessment have been endorsed as scientifically valid by the European Centre for the Validation of Alternative Methods (ECVAM) and its counterparts worldwide for toxic effects including skin and eye irritation, acute lethality, skin allergy, genetic mutation, and toxicity to the developing embryo.¹²

What is the Humane Society doing to help animals used in cosmetics testing?

The Humane Society of the United States and Humane Society Legislative Fund are actively working to end animal testing—permanently. We are working to promote greater reliance on available non-animal testing methods, and are actively supporting the vision of “twenty-first century toxicology” articulated by the U.S. National Research Council, which would see animal tests that are decades old,

⁸ http://www.hsus.org/animals_in_research/animal_testing/toxicity_testing_overview.html

⁹ <http://www.nal.usda.gov/awic/legislat/awa.htm>

¹⁰ http://ec.europa.eu/environment/chemicals/lab_animals/pdf/staff_work_doc_sec1455.pdf

¹¹ http://www.hsus.org/animals_in_research/animal_testing/limitations-of-animal-methods.html

¹² http://www.hsus.org/animals_in_research/animal_testing/alternatives.html

costly, slow and of dubious relevance to people replaced by ultra-modern, efficient and human-relevant non-animal methods.¹³ We are calling for a “big biology” project to meet this challenge, akin to the Human Genome Project of the 1990s, and are forging an international, multi-stakeholder consortium to help make this landmark vision a reality as quickly as possible.

The Humane Society is also a founding member of the Coalition for Consumer Information on Cosmetics (*LeapingBunny.org*), an international federation of animal protection organizations whose goal is to urge cosmetic and household product manufacturers to sign on to our internationally recognized Corporate Standard of Compassion of Animals—a rigorous policy that ensures manufacturers and suppliers will not conduct or commission animal tests and will not use any ingredient or formulation that is tested on animals. Companies that sign the standard may portray the coalition's “leaping bunny” logo on all of their products as proof of their commitment to the manufacturing of truly “cruelty-free” products.



The Humane Society of the United States is the nation's largest animal protection organization—backed by more than 10.5 million Americans. For over 50 years, HSUS has worked to reduce suffering and to create meaningful change for animals in laboratories through public education, scientific outreach, legislative advocacy, and strategic partnerships.

Online at HSUS.org/research

The Humane Society Legislative Fund is a social welfare organization incorporated as a separate lobbying affiliate of the HSUS. HSLF works to pass animal protection laws at the state and federal level, to educate the public about animal protection issues, and to support humane candidates for office.

Online at HSLF.org

¹³ http://www.hsus.org/animals_in_research/animal_testing/hsus-projects/human_toxicology_initiative.html