

NTP Center for Phototoxicology
FDA-NIEHS Phototoxicology Research and Testing Laboratory

Year 2006

In 2000, the National Institute of Environmental Health Sciences (NIEHS) in concert with the Food and Drug Administration (FDA) established a phototoxicology research and testing laboratory at the FDA's National Center for Toxicological Research in Jefferson, Arkansas. The laboratory, which is part of the National Toxicology Program (NTP), is designated the NTP Center for Phototoxicology (NCP) and is under the direction of Dr. Paul C. Howard.

Research at the NCP is important because of the public's increasing exposure to ultraviolet (UV) radiation or sunlight through more leisure time spent in outdoor activities and more frequent use of tanning booths. The increasing exposure to UV radiation parallels an increase in skin cancer, and has increased the concern within many federal and health agencies for probable contribution of lifestyle and chemicals on the increased cancer incidence. Information from studies conducted by the NCP should help identify chemicals, such as environmental contaminants, drugs and cosmetics that may contribute to skin cancer development (risk identification). Such knowledge can be used in making decisions for safeguarding public health (risk management), such as those regarding the use of various skin products on sun exposed skin. In addition, important information will become available to the public concerning safe care of the human body's largest organ, the skin.

Focus of NCP Studies

Research and testing activities at the NCP focus on the toxic effects of chemicals in combination with sunlight (phototoxicology) and changes in UV radiation-induced skin cancer by chemicals or other applied agents (photocarcinogenicity). The NCP also conducts mechanistic studies to learn how these effects might occur. The NTP Board of Scientific Counselors provides oversight to the NCP on its priorities and directions and a standing committee (*The Toxicology Study Selection and Review Committee*) examines experimental protocols and the progress of studies.

NCP researchers can emulate terrestrial light in the facility to duplicate human exposure conditions. Solar light is simulated using 6500-watt xenon-arc lights modulated through the use of glass filters to achieve the desired spectrum of solar light. The facility can also perform studies using light from different types of fluorescent tubes, such as those used in UVB emitting fluorescent lamps and in suntan-bed lamps, or laser radiation. Studies use the SKH-1 hairless mouse as the primary test model, and new animal models are being investigated.

The FDA has had an ongoing interest in the phototoxicity and photocarcinogenicity of therapeutics, cosmetics, devices and food supplements/additives. Currently NCP studies focus on:

- Alpha and beta hydroxy acids -- two components common in a large number of skin-care creams and lotions. The studies examine whether there is a relationship between the appearance of sunlight induced skin cancer and the continuous use of these topically applied acids. Use of products containing these chemicals is increasing as the beauty-conscious public seeks drugs or cosmetic preparations that promise to give a more youthful appearance. These results will soon be available in NTP Technical Report 524.

- Aloe vera plant -- has been used for centuries as a non-routine, acute relief for burns. The possibility of acute toxicity and photocarcinogenesis from chronic, topically applied fractions of the aloe vera plant in combination with simulated sunlight are being investigated. Different fractions of the aloe plant have been included in cosmetics, personal hygiene products, dietary supplements, and "nutriceuticals". The impact of chronic exposure to these fractions with or without sunlight is not understood at this time.
- Retinyl palmitate -- is included in many cosmetic products available in the US. Retinyl palmitate is the palmitic acid ester of retinol. Photochemistry, phototoxicity and photocarcinogenicity studies of this topically applied compound have not been systematically conducted, and are currently in progress.
- Nanoscale titanium dioxide and zinc oxide -- are included as sunscreen agents in topical creams. It is not known if these nanoscale particles (one dimension less than 100 nm) will penetrate the skin, and whether their photocatalytic properties will induce toxicity in the skin when irradiated.
- Permanent makeup inks - - are suspensions of inorganic and organic pigments that are injected into the skin to change color or appearance. There have been many reports of adverse reactions to permanent makeup and tattoo inks, and studies are being conducted to determine the toxicity and phototoxicity of ink components.

Many other compounds are being considered for future phototoxicity and photocarcinogenicity studies at the NTP NCP. Some of these compounds are ingredients of topically applied creams or lotions, while others are taken by mouth and systemically distributed.

How Can the Public Be Involved with NCP?

The NTP welcomes the nomination of chemicals and other substances for study from all interested parties, including the public, industry, scientific and medical communities and state and federal government agencies. Nominations submitted for study undergo the usual review and selection process (see fact sheet: NTP Nomination, Review and Selection Process) that includes scientific review of available data and opportunity for public comment. Substances selected for study are generally those of high concern for public or occupational health. For those nominations selected for study, the NTP initiates studies as time and resources permit.

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