

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

**SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986  
(PROPOSITION 65)**

**NOTICE TO INTERESTED PARTIES**

**April 6, 2001**

**REQUEST FOR INFORMATION ON  
SODIUM SACCHARIN (CAS NO. 128-44-9)  
CHEMICAL TO BE CONSIDERED BY OEHHA'S SCIENCE ADVISORY BOARD'S  
CARCINOGEN IDENTIFICATION COMMITTEE**

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency for the implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). The Carcinogen Identification Committee of OEHHA's Science Advisory Board advises and assists OEHHA in compiling the list of chemicals known to the State to cause cancer, which is mandated by Health and Safety Code Section 25249.8. The Committee serves as the State's qualified experts for rendering an opinion whether a chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer.

Sodium saccharin (CAS No. 128-44-9) was added to the Proposition 65 list as a chemical known to the state to cause cancer on January 1, 1988. This chemical was added to the Proposition 65 list as a result of actions taken by the "State's Qualified Experts" at a public meeting held on December 11, 1987.

Since 1987, there has been considerable scientific information raising concerns regarding whether sodium saccharin poses a human cancer risk. In April 1994, OEHHA and the U.S. Environmental Protection Agency jointly sponsored the scientific workshop *Assessing the Cancer Risk of Saccharin and Sodium Saccharin*, which comprehensively reviewed the information available at that time relevant to cancer risk assessment for these chemicals. In 1999, IARC re-evaluated saccharin and its salts, and based on its conclusion that sodium saccharin produces urothelial bladder tumors in rats by a mechanism not relevant to humans because of critical interspecies differences in urine composition, re-classified saccharin and its salts as "not classifiable as to their carcinogenicity to humans (Group 3)." In 2000, NTP released its Ninth Report on Carcinogens in which it removed saccharin from the list of substances "reasonably anticipated to be a human carcinogen."

In light of the considerable new and relevant information on the carcinogenicity of sodium saccharin available since its consideration for listing by the State's qualified experts in 1987, OEHHA is asking the Carcinogen Identification Committee, i.e., the State's qualified experts for carcinogenicity determinations, to review the listing of sodium saccharin to determine whether the chemical should remain on the Proposition 65 list of substances known to cause cancer.

Therefore, sodium saccharin will be referred to the Carcinogen Identification Committee for its reconsideration whether it should be removed from the Proposition 65 list.

In accordance with the OEHHA's process for preparing information on candidate chemicals for review by the State's qualified experts, OEHHA will review the available literature and data on sodium saccharin and develop a hazard identification document based on the evidence of carcinogenicity for this chemical. The Carcinogen Identification Committee will consider the hazard identification document before rendering an opinion whether this chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer and should remain on the Proposition 65 list.

Interested parties or members of the public wishing to provide information relevant to an assessment of the carcinogenicity of sodium saccharin should forward such information to the address given below. The publication of this notice marks the start of a 60-day data call-in period. This period ends on **Tuesday, June 5, 2001**. The information received during this data call-in period will be reviewed and considered by OEHHA as it develops the draft cancer hazard identification document for this chemical.

OEHHA welcomes public participation and public input as part of the scientific assessment. If there is sufficient public interest, a public workshop or other public forum will be held to encourage scientific dialogue prior to completion of the draft hazard identification document.

The draft hazard identification document will be made available for public comment prior to the committee meeting at which the chemical is considered. Notification of the availability of the draft hazard identification document and of the time, date, location, and agenda of any workshop and of the meeting of the Carcinogen Identification Committee where this chemical will be discussed will be provided in a future notice published in the *California Regulatory Notice Register* and posted on OEHHA's Web site at [www.oehha.ca.gov](http://www.oehha.ca.gov).

Relevant information on sodium saccharin should be sent in **triplicate** by mail or fax to:

Cynthia Oshita  
Office of Environmental Health Hazard Assessment  
Street address : 1001 I Street, 19<sup>th</sup> floor  
Sacramento, California 95814  
Mailing address: P.O. Box 4010  
Sacramento, California 95812-4010  
Fax (916) 323-8803  
Telephone: (916) 445-6900

**Relevant information may also be delivered in person or by courier to the above address. In order to be considered, the relevant information must be postmarked (if sent by mail) or received at OEHHA (if hand-delivered or sent by fax) by 5:00 p.m. on Tuesday, June 5, 2001.**