Candidate for Listing via the Authoritative Bodies Mechanism
Retraction of Notice of Intent to List for Imazalil

Office of Environmental Health Hazard Assessment
February 18, 2000

The U.S. Environmental Protection Agency (U.S. EPA), is an authoritative body for purposes of Proposition 65 (Title 22, California Code of Regulations, section 12306 (22 CCR §12306)). U.S. EPA identifies chemicals as causing developmental or reproductive toxicity in implementing its Toxic Release Inventory (TRI) program (*i.e.*, section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA)). On this basis, the U.S. EPA, in 1994, added a number of chemicals to the TRI list and published its findings in the *Federal Register* (**59:**1788-1859, 1994 and **59:**61432-61485, 1994). The Office of Environmental Health Hazard Assessment (OEHHA) has reviewed the basis for these TRI chemical additions in the context of the regulatory criteria governing Proposition 65 listing via the authoritative bodies mechanism (22 CCR § 12306).

OEHHA determined for numerous TRI chemicals that the 22 CCR § 12306 regulatory criteria were met and added those chemicals to the Proposition 65 list on this basis and is in the process of placing other TRI chemicals on the Proposition 65 list of chemicals known to cause reproductive toxicity. Imazalil (CAS No. 35554-44-0), is one of the TRI chemicals. There was significant confusion in the original April 23, 1999 Notice of Intent to List citations such that the Notice was retracted.

<u>Imazalil (CAS No. 35554-44-0)</u>

In the "Justification Document" prepared in conjunction with the Notice of April 23, 1999, OEHHA's findings regarding the three references cited by the U.S. EPA under its TRI of 1994 that identified imazalil as causing developmental toxicity were: (1) the U.S. EPA Integrated Risk Information System (IRIS) database entry supported the Notice (the IRIS database description cited a Chevron, 1975 study that apparently was submitted to U.S. EPA for pesticide registration); (2) the Thienpont rat article was not suitable for use by OEHHA because the brief study description suggested excessive maternal mortality; and (3) the reporting of methods and results in the Thienpont rabbit study was so incomplete as to limit the usefulness of this study for hazard/risk assessment.

After the Notice of Intent to List was published last April, documentation was provided that the Chevron, 1975 study was not available for review. While direct review of all underlying studies by OEHHA is not specifically required by 22 CCR § 12306, it was brought to our attention that U.S. EPA no longer had the Chevron, 1975 study. Therefore, there had been no meaningful opportunity for interested parties to directly review the Chevron, 1975 study. OEHHA tried to retrieve the Chevron, 1975 study using the Master Record Identification Document number (MRID #) given in the IRIS database and cross checking this MRID # in another database, the National Pesticide Informational Retrieval System. The MRID # corresponds with a study denominated as Janssen 598, not Chevron, 1975, the primary study relied upon by OEHHA in its original Notice. Janssen 598 does not correspond to the study parameters in the IRIS database

for Chevron, 1975. On February 1, 2000, U.S. EPA verified that the Chevron, 1975 study was also known as Janssen 597. Janssen 597 also served as the underlying study reported in the Thienpont article concerning rats. This fact was not known to OEHHA at the time of publication of the Notice of Intent to List.

Given the confusion over the identity of the Chevron, 1975/Janssen 597 study and its relationship to the Theinpont article concerning rats, OEHHA is retracting the April 23, 1999 Notice and will reevaluate the potential basis for the listing.