

(Submitted via Internet 12/18/02)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for the Bicyclic Terpene Hydrocarbon Category.

The Terpene Consortium, which represents 21 companies of the Flavor and Fragrance High Production Volume Consortia, proposes that six simple bicyclic terpene hydrocarbons and four mixtures comprised primarily of these six bicyclic terpenes be considered as a chemical category. In support of this proposal, the Terpene Consortium has submitted a thorough and well-organized Test Plan that effectively summarizes an extensive, well-organized Robust Summary. The Robust Summary effectively presents a compilation of experimental and calculated data describing the chemical/physical properties, environmental fate and toxicology of various members of the group. Chemicals addressed in this Robust Summary/Test Plan occur naturally in a variety of plants, including most fruits, vegetables and many spices. They are also present, particularly pinene, in air as a result of off-gassing of trees, primarily conifers. All members of the proposed category have closely related structures and properties and, in our opinion, are appropriately considered as a category.

Studies and calculated data describing fugacity indicate that these terpenes partition primarily into the atmosphere where they have a relatively short half-life. They also readily degrade in sludge and do not otherwise persist in the environment. Studies of the fate of pinene in humans and test animals mammals indicate that this chemical, which would be expected to be representative of the category, is rapidly absorbed, metabolized, and excreted. There is no evidence that these chemicals would bioaccumulate in tissues. The available data indicate these terpenes have low toxicity to fish, invertebrates, plants and animals. They are negative in studies of genotoxicity and have low toxicity in repeat dose studies. Although studies of the reproductive toxicity of these terpenes do not fully meet HPV criteria, additional reproductive toxicity testing could be viewed as unnecessary for HPV purposes in light of the several other indicators of low toxicity for this category of compounds (we regard this as a close call, however). The Test Plan submitted for the bicyclic terpenes makes use of considerable calculated and bridged data based on structure/activity relationships. Given the structural similarities and apparently low toxicity of these chemicals, we consider this acceptable. In summary, we consider the Test Plan for the bicyclic terpenes acceptable as submitted.

Thank you for this opportunity to comment.

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