

not reasonably expect MEK to be carcinogenic.

In the analysis, we use a hazard quotient (HQ) approach to characterize the chronic noncancer risk associated with the exposure to MEK. The HQ is the ratio of a level of exposure for a given substance over a specific time period to a health criterion or reference level for that substance derived from a similar exposure period. We use the maximum annual average ambient concentration as the exposure for the purposes of the chronic HQ calculation. We use EPA's prospective RfC as the chronic health criterion, and we also calculate an HQ using the petitioner's RfC. These criteria encompass a 70-year lifetime of continuous exposure and address the health effect of concern due to chronic inhalation exposures to MEK. In addition, the criteria include the margins of safety built into the IRIS RfC and are, therefore, protective of sensitive subpopulations.

Based on our evaluation of the modeling data presented in the petition, we judge that maximum ambient annual exposures from stationary sources to MEK are not likely to exceed 1 mg/m³. Using EPA's prospective RfC of 9 mg/m³, the HQ for the maximum annual average ambient exposure to MEK is 0.1. This means that a person's maximum exposure would be 10 percent of the RfC.

We judge that the exposures to MEK of actual persons living in the immediate vicinity of an MEK emission source would more typically be at least a factor of two to ten less than 1 mg/m³. Therefore, replacing the maximum ambient concentration with a more realistic exposure scenario yields an HQ less than 0.1. Based on the current information, and given the conservative nature of the parameters used to estimate the maximum exposure, the protective nature of the prospective RfC, and because the petition and subsequent analyses characterize the vast majority of MEK exposures from stationary sources, we conclude that by applying the prospective RfC of 9 mg/m³, potential ambient exposures to MEK may not reasonably be anticipated to cause adverse human health effects.

With regard to the potential for short-term exposures to MEK to result in adverse health effects, we draw a qualitative conclusion. From the petition's modeled 24-hour maximum concentration of 10 mg/m³, and using the conversion factor from EPA's SCREEN3 model User's Guide, we estimate that the maximum 1-hour concentration would not exceed 25 mg/m³. From the Dick *et al.* study, we see that exposures to MEK of up to 590 mg/

m³ and up to 4 hours did not cause adverse effects to human subjects. While we have not developed a short-term human health criterion from that study, we consider the gap between the adverse effects level in the Dick *et al.* study and the 24-hour and 1-hour concentrations to be large enough that we may not reasonably anticipate adverse effects to occur from these exposures. Further, as we state above, we consider the maximum annual average concentration estimates to be overestimates of true exposure. Given that the 24-hour and 1-hour ambient air concentrations were estimated using the same information and methods as the annual average concentrations, we consider these short-term concentrations to be similarly conservative. This provides us with additional confidence that adverse effects from short-term exposures will not occur.

As discussed previously, we will consider the final RfC that results from the IRIS review and substantive public comment as that information becomes available. In addition, we expect to receive information on MEK from industry's submittal to the Agency's Voluntary Children's Chemical Evaluation Program (VCCEP). The VCCEP is intended to provide information to enable the public to understand the potential health risks to children associated with exposures to certain chemicals. Under that program, EPA has asked industries which manufacture or import certain chemicals to develop assessments regarding the potential health effect, exposures, and risks of those chemicals to children. We anticipate industry's submission to the first tier of the VCCEP program will be available during 2003, and we will consider this information when submitted, along with other information and comments we receive, before taking final action on the proposal.

Given the current data, however, we are confident that in applying the prospective RfC of 9 mg/m³ to ambient annual average concentrations of 1 mg/m³ or less, we may not reasonably anticipate MEK to cause chronic adverse human health effects. Neither may we reasonably anticipate adverse effects to occur from short-term exposures.

E. Ecological Risk Characterization and Conclusions

Our review of the petition's ecological risk characterization supports the findings that MEK has limited persistence in water, soil, and air. We further agree that it has a low octanol/water coefficient, a low adsorption

coefficient, and a low bioconcentration factor; therefore, given the available data, it is not anticipated to persist or accumulate in the environment.

A review of the general literature, including EPA databases, indicates that MEK has low environmental toxicity. For example, the daphnid 48-hour lethal concentrations for 50 percent of the testing sample (LC50) range from 2,200 to 5,091 ppm; the green algae 96-hour effective concentration for 50 percent of the population is 1,200 ppm; and the fish 96-hour LC50 ranges from 2,300 to 3,200 ppm. The fish chronic values range is 220 ppm, the daphnid chronic value is 521 ppm, and the algal chronic value is 45 ppm. These concentrations are significantly higher than what we would expect to see in the environment.

The petition included no data on the potential for ecological effects to occur as a result of exposures to media other than water. There are no available data on avian exposure to MEK from the air pathway. There are also no available data on air exposure to plants from MEK. However, there is a database on laboratory mammals regarding air exposures to MEK from which we routinely extrapolate to draw conclusions regarding potential health effects to humans. From this database, we draw a similar conclusion regarding the potential for adverse health effects in mammals that may be exposed to ambient levels of MEK as we did for humans.

Based on our review of all pertinent data supplemented by additional environmental modeling, we have concluded that there are sufficiently adequate data on environmental effects of MEK to determine that ambient concentrations, bioaccumulation, or deposition of MEK may not reasonably be anticipated to cause adverse environmental effects.

F. Transformation Characterization

Methyl Ethyl Ketone is one of several volatile organic compounds (VOC) that transform into acetaldehyde and formaldehyde in the ambient air. Both acetaldehyde and formaldehyde are HAP and classified as probable human carcinogens. Based on a simplified analysis, the petitioner concluded that the contribution to ambient concentrations of acetaldehyde and formaldehyde from MEK transformation is insignificant. This conclusion is largely based on the knowledge that MEK's half-life, about 9 days, is comparatively longer than its transformation products, acetaldehyde and formaldehyde, whose half-lives are about 14 hours and 3 hours, respectively. This implies that MEK's