

water is also reported to occur at a significant rate, and the petition reports MEK to be readily biodegradable in both aerobic and anaerobic environments. The petitioner concluded that MEK is not anticipated to pose an exposure problem in drinking water, and that inhalation is the primary route of exposure for humans living in the vicinity of MEK emission sources.

The petition states that while in the air, MEK decomposes to carbon dioxide, carbon monoxide, and water through various reactions. One of the intermediaries is a probable carcinogen: acetaldehyde. The petitioner maintained that acetaldehyde formed during MEK's transformation disappeared approximately 70 times faster than it was created. Therefore, the petitioner concluded, the rapid dispersion of MEK, coupled with its half-life of about 9 days and the comparatively short half-life of acetaldehyde (about 14 hours), resulted in low ambient levels of MEK-produced acetaldehyde. The petition states that the resulting concentration levels cannot be reasonably anticipated to cause adverse human health effects.

#### C. Human Health Effects Assessment

The petition presents toxicological data, which are used for hazard identification and to determine dose-response relationships, citing the EPA's Integrated Risk Information System (IRIS). These data are also supplemented by an extensive review of the literature that includes articles published after the most recent review of the IRIS database for MEK which occurred in 1992.

The petition concludes that MEK's acute and chronic toxicity are low, and that it demonstrates little or no subchronic toxicity. The petition also reports that MEK has been shown to be without genotoxic activity, but it has not been specifically tested for carcinogenicity. However, the petition states that data on MEK's structure, metabolism, subchronic health effects, and genotoxic effects indicate that it is not likely to have carcinogenic properties.

The petition states that MEK by itself has little potential to produce damage to the nervous system. The petition discusses MEK's ability to potentiate the neurotoxic effects of other chemicals when both are present at relatively high concentrations and concluded that MEK does not pose a neurotoxic hazard to humans under ambient exposure scenarios. The petition also states that MEK has not been shown to produce birth defects (*i.e.*, teratogenicity) and does not produce reproductive effects in subchronic inhalation studies.

The petition takes the position that MEK's developmental toxicity is low, and that developmental toxicity is the basis for the 1992 EPA IRIS Reference Concentration (RfC) for MEK of 1.0 mg/m<sup>3</sup>. The RfC is a peer-reviewed value defined as an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily inhalation exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious noncancer effects during a life time (*i.e.*, 70 years).

The petition provides a review of EPA's derivation of the IRIS RfC for MEK. Based on this review and the application of EPA guidelines that were published after the 1992 update of the MEK RfC, the petitioner proposed a revised criterion for human health effects. The petitioner's proposed revision suggests an increase in the RfC from 1 mg/m<sup>3</sup> to 3.3 mg/m<sup>3</sup>. (The details of the petitioner's reassessment are contained in the docket.)

For short-term exposure, the petition adjusts the revised RfC by eliminating the uncertainty factor of 10 that is used for extrapolating from subchronic to chronic exposure. The resulting short-term human health criterion submitted in the petition is 33 mg/m<sup>3</sup>.

#### D. Risk Characterization and Conclusions Regarding Risks to Human Health

The petitioner characterized human health risks from exposure to the predicted ambient MEK concentration levels by comparing the maximum estimated annual average concentration to their proposed revised RfC of 3.3 mg/m<sup>3</sup>. Based on the conservatism built into the model estimates, the petitioner concluded that actual maximum annual average ambient concentrations of MEK are unlikely to exceed 1 mg/m<sup>3</sup> for the highest emitting source and will be significantly less than 1 mg/m<sup>3</sup> for all other sources. The petitioner concluded that the available evidence demonstrates that actual exposures are not likely to approach the 1992 IRIS RfC of 1 mg/m<sup>3</sup> and will not exceed the petitioner's revised health criterion of 3.3 mg/m<sup>3</sup>. The petition characterized human health risks from 24-hour exposures by comparing the estimated 24-hour concentrations, 10 mg/m<sup>3</sup> with a human health benchmark of 33 mg/m<sup>3</sup>, and determined that these short-term concentrations will not approach their criterion of 33 mg/m<sup>3</sup>. Therefore, the petitioner concluded that adverse human health effects arising from ambient exposures to MEK emissions cannot be reasonably anticipated to occur.

#### E. Ecological Assessment and Conclusions

The petition presents ecological toxicity data for environmental effects as the basis for its assessment of the potential ecological risks from the release of MEK to the environment. The petition uses data from several EPA databases and from the general literature. The petition includes no data on the potential for ecological effects to occur due to its presence in media other than water. The petitioner concluded that the available data indicate that MEK has low acute toxicity for aquatic organisms. Although there are no data on chronic aquatic toxicity, the petitioner stated that MEK is not expected to be chronically toxic to aquatic organisms because of its limited persistence in aqueous habitats, which results from its rapid volatilization and biodegradation. The petition compares predicted maximum ambient annual average concentrations to the identified ecotoxicity endpoints. Based on that comparison and information on MEK's environmental behavior, the petitioner concluded that MEK cannot reasonably be anticipated to cause significant and widespread adverse environmental effects.

#### IV. EPA Analysis of the Petition

The following section presents EPA's evaluation and analysis of the petition to delist MEK. The technical review was conducted by EPA's Office of Air and Radiation, with assistance from EPA's Office of Research and Development. The supporting review materials are contained in the docket.

##### A. Exposure Assessment

Methyl Ethyl Ketone is a clear, colorless, stable, low-boiling point (79.6 °C), highly volatile (vapor pressure 90.6 torr at 25 °C), highly flammable (flash point 1 °C, auto ignition temperature 515 °C) liquid. It is very soluble in water (240 grams per liter at 20 °C), miscible with organic solvents and forms azeotropes with water and many organic liquids. Methyl ethyl ketone has exceptionally high solvent powers for many natural and synthetic resins. It is used as a solvent in the surface coatings industry, specifically in vinyl lacquers, nitrocellulose lacquers, and acrylics, and is used as a chemical intermediate. Methyl ethyl ketone is also used in other industries for producing adhesives, magnetic tapes, printing inks, degreasing and cleaning fluids, as a dewaxing agent for lubricating oils, as an intermediate in the production of antioxidants, perfumes, and as a catalyst. Methyl ethyl ketone also occurs