

Summary of *Federal Register* notice
"Minimal Risk Levels for Priority Substances and Guidance for Derivation"
(61 Fed. Reg. 25873 - 25882)

On May 23, 1996, the Agency for Toxic Substances and Disease Registry (ATSDR) issued a *Federal Register* notice announcing ATSDR's internal guidance for deriving minimum risk levels (MRLs) for priority hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Section 104. There is no due date for comments.

ATSDR defines an MRL as an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure. MRLs are based on the concept that a threshold level of exposure exists below which no noncancer health effect is likely to occur, and therefore, an exposure level protective against the most sensitive effect also would be protective against all other effects. The most sensitive effect is the first adverse effect that occurs or is expected to occur in humans as dose increases.

MRLs are screening levels used to identify contaminants and potential health effects that may be of concern at hazardous waste sites and releases. Inhalation MRLs are exposure concentrations expressed in units of parts per million for gases and volatile substances. Oral MRLs are expressed as daily doses in units of milligrams per kilogram per day. MRLs for the inhalation and oral routes are derived for acute (1-14 days), intermediate (15-364) days, and chronic (365 days and longer) exposure durations. ATSDR does not establish MRLs for the dermal exposure route.

MRLs are derived from No Observed Adverse Effect Levels (NOAELs), or, from "less serious" Lowest Observed Adverse Effect Levels (LOAELs). ATSDR defines an adverse health effect as a harmful or potentially harmful change in physiologic function, psychological state, or organ structure that may result in an observed deleterious health outcome. This definition is interpreted to indicate that any effect that enhances the susceptibility of an organism to the deleterious effects of other chemical, physical, microbiological, or environmental influences should be considered adverse.

ATSDR acknowledges that a considerable amount of judgment is required in this process and that, in some cases, there will be insufficient data to decide whether an effect will lead to significant dysfunction. ATSDR generally will not derive an MRL if no adverse health effect has been reported in the published peer reviewed literature in any target organ (e.g., all freestanding NOAELs) for a given duration.

The notice also describes ATSDR's method for computing inhalation MRLs. It discusses inter-species extrapolation, LOAEL to NOAEL extrapolation, extrapolation across durations, modifying factors, and intra-human variations. ATSDR states that its current approach for MRL derivation is similar to methods used by EPA to derive Reference Doses (RfDs) and Reference Concentrations (RfCs) for chronic exposures.

The MRLs for Vinyl Chloride can be found in the table on page 25881.

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