

in milligrams of chemical per kilogram of body weight, respectively, at which any test animals died. These values may be more variable than those provided from median lethality tests, but for the purposes of screening large numbers of chemicals, it was deemed necessary to provide a second level screening tool in preference to missing potentially toxic chemicals because they were not adequately tested. For inhalation data, the Agency chose to use LC₅₀ and LC_{LO} values with exposure periods up to eight hours or even with no reported exposure period. EPA recognized that this was a conservative approach, but did not want to miss any acutely toxic chemical of concern.

The Agency also used lethality data from the most sensitive mammalian species and not only those from rats because it was not possible to predict which species is the appropriate surrogate for humans for a given chemical. In addition, because populations are heterogeneous and individuals are expected to vary considerably in their sensitivity to chemical substances, the Agency assumed that humans may be as sensitive as the most sensitive mammalian species tested.

C. Toxicity Data Sources

When the initial list was developed, the Agency used acute toxicity data from the Registry of Toxic Effects of Chemical Substances (RTECS), maintained by the National Institute of Occupational Safety and Health (NIOSH). The RTECS data was compared with the EHS listing toxicity criteria (both primary and secondary). The RTECS data base was used as the principal source of toxicity data for identifying acutely toxic chemicals because it represents the most comprehensive repository of acute toxicity information available with basic toxicity information and other data on more than 79,000 chemicals. Although RTECS is not formally peer-reviewed, data from RTECS is widely accepted and used as a toxicity data source by industry and regulatory agencies alike. The data presented are from scientific literature which has been edited by the scientific community before publication.

III. Proposed Modification of EHS List

A. Basis of Phosmet Listing

Phosmet was originally listed on the EHS list because a four-hour rat inhalation LC₅₀ of 0.054 mg/L, reported in the 1985 RTECS database, met the EHS primary toxicity inhalation criteria of LC₅₀ ≤ 0.5 mg/L. The value in RTECS

was cited from a 1982 Russian publication, which was a compilation of toxicity data for many chemicals.

The TPQ for phosmet depends on its physical state. As a solid, phosmet has a TPQ of 10 pounds if it: (1) Is a powder with particle size less than 100 microns, (2) is in molten form, (3) is in solution, or (4) has a National Fire Protection Association (NFPA) reactivity rating of 2, 3, or 4. Otherwise, the TPQ for phosmet is 10,000 pounds.

B. Gowan's Phosmet Petition

Gowan Company of Yuma, Arizona submitted to EPA a petition dated August 8, 1996 requesting that EPA remove phosmet from the EHS list because it does not meet the toxicity criteria. During EPA's review of the petition, Gowan submitted additional toxicity data and other information. EPA also reviewed acute toxicity data for phosmet previously submitted to EPA's Office of Pesticide Programs (OPP) for the registration of phosmet as a pesticide. Gowan argued that the inhalation LC₅₀ (rat) value of 0.054 mg/liter/4 hours, as cited in RTECS, is unverifiable because the experimental details, study protocol, and quality control procedures are unavailable. Without these experimental details, Gowan maintained that it is impossible to reconstruct and validate the original experiment. In addition, Gowan asserted that this LC₅₀ value is inconsistent with all other available inhalation toxicity data for technical grade (95% purity or higher) phosmet. Gowan also asserted that the phosmet technical grade does not meet the toxicity criteria for listing as an EHS following exposure by the oral or dermal routes, as indicated by a number of experimental studies. Gowan submitted with their petition data from a number of acute inhalation toxicity tests which they believe show that phosmet technical poses a low risk of acute toxicity by inhalation, as indicated by the absence of mortality when test animals were exposed to phosmet vapor or dust. Gowan also claimed that the toxicity studies on phosmet formulations, including wettable powders and liquid formulations, indicate that these phosmet products do not meet the criteria for the EHS list.

Because phosmet is not a high production chemical (less than 2 million pounds annually), EPA focused its efforts on evaluating whether the existing toxicity data meets the primary listing criteria. In addition to the phosmet toxicity data submitted by Gowan and available data from OPP, EPA found data from acute mouse oral toxicity studies identified from a search

of toxicity databases and literature. In July 2001, Gowan supplied EPA with data from five acute oral mouse studies and EPA obtained a journal article on an acute mouse oral toxicity study conducted by the National Center for Toxicological Research (NCTR) of the Food and Drug Administration (FDA). More details of the phosmet toxicity studies and their evaluation can be found in the February 2003 Technical Background Document: Proposed Rule to Delist Phosmet from the EHS List available in the public docket.

C. Review of Phosmet Acute Toxicity Data

1. Phosmet Acute Inhalation Toxicity

The four-hour rat inhalation LC₅₀ of 0.054 mg/L, reported in 1985 RTECS was cited from a Russian publication (Izmerov *et al.* 1982. Toxicometric Parameters of Industrial Toxic Chemical Under Single Exposure) which contained compiled toxicity values for many chemicals, but no study details. In both the Russian and English translation version of this document, the chemical structure given for phosmet is incorrect, which led Gowan to assert that there was some uncertainty as to whether the chemical being tested was indeed phosmet. EPA was not able to obtain the actual phosmet toxicity study conducted by a Russian researcher L.P. Danilenko, but was able to obtain a translation of a Russian 1969 journal article by Danilenko that discussed the rat inhalation study and the results. Based on the chemical name and chemical synonyms (O,O-dimethyl-phthalimidio-methyl-dithiophosphate or phthalophos) used in (Danilenko 1969), EPA believes the chemical being tested was indeed phosmet. No chemical structure was given in the article.

In Danilenko (1969), the following acute toxicity results were reported for phthalophos, also known as Imidan or phosmet: a four-hour rat inhalation LC₅₀ of 54 mg/m³ (0.054 mg/L); a four-hour rat inhalation LC_{LO} of 31 mg/m³ (0.031 mg/L); and a four-hour cat inhalation LC_{LO} of 65 mg/m³ (0.065 mg/L). The tests were performed using an aqueous emulsion of phthalophos (phosmet) on albino rats and cats. The animals were exposed to a liquid aerosol produced by atomization of the preparation with a special sprayer (Boitenko). The concentration of phthalophos (phosmet) in the chamber air was determined by a thin-layer chromatographic method.

However, the Danilenko (1969) article severely lacks key details of the experimental methods, such as the purity of phosmet, extent of animal