

Evaluation and Classification of Inert Ingredients in Pesticide Products

Patti L. TenBrook, Ph.D.

U.S. EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105, tenbrook.patti@epa.gov

The U.S. EPA is authorized by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to register pesticide products. Pesticide products consist of one or more active ingredients, and may contain one or more inert ingredients (inerts). An inert ingredient is any substance, other than an active ingredient, which is intentionally included in a pesticide product. Inerts may be added to improve plant uptake, extend shelf-life, enhance water solubility/dispersion, make application easier, etc. Just as with pesticide active ingredients, inerts are evaluated by the Environmental Protection Agency (EPA) to ensure that there will be reasonable certainty of no harm to human health or the environment if used according to the label. For its evaluation of inerts EPA requires the same minimal data set that it requires for active ingredients. Data requirements (at 40 CFR 158) include residue chemistry, product chemistry, toxicology for human health risk assessment, ecotoxicology, and environmental fate.

Under the List Category Policy of 1987, EPA categorized inerts into four groups, or lists, based on toxicity. List 1 included inerts of toxicological concern; List 2 included potentially toxic inerts with high priority for further testing; List 3 included inerts of unknown toxicity; List 4 was split into two parts: 4a included minimal risk inerts, and 4b included compounds that were generally regarded as safe for current use patterns, but that would need further evaluation for proposed new use patterns.

Due to the toxicological concern, EPA issued a Pesticide Registration notice in 1987 requiring registrants to identify List 1 inerts on pesticide labels. The notice was updated in 1990 to include additional List 1 inerts. Prior to 1987, no inert ingredients were required to be identified on pesticide labels, as registrants consider the identity and composition of inerts to be trade secrets, which are protected under FIFRA.

With passage of the Food Quality Protection Act (FQPA) in 1996 EPA was charged with reassessing all food tolerances and tolerance exemptions for inert ingredients. Based on the reassessments (completed in 2006), EPA now classifies inert ingredients as either food use, non-food use, or minimal risk. Food-use inerts are approved for use in pesticide products applied to food and are those that have tolerances or tolerance exemptions at 40 CFR part 180. Non-food use inerts are permitted for use in products applied to non-food use sites, such as ornamental plants, highway rights-of-way, or rodent control areas. Minimal risk inerts are approved for use under FIFRA Section 25(b), and are often called "4a inerts" in reference to the lists established

by the 1987 policy. The current list of minimal risk inerts is available on the EPA website (www.epa.gov/opprd001/inerts).

In 1997 EPA issued another Pesticide Registration notice regarding inert ingredients. Recognizing that many chemicals that are not the stated active ingredients in pesticide products are not chemically inert (i.e., inactive), and concerned that the term “inert” is often interpreted by consumers to mean “harmless,” EPA encouraged registrants to use the term “other ingredients” rather than “inert ingredients” on pesticide labels.

Two inert ingredients that were reassessed in 2005 are the preservatives butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT). Both of these chemicals are used extensively in food, drugs and cosmetics. EPA had placed them on List 3 (unknown toxicity) based on the 1987 List Category Policy. EPA did a human health hazard assessment based on a suite of toxicological studies that included acute, subchronic and chronic tests, oral and dermal exposures, mutagenicity, carcinogenicity, and reproductive/developmental toxicity. Potential exposure to humans and the environment were evaluated using environmental fate data. Aggregate exposure to humans from all sources was also evaluated. Given the expected BHA and BHT use rates, EPA found reasonable certainty of no harm in its human health risk characterization, and unlikely significant hazard to aquatic or terrestrial organisms in its ecological risk characterization. Both chemicals were exempted from tolerances and so were classified as food use inerts.

References

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