

MANCOZEB

APPENDIX B

PRODUCT FORMULATIONS CONTAINING MULTIPLE ACTIVE INGREDIENTS

The Agency does not routinely include, in its risk assessments, an evaluation of mixtures of active ingredients, either those mixtures of multiple active ingredients in product formulations or those in the applicator's tank. In the case of the product formulations of active ingredients (that is, a registered product containing more than one active ingredient), each active ingredient is subject to an individual risk assessment for regulatory decision regarding the active ingredient on a particular use site. If effects data are available for a formulated product containing more than one active ingredient, they may be used qualitatively or quantitatively.^{1,2}

Acute oral toxicity data (i.e., LD50 values) from mammalian studies for formulated products that contain mancozeb and one or more additional active ingredients are summarized below.

Currently, the Agency's guidance for assessing the potential risk of chemical mixtures is limited to human health applications (USEPA, 2000). However, the guidance includes principles for evaluating mixtures to assess potential interactive effects that are generally applicable. Consistent with EPA's Overview Document (USEPA 2004), the Agency's mixture guidance (USEPA 2000) discusses limitations in quantifying the risk of specified mixtures when there is differential degradation, transport and fate of chemical components following environmental release or application. The LD50 values are potentially useful only to the extent that a wild mammal would consume plants or animals immediately after these dietary items were directly sprayed by the product. Increasing time post application, the differential rates of degradation, transport, etc. for the active ingredients in the formulation only permit a qualitative discussion of potential acute risk (USEPA 2004).

As discussed in USEPA (2000) a quantitative component-based evaluation of mixture toxicity requires data of appropriate quality for each component of a mixture. In this mixture evaluation LD50s, with associated 95% confidence intervals, are needed for the formulated products. The same quality of data is also required for each component of the mixture. Most of the formulated products containing mancozeb have LD50 values greater than the limit dose (>5000 mg/kg) with no associated 95% confidence intervals. Of the formulated products, only five products (EPA Reg. Nos.

¹ Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, Environmental Protection Agency (January 2004) (Overview Document).

² Memorandum to Office of Prevention, Pesticides and Toxic Substance, US EPA conveying an evaluation by the U.S. Fish and Wildlife Service and National Marine Fisheries Service of an approach to assessing the ecological risks of pesticide products (January 2004).

241-00383, 241-00395, 241-00411, 352-00690 and 67690-00035) have definitive LD50 values and associated confidence intervals. Since there are no confidence intervals associated with mancozeb, it is not possible to undertake a quantitative or qualitative analysis for potential interactive effects. However, because the active ingredients are not expected to have similar mechanisms of action, metabolites, or toxicokinetic behavior, it is reasonable to conclude that an assumption of dose-addition would be inappropriate. Consequently, an assessment based on the toxicity of mancozeb is the only reasonable approach that employs the available data to address the potential acute risks of the formulated products.

Pesticide Products Formulated with Mancozeb and Other Pesticide Active Ingredients

MANCOZEB PRODUCTS ^{3,4}

PRODUCT/TRADE NAME	EPA Reg.No.	% Mancozeb	PRODUCT		ADJUSTED FOR ACTIVE INGREDIENT	
			LD 50 (mg/kg)	CI (mg/kg)	A.I Adjusted CI (mg/kg)	A.I Adjusted LD50 (mg/kg)
Ridomil Gold MZ	000100-00803	64	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
Maxim (R) MZ Potato Seed Protectant	000100-00944	9.6	>5050	NA Limit Dose	NA Limit Dose	NA Limit Dose
Maxim MZ	000100-01158	5.7	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
Ridomil Gold MZ WG	000100-01269	64	No Data	No Data	No Data	No Data
Acrobat MZ Fungicide	000241-00383	60	2770	2273-3375	1662	1364-2025
Acrobat MZ WDG Fungicide	000241-00395	60	2770	2273-3375	1662	1364-2025
Stature MZ Fungicide	000241-00411	60	2770	2273-3375	1662	1364-2025

³ From registrant submitted data to support registration. Compiled by Office of Pesticide Programs Health Effects Division.

⁴ Mancozeb LD50: >5000 mg/kg; CI= NA

NA= Not Applicable

			PRODUCT		ADJUSTED FOR ACTIVE INGREDIENT	
PRODUCT/TRADE NAME	EPA Reg.No.	% Mancozeb	LD 50 (mg/kg)	CI (mg/kg)	A.I Adjusted CI (mg/kg)	A.I Adjusted LD50 (mg/kg)
Tops MZ Potato Seed-Piece Treatment Fungicide	000264-00958	6	>5050	NA Limit Dose	NA Limit Dose	NA Limit Dose
MZ-Curzate Potato Seed-Piece Treatment	000264-00972	6	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
Evolve Potato Seed Piece Treatment Fungicide	000264-00973	6	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
Tops-MZ-Gaucha Potato Seed-Piece Treatment	000264-00977	6	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
Gaucha-MZ Potato Seed-Piece Treatment	000264-00978	6	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
DuPont Mankocide Fungicide	000352-00690	15	1925	1179-3144	289	177-472
Potato Seed Treater A-Strep	003468-00059	8	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
Duosan WSB Wettable Powder Turf and Ornamental Fungicide	058185-00031	64	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
Duosan Broad Spectrum Contact Turf Fungicide	058185-00032	64	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
RH-0611	062719-00418	60	No Data	No Data	No Data	No Data

			PRODUCT		ADJUSTED FOR ACTIVE INGREDIENT	
PRODUCT/TRADE NAME	EPA Reg.No.	% Mancozeb	LD 50 (mg/kg)	CI (mg/kg)	A.I Adjusted CI (mg/kg)	A.I Adjusted LD50 (mg/kg)
Gavel 75 DF Agricultural Fungicide	062719-00441	66.7	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
Junction	067690-00035	15	1925	1179-3144	289	177-472
Cuprofix MZ Disperss	070506-00197	30.4	>2000	NA	NA	NA
Moncoat MZ	071711-00008	6	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose