

APPENDIX A

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}.

There are no product LD50 values, with associated 95% Confidence Intervals (CIs) available for malathion.

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 an LD50 with associated 95% CI is needed for the formulated product. The same quality of data is also required for each component of the mixture. Given that the formulated products for malathion do not have LD50 data available 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 malathion is the only reasonable approach that employs the available data to address the potential acute risks of the formulated products.

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).

Pesticide Products Formulated with Malathion and Other Pesticide Active Ingredients

MALATHION PRODUCTS ^{3 4}

PRODUCT/TRADE NAME	EPA Reg.No.	% Malathion	PRODUCT		ADJUSTED FOR ACTIVE INGREDIENT	
			LD 50 (mg/kg)	CI (mg/kg)	LD50 (mg/kg)	CI (mg/kg)
Bonide Fruit Tree Spray	4-59	3	>5000	NA Limit Dose	NA	No Data
Bonide A Complete Fruit Tree Spray	4-122	6	>500	No Data	NA	No Data
Bonide Home Orchard Spray	4-355	6	>5000	NA Limit Dose	NA	No Data
SMCP M/V Fog Solution	769-644	1.5	No Data	No Data	No Data	No Data
X-Cel Oil Plus Malathion	769-646	5.5	No Data	No Data	No Data	No Data
SA-50 Brand Malathion Oil Spray	829-175	5	No Data	No Data	No Data	No Data
Malathion-Methyl Parathion Emulsifiable Liquid	5905-534	39.94	No Data	No Data	No Data	No Data
Ferti-Lome A-C-G Insecticide & Fungicide	7401-163	7.5	No Data	No Data	No Data	No Data
Ferti-Lome Liquid Fruit Tree Spray	7401-438	7.5	No Data	No Data	No Data	No Data

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

⁴ Malathion LD50: Males: 5400 mg/kg; CI: N/A
Females: 5700 mg/kg; CI: N/A

			PRODUCT		ADJUSTED FOR ACTIVE INGREDIENT	
PRODUCT/TRADE NAME	EPA Reg.No.	% Malathion	LD 50 (mg/kg)	CI (mg/kg)	LD50 (mg/kg)	CI (mg/kg)
Clarke ULV Mosquitocide 731	83290-14	63.973	No Data	No Data	No Data	No Data
ULV Mosquitocide 731 Plus	83290-29	30.636	No Data	No Data	No Data	No Data
TOMIC-Malathion Malathion-Pyrenone Residual Spray	11474-96	2	No Data	No Data	No Data	No Data
B.W.A.C.T.	65458-1	37.27	>680	No Data	No Data	No Data