

Appendix A

Diquat Dibromide 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 diquat dibromide 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 product. The same quality of data is also required for each component of the mixture. Given that most of the formulated products do not have LD₅₀ values of the required quality and since LD₅₀ values are not available for all the components of these formulations a quantitative analysis of potential interactive effects is not possible.

In the case of diquat dibromide there are no confidence intervals associated with the LD₅₀ for the active ingredient and 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 diquat

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).

dibromide is the only reasonable approach that employs the available data to address the potential acute risks of the formulated products.

Pesticide Products Formulated with Diquat Dibromide and Other Pesticide Active Ingredients

DIQUAT DIBROMIDE PRODUCTS^{3 4}

			PRODUCT		ADJUSTED FOR DIQUAT CATION	
PRODUCT/TRADE NAME	EPA Reg.No.	% Diquat Cation	LD 50 (mg/kg)	CI (mg/kg)	Adjusted LD50 (mg/kg)	Adjusted CI (mg/kg)
TOUCHDOWN DIQUAT HOME AND GARDEN CONCENTRATE	000100-01179	0.73	>5000	N/A	N/A	N/A
TOUCHDOWN DIQUAT HOME AND GARDEN READY TO USE	000100-01180	0.06	>5000	N/A	N/A	N/A
RAZOR BURN	000228-00446	2.1	>5000	N/A	N/A	N/A
RAZOR BURN READY-TO-USE	000228-00515	0.1	>5000	N/A	N/A	N/A
RAZOR BURN RESIDENTIAL	000228-00516	0.73	>5000	N/A	N/A	N/A
ORTHO SEASON-LONG GRASS & WEED KILLER	000239-02694	0.1	>5000	N/A	N/A	N/A
MON 78365 HERBICIDE	000524-00535	2.9	No Data	No Data	N/A	N/A
MON 79158 HERBICIDE	000524-00546	0.73	>5000	N/A	N/A	N/A
MON 78868 HERBICIDE	000524-00547	0.04	>5000	N/A	N/A	N/A
CHEMSICO GRASS & WEED KILLER M	009688-00106	2.3	3496	3152-3178	80	72-73
CHEMSICO GRASS & WEED KILLER Z	009688-00108	0.23	>5000	N/A	N/A	N/A

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

⁴ Diquat dibromide: rat oral LD50= 810 mg/kg (males); 600 mg/kg (females)

CHEMSICO GRASS & WEED KILLER PP RTU	009688-00126	0.18	>5000	N/A	N/A	N/A
CHEMSICO HERBICIDE CONCENTRATE DG	009688-00188	2.6	>2000	N/A	N/A	N/A
CHEMSICO HERBICIDE DG RTU	009688-00191	0.1	>5000	N/A	N/A	N/A
CHEMSICO HERBICIDE CONCENTRATE DP	009688-00198	0.72	>5000	N/A	N/A	N/A
CHEMSICO HERBICIDE CONCENTRATE DG II	009688-00205	1.9	>5000	N/A	N/A	N/A
CHEMSICO HERBICIDE CONCENTRATE DFC (ALTERNATE II)	009688-00206	2.3	>5000	N/A	N/A	N/A
CHEMSICO HERBICIDE RTU DFC	009688-00208	0.18	>5000	N/A	N/A	N/A
CHEMSICO HERBICIDE CONCENTRATE DT	009688-00211	1.9	>5000	N/A	N/A	N/A
CHEMSICO HERBICIDE RTU DT	009688-00213	0.1	>5000	N/A	N/A	N/A
CHEMSICO HERBICIDE RTU DP	009688-00218	0.045	>5000	N/A	N/A	N/A
CHEMSICO HERBICIDE TSG RTU	009688-00244	0.18	>5000	N/A	N/A	N/A
CHEMSICO HERBICIDE TSA	009688-00248	0.18	>5000	N/A	N/A	N/A
CHEMSICO HERBICIDE CONCENTRATE 4A	009688-00259	2.3	>5000	N/A	N/A	N/A
CHEMSICO HERBICIDE RTU 4A	009688-00264	0.12	>5000	N/A	N/A	N/A
CHEMSICO HEERBICIDE CONCENTRATE 3A	009688-00265	2.3	>5000	N/A	N/A	N/A
MON 78567 HERBICIDE	071995-00028	0.73	>5000	N/A	N/A	N/A

ROUNDUP WEED & GRASS KILLER CONCENTRATE PLUS	071995-00029	0.73	>5000	N/A	N/A	N/A
MON 78365 HERBICIDE	071995-00030	2.9	4443	3608-5472	129	105-159
MON 78906 HERBICIDE	071995-00035	0.04	>5000	N/A	N/A	N/A
MON 78868 HERBICIDE	071995-00038	0.04	No Data	No Data	N/A	N/A
GLYPHOSATE RESIDUAL CONCENTRATE	071995-00040	0.73	>5000	N/A	N/A	N/A
RD 1686 HERBICIDE	071995-00049	0.73	>5000	N/A	N/A	N/A
RD 1689 HERBICIDE	071995-00050	1	>5000	N/A	N/A	N/A