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].

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 an LD50 with associated 95% Confidence Interval (CI) is needed for the formulated product. The same quality of data is also required for each component of the mixture. In the case of Triclopyr, only one product (EPA Reg. No. 71085-29) has a definitive LD50 value with an associated 95% CI. In the case of EPA Reg. No. 71085-29, the toxicity can be attributed to propanil (the other active ingredient in the formulated product). When the LD50 (1750 mg/kg) for this product and its confidence interval (1239-4450 mg/kg) are adjusted for the percent propanil (36.5%), the adjusted LD50 value of 639 mg/kg (CI: 452-1624 mg/kg), the adjusted confidence interval falls within the confidence interval for the propanil technical (868-1343 mg/kg).

Given that the active would not be expected to have similar mechanisms of action, metabolites or toxicokinetic behavior it is also reasonable to conclude that an assumption of dose-addition would be inappropriate. Consequently, an assessment of Triclopyr's

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[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).

potential effect on the CRLF when it is co-formulated with other active ingredients can be based on the toxicity of Triclopyr.

Pesticide Products Formulated with Triclopyr and Other Pesticide Active Ingredients

TRICLOPYR PRODUCTS[3,4]

PRODUCT/TRADE NAME	EPA Reg. No.	% Triclopyr	PRODUCT		ADJUSTED FOR ACTIVE INGREDIENT	
			LD 50 (mg/kg)	CI (mg/kg)	LD50 (mg/kg)	CI (mg/kg)
TAILSPIN	034704-00958	16.1	No Data	No Data	N/A	N/A
GF-1249	062719-00528	22.2	1847	No Data	410	N/A
RICEPYR	071085-00029	3.8	1750	1239-4450	20.9	15-58

[3] From registrant submitted data to support registration. Compiled by Office of Pesticide Programs Registration and Health Effects Divisions.
[4] Triclopyr: Oral LD50= Males: 729 mg/kg; Females : 630 mg/kg, (No CIs reported)
N/A= Not Applicable