APPENDIX A
MULTIPLE ACTIVE INGREDIENT PRODUCT ANALYSIS

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].

In the case of simazine, the acute oral mammalian LD50 value for the technical is at the limit dose (5000 mg/kg) and has no associated confidence interval. 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 and the same quality of data is also required for each component of the mixture. Given that simazine does not have LD50 data with associated confidence interval, 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 simazine is the only reasonable approach that employs the available data to address the potential acute risks of the formulated products.

Review of Open Literature Studies on Multiple Active Ingredient Products

Based on a review of the open literature (February, 2010) for toxicity data on multiple active ingredient registered products containing simazine, no additional data was found.

[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 Simazine and Other Pesticide Active Ingredients

SIMAZINE PRODUCTS [1] [2]

PRODUCT/TRADE NAME	EPA Reg.No.	% Simazine	PRODUCT		ADJUSTED FOR ACTIVE INGREDIENT	
			LD 50 (mg/kg)	CI (mg/kg)	LD50 (mg/kg)	CI (mg/kg)
AllPro Baracide 5PS pelleted herbicide	769-978	0.76	No Data	No Data	No Data	No Data
Drexel Simazat 4L herbicide	19713-171	21.41	3600	2600-5000	771	557-1071
Drexel Simazat 90DF	19713-553	45.0	>2000	NA Limit Dose	No Data	No Data
Prometon 5PS	53883-97	0.76	2745	2466-3024	2086	1874-2298
Pramitol 5PS Pelleted herbicide	66222-23	0.76	3396	3063-3766	26	23-29

[1] From registrant submitted data to support registration. Compiled by Office of Pesticide Programs Health Effects Division.
[2] Simazine LD50= >5000 mg/kg;
CI=Concentration Interval.
NA= Not Applicable