

## **Appendix B: Oryzalin 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<sup>1,2</sup>.

There are no product LD<sub>50</sub> values, with associated 95% Confidence Intervals (CIs) available for oryzalin. 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 LD<sub>50</sub> 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 oryzalin do not have LD<sub>50</sub> 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 oryzalin is the only reasonable approach that employs the available data to address the potential acute risks of the formulated products.

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

<sup>2</sup> 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 Oryzalin and Other Active Ingredients<sup>3,4</sup>**

PRODUCT/TRADE NAME	EPA Reg.No.	% Oryzalin	PRODUCT		ADJUSTED FOR ACTIVE INGREDIENT	
			LD <sub>50</sub> (mg/kg)	CI (mg/kg)	LD <sub>50</sub> (mg/kg)	CI (mg/kg)
HELENA XL2G	00590500556	1	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
XL2G	03816700030	1	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
ORYZALIN 2G	05388300220	1	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
ROUT ORNAMENTAL HERBICIDE	05818500027	1	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
XL 2G TURF AND ORNAMENTAL FERTILIZER CONTAINS BALAN 0.575% + SURFLAN 0.575%	07050600045	1	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
	07050600049	0.575	4444	No Data NA	No CI Data NA	No CI Data NA
UP-SHOT DF HERBICIDE TURF FERTILIZER CONTAINS GALLEY PLUS SURFLAN	07050600053	60	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
	07050600055	0.86	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
XL 2GR DOUBLE O G-PRO HERBICIDE	07050600056	1	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose
	07967600020	1	>5000	NA Limit Dose	NA Limit Dose	NA Limit Dose

<sup>3</sup>From registrant submitted data to support registration. Compiled by the Office of Pesticide Programs Registration Division.

<sup>4</sup>Oryzalin LD<sub>50</sub>= >10000 mg/kg