

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}.

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

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 single formulated product for paraquat dichloride does 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 paraquat dichloride 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 Paraquat Dichloride and Other Pesticide Active Ingredients

PARAQUAT DICHLORIDE PRODUCTS ³

| | | | PRODUCT | | ADJUSTED FOR ACTIVE INGREDIENT | |
|--------------------|-------------|-----------------------|---------------|------------|--------------------------------|---------------------------|
| PRODUCT/TRADE NAME | EPA Reg.No. | % Paraquat Dichloride | LD 50 (mg/kg) | CI (mg/kg) | A.I Adjusted CI (mg/kg) | A.I Adjusted LD50 (mg/kg) |
| Cyclone Star | 100-01316 | 30.1 | No Data | No Data | No Data | No Data |

³ From registrant submitted data to support registration. Compiled by Office of Pesticide Programs Registration and Health Effects Divisions.
Paraquat Dichloride: LD50= Males: 189 mg/kg; Females 125 mg/kg