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MEMORANDUM

SUBJECT: Review of BASF Acute Dietary Risk Assessment

FROM: Kathryn Boyle, Chemist *Kathryn Boyle 3/9/96*  
Risk Characterization and Analysis Branch  
Health Effects Division (7509C)

THRU: Michael Metzger, Acting Chief *Michael Metzger*  
Risk Characterization and Analysis Branch  
Health Effects Division (7509C)

TO: Mark Wilhite  
Accelerated Reregistration Branch  
Special Review and Reregistration Division (7508W)

In response to the acute dietary assessment performed by Health Effects Division (HED) and documented in HED's Vinclozolin Chapter (signed 4/8/96), BASF submitted "Acute Dietary Exposure: Vinclozolin" BASF Reg. Doc. No. 96/5034 (MRID 43983501). BASF's consultant TAS (Technical Assessment System's Inc.) performed an acute dietary assessment using TAS EXPOSURE 4 software with the Monte Carlo option.

TAS's acute dietary assessment was performed using the acute anticipated residues, the percent crop treated data (%CT), and the percent import (%I) data (as supplied by USDA) that were in the HED chapter. The Monte Carlo modeling assumed that vinclozolin residues would be present in the raw agricultural commodity at the specified acute anticipated residue level or that the vinclozolin residue would be zero. The residue distribution was determined by the %CT or %I data. The population subgroup females 13+ years was used since there are developmental concerns for vinclozolin.

One difference from HED's acute dietary risk assessment was that the TAS assessment did not include prunes and plums. Another difference was the use of consumption data from USDA's Continuing Survey of Food Intake by Individuals (CSFII) conducted from 1989 through 1992. HED has in the past accepted the use of this dataset.



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TAS's acute dietary assessment was reviewed by Elizabeth Doyle, SAB, who determined that "the assessment was conducted in conformance with the Acute Dietary Risk Assessment Guidelines and is acceptable for regulatory purposes" and by William Cutchins, CBTS, who concluded that "the residue data and processing factors used in the contractor's DRES analysis are correct".

The TAS estimated exposure using Monte Carlo analysis at the 95th percentile is 0.010527 mg/kg/day. The estimated exposure at the 99th percentile is 0.027761 mg/kg/day.

BASF considered these percentiles appropriate for estimating risk; however, HED has serious concerns on using the 95th or 99th percentile in an acute dietary assessment that incorporates anticipated residues, percent crop treated data, and Monte Carlo analysis. As more and more realistic parameters are incorporated into dietary risk assessments, the resulting risk cannot be considered to be an over-estimation, but a very realistic reflection of actual circumstances.

There are developmental concerns for vinclozolin. The recently signed Food Quality Protection Act mandates the incorporation of special provisions for the protection of infants and children. Therefore, HED believes that the 99.9 percentile is more protective of the special needs of the population subgroup female 13+ years.

The TAS estimated exposure using Monte Carlo analysis at the 99.9 percentile is 0.0608848 mg/kg/day.

The NOEL for calculating the acute dietary risk for vinclozolin is 5.5 mg/kg/day. An MOE of 100 is considered to be protective when the NOEL is taken from an animal study. For the 99.9 percentile females 13+ years,

$$\text{MOE} = 5.5/0.0608848 = 90$$

Thus, for acute dietary consumption of vinclozolin, 0.1 % of the 13+ female population are at risk of having an MOE that is less than 90. The MOE is less than 100. The 0.1% of the population that is at risk can be considered to be in the range of a 10-3 acute dietary risk. HED has concerns for the acute dietary risk scenario, and believes that discussions with the registrant, BASF, are necessary.

This information will be incorporated into HED's revision of the Vinclozolin Chapter.

cc: Elizabeth Doyle  
Bill Cutchins  
Paula Deschamp  
Mike Metzger  
RCAB files