



Department of Pesticide Regulation



Paul E. Helliker
Director

MEMORANDUM

Gray Davis
Governor
Winston H. Hickox
Secretary, California
Environmental
Protection Agency

TO: Ann Prichard, Sr. Environ. Research Scientist
Pesticide Registration Branch HSM-03010

VIA: Joseph P. Frank, Senior Toxicologist
Worker Health and Safety Branch

FROM: Michael H. Dong, Staff Toxicologist (Specialist) *[original signed by M. Dong]*
Worker Health and Safety Branch
(916) 445-4263

DATE: April 25, 2003

SUBJECT: RESPONSE TO BASF'S COMMENTS ON THE HYDRAMETHYLNON RCD
DRAFT

Below is the response to BASF's concerns (received January 3, 2003; Tracking No. SBRA-198658-E) regarding one toxicity-related and two exposure-related estimates used in the risk characterization document (RCD) for hydramethylnon.

BASF suggested that for short-term and intermediate exposures of agricultural handlers, the most appropriate mammalian toxicity study used should be the 21-day rabbit dermal study that had been submitted to the Department for review. The toxicological critical end points are addressed by the Medical Toxicology Branch.

BASF believed that the most appropriate value for dermal bioavailability is derived from the submitted dermal absorption study, which used gel formulations and indicated a lower absorption rate of 1 to 2% (of the applied dermal dose). As stated in an earlier response (Dong, 2003), WH&S used a 5% absorption rate because granular formulation for outdoor uses was the target. It is also explained in the exposure assessment document (p.6) that the use of a gel formulation in the absorption study *might* underestimate the dermal absorption for the granular formulation. While the exposure assessor does not know for certain that this is indeed the case, the typical formulation used for a dermal absorption study acceptable for exposure assessment is the technical.

BASF's third and final concern is that WH&S overestimated the field reentry exposure by using initial deposition values of foliar residues that were based on liquid pesticides sprayed to foliage, instead of those on granular applications. However, WH&S already addressed this issue in its exposure assessment document (p.17) and acknowledged that the hydramethylnon granules, though oily in nature, are likely not as adhesive to the foliage as the sprays that were used in the 21 studies, from which the 95% upper confidence limit of the mean initial deposition foliar residues was derived. The exposure assessor tends to agree with BASF that the dislodgeable foliar residues (DFR) typically are higher from a liquid spray than from a granular application. Nonetheless, this difference cannot be quantified easily even with an extensive review of the limited literature data available today. Based on the data compiled by Klonne (2000), which were referenced by BASF, the difference in DFR between liquid and granular formulations appear to range from approximately 5 to 15% depending on whether geometric or arithmetic



means were used for the comparison. Sears *et al.* (1987) reported similar findings when they compared the DFR of diazinon obtained immediately following application with a liquid and a granular formulation. However, at day 1 post-application and on subsequent days, their data did not show any significant difference in the DFR obtained from treatments with the two different diazinon formulations. Still another uncertainty is that the foliar residue data provided by Sears *et al.* and by Klonne were all on turfgrasses, which typically have slender, shorter, and tender foliage that might be less suitable for the deposition of granules, when compared to the foliage of some other crops on which granular hydramethylnon is allowed. Furthermore, even if adequate data were available to quantify how much the DFR values from the liquid formulation would overestimate those from the granular formulation, the regulatory position would not change as the margins of exposure calculated in the RCD draft were all well above 100, which is the Department's risk assessment benchmark for hydramethylnon.

References

Dong MH, 2003. Review Memo: Response to Clorox' Comments on the Hydramethylnon RCD Draft. HSM-03009. Cal/EPA Department of Pesticide Regulation, dated April 25.

Klonne D, 2000. Evaluation of Transferable Turf Residue Data From Studies Conducted or Purchased by the ORETF. Cal/EPA Department of Pesticide Regulation Data Registration No. 52103-022.

Sears MK, Bowhey C, Braun H, Stephenson GR, 1987. Dislodgeable Residues and Persistence of Diazinon, Chlorpyrifos and Isofenphos Following Their Application to Turfgrass. *Pesticide Science* 20:223-231.