UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

23 AUG 1982

MEMORANDUM

TO: Robert Taylor (25)
Registration Division (TS-767)

SUBJECT: Oryzalin; 3rd Species Teratology Considerations;
TMRC Analysis. CASWELL #623A

Re: Toxicology Branch memos, EPA Reg. No. 1471-1000 (11/27/81, Jaeger); PP#2G2612/EPA Reg No. 1471-1000 (3/24/82, Jaeger); EPA Reg. No. 1471-96/-112 (8/4/82, Jaeger); EPA Reg. No. 1471-1000 (1/15/82, Mauer).

Toxicology Branch has reviewed all available data on Oryzalin with respect to reproduction and teratogenic effects, and is not of the opinion that a third species teratology study is needed. A Rat Teratology Study (NOEL = 2250 ppm), Rabbit Teratology Study (Repeat, NOEL = 125 mg/kg); Rat 3-Generation Reproduction Study (NOEL = 250 ppm); Mutagenicity Studies (negative) support Toxicology Branch's conclusion that Oryzalin has not demonstrated the potential to cause teratogenic effects in the animals evaluated. Toxicology Branch reiterates its request for the repeat Rat Dominant Lethal Assay, which is the only study outstanding in this respect.

Furthermore, EPA's investigation of Oryzalin's safety and health of workers producing it did not determine whether Oryzalin caused the birth defects reported at the Rensselaer factory. The medical histories of persons exposed to Oryzalin during the manufacturing process, summarized by Dr. Price (Elanco) and reviewed by TB, did not contain any adverse data concerning the alledged birth defects in humans. The ongoing OSHA and NIOSH investigation may resolve this issue. It is hoped that Toxicology Branch will stay informed on the OSHA and NIOSH investigations and will be able to provide whatever assistance is necessary in reviewing the available data.

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Toxicology Branch has received an RCB review of Oryzalin residues on various RACs (EPA Reg. No. 1471-1000, 7/21/82, Probst). RCB concluded that there are no finite residues of Oryzalin above 0.01 ppm (limit of detection) for any of the presently published tolerances except peas, which contained residues ranging from NDR (< 0.01 ppm) to 0.02 ppm. Toxicology Branch assumes a similar pattern for potatoes, peppermint hay and spearmint hay but we defer to RCB to conclude such is the case. It is often very nebulous to conclude anything from limit of detection data; however, Toxicology Branch will assume these represent maximum levels likely to be found from the registered uses of Oryzalin, in accordance with label directions. Accordingly, Toxicology Branch concludes that the TMRC for the above considered RACs is from 3.14×10^{-4} to 8.55×10^{-3} mg/day (pending RCB conclusions regarding potatoes, peppermint and spearmint hay). The risk "R" calculated from this dietary exposure is approximately 1.76×10^{-7} to 4.81×10^{-6}.

However, if the residue analysis for potatoes, spearmint hay and peppermint hay is consistent with the other RACs (e.g. limit of detection) Toxicology Branch would conclude an "R" equivalent to the lower value calculated (e.g. 6.41×10^{-7}). Based on the determination by RCB that there is no expectation of residues in meat, milk, poultry or eggs from the intended uses of Oryzalin, Toxicology Branch considers R, the "risk", (calculated above), a very "conservative" value.

R. Bruce Jaeger, Section Head
Review Section I
Toxicology Branch

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