UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: July 5, 1978

SUBJECT: Tolerance for Carbaryl, 100 ppm on Birdsfoot Trefoil, Petition 8E2035 Caswell No. 160

FROM: Toxicology Branch

TO: Mr. Clinton Fletcher
Special Registration Section

Petitioner: IR-4, Project

Residue Chemistry Considerations.

The Residue Chemistry review is not completed, thus our considerations are tentative only. If, however, CB concludes that residues on trefoil are not transfered to meat and milk, tox branch evaluation below becomes valid.

Recommendations:

Contingent on the above the requested tolerance is toxicologically supported.

Review

No toxicology data is contained in the Petition, Union Carbide data is referenced. Below follows an 8 point Summary of Tox considerations.

1. Data base for tolerances.

Oral LD_{50} rat	510 mg/kg
Teratology and reproduction:	
rat teratology	no teratogenic effects at highest level (375 mg/kg).
monkey teratology	no effects at hightes level of 20 mg/kg.
dog teratology	no effects at 3 mg/kg, terate at higher levels.
3 generation reproduction study	NOEL 200 mg/kg/day (highest level).
dominant lethal assay (rat)	NOEL 200 mg/kg/day (highest level).

Chronic/Subchronic/oncogenicity Studies:

one year dog feeding study	NOEL 400 ppm
2 year rat feeding study	NOEL 200 ppm, slight systemic effects at 400 ppm
18 month mouse oncogenicity	negative at 400 ppm, highest level.
18 month mouse oncogenicity	negative at 14 ppm (Bionetic study).

2. Additional Studies required.

   With exception of mutagenicity testing, and contingent on Chemical Standard review, data base on Carbaryl is complete.

3. No action to obtain additional studies

4. Tolerances for Carbaryl are established under 180.169 including tolerances of 100 ppm on Alfalfa and hay, forage, and fodder of a large number of animal feeds.

5-6. Consideration re ADI and Theoretical maximal residue concentrations (TMRC) do not apply to this tolerance since the increment of residues in human food is zero.

7. Carbaryl is an RPAR Chemical, the RPAR document is in the process of being published. The RPAR triggers are teratogenicity in dogs and reduction in non target species.

8. Although an RPAR process is initated on Carbaryl the tolerance can be toxicologically supported since the risk increment for the general public is absolutely zero (Sec. # 5-6 above). (The risk increment for applicators may not be absolutely zero but is insignificant considering the other registered uses of Carbaryl formulation)

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Toxicology Branch
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