

DATA EVALUATION RECORD

1. CHEMICAL: Metolachlor (108801)
2. FORMULATION: Technical
3. CITATIONS: Coquet, B.; Galland, L.; Guyot, D.; Fouillet, X.; Rouaud, J.L. (1974) Three-Month Oral Toxicity Test of CGA 24705 in Dog. A Translation of: Essai de Toxicite de 3 Mois Chez Le Chien par Voie Orale du Produit CGA 24705: IC-DREB-R 740119. Received September 26, 1974 under 5G1553. (Unpublished report Prepared by the Oncins Research and Breeding Center for CIBA-GEIGY Corp., Greensboro, N.C.; CDL:94223-A)
4. TRADE SECRET CLAIM: Yes
5. REASON FOR REVIEW: Generic Standard for Metolachlor
6. REVIEWED BY: W. Thomas Edwards
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Criteria and Evaluation Division
7. DATE OF REVIEW: January 20, 1978
8. TEST TYPE: Subacute Oral Toxicity

- A. Materials and Methods: The test compound was metolachlor, technical, dual, technical, CGA-24704, 93% industrial grade.

The animals were beagle dogs bred on oncins.

The dogs were 6 to 7 months old at start of treatment, and vaccinated against several diseases. They were housed individually, with temperature and humidity controlled. The feed consisted of a paste prepared from dry feed and water. Batches of feed mixtures were prepared weekly containing the different required metolachlor concentrations. The animals were divided into the following groups.

Controls 0 ppm Metolachlor for 15 weeks

Group I: 50 ppm Metolachlor for 8 weeks
1000 ppm Metolachlor for 15 weeks

Group II: 150 ppm Metolachlor

Group III: 500 ppm Metolachlor for 15 weeks except one
was transferred from group III to group I
after 8 weeks.

The dose change after week 8 was reported to be due to the total absence of toxic effects in any of the animals at this stage of the treatment.

- B. Reported Results: No animals died and no abnormal behavior or digestive disorders were reported. No significant differences were noted between control and test animals in blood or urine analyses or by gross of histopathology. Weight change data suggests a somewhat lower feed consumption near end of treating at the 500 and 1000 levels, which might suggest unpalatability. Weight changes were somewhat irregular for all dose levels, even for controls, which suggest that the animals were unwell. No organ weights were included.

Histopathology showed pulmonary lesions. Similar kinds, severity and numbers of lesions were found in all groups including controls and these were "similar to those seen in some bacterial or viral infections."

- C. Conclusions: At dose levels 150 (i.e. 4-5 mg/kg per day) and 500 ppm (i.e., 14-19 mg/kg per day) administered over a period of 15 weeks and also 1000 ppm (i.e., 27-36 mg/kg per day) administered over a period of seven consecutive weeks, there were found no manifestly toxic effects which could be attributed to metolachlor. Although it is inadvisable to have many lesions found in control animals, it is the opinion of this reviewer that this study be accepted as sufficient for our needs.