

US EPA ARCHIVE DOCUMENT

DATE:

8/14/78

Tox Rev 263 OK

SUBJECT: Roundup - glyphosate; Evaluation of Validation of I.B.T. C-1021, BTL 71-58; 90-day Subacute Oral Toxicity Study with Cp7573 in Beagle Dogs,

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WSD 8/14/78

TO: Robert Taylor (25)

EPA Reg.# 528-308  
Caswell# 661A

Registrant: Monsanto Agricultural Products  
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Recommendations:

1. The validated report does not impact adversely on the original TB review. The study is regarded as core minimum data and the NOEL is greater than 2000 ppm in the diet of dogs for 90 days.

Review: Roundup; BTL 71-58; I.B.T. C-1021

- a. Original review by Raymond Landolt, PP4G1444

Four purebred beagle dogs of each sex were fed dietary levels of 0, 200, 600 and 2000 ppm of technical material in their daily diet for 90 days. The animals were observed daily for signs of toxicity and weighed weekly. The following hematologic and blood chemistry determinations were made on all levels tested initially at 42 days and 85 days of the study; RBC, WBC, differential hemoglobin, hematocrit, BUN, serum glucose, SAP, SGOT, SGPT. The following urine analyses were made: albumin; glucose, pH and microscopic elements. The following tissues were weighed: liver, kidney, heart, brain, spleen, gonads, adrenals, thyroid, pituitary gland, small intestine, spinal cord, spleen, stomach, trachea, thyroid gland, uterus, urinary bladder.

Results

No significant abnormalities were reported in any of the parameters investigated for the animals fed 200, 600 and 2000 ppm of Roundup for 90 days.

Conclusion

The no effect level for dogs fed glyphosate for 3 months was greater than 2000 ppm.

b. Package of Materials relating to Validation.

1. Certification statement signed Monte C. Throdhal, Monsanto Company.
2. Exhibit A - Biography of G.L. Wesp.
3. Exhibit B - Biography of F.R. Johansen
4. Exhibit C - Biography of G.J. Levinskas
5. Exhibit D - Audit Statement of G.L. Wesp.
- I. Individual Body Weight Data  
No discrepancies.
- II. Food Consumption Data  
No discrepancies
- III. Hematology  
5 minor discrepancies which do not adversely impact on original TB review.
- IV. Blood Chemistry  
5 minor discrepancies which do not adversely impact on TB review
- V. Urine Analysis  
No discrepancies.
- VI. Individual Organ Weight Data  
4 minor discrepancies which do not impact adversely or original; TB review.
- VIII. Gross & Histologic Findings
  - a. Gross Findings - no discrepancies.
  - b. Histologic findings: focal testicular degeneration was not listed for dogs Nos. 1, 2, 20 & 25. (2 control males 1 male 600 ppm, 1 male 2000 ppm.  
Discrepancies do not adversely impact on original TB review.
6. Validation Statement of F.R. Johansen.
7. Responses to EPA questions.
8. Stability reports - do not adversely impact on original TB Review.
9. Marked Copy of I.B.T. C-1021 showing discrepancies.

Conclusion

The evaluation of the validated I.B.T. C-1021 does not impact adversely on original TB review.

HED/TOX: init: Reto Engler 8/4/78  
gjl

*ES/11/78*