



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

12/13/1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: New Chemical Screen for **Cloransulam-Methyl (XDE-565)**
TECHNICAL. Toxicology and Chemistry Data Requirements.

FROM: Richard Griffin
Registration Section *Richard Griffin* 12/10/95
Risk Characterization and Analysis Branch

THROUGH: Karen Whitby, Section Head *KW* 12/13/95
Registration Section, RCAB
Health Effects Division (7509C)

TO: Karen Hicks, PM 25
Fungicide-Herbicide Branch
Registration Division (7505W)

The following Toxicology and Chemistry data packages supporting the proposed registration of cloransulam-methyl for use on soybeans (5F04560) have been screened for completeness and general acceptability for scientific review.

TOXICOLOGY

1. Metabolism of Triazole-Pyrimidine Ring 14C-Labeled XDE-565 in Fischer 344 Rats. Supplemental Data
GL 85-1
MRID 437234-01/43729401 (submitted twice)
2. XDE-565: Oral Gavage Teratology Study in New Zealand White Rabbits.
GL 83-3b
MRID 437189-04
3. XDE-565: Acute Neurotoxicity Study in Fischer 344 Rats.
GL 81-8
MRID 436689-07
4. XDE-565: Probe and 21-Day Repeated Dose Dermal Toxicity Study in New Zealand White Rabbits.
GL 82-2
MRID 436689-08



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5. XDE-565: 1-Year Dietary Toxicity Study in Beagle Dogs.
GL 83-1(b)
MRID 436689-09
6. XDE-565: Two-Year Chronic Oncogenicity Study in B6C3F1 Mice.
GL 83-2
MRID 436689-10 (6 vols)
7. XDE-565: Two-Generation Dietary Reproduction Study in Sprague-Dawley Rats.
GL 83-4
MRID 436689-11 (4 vols)
8. XDE-565: Two-Year Dietary Chronic Toxicity/Oncogenicity Study in Fischer 344 Rats.
GL 83-5
MRID 436689-12 (7 vols)
9. XDE-565: Tissue Distribution and Metabolism of 14C-Labeled XDE-565 in Fischer 344 Rats.
GL 85-1
MRID 436689-13
10. DE-565: Integrative Summary
MRID 436689-14
11. NAF-75: Probe and 21-Day Repeated Dose Dermal Toxicity Study in New Zealand White Rabbits.
GL 82-2
MRID 436689-15

In support of an EUP with crop destruct, cloransulam-methyl Technical/NAF-75 acute, mutagenic, developmental, and subchronic toxicity studies have been reviewed and determined acceptable (except the Ames/mutagenic test) (A. Levy memo, 3/11/94).

CHEMISTRY

1. Product Identity and Composition of Cloransulam-methyl Technical.
GL Series 61
MRID 436689-01
2. Analysis and Certification of Product Ingredients of Cloransulam-methyl Technical Grade of Active Ingredient.
GL Series 62
MRID 436689-02

3. Determination of the Oxidizing/Reducing Action and Explodability of XDE-565.
GL 63-14 and 63-16
MRID 436689-03
4. Product Identity and Composition of NAF-75, A Water Dispersible Granule Containing Cloransulam-methyl.
GL Series 61
MRID 436689-04
5. A Confined Rotational Crop Study with [14C]XDE-565 Using Wheat, Lettuce, and Potatoes.
GL Subdivision N, 165-1
MRID 436689-19
6. Behavior of DE-565 in Multi-Residue Method Testing Using Methods Outlined in FDA Pesticide Analytical Manual Volume I (PAM I).
GL 171-4
MRID 436689-20
7. [14C]XDE-565: Nature of the Residue in Soybeans Following Postemergent Application.
GL 171-4(a)
MRID 436689-21
8. [14C]XDE-565: Nature of the Residue Study in Soybeans Following Preplant Incorporation.
GL 171-4(a)
MRID 436689-22
9. Nature of the Residue of [14C]XDE-565 in Lactating Goats.
GL 171-4(b) (3)
MRID 436689-23
10. Nature of [14C]XDE-565 Residues in Laying Hen.
GL 171-4(b)
MRID 436689-24
11. Amended Report for Validation Report for the Determination of Residues of XDE-565 in Soybean Grain, Forage and Hay by Capillary Gas Chromatography/Mass Spectrometry.
GL 171-4(c)
MRID 436689-25
12. Amended Report for Independent Laboratory Validation of Method GRM 94.07.RI - Determination of Residues of XDE-565 in Soybean Grain, Forage and Hay by Capillary Gas Chromatography/Mass Spectrometry.
GL 171-4(c)
MRID 436689-26

13. Validation Report for the Determination of Residues of XDE-565 in Soybean Hulls and Crude and Refined Oil by Capillary Gas Chromatography/Mass Spectrometry.
GL 171-4(c) and (d)
MRID 436689-27
14. Frozen Storage Stability of DE-565 in Soybean Forage and Hay.
GL 171-4(e)
MRID 436689-28
15. Magnitude of the Residues of DE-565 in Soybean Forage, Hay, and Grain Following Preplant Incorporated and Postemergence Applications.
GL 171-4(k)
MRID 436689-29
16. Magnitude of the Residues of DE-565 in Soybean Forage, Hay, and Grain Following Preplant Incorporated and Postemergence Applications.
GL 171-4(k)
MRID 436689-29
17. DE-565 Herbicide Applied Postemergent and Preplant Incorporated to Soybeans-Residue Study to Provide Data for Registration.
GL 171-4(k)
MRID 436689-30
18. Magnitude of the Residues of DE-565 in Soybean Grain and its Processed Products.
GL 171-4(l)
MRID 436689-31
19. Interpretive Summary of Cloransulam-methyl (DE-565) Soybean Residue Chemistry.
GL N/A
MRID 436689-32
20. Practical Methods for Removing Residues of Cloransulam-methyl (DE-565) From Soybeans (Section E of Pesticide Petition).
GL 171-5
No MRID
21. Proposed Temporary Tolerances for Cloransulam-methyl (DE-565) on Soybeans (Section F of Pesticide Petition).
GL 171-6
No MRID

22. Reasonable Grounds in Support of the Petition for the
Establishment of Temporary Tolerances for Cloransulam-methyl
(DE-565) on Soybeans.

GL 171-7

No MRID

Based on my comparison of the toxicology and chemistry
guidelines/acceptance criteria with the submitted data packages,
the requirements have been met, and the studies may be assigned
for review.