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CASWELL FILE

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

JUL 26 1993

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Sulfosate: Supplemental Data Pertaining to a 90-Day Oral Toxicity Study in Dogs.

Tox. Chem. No.: 893C
EPA ID No: 128501
Submission No: S383652
DP Barcode: D156528

TO: R. Taylor, PM # 25
Registration Division (H7505C)

for THRU: Roger Gardner, Section Head Pamela M. Hurley 7/20/93
Review Section 1
Toxicology Branch
Health Effects Division (H7509C)

FROM: Nguyen Bich Thoa, Ph.D NBT 07/20/93 KB 7/23/93
Reregistration Section
Chemical Coordination Branch
Health Effects Division (H7509C)

Registrant: ICI Americas, Inc.
Farmington, CT.

ACTIONS REQUESTED:

Review Supplemental data pertaining to a 90-day oral toxicity study in dogs (MRID # 41209903).

CONCLUSIONS:

The supplemental Data in question have been reviewed by TB in 1991 under a different DP barcode (D156532). TB is enclosing a copy of the supplemental data review (memo N. B. Thoa to RD; dated 05/13/91) for RD consideration.

REVIEWER

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

MEMORANDUM

MAY 13

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Sulfosate (trimethylsulfonium carboxymethylamino-methylphosphonate; formerly SC-0224): Company Response.

Project No.: 0-1997
EPA Nos.: 9F03796
MRID No.: 416330-01
Tox. Chem. No.: 893C
Submission No.: S383655
DP BAR CODE: D156532

TO: R.Taylor/C.Giles, PM Team # 25
Registration Division (H7505C)

FROM: Nguyen B. Thoa, Ph.D.
Section I, Toxicology Branch I
Health Effects Division (H7509C) 5/12/91

THRU: Roger L. Gardner, Section Head
Section I, Toxicology Branch I
Health Effects Division (H7509C) 5/12/91 KB 5/16/91

REGISTRANT: ICI Agricultural Products, Wilmington, Delaware.

I. Conclusions:

Technical grade sulfosate (tech SC-0224) is usually supplied as an aqueous solution containing about 52.2% active ingredient. The very viscous nature of sulfosate precludes the practical manufacture of a technical grade with a standard a.i. content (sulfosate forms an intractable glass-like product if its water content is ≤ 30%).

SC-0224 used in the 3-month subchronic oral toxicity study in Beagle dogs (MRID 41209903) is an aqueous solution of the technical product containing 19.2% a.i..

A review of the TOX ONE-LINERS further reveals that several technical sulfosates, each one an aqueous solution with a different a.i. content, were used (1982-present time) in the toxicological studies conducted to support registration of the technical material. These a.i.contents vary from 19.2 to 72%.

II. Action Requested:

Review Addendum to MRID 41209903 (Three months subchronic oral toxicity study with SC-0224 in Beagle dogs) for adequacy of

a.i. concentration of the technical grade test material used.

III. Background:

TB wished to know why the technical grade SC-0224 used in a 3-month subchronic oral toxicity study in Beagle dogs (MRID 41209903) had only an a.i. content of 19.2% (w/w).

The registrant's explanations are on page 5 of their response, a copy of which is attached. The confidential appendix referred on this page is not attached.

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SUMMARY

The Toxicology Branch has requested an explanation of why MRID# 41209903 "Three Month Subchronic Oral Toxicity Study with SC-0224 in Beagle Dogs", Report No. T-11002 was conducted with lower strength technical (19.2% w/w) than we seek to register for use in corn (Tolerance Petition No.9F3796). In the early stages of development before the optimum sulfosate concentration level was established, a 19.2% aqueous solution of the trimethylsulfonium salt of N-phosphonomethyl glycine (SC-0224) was prepared to support certain toxicology studies. A comparison of composition analysis (see Confidential Appendix, Table 1) for typical technical batches containing 19.1% w/w and 52.2% w/w (EPA Reg. No. 10182-00276), indicates the impurities in the batches are essentially the same with only a change in water content. Thus, the sulfosate product has remained essentially the same over time with the only change being a reduction in water.

Experience has shown that if the water content of SC0224 technical is reduced below 30%, the viscosity of the technical is increased until an intractable glass is formed. In this glass form, SC-0224 technical is extremely difficult to remove from a container and is impractical to formulate. Additionally, reducing the water content of SC-0224 requires heating at relatively high temperatures which decreases the chemical stability. For these reasons, experience has show that the only practical way to supply technical sulfosate is as an aqueous solution, preferably near the 52% concentration.

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