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

005745

FEB 26 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

TB Project 1853/1854/1855/1856

SUBJECT: Monocrotophos (AZODRIN) - Appraisal of Company Response to Data Gaps Identified in the Monocrotophos (AZODRIN Insecticide) Registration Standard Accession No. 262893 - ID No. 201-219

Caswell No. 377

FROM: Irving Mauer, Ph.D.
Toxicology Branch
Hazard Evaluation Division (TS-769C)

02-03-87

TO: William H. Miller/Gary F. Otakie, PM Team 16
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

THRU: Judith W. Hauswirth, Ph.D.
Acting Head, Section VI
Toxicology Branch
Hazard Evaluation Division (TS-769C)

Judith W. Hauswirth 2/5/87

2/26/87

Registrant: Shell Oil Company, Washington, D.C.

Action Requested:

Comment on and appraise the following program of toxicological items consisting of additional information and data waiver requests submitted under cover letter dated May 15, 1986 (Hobson to Miller), and given EPA Accession No. 262893 (items numbered as in cover letter):

Letter Items

(4) A request to waive inhalation studies in the rat (81-3), based upon the physical characteristics of the technical product (found at TAB 3 of the registrant's submission).

(5) Additional information (TAB 4 of submission) on the mouse oncogenicity study, SBGR.81.218 (83-2), previously submitted and classified CORE-SUPPLEMENTARY DATA (TB Doc. Nos. 004213/004284).

(6) A protocol for general metabolism in the rat (85-1), but only for a single oral high-dose study. The registrant requests data waivers for a single oral low-dose, multiple oral low-dose, and IV low-dose studies, citing toxicological and analytical justifications (TAB 5 of submission).

(7) A protocol for dermal absorption/penetration (85-2) in the rat (TAB 6 of submission).

(8) A request to waive data on domestic animal safety (86-1), based upon the use pattern of AZODRIN and its known toxicities (TAB 7 of submission).

Background:

The Monocrotophos (AZODRIN) Registration Standard (TB Doc. No. 004284 dated April 2, 1985) identified the following data requirements under FIFRA section 3(c)(2)(B) (p. 20 of the Standard):

1. Inhalation studies in the rat, specifically to determine an LC_{50}, and a 21-day inhalation study among other studies, may be required depending on the amount and nature of residue in tobacco.

2. Dermal sensitization study in the guinea pig.

3. Teratology study in the rabbit.

4. Additional information on the strain of mouse used in the oncogenicity study.

5. General metabolism of low dose, repeated low dose, and high dose in the rat to assess tissue distribution and fate of radioactive AZODRIN/metabolites (especially OP-active derivatives).

The protocol for general metabolism submitted herein ("General Metabolism Data Requirement," found at TAB 5 of Shell's current submission, EPA Accession No. 262893) has been found inadequate by Agency Test Guidelines, Part 2, Subpart H published in the FEDERAL REGISTER September 1985 50 FR, pp. 39470-39471 (see attached memorandum: Mauer to Miller/Otakie,

plus attachments dated July 15, 1986). Further, the protocol for dermal absorption in rats also submitted here ("Dermal Absorption of AZODRIN by Rats," Shell Protocol No. WTP-353, found at TAB 6 of EPA Accession No. 262893), appears to be adequate. It should be noted, however, that a dermal sensitization study in the guinea pig still remains a data gap.

TB Conclusions/Recommendations:

The remainder of the toxicological program of this submission (EPA Accession No. 262893, i.e., Letter Item Nos. (4), (5), and (8)) are appraised in this memorandum.

Letter Item (4): Request to waive acute inhalation LC_{50} study (TAB 3):

In support of his request for a waiver, the registrant suggests the conduct of an adequate acute inhalation study on technical AZODRIN "cannot be accomplished" since:

1. He maintains that the product does not meet the testing criteria under FIFRA Guidelines by its physical characteristics, namely, it is neither a gas nor a solid or liquid which may produce significant vapor hazard, based on its toxicity and expected use; and with such a low vapor pressure, 7.0×10^{-6} mm Hg at 68 °F, either achieving an effective dose, or generating particles of inhalable size for man (15 um diameter), is precluded.

2. He submits a copy of the Material Safety Data Sheet (MSDS No. 820, 002-1, as Attachment I), as well as calculations which determine a maximally achievable total 4-hour inhaled dose of 0.003 mg/kg (based upon saturated vapor concentrations), ". . . a level 5140-fold below the lowest reported level for the acute oral LD_{50} for technical AZODRIN, 16 mg/kg, in rats" (as Attachment II).

Agency Response:

TB has no objections to waiving the requirement for an acute LC_{50} study, based upon the registrant's submission and the rationale derived by Dr. Stanley B. Gross, the Branch inhalation expert (copy of memorandum: Gross to Hauswirth, dated January 29, 1987, attached).

Letter Item (5): Additional information on the mouse oncogenicity study, Report No. SBGR-81-218 (TAB 4):

In response to TB's original review of this study (judged CORE-SUPPLEMENTARY, pending provision of background information on the mouse strain used), the registrant has submitted a narrative addressing each concern, as follows:

1. Mouse strain designation and origin:

The registrant acknowledges not providing full designation and background information for the strain of mouse employed in this study (referred to only as "CD" or "CD-1"). In the current submission the following information is provided, along with copies of relevant literature references to previously submitted studies:

- STRAIN DESIGNATION - Crl:CD®-1(ICR)BR

  ORIGIN- Developed by Dr. T.S. Hauschka, Roswell Park Memorial Institute, Buffalo, NY, from an outbred albino line of Swiss origin; acquired in 1959 by Charles River Breeding Laboratories, Wilmington, MA, and maintained there by cesarean derivation as strain "CD®-1 HaM/ICR," later (to conform to standardized nomenclature) as strain "Crl:CD®-1 (ICR)BR"; purchased as such in 1977 from Charles River UK, Ltd., Manston Road, Margate, Kent, England, and maintained since then at Shell Research Centre (SRC) Laboratory by cesarean section fostered on Specific Pathogen-Free CF1 lactating females.

- BACKGROUND TUMOR RATE - In 1000 consecutive autopsies, the most common lesions (in decreasing order of frequency) were: lymphoreticular, mammary, and pulmonary tumors; osteogenic sarcomas; hemangiosarcomas; and renal and hepatic tumors, with an age-related increased incidence from less than 1/100 among the youngest age group to 50/100 in mice over 20 months (Percy and Jonas, J. Nat. Cancer Inst. 46:1045-1065, 1971 - copy provided as Section 1 of TAB 4).

- INDUCED TUMOR RATE - Seven representative references (copies of articles provided as Section 2) indicate this strain is susceptible

to tumor formation induced by a variety of chemicals (including pesticides such as maleic hydrazide and piperonyl butoxide).

2. Spontaneous convulsions:

In the two oncogenicity studies employing this mouse strain (BLADEX, Report No. SBGR.81.171, MRID 00100503; AZODRIN, Report No. SBGR.81.218, MRID GS015404), the incidence of "convulsive episodes" (described by the registrant as "fright induced seizure," which occur in other species, but ". . . are often not noted as a clinical sign . . . .") in male and female controls was comparable (18.3 and 3.0% in the BLADEX study, 18.8 and 9.1% in the AZODRIN study), and increases in a dose-related manner in treated groups. The registrant, however, does not regard these episodes as "true convulsions," which, narrowly defined, involve ". . . a series of whole body contractions and relaxations, often of a violent nature . . ." and were not observed in the AZODRIN study. In any event, he maintains here that these episodes did not affect the outcome of the study (e.g., by causing increased mortality), as stated in the final report of the study (p. 127).

3. Ocular effects:

The registrant provides references (as Section 4) describing the nature and progression of ocular changes in laboratory rodents, especially those exposed to ". . . the high light intensities of laboratory environments," but notes that no compound-related changes were found in either decedents or survivors. The small number of animals routinely examined (and reason for failure to correlate histological and ophthalmoscopic findings) was gratuitous, since ophthalmoscopy is not a requirement for oncogenicity studies.

4. Identification of "Centrimide":

The registrant describes this substance as follows:

> Cetrimide (Ph.Eur.) is a non-irritant, non-toxic, quaternary ammonium compound with bactericidal and detergent

properties; it is particularly effective against Gram-positive organisms, e.g., Staph. aureus. It is used in wound and burns therapy, as a skin disinfectant and for removal of cutaneous scabs and crusts. It is manufactured in the United Kingdom by Imperial Chemical Industries (I.C.I.) plc.

Agency Response:

TB accepts the additional information on the mouse strain used in the oncogenicity study (SBGR.81.218) as satisfying the reporting deficiencies noted in Agency reviews. This study is upgraded to CORE-MINIMUM DATA.

Letter Item (8): Request to waive data on Domestic Animal Safety (86-1), (TAB 7):

The registrant bases his request for waiver " . . . on the use pattern of this product and what is known about compound toxicity . . . " and submits the following rationale (TAB 7 of EPA Accession No. 262893):

1. AZODRIN Insecticide is not registered for dermal application to domestic animals, nor would such exposure occur if the product is used according to label directions.

2. Established tolerances for treated RAC (or processed items) likely to be incorporated into animal feed (cottonseed, 0.1 ppm; peanut hulls, 0.05 ppm; and sugarcane, 0.1 ppm) are sufficient to vitiate any significant hazard considering (a) the restrictions on grazing treated fields and feeding field trash or treated vines and hay; (b) highest dietary usages of such feed items represent a minority of the diet of domestic animals (for beef cattle: peanut hulls at 5%, and cottonseed at 25%; for dairy cattle, sugarcane at 40%; for poultry, 10% for all possible feed items); and (c) concentration of residues does not occur by processing RAC used as feed items.

3. Dietary exposure studies with radiolabeled monocrotophos at levels well above residue

tolerances conducted in four cows (1,2)* revealed no clinical toxicity, hematological effects, or gross pathological changes (at measured residue levels well below crop tolerances). Milk from the two lactating cows treated contained an average of 0.01 ppm (daily range = 0.004 to 0.22 ppm); tissue residues were 0.02 and 0.03 ppm for meat, and 0.13 and 0.11 ppm for liver. (Cholinesterase activity was not measured in these studies.)

4. No toxicity was observed in one (lactating) goat given a single capsule containing 1 mg/kg doubly radiolabeled monocrotophos (a dose reportedly < 5% of the oral LD_{50} for goats (3)**. Although most of the radioactivity was excreted by 72 hours, the identity of the C-14 activity was not determined (the majority of the P-32 activity was reportedly unchanged monocrotophos); 1.4% of P-32 and 2.9% of C-14 activity appeared in milk within 72 hours. (The registrant has been requested to conduct another goat metabolism study with C-14 monocrotophos to identify and quantitate residues in milk and tissue.)

Footnotes

(1)* Potter, J.C. (1965) Residues of AZODRIN Insecticide in milk. Technical Report No. M-24-65, Modesto, Shell Development Company.

(2)* Young, R. (1965) Cattle tolerance and acceptance of SD 9129 (AZODRIN Insecticide). Technical Report No. M-9-65, Modesto, Shell Development Company.

(3)** Tucker, R.K.; Crabtree, D.G. (1970) Handbook of toxicity of pesticides to wildlife. USDI Fish and Wildlife Service, Publication No. 84, pp. 21-13.

(4)** Menzer, R.E.; Casida, J.E. (1965) Nature of toxic metabolites formed in mammals, insects, and plants from 3(-dimethoxyphosphinyloxy)-N,N-dimethyl-cis-crotonamide and its N-methyl analog. J. Agric. Food Chem. 13:102-112.

Agency Response:

Subject to concurrence by RCB, TB accepts the information provided here which supports a sufficient safety margin for possible secondary residue exposure to humans from edible products of food-producing farm animals ingesting feed containing AZODRIN. It should be noted, however, that an adequate rat metabolism study is still required to satisfy the TB requirement.

Attachments (2)

ATTACHMENTS

REVIEWER

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

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JUL 15 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Monocrotophos --- Company Response to Data Gaps Identified in the MONOCROTOPHOS (AZODRIN INSECTICIDE) REGISTRATION STANDARD (ID # 201-219), submitted under ACCESSION No. 262893.

CASWELL 377

TO: Wm. Miller/G. Otakie, PM 16
Registration Division (TS-767)

FROM: Irving Mauer, Ph. D
Toxicology Branch
Hazard Evaluation Division (TS-769)

07-11-86

THRU: Jane E. Harris, Ph. D., Head
Section VI, Toxicology Branch
Hazard Evaluation Division (TS-769)

for JEH 7/15/86

7/15/86

Registrant: Shell Oil Company

Action Requested: The registrant has responded by letter of May 15, 1986, to additional data requirements identified in the Toxicology Chapter of the Monocrotophos RS (p. 20 of that document, attached to this memo), submitting the following:

(1) A request to waive inhalation studies in the rat (81-3), based upon the physical characteristics of the technical product (found at TAB 3 of the registrant's submission);

(2) Additional information (TAB 4 of submission) on the mouse oncogenicity study, SBGR.81.218 (83-2), previously submitted and classified CORE-SUPPLEMENTARY DATA (TB Doc.#'s 004213/004284);

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(3) A protocol for general metabolism in the rat (85-1), but only for a single oral high-dose study. The registrant requests data waivers for a single oral low-dose, multiple oral low-dose and IV low-dose studies, citing toxicological and analytical justifications (TAB 5 of submission);

(4) A protocol for dermal absorption/penetration (85-2) in the rat (TAB 6 of submission); and,

(5) A request to waive data on domestic animal safety (86-1), based upon the use pattern of AZODRIN and its known toxicities (TAB 7 of submission).

TB CONCLUSIONS: In RD's original request of 05/28/86, the projected return date was 08/11/86 for reviewing the entire submission (Items 1 thru 5 above), and TB project numbers 1853, 1854, 1855 and 1856 assigned to this task. A more recent request by RD (dated 06/17/86) required a more expeditious return (by 07/17/86) for reviews of protocols (Items 3 and 4), assigned TB Project # 2000. In order to honor this shorter turn-around time for the subject of RD's later request, this memo can only address the registrant's submission of the protocols for the metabolism and dermal absorption studies (Items 3 and 4 above). TB defers the balance of this package (Items 1, 2, and 5) to the original projected return date (08/11/86), since these items require more extensive appraisal and/or evaluation.

ITEM 3: PROTOCOL REVIEW, and APPRAISAL OF WAIVER REQUESTS.

"General Metabolism Data Requirement" (TAB 5 of Shell submission)

As provided in the E P A Test Guidelines (50 FR No. 188 [PART 2], Friday, September 27, 1985 SUBPART H ---- pp. 39470, -1), TB recommends that the registrant change the expermental design for the 14C-monocrotophos general metabolism protocol submitted, so as to include all the studies required to assess tissue distribution and fate of the compound, and not merely the single oral high-dose study proposed by him.

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Based upon cursory calculations performed by TB toxicologists, we conclude that test dosages needed for single oral low-dose, multiple oral low-dose and IV low-dose studies may be met with approximately one-tenth the high dose of 2 mg/kg. Further, we recommend that the test material be labeled at the phosphorus, as well as the carbon side-chain.

Hence, TB sees no reason to waive data for these essential studies.

ITEM 4: PROTOCOL REVIEW
"Dermal Absorption of AZODRIN by Rats" (TAB 6)
(Shell Protocol No. WTP-353)

Shell's Protocol WTP-353 appears to be adequate to determine the dermal absorption of AZODRIN-5 by rats. The four items for which the registrant requests EPA concurrence are partially addressed in a draft comment prepared by Dr. Robert P. Zendzian (ATTACHMENT II to this memo), specifically regarding dose selection, but also indicating application of the rodent results to human risk. We also concur with the registrant with reference to the specific activity and composition of the test material, as well as the method proposed to account for the label (C-14) lost because of the volatility of AZODRIN.

ATTACHMENTS (2)

ATTACHMENT - I

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III. SUMMARY OF ADDITIONAL DATA REQUIRED ("Data Gaps")

Based upon TB review and evaluation of the available toxicological data submitted and/or located, the following additional information or new studies are required under FIFRA 3(c)(2)(B):

1. Inhalation studies in the rat, specifically to determine a LC_{50} and a 21-day inhalation study among other studies may be required depending on the amount and nature of residue in tobacco.

2. Dermal sensitization study in the guinea pig.

~~3. Teratology study in the rabbit.~~ — [illegible]

4. Additional information on the strain of mouse used in the oncogenicity study.

5. General metabolism of low dose, repeated low dose and high dose in the rat to assess tissue distribution and fate of radioactive AZODRIN and/or metabolites (especially OP-active derivatives).

BEST AVAILABLE COPY

IRVING MAUER PH.D.

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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Monocrotophos (AZODRIN) RS: Toxicology Chapter.

FROM: Irving Mauer, Ph.D.
Section VI, Toxicology Branch
Hazard Evaluation Division (TS-769) 3-22-85

TO: Willa Garner
Science Integration Staff/HED (TS-769)

THRU: Jane E. Harris, Ph.D.
Section Head, Section VI
Toxicology Branch/HED (TS-769) JEH 4/2/85

THRU: Theodore M. Farber, Ph.D., Chief
Toxicology Branch
Hazard Evaluation Division (TS-769) WAB 4-2-85

Attached find subject document, organized in the following sequence of sections:

I. Summary of available toxicological studies ("one-liners")

II. Discussion of test data base relative to satisfying regulatory requirements ("areas of concern")

III. Summary of additional data required ("data gaps")

IV. Tolerance re-assessment

V. Summary of data requirements under FIFRA 3(c)(2)(B) (Harrison Tables A/B)

VI. Other toxicological concerns

VII. References (but only those not included in Sequence Bibliographies provided by PMSD)

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Please note Toxicology Branch's concerns:

(i) Previously established tolerances (40 CFR 180.296) were based upon a NOEL of 1.6 ppm (0.040 mg/kg) for cholinesterase inhibition from an older chronic dog study (Woodard, 1967); the TMRC (0.0357 mg/day) thus occupied about 15% of the ADI (0.0040 mg/kg/day). A more recently submitted rat

ATTACHMENT II: In re: "Dermal Absorption of AZODRIN by Rats," Protocol WTP-353, submitted by Shell Oil Co., May 15, 1986 under ACC.# 262893. Comments prepared by Dr.R.P.Zendzian, July 02, 1986 for TB. Project No. 2000 (ref., TB Project No.'s 1853, 1854, 1855, 1856)

DRAFT

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Dose Selection

There are no exact rules for dose selection. The following is offered as a guide to producing data which can be utilized for determining the absorption of a pesticide under the conditions of field exposure.

Doses should be selected to span the the range of doses per unit area of skin which can be expected to occur in human exposure. Experience has shown that whole log intervals between doses produce the most useable data. Two factors must be considered 1) the concentration of test material in each dose preparation and 2) the quantity of that preparation applied for each dose.

In general the highest concentration of active ingredient to which one can expect the applicator to be exposed is the concentrated form sold by the manufacturer. This material, with the pesticide suitably labeled, should be used for the high dose. The lowest concentration of active ingredient to which one can usually expect the applicator to be exposed is the field mix. This mixture, with the pesticide suitably labeled, should be used for the low dose. Additional concentrations of active ingredient between these two should be made at log intervals. All concentrations lower than the concentrated form should be made by diluting the high dose material with the field solvent.

The actual doses applied to the rat skin can be determined by field exposure studies and must be expressed as quantity per unit area of skin for exposure to the concentrate and the field mix. This information will determine the quantity of the appropriate 'dosing' preparation to be used used for each dose.

Actual exposure data may require lower or (rarely) higher doses.

Example

We are using Wipeout™ 30EC, a 30% emulsifiable concentrate of the active. It is used in the field as a 100 fold dilution in water to give a 0.3% suspension. Exposures expected are as follows;

1. Spilling the 30EC on the hands during mixing.

2. Spilling the 100 fold dilution on the hands during loading.

3. Spraying with the 100 fold dilution with exposure on all exposed skin.

1. Spilling of the 30EC on the hands. The maximum exposure will be considered as that quantity of 30EC which will adhere to the skin of the hands per unit area (cm^2). This can be determined experimentally. Several subjects are be used. For each subject the surface area of the hands is determined. One approach utilized glove size with the following conversion. Small = 300 cm^2, Medium = 350 cm^2 and large = 400 cm^2.

A quantity of the vehicle* for the EC is placed in a container of a size sufficient to fully immerse the hands and the container and contents weighed. The subject immerses the hands, removes the hands and allows them to drip into the container. The container and contents is again weighted and the quantity remaining on the skin determined by subtraction. Using the specific gravity of the vehicle one determines the volume on the skin and the volume per unit area of skin.

2. Spilling of the 100 fold dilution on the hands. One uses exactly the same experiment as with the EC but uses a 100 fold dilution of the vehicle in water.

3. Spraying exposure on all exposed skin. For this one we use the results for number 2 and assume that the quantity that adheres to any part of the skin is the same as the quantity that adheres to the hands.

*Make sure the vehicle is 'safe' for this purpose. Some vehicles contain toxic components.

Another approach involves using information from models developed by the Agency. The Exposure Assesment Branch of OPP has developed models of field exposure to pesticides which enable one to use application parimeters (concentration of active, spray rate, area of application & ect.) to estimate inhalation and dermal exposure. For many pesticides inhalation exposure is insignificant and all exposure can be considered essentually dermal. From these models an average dose/kg body weight is determined. This information can be used to determine a dose for the rat dermal absorption study but it cannot be used directly. One cannot go from X mg/kg in man to the same X mg/kg in the rat.

In transfering the human dose to the rat one must realize that the important dose is the quantity per unit area of skin and this value must be equal in man and rat. The rate of absorption of a compound per unit time is related to the quantity per unit area of exposed skin. For most compounds although the quantity absorbed increases with dose (per unit area per unit time) the rate of absorption expressed as percent per unit area per unit time, decreases. The

relationship is not linear. In order to obtain usable information from the rat study one needs an equal exposure per unit area.

Example. The Registrant has determined the applicator exposure from an OPP model as 5mg/kg per working day. All exposure is dermal. From this dose the dermal dose/unit area (cm^2) is calculated for man.

Human dose

dose	5 mg/kg
weight man	70 kg
total dose	350 mg/man
Surface area exposed	3000 cm^2*
dose/cm^2	0.12 mg/cm^2

*Assumes applicator is wearing shoes, slacks, short sleeved open neck shirt and a hat.

Using the same dose/kg the dermal dose per unit area (cm^2) is calculated for the rat.

Rat dose

dose	5 mg/kg
weight rat	0.225 kg
total dose	1.125 mg/rat
surface area exposed	26 cm^2*
dose/cm^2	0.04 mg/cm^2

*Area determined by the experimental design.

By this method the dose per unit area in the rat is only 33% of the dose in man. This will produce a significantly lower quantity absorbed per unit time and a significantly higher rate (percent) absorbed per unit time. Also, since the exposed area in the rat study will be the same for each rat, if one uses the same mg/kg dose for each rat the dose per unit area will be different for rats of different weights. To obtain the correct dose per rat, one multiplies the human dose of 0.12 mg/cm^2 by the exposed area of 26 cm^2 on the rat to obtain a dose of 3.12 mg/rat.

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CONSULT January 29, 1987

SUBJECT: Monocrotophos (Azodrin): Shell Oil Company request for waiver for acute inhalation study using technical formulation (75% a.i.) Caswell 37% Tracking 1853-56

TO: Judy Hauswirth, Toxicology Branch (TS-769C)

FROM: Stan Gross, Toxicology Branch (TS-769C)

Re: EPA Accession No. 262893, May 1986. Letter of May 15, 1986 to Wm. Miller (RD) from E.L. Hobson (Shell, Washington, DC)

Request:

Shell asked for waiver of the acute inhalation study based on 1) azodrin Technical (75% a.i.) is a slurry at room temperature; and 2) pure Azodrin has a low vapor pressure (7×10^{-7} torr at 68°F.)

Recommendation:

The waiver can be granted based on reasons cited below.

Comments:

1) The September 1985 "Guidance for Reregistration of Manufacturing-use and Certain End-Use Pesticide Products Containing Monocrotophos" does not show any direct pesticide application for the technical formulation. End-use products and/or end-use dilutions are used for pesticide applications involving aerosol applications which should require inhalation testing. EPA's labeling requirements therefore apply only to containers for the technical products.

2) Based on the information provided by the Company, I agree with the Company's contention that the slurry (Azodrin Technical) would not provide a significant inhalation hazard to pesticide applicators from inhalable particles or vapors (at environmental temperatures). I have not assessed possible inhalation exposures to formulators an area of concern to the Occupational Health and Safety Administration not covered under EPA's guidelines.

3) The Material Safety Data Sheet (contained in Tab 3 of the submission) cautions that the product is presumed to be toxic and harmful if inhaled. Analytical Azaodrin (99.5% pure) is a powder which could be inhaled from accidental exposure but is assumed here not to be of pesticidal use importance.

Background Investigation

Caswell file
Farm Chemical Handbook
PM/RD Hazis Restricted

Thanks for the consult.