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PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

AUG 31 1994

MEMORANDUM

SUBJECT: The HED Chapter of the Reregistration Eligibility
Decision Document (RED) for Ethalfluralin

Case: 2260

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[Signature] 8/25/94

Thru: Debra Edwards, Chief
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and

Richard D. Schmitt, Ph.D., Acting-Director
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To: ~~JAY Ellenberger~~
~~Esther Saito, Acting Chief~~
Reregistration Branch
Special Review and Reregistration Division (7508W)

Please find attached the Human Health Assessment for the Ethalfluralin Reregistration Eligibility Decision Document (RED). This chapter includes the Hazard Assessment from P. McLaughlin in TBII (ATTACHMENT I), the Occupational/Residential Exposure Assessment from L. Morris in OREB) (ATTACHMENT II), the Product and Residue Chemistry Assessments from S. Funk in CBRs (ATTACHMENT III), and the Dietary Risk Analysis from J. Wintersteen in SAB (ATTACHMENT IV).

Ethalfluralin [N-ethyl-N-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)-benzenamine] is a selective preemergence herbicide registered for use on a variety of food and feed crops including alfalfa (grown for seed), beans (dried type), cucumbers, melons, peanuts, peas (dried type), pumpkin, soybean, squash (summer and winter), sunflower, and watermelon. The ethalfluralin formulations registered for use on these crops include the granular (G), the dry flowable (DF), and the emulsifiable concentrate (EC). These formulations may be applied preplant, postplant prior to emergence, postemergence, or post-transplant as a soil incorporated, band, or broadcast application



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using ground equipment. Ethalfluralin is only used outdoors.

The toxicological data base on ethalfluralin is adequate and will support reregistration eligibility.

The product chemistry data is adequate and will support reregistration, provided additional data for the following product chemistry guidelines are submitted: 61-1; 62-1; 62-2; and 62-3.

Additional residue data are required for the following residue chemistry guidelines: 171-4(a); and 171-4(k). Confirmatory field trial data are required for cucurbits, and a third metabolism study is required (cucurbits). Residue data are available to support food additive tolerances on the following crops: alfalfa (grown from seed); beans (dried); cucurbits (postplant-preemergence); peanuts; peas (dried); soybeans; and sunflowers. Postemergence/post-transplant application to cucurbits data are not available. This use should be removed from all labels.

HED has used the following toxicology endpoints in the risk assessments of ethalfluralin:

- 1) Acute Dietary Endpoint (One Day) Developmental Toxicity in the rabbit - NOEL = 75 mg/kg/day, and LOEL = 150 mg/kg/day; and
- 2) Ethalfluralin is classified as quantifiable Group C carcinogen ($Q_1^* = 8.9 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$), based on female rat mammary gland (adenomas and/or fibroadenomas) tumor rates. This endpoint is appropriate for chronic dietary and worker exposure; and
- 3) A RfD of 0.04 mg/kg/day, based on a NOEL of 4.0 mg/kg/day (altered red cell morphology, increased urinary bilirubin at the 20.0 mg/kg/day level) in a one-year oral dog study.

There are no endpoints of concern for Short Term (1 to 7 days) or an Intermediate term (1 week to several months) Occupational or Residential Exposure due to the low dermal absorption (2.8%).

The chronic dietary risk from exposure of ethalfluralin appears to be of minimal concern, with all subgroups having TMRC and ARC values well below the Reference Dose (2% of RfD for U.S. Population and 9% of the RfD for Non-Nursing Infants using either Tolerances or Anticipated Residues).

The upper bound cancer risk from ethalfluralin is below the level of risk that the Agency generally considers as negligible

(excluding cucurbits, would be 8.8×10^{-8}), if recommended revocations are excluded from the risk estimate. The upper-bound risk if these tolerances are not revoked is estimated to be 6.2×10^{-5} .

The acute dietary analysis of ethalfluralin is not of concern for females of child-bearing age.

Worker risk is in the range of 3×10^{-6} to 4×10^{-4} . The worst case scenario is for the commercial mixer/loader using the liquid/dry flowable formulation with an extra cancer risk of 4×10^{-4} . Exposure assessments for all other mixer/loader/applicator scenarios resulted in acceptable risks, based on the data currently available.

The minimum PPE for all end-use products containing ethalfluralin is: coveralls and chemical-resistant gloves for all handlers plus a chemical-resistant apron for mixers and loaders.

For occupational end-use products containing ethalfluralin as an active ingredient, HED recommends establishing a 24-hour restricted-entry interval pertaining to each use of the product that is within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS).

The following requirements and recommendations exist for ethalfluralin:

- 1) Additional data are required to upgrade for the following product chemistry guidelines: 61-1; 62-1; 62-2; and 62-3;
- 2) Additional residue data are required to upgrade the following residue chemistry guidelines: 171-4(a); 171-4(k). Confirmatory field trial data are required for cucurbits (preemergence), and a third metabolism study is required (cucurbits);
- 3) Postemergence/post-transplant application to cucurbits data are not available. This use should be removed from all labels;
- 4) Field trial data are required for residues of ethalfluralin in/on alfalfa hay and forage, pea and bean hay and forage, soybean hay and forage, and peanut hay. These data are considered confirmatory;
- 5) Grazing, foraging, and haying restrictions must be removed from the labels, except sunflower forage;
- 6) Data pertaining to the nitrosamine content are outstanding; nitrosamine analysis is required since

ethalfluralin contains a tertiary alkylamine; and

7) HED has concluded that residues of ethalfluralin from up to 10x dietary burden would not be quantifiable (<0.05 ppm). This is considered a Category 3 use (40 CFR §180.6), and the existing tolerances (expressed in terms of ethalfluralin *per se*) for eggs, milk, and fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep should be revoked.

Attachments

cc:

P. McLaughlin (TBII)

L. Morris (OREB)

S. Funk (CBRS)

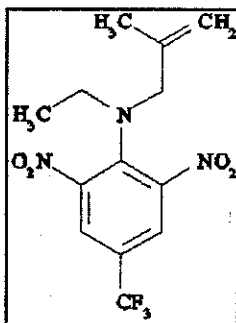
J. Wintersteen SAB

PRODUCT CHEMISTRY ASSESSMENT

Ethalffluralin [N-ethyl-N-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)-benzenamine] is a selective preemergence herbicide registered for use on a variety of food and feed crops including alfalfa (grown for seed), beans (dried type), cucumbers, melons, peanuts, peas (dried type), pumpkin, soybean, squash (summer and winter), sunflower, and watermelon. The ethalffluralin formulations registered for use on these crops include the granular (G), the dry flowable (DF), and the emulsifiable concentrate (EC). These formulations may be applied preplant, postplant prior to emergence, postemergence, or post-transplant as a soil incorporated, band, or broadcast application using ground equipment. Ethalffluralin is only used outdoors.

1. DESCRIPTION OF CHEMICAL

Ethalffluralin [N-ethyl-N-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl) benzenamine] has the following chemical structure.



Empirical Formula: $C_{13}H_{14}F_3N_3O_4$
 Molecular Weight: 333.27
 CAS Registry No.: 55283-68-6
 Shaughnessy No.: 113101

2. IDENTIFICATION OF ACTIVE INGREDIENT

Ethalffluralin is a yellow crystalline solid with a melting point of 57 C. Ethalffluralin is readily soluble in organic solvents (acetone, acetonitrile, benzene, chloroform, hexane, methanol, methylene chloride, and xylene), and is soluble in water at 0.3 ppm at 25 C.

3. MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 1/18/94 identified a single manufacturing-use product registered under Shaughnessy No. 113101 to DowElanco. Although REFS identifies the product as a 95% technical (T; EPA Reg. No. 62719-132), a Confidential Statement of Formula (CSF) reviewed by the Agency (CBRS No. 10287, D180905, dated 9/8/93 by P. Deschamp) confirmed that the nominal concentration of 96% is the correct label claim for the product. Only the DowElanco ethalfluralin technical is subject to a reregistration eligibility decision.

4. DATA REQUIREMENTS

The current status of the product chemistry data requirements for the DowElanco ethalfluralin technical is presented in the Appendix. Data pertaining to the nitrosamine content are outstanding; nitrosamine analysis is required since ethalfluralin contains a tertiary alkylamine. DowElanco has requested (letter dated 12/23/93, from D. Roby to T. Myers, SRRD) a time extension for submission of additional data until 12/1/94. The requested extension includes planned production of ethalfluralin in February 1994 and the time required subsequent to production to conduct outstanding analysis and complete new method development.

The registrant is required to submit the data required in the product chemistry summary table in the Appendix (footnotes c, f, g and h) for the DowElanco ethalfluralin 96% T, and either to certify that the suppliers of starting materials and the manufacturing process for ethalfluralin have not changed since the last comprehensive product chemistry review or to submit a complete updated product chemistry data package.

B. HUMAN HEALTH ASSESSMENT**1. Toxicology Data Base**

The toxicological data base on ethalfluralin is adequate and will support reregistration eligibility.

A. Acute Toxicity**ACUTE TOXICITY DATA**

TEST	RESULTS	CATEGORY
Oral LD ₅₀ --rat	LD ₅₀ >5000 mg/kg	IV
Dermal LD ₅₀ --rabbit	LD ₅₀ >5000 mg/kg	IV
Inhalation LC ₅₀ --rat	LC50 >0.94 mg/L	III
Eye irritation--rabbit	moderate	II
Dermal irritation--rabbit	moderate to severe	II
Skin sensitization-- guinea pig	sensitizer	---

An acute oral toxicity study with rats found the LD₅₀ was greater than 5000 mg/kg, which was toxicity category IV (guideline 81-1; MRID 41613908). An acute dermal toxicity study with rabbits found the LD₅₀ was greater than 5000 mg/kg. This was toxicity category IV (guideline 81-2; MRID 41613909).

An acute inhalation study with rats found the LC₅₀ was greater than 0.94 mg/L, which was toxicity category III (guideline 81-3; MRID 41977601).

An eye irritation study with rabbits found slight to moderate corneal opacity and edema with slight to severe iritis and irritation up to the third day, generally followed by clearing by the seventh day. One animal retained scattered opacity through day 7, clearing by day 14. This was toxicity category II (guideline 81-4; MRID 41613910). A dermal irritation study with rabbits found slight to moderate irritation and edema from 24 hours through 7 days after 24 hour dermal treatment. There were desquamation, slight to severe edema and irritation, with coriaceous formation, through 14 days. One animal had epidermal fissures and bleeding by the fourteenth day. This was toxicity category II (guideline 81-5; MRID 41613909).

A guinea pig dermal sensitization study conducted by the modified Buehler method found no sensitization, whereas a study conducted by the Magnusson and Kligman maximization method found ethalfluralin was positive (guideline 81-6; MRID 00094788, ACC

070683a).

B. Subchronic Toxicity

A three month feeding study with B6C3F1 mice used doses of 0, 560, 1110, 2250, 4000, and 8000 ppm (68, 136, 285, 538, and 1205 mg/kg/day). The NOEL was 560 ppm. The LOEL was 1110 ppm based on low bilirubin and low kidney weights in males. Higher doses showed depressed weight gain, increased SGPT, increased serum alkaline phosphatase, and increased relative liver weights. (guideline 82-1; MRID 00094774)

Ethalfuralin was administered to B6C3F1 mice for one year at dietary concentrations of 0, 100, 400, or 1500 ppm (equivalent to 0, 12, 47.0, or 173 mg/kg/day for males; 0, 12, 49, or 184 mg/kg/day for females). The NOEL was 100 ppm. The LOEL was 400 ppm, based on increased alkaline phosphatase levels at this and the high dose. At the high dose, there were decreased BUN and creatinine, increased SGPT, and increased relative liver weights. (adequate for a subchronic study, guideline 82-1; MRID 00094778)

Ethalfuralin was fed to Fisher 344 rats for one year. The doses were 0, 100, 250, or 750 ppm in the diet (equivalent to 0, 3.9, 9.7, or 28.4 mg/kg/day for males; 0, 4.9, 11.9, or 34.4 mg/kg/day for females). The NOEL was 100 ppm. The LOEL was 250 ppm, based on blood chemistry changes at the two higher doses, with increased relative liver weights and decreased body weight gain at the high dose. (This study fulfills guideline 82-1; MRID 00094775)

The doses for the preceding study, and for the two year rat study discussed below, were derived from a three month study in which Fischer 344 rats were fed 0, 250, 500, 1100, 2500, or 5000 ppm test material. The NOEL was 500 ppm (29 mg/kg/day). Higher doses showed increased liver and kidney weights, lower RBC, hematocrit and hemoglobin, as well as some enzyme activity changes (MRID 00135191). Although, this is a supplemental study it provides the rationale for dose selection in the above mentioned studies.

A three month oral study with beagle dogs gave doses of 0, 6.25, 27.5, or 125/80 mg/kg/day by capsule. The systemic NOEL was 27.5 mg/kg/day. The systemic LOEL was 80 mg/kg/day (the high dose) based on elevated alkaline phosphatase, slight fatty metamorphosis of the liver, increased cholesterol, and increased BUN. (guideline 82-1; MRID 00135193)

In a 21 day dermal toxicity study, New Zealand white rabbits were treated with 0 or 1000 mg/kg/day, a limit dose. No systemic effects were found at this dose; skin effects were slight to severe dermal irritation, as well as edema and coriaceous skin with epidermal fissures. (guideline 82-2; MRID 00145767)

C. Chronic Toxicity and Carcinogenicity

Ethalffluralin was administered to Fisher 344 rats in the diet for two years in combined chronic toxicity and carcinogenicity replicate studies. The doses were 0, 0.01, 0.025, or 0.075 percent in the diet (equivalent to 0, 4.2, 10.7, or 32.3 mg/kg/day). The NOEL for systemic effects was 32.3 mg/kg/day, the high dose. Mammary gland fibroadenomas were found in dosed female rats. (guidelines 83-1, 83-2; MRID 00094776 and 92062013)

Ethalffluralin was administered to B6C3F1 mice in the diet for two years in combined chronic toxicity and carcinogenicity replicate studies. The doses were 0, 100, 400, or 1500 ppm in the diet (equivalent to 0, 10.3, 41.9, or 163.3 mg/kg/day). No increased incidence of neoplasms was attributed to the treatment. The NOEL was 10.3 mg/kg/day. The mid dose (LOEL) and high dose showed focal hepatocellular hyperplasia in both sexes. There were increased relative liver, kidney, and heart weights in females. Some blood changes were found also, including decreased hematocrit, hemoglobin, and erythrocyte count accompanied by increased mean corpuscular hemoglobin concentration in high dose females. Alkaline phosphatase values were increased at the high dose in both sexes. Body weight gain decreased at the high dose (guidelines 83-1, 83-2; MRID 00094777 and 92062016)

Beagle dogs were given 0, 4, 20, or 80 mg/kg/day orally, by capsule, for one year. The NOEL was 4 mg/kg/day. The LOEL was 20 mg/kg/day, based on increased urinary bilirubin, variations in erythrocyte morphology, increased thrombocyte count, and increased erythroid series of the bone marrow. Elevated alkaline phosphatase levels were found at the two higher doses and siderosis of the liver at the high dose (guideline 83-1; MRID 00153371 and 92062014)

The Carcinogenicity Peer Review Committee on June 8, 1994, concluded that ethalffluralin should be classified as Group C, a possible human carcinogen, based on increased mammary gland fibroadenomas and adenomas/fibroadenomas combined in female rats. The tumor incidences were statistically significant at both the mid and high dose, and were well in excess of the upper range of historical controls. The unit risk, Q_1 of ethalffluralin is 8.9×10^{-2} (mg/kg/day)⁻¹.

D. Developmental Toxicity

Ethalffluralin was administered orally to Sprague Dawley rats at 0, 50, 250, or 1000 mg/kg/day on gestation days 6-15. The maternal NOEL was 50 mg/kg/day. The maternal LOEL was 250 mg/kg/day, based on decreased body weight gain and dark urine. The developmental NOEL was 1000 mg/kg/day, the highest dose.

(guideline 83-3; MRID 0015337 and 92062017)

Dutch Belted rabbits were given 0, 25, 75, 150, or 300 mg/kg/day of ethalfluralin by gavage on gestation days 6-18. The NOELs for maternal and developmental toxicity were 75 mg/kg/day. The maternal LOEL at 150 mg/kg/day was based on abortions and decreased food consumption. These effects as well as decreased weight gain, enlarged liver, and orange urine were found at 300 mg/kg/day. The developmental LOEL was 150 mg/kg/day, based on slightly increased resorptions, abnormal cranial development, and increased sternal variants. (guideline 83-3; MRID 00129057)

E. Reproduction

A three-generation reproduction study in Fischer 344 rats gave doses of 0, 100, 250, or 750 ppm in the diet (equivalent to 0, 5.0, 12.5, or 37.5 mg/kg/day). The parental NOEL was 12.5 mg/kg/day. The parental LOEL was 37.5 mg/kg/day, based on depressed mean body weight gains in males in all generations. No treatment-related effects were noted on reproductive parameters and the NOEL was 37.5 mg/kg/day or greater. (MRID 00094784 and 92062019)

A seven month multigeneration bridging study was conducted with doses of 0, 100, 250, or 750 ppm (equivalent to 0, 8, 20, or 61 mg/kg/day) in the diet of Fischer 344 rats. The parental NOEL was 20 mg/kg/day. The parental LOEL was 61 mg/kg/day, based on increased liver weights. No treatment-related effects were noted on reproductive parameters and the reproductive NOEL was equal to or greater than 61 mg/kg/day (MRID 42300301). (These two studies combined fill guideline 83-4.)

F. Mutagenicity

Ethalfluralin was weakly mutagenic in activated strains TA1535 and TA100 of Salmonella typhimurium but not in strains TA1537, TA1538, and TA98 in an Ames assay. In a modified Ames assay with Salmonella typhimurium and Escherichia coli, ethalfluralin was weakly mutagenic in strains TA1535 and TA100, with and without activation, and in strain TA 98 without activation, at the highest dose (MRID 00128693 and 00128694). No mutagenicity was found in the mouse lymphoma assay for forward mutation (MRID 00128696). Ethalfluralin did not induce unscheduled DNA synthesis in rat hepatocytes. (MRID 00128695) In Chinese hamster ovary cells, the chemical was negative without S9 activation, but it was clastogenic with activation (MRID 00152219). (These studies fill guidelines 84.)

G. Metabolism

Fischer 344 rats were treated orally with a single low dose, a single high dose, or repeated low doses of radiolabeled ethalfluralin. Absorption of ethalfluralin was estimated at 79-

87% of the dose for all dose levels. Ethalfluralin was rapidly and extensively metabolized, and 95% of the chemical was excreted in urine and feces by seven days. The major route of elimination for the radiolabel was in the feces, 50.9-63.2%, and the levels remaining in the tissues after 72 hours were negligible. The major metabolites in urine and feces were identified. (guideline 85-1; MRID 42822901)

A study with Rhesus monkeys indicated that 2.8% of a dermal dose was absorbed through the skin (Guideline 85-2; MRID 00132820).

H. Reference Dose (RfD)

The RfD was determined to be 0.04 mg/kg/day, based on a NOEL of 4.0 mg/kg/day (altered red cell morphology, increased urinary bilirubin in a one-year oral dog study. An uncertainty factor of 100 was used to account for inter-species extrapolation and intra-species variability.

There has been no WHO RfD determination as of yet.

2. EXPOSURE ASSESSMENT

A. DIETARY

Tolerances for residues in/on plants (dry beans, cucurbit vegetables group, peanuts, peanut hulls, dry peas, soybean, and sunflower seed) and in animal commodities (eggs, milk, and fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep) are expressed in terms of ethalfluralin per se [40 CFR §180.416]. All of these tolerances are established at 0.05 ppm. No food/feed additive tolerances have been established. Adequate enforcement methods are available for the determination of ethalfluralin residues in/on plant and animal commodities.

GLN 171-3: Directions for use

A REFS search conducted 1/18/94 indicated that there are five ethalfluralin end-use products (EPs) with food/feed uses which are registered to DowElanco and Platte Chemical Company. Restrictions on grazing, foraging, haying for beans, peas, soybeans, peanuts, and alfalfa must be removed from all labels.

GLN 171-4 (a): Plant Metabolism

The qualitative nature of the residue in beans and peanuts is tentatively understood pending submission of additional confirmatory data (i.e., raw data and storage stability information). These studies (MRID 00145955 and 00094754) were

conducted under the registered use patterns. Sufficient radioactive residues in/on bean and peanut commodities were obtained following preplant soil-incorporated application of uniformly ring-labeled [^{14}C]ethalfluralin at ~1x the maximum registered rate. The major portion of the radioactivity was characterized as lignin, cellulose, and protein. The parent, ethalfluralin, was a minor residue. The tentatively terminal residue of concern in plants is ethalfluralin *per se*; the current tolerance expression for plants is adequate. However, before plant metabolism may be considered fully understood, an acceptable cucurbit metabolism study must be submitted. A cucurbit metabolism study is on-going. The cucurbit study and the outstanding raw data for the peanut and bean studies will be considered confirmatory.

GLN 171-4 (b): Animal Metabolism

The qualitative nature of the residue in animals is adequately understood based on acceptable poultry and ruminant metabolism studies. In the poultry metabolism study, laying hens were dosed with uniformly ring-labeled [^{14}C]ethalfluralin at 10 ppm in the diet (about 200x the maximum theoretical dietary burden) for ten consecutive days. The maximum total radioactive residues were 0.169 ppm in eggs, 0.697 ppm in liver, 0.070 ppm in muscle, and 0.194 ppm in skin. The parent compound, ethalfluralin, was the major compound identified in skin, but was a minor component in eggs, liver, and muscle. Four other metabolites, 2,6-dinitro-4-(trifluoromethyl)phenol, N-ethyl-2,6-dinitro-4-(trifluoromethyl)benzenamine, N-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)benzenamine, and 2,6-dinitro-4-(trifluoromethyl)benzenamine, were identified; each identified metabolite was present at ≤ 0.05 ppm.

In the ruminant metabolism study, a lactating dairy cow was dosed with uniformly ring-labeled [^{14}C]ethalfluralin at 10 ppm in the diet (about 200x the maximum theoretical dietary burden) for three consecutive days. The total radioactive residues were 0.011 ppm in fat, 0.050 ppm in kidney, 0.104 ppm in liver, 0.002 ppm in muscle, and up to 0.006 ppm in milk. Ethalfluralin was identified in milk and fat; neither parent nor metabolites were identified in kidney or liver.

The residue of concern in milk, eggs, and animal tissues is ethalfluralin *per se*. As a result of the low levels of radiolabeled residues found with the exaggerated (200x) feeding levels, the requirements for animal feeding studies were waived. It was also concluded that residues of ethalfluralin from up to 10x dietary burden would not be quantifiable (< 0.05 ppm). Therefore, this is considered a Category 3 use (40 CFR §180.6), and the existing tolerances (expressed in terms of ethalfluralin *per se*) for eggs, milk, and fat, meat, and meat byproducts of

cattle, goats, hogs, horses, poultry, and sheep should be revoked.

GLN 171-4 (c) and (d): Residue Analytical Methods-Plants and Animals

Adequate residue analytical methods are available for purposes of reregistration. Two GC methods, Method I and II, both with electron capture detection (ECD) are listed in the Pesticide Analytical Manual (PAM, Vol. II, Section 180.416) for tolerance enforcement. Method I is applicable for the analysis of ethalfluralin residues in/on plant commodities (cottonseed, cucurbits, forage legumes, peanuts, seed and pod vegetables, and sunflower seed). Method II is applicable for tolerance enforcement of ethalfluralin residues in animal commodities (eggs, milk, and fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep). The limits of detection are 0.01 ppm and <0.01 ppm, for Method I and Method II respectively.

The principal analytical method used for residue data collection in plant commodities was the enforcement method, Method I. Adequate concurrent method recoveries (70-120%) support the results of field residue and storage stability studies that were used for tolerance reassessments. The qualitative nature of the residue in cucurbits has not been adequately described. If the requested data on cucurbit metabolism indicate the presence of additional metabolites of toxicological concern, then relevant additional analytical methods and data may be required.

Representative samples from the submitted bean and peanut metabolism studies were not analyzed using the current enforcement method. However, since no additional terminal residues of concern were found in dried bean stems and peanut nutmeats and hulls, radio-validation data will not be needed.

The FDA PESTDATA database dated August 1993 (PAM Vol. I, Section 180.416) indicates that ethalfluralin is completely recovered (>80%) using multiresidue method protocols D and E (fatty and nonfatty).

GLN 171-4 (e): Storage Stability

Storage stability studies have been conducted using fortified samples of beans (dry), cucumbers, peanuts, peas (dry), soybean, soybean processed commodities, and sunflower seed. Residues of ethalfluralin are stable under frozen storage conditions (-20 C) in/on beans (dry), soybean processed commodities, and sunflower seed for up to 6 months, in/on peas (dry) for up to 10 months, and in/on cucumbers, peanuts, and soybean for up to 12 months. Storage stability data for soybean processed commodities may be translated to peanut processed commodities. Storage stability

data for cucumbers may be translated to melons, pumpkin, squash (summer and winter), and watermelon.

Additional confirmatory data indicate that ethalfluralin residues are stable in sunflower seed stored at room temperature and then frozen, reflecting sample handling which occurred during the sunflower seed crop field trial study.

Samples of eggs, milk, and tissues from the poultry and ruminant metabolism studies were analyzed within two months of sample collection. Therefore, storage stability data to validate the results from the animal metabolism studies are not required.

GLN 171-4 (k): Magnitude of the Residue in Plants

All data requirements for magnitude of ethalfluralin residue in plants have been evaluated and deemed adequate except for cucurbits and the forage and hay of various crops. To support the use on cucurbits data from residue field trials on cucumbers, squash, and melons are required to fulfill the data requirements; they are currently outstanding.

The registered uses of ethalfluralin on beans (dry), peanuts, peas (dry), soybean, and sunflower along with the established tolerances on these commodities are supported by acceptable field residue data from trials reflecting the maximum registered use patterns. In all cases, the residues were < 0.01 ppm. Field trial studies for cucurbits, specifically summer and winter squash, pumpkins, cucumbers, and melons, are being conducted. Previous studies, not submitted by the registrants for reregistration purposes, indicated that residues were nondetected (< 0.01 ppm) in/on squash, cantaloupe, cucumber, watermelon, and pumpkin from postplant surface application at rates of 1.25 - 2.5 lbs. a.i./acre. The similarity of the preemergence use pattern among crops and the comparability of residue results (< 0.01 ppm) combined with the previous field trial results provide adequate data to support the existing tolerance of 0.05 ppm for residues of ethalfluralin in/on cucurbits for postplant-preemergence use only until new field trial studies are submitted within one year. The postemergence/post-transplant use on cucurbits is not similar to other crop use patterns and must, in the absence of acceptable field trial data, be removed from all labels.

As the result of recent changes in Table 2, Subdivision o (6/94), label restrictions on grazing, haying, and foraging are generally no longer permitted. Field trial data are required for residues of ethalfluralin in/on alfalfa forage and hay, bean forage and hay, pea forage and hay, peanut hay, and soybean forage and hay. These data are considered confirmatory.

GLN 171-4 (l): Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for processing studies are fulfilled. Adequate processing studies have been conducted on the following RACs: peanuts, soybean, and sunflower seed. Field residue data resulting from up to 5x label rates show nondetectable (<0.01 ppm) residues of ethalfluralin in peanuts, soybean, and sunflower seed. For the purposes of reregistration, it is concluded that residues are not likely to concentrate in the processed commodities of peanuts, soybean, and sunflower seed. No food or feed additive tolerances are required.

GLN 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

The data requirements for magnitude of ethalfluralin residue in meat, milk, poultry, and eggs have been waived. The results of nature of the residue studies in poultry and ruminants, using exaggerated feeding rates (200x) indicate that residues of ethalfluralin at levels 1-10x the dietary burden will not be quantifiable (<0.05 ppm). Therefore, this is considered a Category 3 use (40 CFR § 180.6), and the existing tolerances for eggs, milk, and fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep should be revoked.

GLN 165-1 and 165-2: Confined/Field Rotational Crops

A confined rotational crop study has been submitted and deemed adequate. In that study, radioactive residues were ≥ 0.01 ppm in/on mature commodities of rotational crops (root crops, leafy vegetables, and small grain) grown in soils that had been treated with [phenyl- ^{14}C]ethalfluralin at 1x the maximum registered rate. Ethalfluralin at 0.01 ppm (2.3% TRR) was found in only one sample of mature barley chaff from the 30-day plantback interval. Ethalfluralin was not identified in any other plant commodity at any plantback interval. The major metabolite, designated as Unknown 1, was found at 0.03-0.11 ppm (18-83% TRR) and was characterized to be polar in nature but not a potential residue of concern. Field rotational crop studies are not required since no residues of concern were found at significant levels in rotational crops. Furthermore, tolerances for rotational crop commodities and plantback restrictions need not be established.

B. Residential and Occupational Exposure**1. Use patterns**

Ethalfluralin is a herbicide formulated as a granular (containing 10 percent a.i.), dry flowable (50 percent a.i.), and as several emulsifiable concentrates (containing 31.5 percent to

36.1 percent a.i.).

Ethalfluralin is used as a pre-emergent, soil-incorporated application. It is applied as a band or broadcast treatment using low-pressure groundboom or granular spreader equipment. It is also impregnated on dry bulk fertilizers. It appears to be used outdoors only.

All products containing ethalfluralin appear to be primarily for occupational use.

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food and feed crops). Uses within scope of WPS include uses on plants and uses on the soil or planting medium the plants are (or will be) grown in. At this time all of the registered uses of ethalfluralin appear to be within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS).

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators) during use or to persons entering treated sites after application is complete.

Because ethalfluralin is classified as a Group C carcinogen, the toxicology criteria are triggered.

2. Handlers (Mixers/Loaders/Applicators) Exposure

There is potential exposure to mixers, loaders, applicators, or other handlers during usual use-patterns associated with ethalfluralin. There is a concern about potential exposures arising from mixing and loading liquid or dry flowable formulations, from loading granular formulations, and from applying with groundboom and granular spreader equipment.

Requirements for mixer/loader/applicator (i.e., handler) exposure studies are addressed in Subdivision U of the Pesticide Assessment Guidelines. Mixer/loader/applicator (M/L/A) exposure data for ethalfluralin were not required during Phase IV of the reregistration process, since no toxicological criteria had been triggered at that time. A review of the toxicological and exposure data indicates that exposure criteria for requesting data are met, and an exposure assessment is required since ethalfluralin is now classified as a quantifiable Group C

carcinogen. Surrogate and chemical specific data are available to conduct an exposure assessment and additional data are not required.

Ethalfluralin mixer/loader/applicator data for the granular formulation (Edge 5G) were developed by the registrant for Health Canada and were also submitted to the Pesticide Handler Exposure Database (PHED). A limited exposure/risk assessment for handlers was conducted for ethalfluralin using that data and other generic data obtained from PHED.

Based on the use-patterns and potential exposures described above, four major exposure scenarios are identified for ethalfluralin: (1) mixing/loading the liquid/dry flowable formulation, (2) loading the dry (granular) formulation, (3) applying the liquid/dry flowable formulation with a groundboom sprayer, and (4) applying the dry formulation with granular spreader equipment. The exposure scenarios are presented in Table 1 along with the corresponding exposure/risk assessment. Table 2 summarizes the caveats and parameters specific to each exposure scenario. Protection factors were applied to the exposure data reported in Table 1 to simulate personal protective equipment use of coveralls and chemical-resistant gloves. The actual clothing and equipment worn by persons being monitored in the exposure studies are described in Table 2.

Table 1. Summary Exposure/Risk Values for Ethalfuralin

Exposure Scenario (Scen. #)	Dermal Exposure ^a (mg/lb ai)	Inhalation Exposure ^b (µg/lb ai)	Maximum Label Application Rate ^c (lb/ai acre)	Daily Max ^d Treated (acres)	Daily Dermal Dose ^e (mg/kg/day)	Commercial Mixer/Loader/Applicator	
						Dermal LADD ^f (mg/kg/day)	RISK ^g
Mixer/Loader Exposure							
Liquids/Dry Flowable (Ground Application) (I)	0.2	0.4	1.7	80	0.39	5x10 ³	4x10 ⁻⁴
Granules (Ground Application) (II)	0.007 ^h	1.0	1.7	80	0.014	2x10 ⁻⁴	2x10 ⁻⁵
Applicator Exposure							
Groundboom Application (III)	0.02	1.3	1.7	80	0.039	5x10 ⁻⁴	4x10 ⁻⁵
Solid Broadcast (Tractor) (IV)	0.0008	0.1	1.7	80	0.002	3x10 ⁻⁵	3x10 ⁻⁶

^a Dermal unit exposures are reported as the best fit mean to simulate workers wearing long pants, long-sleeved shirts, and chemical resistant gloves. The best fit mean is the composite total dermal exposure based on using the geometric mean for lognormal distributed data, arithmetic mean for normal distributed data, and the median for all other distribution types. The ethalfuralin generated mixer/loader and applicator data are reported as the geometric mean. Protection factors were used to calculate dermal exposure values because insufficient data are available for PPE in these scenarios. Fifty percent of the total dermal exposure is assumed to be attributed to hand exposure. Fifty percent protection factor is applied to the hand exposure for chemical resistant gloves.

^b Inhalation exposure values are reported as geometric means (lognormal distribution). No adjustment has been made to simulate workers wearing dust/mist respirators. Inhalation exposure (µg/lb ai) is considered to be significantly less than potential dermal exposure.

^c Luis Report and ethalfuralin labels.

^d Values represent the maximum area which is assumed to be used in a single day to complete treatments for each exposure scenario of concern.

^e Daily Dermal Dose (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)} * \text{Max. Appl. Rate (lb ai/acre)} * \text{Max. Treated}}{70 \text{ kg}}$

^f LADD (mg/kg/day) = Daily Dermal Dose (mg/kg/day) * (Work Days Per Yr/365 Days Per Year) * (35 Yrs/70 Yrs)

^g Commercial applicator is defined as an intermediate exposed individual (i.e., 10 days).

^h Risk = Dermal LADD (mg/kg/day) * Q_i *
No protection factor necessary

Table 2. Exposure Scenario Descriptions for Ethalfuralin

Exposure Scenario (Scen. #)	Data Source	Clothing Scenario ^a	Equipment	Standard Assumptions ^b (8-hr work day)	Comments ^c
Mixer/Loader Exposure					
Liquids/Dry Flowables for Ground Application (I)	PHED	Long Pants, Long-Sleeved Shirt, No Gloves	Open Mixing	80 acres	Acceptable grades; Dermal = 14 + replicates; Inhalation = 40 replicates High confidence in data
Granules for Ground Application (II)	DowElanco	Single layer coveralls, Gloves	Open Mixing	80 acres	Acceptable dermal grades; Inhalation grades 25A and 5C; Dermal = 24 replicates; Inhalation = 30 replicates High confidence in data
Applicator Exposure					
Groundboom Application (II)	PHED	Long Pants, Long-Sleeved Shirt, No Gloves	Open cab	80 acres	Grades A, B, C; Dermal = 6 + replicates Inhalation = 56 replicates Low - Medium confidence in data
Solid Broadcast - Tractor (V)	DowElanco	Single layer coveralls, No gloves	All but four replicates closed cab; both cultivator mounted and pull-behind applicator equipment	80 acres	Acceptable dermal grades; Inhalation grades 24A and 5C; Dermal = 27 replicates; Inhalation = 29 replicates High confidence in data

^aClothing scenario represents actual monitored exposure data. The dermal exposure values on Table 1 have been adjusted using protection factors to simulate long pants, long-sleeved shirt and chemical resistant gloves.

^bStandard Assumptions based on an 8-hour work day as estimated by OREB. BEAD data were not available.

^c"Acceptable grades," as defined by OREB SOP for meeting Subdivision U Guidelines, are grades A and B for dermal inhalation, and grade C for hand rise method. All grades that do not meet OREB's SOP are listed individually.

Post-Application Exposure

OREB has determined that there is potential exposure to persons entering treated sites after application is complete, only under one of the following conditions: (1) the application is not incorporated correctly or (2) the entry task involves contact with the soil subsurface. The potential exposure to persons entering treated sites after application should be minimal and does not trigger the post-application criteria.

3. RISK ASSESSMENT

A. DIETARY

Based upon the review of the toxicology database for ethalfluralin, there are toxicological endpoints of concern identified Toxicology Endpoint Selection Committee (May 19, 1994). However, dermal absorption is too low for toxicological effects to cause concern (i.e., 2.8 percent), and precludes the need for a short or intermediate term exposure assessment. Ethalfluralin is classified as quantifiable Group C carcinogen ($Q_1^* = 8.9 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$).

An acute dietary risk assessment has been requested in the Toxicology Endpoint Selection Document for Ethalfluralin (M. Ioannou and M. Van Gemert memo, 5/19/94). The NOEL of concern for risk assessment is 75 mg/kg/day from the developmental toxicity study in rabbits. The effects seen at 150 mg/kg/day were increased resorptions and increased sternal and cranial variations.

For chronic exposure a Reference Dose (RfD) of 0.04 mg/kg body weight/day was appropriate for risk assessment. Additionally for chronic exposure, a cancer risk assessment using the Q_1^* of $8.9 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$ is appropriate.

Residues

Food uses in this analysis include all published tolerances listed in the Tolerance Index System (TIS) and 40 CFR §180.416. Although data are not available for the reregistration of ethalfluralin on cucurbits, the DRES analysis considered cucurbits as a published commodity for this analysis, as the worst case scenario.

Currently tolerances exist for fat, meat and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep as well as milk and eggs. Although HED recommended the revocation of existing tolerances the published tolerances for these

commodities were still included in the chronic, acute and carcinogenic analyses.

Anticipated residues (ARs) are provided in Table D of the Residue Chemistry Chapter of the Reregistration Eligibility Document.

Percent of crop treated information was provided in a G. Ali memo dated 12/93 "Typical Annual Usage (1992) and Percentage of various U.S. Crops Treated with Ethalfluralin". A summary of the residue information used in this analysis is attached as Table 1 of the DRES Chapter.

Chronic Exposure

The DRES chronic analysis used tolerance level residues to calculate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. Refinements in residue and percent crop treated information were considered in calculating the Anticipated Residue Contribution (ARC) for those same population groups. The ARC is considered the more accurate estimate of dietary exposure. These exposure estimates were then compared to the RfD for ethalfluralin to calculate estimates of chronic dietary risk.

Using Tolerances:

The Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population from published and proposed uses recommended through reregistration are listed below.

<u>Population group</u>	<u>Exposure(mg/kg/day)</u>	<u>%Reference Dose</u>
U.S. population	0.000735	2
Non-nursing Infants	0.003565	9

Using Anticipated Residues:

The Anticipated Residue Contribution (ARC) for the overall U.S. population from published and proposed uses recommended through reregistration are listed below.

<u>Population group</u>	<u>Exposure(mg/kg/day)</u>	<u>%Reference Dose</u>
U.S. population	0.000699	2
Non-nursing Infants	0.003474	9

Summaries of the TMRCs, ARCs, and their representations as percentages of the RfD are attached as Tables 2 and 3 of the DRES Chapter.

The U.S. population and all the DRES subgroups have ARCs for

chronic dietary risk well below the RfD when published commodities are considered.

The upper bound carcinogenic risk from food uses of ethalfluralin were calculated using the following equation:

$$\text{Upper Bound Cancer Risk} = \text{Dietary Exposure (ARC)} \times Q_1^*$$

Based on a Q_1^* of $0.089 \text{ (mg/kg/day)}^{-1}$, the upper bound cancer risk was calculated to be 6.2×10^{-5} , contributed through all the published uses for ethalfluralin. When meat, milk, poultry and eggs are removed from the calculation the resulting risk is 5.7×10^{-7} . HED recommends for the revocation of the meat, milk, poultry and egg tolerances for reregistration. Cucurbits contribute 4.8×10^{-7} to the risk estimate of 5.7×10^{-7} given above. The resulting upper bound carcinogenic risk, excluding cucurbits, would be 8.8×10^{-8} .

A summary of the commodity contribution by raw agricultural commodity (RAC) for the overall U.S. population subgroup is attached as Table 4 of the DRES Chapter.

Acute Exposure

The DRES detailed acute exposure analysis evaluates individual food consumption as reported by respondents in the USDA 77-78 Nationwide Food Consumption Survey (NFCS) and estimates the distribution of single day exposures through the diet for the U.S. population and certain subgroups. The analysis assumes uniform distribution of ethalfluralin in the commodity supply. Since the toxicological effect to which high end exposure is being compared to in this analysis is developmental toxicity, the DRES subgroup of concern is females (13+ years) which approximates women of child-bearing age.

The Margin of Exposure (MOE) is a measure of how closely the high end exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory study), and is calculated as the ratio of the NOEL to the exposure ($\text{NOEL/exposure} = \text{MOE}$). For substances whose acute NOEL is based on animal studies, the Agency is not generally concerned unless the MOE is below 100.

In the analysis, tolerance level residues were used to calculate the high-end exposure for the females (13+ years) subgroup. High end exposure was compared to the NOEL of 75 mg/kg bwt/day from the rabbit developmental study to get a high end Margin of Exposure. The MOE for females was calculated in the attached table and the results are as follows:

Females (13+ years) High End Exposure = 0.003
 NOEL/ Exposure = $75 \text{ mg/kg/day} \div 0.003 = 25,000$

This is the first time that acute exposure has been calculated for ethalfluralin using the DRES system. Using the given endpoints, the MOE is not of concern for the subgroup females (13+ years) with an estimated MOE of 25000.

B. Occupational and Residential

Worker risk is in the range of 3×10^{-6} to 4×10^{-4} . The worst case scenario is for the commercial mixer/loader using the liquid/dry flowable formulation with an extra cancer risk of 4×10^{-4} . Exposure assessments for all other mixer/loader/applicator scenarios resulted in acceptable risks, based on the data currently available.

Risk was calculated as follows:

Values represent the maximum area which is assumed to be used in a single day to complete treatments for each exposure scenario of concern.

Daily Dermal Dose (mg/kg/day) = (Exposure (mg/lb ai) * Max. Appl. Rate (lb ai/cycle) * Max. Treated) / 70 kg

LADD (mg/kg/day) = Daily Dermal Dose (mg/kg/day) * (Work Days Per Yr / 365 Days Per Year) * (35 Yrs / 70 Yrs)

Commercial applicator is defined as an intermediate exposed individual (i.e., 10 days).

Risk = Dermal LADD (mg/kg/day) * Q_1 *

No adjustment has been made to simulate workers wearing dust/mist respirators. Inhalation exposure (μ g/lb ai) is considered to be significantly less than potential dermal exposure.

Personal Protective Equipment (PPE) for Handlers (Mixer/Loader/Applicators)

There appears to be no engineering control requirements, such as closed systems or enclosed cabs, currently required on labeling for ethalfluralin products.

For each end-use product, PPE requirements for pesticide handlers will be set during reregistration in one of two ways:

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be established based on the acute toxicity of the end-use product. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more

recent EPA guidelines.

2. If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects, cancer, developmental toxicity, or reproductive effects:

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most occupational end-use products containing that active ingredient.

- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product.

- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

There are special toxicological concerns (i.e., classification as a Group C carcinogen) about ethalfluralin that warrant the establishment of active-ingredient-based PPE requirements.

Handler PPE for Occupational-Use Products

WPS Uses: At this time all of the registered uses of ethalfluralin appear to be within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The minimum (baseline) PPE for all end-use products containing ethalfluralin is: coveralls and chemical-resistant gloves for all handlers plus a chemical-resistant apron for mixers and loaders.

NonWPS Occupational Uses: At this time all of the registered uses of ethalfluralin appear to be within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS).

Handler PPE for Home-Use Products

At this time there appear to be no products containing ethalfluralin that are intended primarily for home use.

Entry Restrictions

Entry Restrictions for Occupational-Use Products

Restricted Entry Interval: Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are established based on the acute toxicity of the active ingredient. The toxicity categories

of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: product-specific REI's established on the basis of adequate data and interim REI's that are longer than those that would be established under the WPS.

For occupational end-use products containing ethalfluralin as an active ingredient, HED recommends establishing a 24-hour restricted-entry interval pertaining to each use of the product that is within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). This recommendation is based on ethalfluralin being categorized as toxicity category II (moderate) for skin irritation potential and classified as a Group C carcinogen. HED found no extenuating circumstance for retaining the 12-hour interim restricted-entry interval placed on ethalfluralin products by PR Notice 93-7. HED notes that the 12-hour interim WPS restricted-entry interval was established because early data indicated that ethalfluralin was in toxicity category III for skin irritation potential.

HED notes that the WPS established very specific restrictions on entry during restricted-entry intervals that involves contact with treated surfaces and HED believes that these existing WPS protections are sufficient to mitigate post-application exposures of workers who contact ethalfluralin-treated soil. HED also notes that if ethalfluralin has been correctly incorporated, workers may enter the treated area during the restricted-entry interval without personal protective equipment or any other restriction if they are performing tasks that do not involve contact with the soil subsurface.

Early Entry PPE -- Personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the toxicity concerns about the active ingredient. The requirements are set in one of two ways.

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements based on the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient.

2.If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects, cancer, developmental toxicity, or reproductive effects, it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Since ethalfluralin is classified as toxicity category II for skin irritation potential and eye irritation potential and is categorized as a Group C carcinogen, the PPE required for early entry is coveralls over short-sleeved shirt and short pants, chemical-resistant gloves, chemical-resistant footwear plus socks and protective eyewear.

NonWPS Uses: At this time none of the registered occupational uses of ethalfluralin are outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS).

PPE for Home-Use Products

At this time there appear to be no products containing ethalfluralin that are intended primarily for home use.

Other Labeling Requirements

The Agency is requiring the following labeling statements to be located on all end-use products containing ethalfluralin that are intended primarily for occupational use:

Application Restrictions:

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

Engineering Controls:

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240 (d) (4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations:

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

In addition, because ethalfluralin is classified as a skin sensitizer, EPA requires that the following statement appear on all ethalfluralin labels in the "Hazards to Humans (and Domestic Animals)" section of the Precautionary Statements:

"This product may cause skin sensitization reactions in certain individuals."

Registrants may add the following statement to their labeling in the Agricultural Use Requirements box immediately following the restricted entry interval:

"Exception: if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."

Data Gaps and Additional Requirements:

The following requirements and recommendations exist for ethalfluralin:

- 1) Additional data are required to upgrade for the following product chemistry guidelines: 61-1; 62-1; 62-2; and 62-3;
- 2) Additional residue data are required to upgrade the following residue chemistry guidelines: 171-4(a); 171-4(k). Confirmatory field trial data are required for cucurbits (preemergence), and a third metabolism study is required (cucurbits);
- 3) Postemergence/post-transplant application to cucurbits data are not available. This use should be removed from all labels;
- 4) Field trial data are required for residues of ethalfluralin in/on alfalfa hay and forage, pea and bean hay and forage, soybean hay and forage, and peanut hay. These

data are considered confirmatory;

5) Grazing, foraging, and haying restrictions must be removed from the labels, except sunflower forage;

6) Data pertaining to the nitrosamine content are outstanding; nitrosamine analysis is required since ethalfluralin contains a tertiary alkylamine; and

7) HED has concluded that residues of ethalfluralin from up to 10x dietary burden would not be quantifiable (<0.05 ppm). This is considered a Category 3 use (40 CFR §180.6), and the existing tolerances (expressed in terms of ethalfluralin per se) for eggs, milk, and fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep should be revoked.

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APPENDIX

Case No. 2260

Chemical No. 113101

Case Name: Ethalfluralin

Registrant: DowElanco

Product(s): 96% T (EPA Reg. No. 62719-132)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ^a	MRID Number ^b
61-1	Product Identity and Disclosure of Ingredients	N ^c	<u>42042501</u> 42370201 ^d
61-2	Starting Materials and Manufacturing Process	Y	<u>42042501</u> 42779201 ^c
61-3	Discussion of Formation of Impurities	Y	<u>42042501</u>
62-1	Preliminary Analysis	N ^c	42370201 ^d
62-2	Certification of Ingredient Limits	N ^c	42370201 ^d
62-3	Analytical Methods to Verify the Certified Limits	N ^c	42370201 ^d
63-2	Color	Y	00135194 ⁱ
63-3	Physical State	Y	00135194 ⁱ
63-4	Odor	Y	00135194 ⁱ
63-5	Melting Point	Y	00135194 ⁱ
63-6	Boiling Point	N/A ^j	
63-7	Density, Bulk Density or Specific Gravity	Y	42308801 ^k
63-8	Solubility	Y	00135194 ⁱ
63-9	Vapor Pressure	Y	42437201 ^j
63-10	Dissociation Constant	N/A ^j	
63-11	Octanol/Water Partition Coefficient	Y	<u>41890101</u>
63-12	pH	N/A ^j	
63-13	Stability	Y	41613901 ^m 41086401 ⁿ 42929601 ⁿ

^a Y = Yes; N = No; N/A = Not Applicable. DowElanco has requested (letter dated 12/23/93, from D. Roby to T. Myers, SRRD) a time extension for submission of additional data until 12/1/94. The requested extension includes planned production of ethalfluralin in February 1994 and the time required subsequent to production to conduct outstanding analysis and complete new method development.

^b Underlined citations were reviewed under CBRS Nos. 8193 and 8809, D170327 and D167184, dated 5/1/92, by K. Dockter; all other citations were reviewed as noted.

^c These data do not fully satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product identity because two compounds were incorrectly identified on the CSF. Furthermore, the registrant must provide definitive chemical names for all "isomers" and CAS numbers for all components.

^d CBRS No. 10287, D180905, dated 9/8/93, by P. Deschamp.

^e CBRS No. 12066, D192185, dated 8/30/93, by K. Dockter.

^f These data do not fully satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis because preliminary analysis data on five samples from different batches of the 96% T manufactured using the current manufacturing process must be submitted. We note that if the manufacturing process has changed from the one previously reviewed by the Agency (CBRS Nos. 8193 and 8809, dated 5/1/92), then the registrant must submit a complete description of the manufacturing process for review (under GLN 61-2). The registrant must also indicate how the components of a group of impurities (active ingredient isomers) were distinguished and confirm the identification of one compound listed on the CSF from the tentative identification made in preliminary analysis. In addition, the nitrosamine analysis must be performed using a sample analyzed at 0, 3, and 6 months after production; only an initial analysis was provided. Finally, the registrant must submit preliminary analysis data for an impurity included on the CSF dated 5/26/92.

^g These data do not fully satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certification of limits because a lower certified limit must be proposed for an impurity which is pesticidally active. We note that this compound should also be added to the label claim. In addition, the registrant must identify which of the two manufacturing processes discussed in preliminary analysis the proposed certified limits are intended to support.

^h These data do not fully satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods because complete validation data must be submitted for the method used to determine the active ingredient. In addition, the registrant must submit a complete description and supporting validation data for the analytical methods used to determine the impurities.

ⁱ CBRS No. 13256, D199662, dated 3/9/94, by S. Funk.

^j CBRS has concluded that these requirements are not applicable (CBRS Nos. 8193 and 8809, D170327 and D167184, dated 5/1/92, by K. Dockter).

^k CBRS No. 9990, D179014, dated 7/23/92, by K. Dockter.

^l CBRS No. 10596, D182718, dated 2/23/93, by A. Aikens.

^m CBRS Nos. 8186, D167177, dated 7/30/92, by P. Deschamp.

ⁿ CBRS No. 12630, D195501, dated 11/2/93, by S. Funk.



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R056049

Chemical: Ethalfluralin

PC Code: 113101

HED File Code 13000 Tox Reviews

Memo Date: 08/31/94 12:00:00 AM

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