

6/16/93

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EEB Out :

To: JOANNE MILLER  
Product Manager  
Registration Division (H7505C)

From: Douglas J. Urban, Acting Chief  
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 8340-ET, EI, EO, & GR  
Chemical Name : GLUFOSINATE / IGNITE  
Type Product : HERBICIDE  
Product Name :  
Company Name : HOECHST CELANESE CORP  
Purpose : REVIEW RESPONSE TO PREVIOUS REVIEW DATED  
12-20-90, DATA SUBMITTED FOR EVALUATION, DETERMINE STATUS  
OF DATA REQUIREMENTS FOR REGISTRATION, ASSESS RISK TO NONTARGETS  
Action Code : 115 Date Due : 8-7-92  
Reviewer : MIKE REXRODE

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2	42262404	
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)	42262402 42262403		123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur  
P=Partial (Study partially fulfilled Guideline but additional information is needed  
S=Supplemental (Study provided useful information but Guideline was not satisfied)



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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

**Subject:** Review Response to Previous Glufosinate (12/20/90).  
Review DER's Submitted for Evaluation. Determine  
Data Requirements for Registration. Assess Risk  
to Nontargets

**FROM:** *for* Anthony Maciorowski, Chief *Douglas J. Wilson*  
Ecological Effects Branch  
Environmental Fate and Effects Division (H7507C) *4/16/93*

**TO:** Joanne Miller, PM 23  
Registration Division (H7504C)

The EPA's Ecological Effects Branch (EEB) is replying to the letter that Hoechst Celanese Corporation submitted to the Agency on 6/1/93. This letter addressed certain issues regarding the herbicide, Ignite (glufosinate-ammonium) and particular comments outlined in an earlier EEB review that evaluated the ecological effects of this same compound (12/20/90). EEB's review of the various issues will be addressed in the context of Agency response and registrant comments in order to maintain continuity in this process as follows:

**I. Adequacy of Labeling**

**EEB Comments (12/20/90)**

The EEB recommended the following label revisions:

- (a) Correction of discrepancy for maximum seasonal use rate on soybeans in the Ignite crop label.
- (b) Inclusion of additional environmental hazard precautionary statements in the Ignite non-crop label.
- (c) Deletion of the following sites from the Ignite non-crop label: dry ditches, dry canals and ditchbanks.
- (d) Inclusion of the total number of applications allowed per acre per year in the Ignite non-crop label.



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contains at least 50% recycled fiber

(e) Revision of the drift/runoff warning statement in the special notes of the Ignite non-crop label.

**Applicant Response (4/1/92)**

The applicant has made the following label revisions after considering EEB comments:

(a) The maximum seasonal use rate on soybeans is now consistently specified as 7.0 pints/acre/year on pages 4 and 9 of the Ignite crop label.

(b) The additional environmental hazard precautionary statements in the review are now included in the labels for Ignite Herbicide (crop and non-crop).

(c) The indicated use sites have been deleted from the Ignite non-crop label.

(d) In lieu of the total number of applications allowed per acre per year, we have stated the total amount of product to be applied per acre in one year. For the Ignite non-crop label, this is stated on page 4 as a maximum of 28 pints/acre/year. The maximum seasonal use rate per year is preferred over the maximum number of applications per year because the rate for individual applications is variable over a wide range.

(e) The revised EEB drift/runoff warning statement has been added to the special notes in each of the product labels.

**EEB Response (6/14/93)**

EEB will address each issue as follows:

(a) The discrepancy regarding seasonal use rate has been corrected by the registrant to 7.0 pints/acre/year. EEB finds this acceptable.

(b) Environmental hazard precautionary statement for Ignite non-crop and crop labels will state "Do not apply directly to water or to swamps, bogs, marshes, or potholes." "Do not apply in areas that drain into shallow water bodies or low-lying areas." EEB finds this acceptable.

(c) Sites to be deleted from the Ignite non-crop label will include: dry ditches, dry canals and ditch banks. EEB finds this acceptable.

(d) EEB wanted a statement referring to total number of applications of Ignite (non-crop) per acre per year. However, the registrant has agreed to list the total amount of herbicide to be applied per acre in one year (maximum of 28 pints/acre/year). EEB finds this acceptable.

(e) Registrant has agreed to add the revised EEB drift/runoff warning statement as follows: "Ignite herbicide will damage all foliage it comes into contact with; therefore, avoid contact to all desirable foliage." Additional precautions regarding adverse effects to non-target and endangered plant species due to runoff from the treated site will be modified as follows to account for runoff effects as well as foliar effects: "Ignite herbicide drift or runoff from the treatment area will damage all plants it comes in contact with; therefore, avoid contact with all non-target vegetation." EEB finds this acceptable.

## II. Endangered Species

### EEB Comment (12/20/93)

EEB stated that until they received a consultation from the Fish and Wildlife Service, the registrant must disallow Ignite use in counties where endangered/threatened plant species exist. The EEB recommended that the Ignite label list the county or area within a county in which Ignite cannot be used and supply the registrant with a list of endangered/threatened plant species.

### Applicant Response (4/1/93)

The applicant concluded that the preceding approach was not consistent with the pending EPA endangered species protection program that was expected to be implemented for all pesticide products in 1992 or 1993. They noted that a listing of all counties and/or endangered species habitat areas on the label would be cumbersome and unwieldy for both the applicant and the user. In place of this, they suggested that a generic endangered species protection statement be used on the label. This statement was expected to refer the user to an endangered species bulletin for his area, if appropriate, and the bulletin rather than the label would contain any appropriate limitations on pesticide use in the specified area. The applicant has examined several interim endangered species bulletins (issued by the Agency in September 1990) and believes it is appropriate to list Ignite products along with other non-selective herbicides that have already been included. The bulletin itself will then contain the

appropriate and standardized use limitations for Ignite and similar products in the indicated areas.

**EEB Response (6/11/93)**

EEB has not completed the EPA Endangered Species Protection Program and is not prepared to suggest a generic endangered species protection statement that will refer the user to an endangered species bulletin for an area of concern. However, since Ignite is to be used only with ground application, EEB is requiring a 100 yard buffer zone separating areas that have endangered species from areas of glufosinate use.

**III. Adequacy of Toxicity Data**

**EEB Comment (12/20/93)**

The EEB stated that it still needed clarification of the residue analysis data for the avian feed used in the mallard duck and Bobwhite quail reproduction studies. Apparently these data are still unclear even after this issue was addressed in the applicant's prior response to the first EEB review.

**Applicant Response (4/1/93)**

An additional explanation to the question of the residue analysis data for the avian feed in the reproduction studies was provided in Section III in Volume 1 of the enclosed submission.

**EEB Response (6/14/93)**

The registrant has submitted data that confirms the homogeneity and stability of dietary mixtures. Representative samples of dietary mixtures were taken at the time of preparation during the first week of the preliminary study. The mixtures were divided top, middle and bottom and samples were taken from these points. Analysis were completed between 10 and 30 days after diet preparation on each concentration level and shows that the mixture used in the avian reproduction studies was homogenous and stable (less than a 1.5% difference between test substance that was initially added and that which was found after two to four weeks). The EEB accepts this information and will upgrade the Mallard duck and Bobwhite quail reproduction studies from supplemental to core (acceptable for registration).

#### IV. Additional Data Submission

##### EEB Comment (12/20/93)

Outstanding data requirements for Ignite Herbicide:

(a) 72-3: MRID # 422624-02; Acute Embryo Larvae Study (*Mercenaria mercenaria*). Testing was to be done on TEP.

(b) 72-3: MRID # 422624-03; Acute Mollusc Shell Deposition Study (*Crassostrea virginica*). Testing was to be done on TEP.

New data requirements for Ignite Herbicide:

(a) Tier III non-target plant phytotoxicity field study. However, prior to requiring this Tier III study, a 123-2 Tier II test on *Lemna gibba* is required.

##### Applicant Response (4/1/93)

Mollusc embryo larvae (*Mercenaria mercenaria*) and mollusc shell deposition (*Crassostrea virginica*) studies have been conducted with Ignite Herbicide formulated product (TEP) and are being submitted at this time. An aquatic plant growth and reproduction study with *Lemna gibba* (EPA guidelines No. 123-2) was also conducted and is also being submitted. The applicant disagrees with the requirement for a Tier III non-target plant phytotoxicity field study for reasons which are enumerated in Volume 1 of the response. It should also be noted that subsequent to the issuance of this review, the Agency has placed all requirements for this type of testing "on hold" until adequate testing methodology and protocols are developed.

##### EEB Response (6/14/93)

The EEB has reviewed the following studies for Ignite herbicide:

1) 72-3(b) MRID # 422624-03; Mollusc Shell Deposition using the TEP. This study is scientifically sound and will fulfill data requirements. The 96-hr  $EC_{50} = 29$  mg/L shows that Ignite formulation is moderately toxic to the eastern oyster (*Crassostrea virginica*). The NOEC was calculated at 1.32 mg/L. Since the study was conducted on a formulation, it will be considered supplemental.

2) 72-3(c) MRID # 422624-02; Acute Mollusc Embryo Larvae EC<sub>50</sub> study using the TEP. This study is scientifically sound but will not fulfill guideline requirements. The 48-hr EC<sub>50</sub> = 0.69 mg/L (0.64 - 0.75 mg/L) shows that Ignite formulation is highly toxic to the hard shell clam (*Mercenaria mercenaria*) embryo larvae. The NOEC was calculated at <0.52 mg/L. The study report did not show mortality data (only mean survival was reported), stage of embryo development was not noted prior to dosing, and the time between fertilization and initiation of test was not reported. This study will be considered supplemental.

3) 123-2 MRID # 422624-04; Growth and Reproduction of Aquatic Plants (*Lemna gibba*). This study is scientifically sound and meets guideline requirements for a Tier II non-target aquatic plant study. The NOEC, LOEC and EC<sub>50</sub> for *L. gibba* that were exposed to glufosinate technical were calculated at 0.80, 1.35 and 1.47 mg/L, respectively.

These studies are acceptable for use in developing a risk assessment for Ignite. The previously required Tier III non-target plant phytotoxicity test will be waived. EEB will complete a risk assessment without this field study.

#### V. Risk Assessment of Glufosinate to Non-Target Organisms

EEB calculated an estimated environmental concentration (EEC) for glufosinate aquatic exposure for the 12/20/90 review using registrant generated fate data. This runoff scenario took into consideration the following: 1) high water solubility (1,370,000 ppm) 2) high mobility in soil, and 3) high stability in soil and water (23-39 days). Because of these considerations, an exposure level was calculated using 1.44 lbs ai/acre with 5% runoff into a 1 acre pond from a 10 acre drainage area. The EEC's that were derived, apply to one application and resulted in theoretical residues of 0.04 ppm (6 foot of water) and 0.53 ppm (6 inches of water). According to the available laboratory data and the EEB Regulatory Risk Criteria (1/10 LC50) the use of glufosinate is not expected to be acutely toxic to nontarget freshwater/marine fish, freshwater invertebrates, and marine shrimp. However, information from a toxicity study on oyster larvae (*Crassostrea virginica*) suggests that glufosinate has the potential to acutely affect mollusc early life stages (1/10 LC50 = 0.069 ppm).

The present crop label allows for a maximum of three applications of glufosinate per year, not to exceed a maximum of 4.51 lbs ai/acre/year. Since, this compound is highly persistent (20 - 39 days) and water soluble (1,370,000 ppm) and has a potential for hazardous impact on oyster embryo larvae, EEB completed an extension of the first EEC to include multiple applications. As a conservative estimate of persistence, EEB will assume that the compound has a 1/2 life in water of 20 - 30 days with applications at 30 day intervals. The following residue levels were calculated:

- 1) First Application Glufosinate  
6 feet of water = 0.04 ppm  
6 inches of water = 0.53 ppm
- 2) Second Application Glufosinate  
6 feet of water = 0.06 ppm  
6 inches of water = 0.80 ppm
- 3) Third Application Glufosinate  
6 feet of water = 0.07 ppm  
6 inches of water = 0.93 ppm

Relative to these calculated values, repeated application of glufosinate may result in acute effects to oyster embryo larvae and possibly other invertebrate developmental stages. This may be especially critical after a second and third application when intervals are less than 30 days. Since, this compound is to be registered on two large acreage crops (soybeans and corn) a possible risk mitigation that could be considered should include the establishment of > 60 day interval between applications.

The non-crop label allows for multiple applications not to exceed 17 lbs ai/acre. The registrant has agreed to delete dry-ditches, dry canals and ditch banks from the non-crop label. This action should mitigate residue exposure to non-target aquatic organisms (fish and aquatic invertebrates) that may be exposed during non-crop use.

Since, glufosinate is a very persistent, water soluble, non-selective contact herbicide, any off-target movement of the compound is expected to adversely affect non-target terrestrial plant species. However, minimal exposure is expected to occur from drift (review 12/20/90) during application since the registrant has included the "ground application only" restriction on the label.



## VI. Conclusions

The proposed use of glufosinate on crop and non-crop areas is not expected to adversely affect birds, mammals or fish. However, glufosinate exposure to marine/estuarine molluscs, after two or more applications (< 30 day intervals), may result in acute effects to embryo larvae stages. Since, this compound is to be registered on two large acreage crops (soybeans and corn) a possible risk mitigation that could be considered should include the establishment of > 60 day interval between applications (assuming a 30 day half-life from registrant generated data).

The non-crop label allows for multiple applications not to exceed 17 lbs ai/acre. The registrant has agreed to delete dry-ditches, dry canals and ditch banks from the non-crop label. This action should mitigate residue exposure to aquatic organisms (fish and aquatic invertebrates) that may be exposed during non-crop use.

Since, glufosinate is a very persistent, water soluble, non-selective contact herbicide, any off-target movement of the compound is expected to adversely affect non-target terrestrial plant species. Although a minimal exposure is expected to occur from drift (review 12/20/90), a label restriction that specifies "ground application only" is expected to help mitigate this exposure.

EEB has not completed the EPA Endangered Species Protection Program and is not prepared to suggest a generic endangered species protection statement that will refer the user to an endangered species bulletin for an area of concern. However, since Ignite is to be used only with ground application, EEB is requiring a 100 yard buffer zone separating areas that have endangered species from areas of glufosinate use (Miachel Rexrode (703) 305-5578).

**NOTE TO PM RE: Glufosinate**

**Status of Data Requirements:** The EEB has sufficient data to perform a risk assessment for corn, soybean and noncropland use. No additional data are required. The mollusc study (422624-02) does not have to be repeated.

**Risk Criteria Exceeded:** The risk criterium that has been exceeded (1/10 the EC50 for mollusc) is the one indicating risk that may be mitigated by, among other things, classifying the pesticide as restricted use. Levels of Concern indicating high risk to aquatic vertebrates and invertebrates (1/2 the LC50's or EC50's) have not been exceeded. Along with the mitigation measures proposed by the registrant (such as ground application only, deleting dry ditch banks, dry canals and ditch banks) and recommended by EEB (60-day between harvest interval) restricted use should reduce risk to an acceptable level.

 6/16-93  
Daniel Rieder