

US EPA ARCHIVE DOCUMENT



DP Barcode: _____

Shaughnessy No.: 121601

Date out of EFGWB: 1/18/91

TO: J. Miller/J. Mayes
Product Manager #23
Registration Division (H7505C)

FROM: Paul Mastradone, Chief *PM*
Chemistry Review Section #1
Environmental Fate and Ground Water Branch

THRU: Hank Jacoby, Chief *Hank Jacoby*
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Attached, please find the EFGWB review of ...

Reg./File #: 010182-EUP-LU

Chemical Name: 2-Chloro-2'-methyl-6'-N-ethoxymethylacetanilide

Type Product: Herbicide

Common Name: Acetochlor

Company Name: ICI Americas Inc.

Purpose: Review addendum to application for EUP on corn

Date Received: 19 October 1991 Date Completed: _____

Action Code: 240

EFGWB #(s): 90-0871

Total Reviewing Time: 1.0 day

Deferrals to: Ecological Effects Branch, EFED
Science Integration and Policy Staff, EFED
Non-Dietary Exposure Branch, HED
Dietary Exposure Branch, HED
Toxicology Branch

1. CHEMICAL:

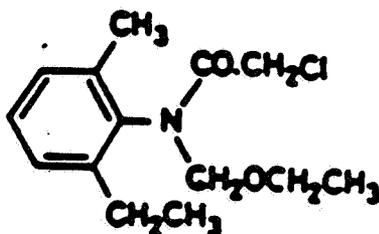
Chemical name: 2-Chloro-2'-methyl-6'-N-ethoxymethylacetanilide

CAS no.: 34256-28-1

Common name: Acetochlor

Trade name: ICIA5676

Chemical structure:



Formulation: Acetochlor.....70.9%
Inert Ingredients.....29.1%

Physical/Chemical properties of active ingredient:

Physical characteristics: Colorless thick liquid, aromatic odor

Molecular formula: C₁₄H₂₀ClNO₂

Molecular weight: 269.8

Vapor Pressure: 4.4 X 10⁻⁵ mm Hg

Solubility: 233 mg/L at 25°C

Octanol/water partition coefficient: 3.0

2. TEST MATERIAL:

N/A

3. STUDY/ACTION TYPE:

Review of addendum to application for ICIA5676 Experimental Use Permit (EUP) on corn.

4. STUDY IDENTIFICATION:

Kaminski, B. RESPONSE TO EPA REVIEW. ICI Agricultural Products, Wilmington, DE.

5. REVIEWED BY:

Gail Maske
Chemist, Review section #1
OPP/EFED/EFGWB

Signature: *Gail Maske*
Date: _____

6. APPROVED BY:

Paul Mastradone
Chief
Review section #1
OPP/EFED/EFGWB

Signature: *Paul Mastradone*
Date: _____

7. CONCLUSIONS:

Based on a review of the environmental fate data, there is marginally sufficient to support the Experimental Use Permit (EUP) request for use of ICIA-5676, active ingredient is acetochlor, on corn for the following reasons:

INERT INGREDIENT INFORMATION IS NOT INCLUDED

1. EFGWB did not received a new aerobic soil metabolism study for acetochlor as stated in the package. However, the supplemental data ~~are~~ sufficient for the purposes of the EUP, but ~~they are~~ not acceptable for the purposes of a Section 3 registration. Additional aerobic soil metabolism data as outlined ~~are~~ needed for a Section 3 registration.
2. In addition, EFGWB did not received a new accumulation in fish study as stated in the package. Additional accumulation in fish data ~~are~~ needed to fully understand the environmental fate of acetochlor.
3. Confined rotational crop data were not submitted. However, the registrant stated in the EUP protocol "DO NOT ROTATE TO ANY CROP OTHER THAN CORN".
4. EFGWB has not completed the review of the following data needed to evaluate the environmental fate of the [REDACTED] for the proposed use on corn. The reasons for requiring this data have been stated in several reviews (WGM;91). Data needed to support the proposed EUP are:

161-1	Hydrolysis
162-1	Aerobic soil metabolism
163-1	Leaching, adsorption/ desorption
165-1	Rotational crops-confined
165-4	Accumulation in fish

8. RECOMMENDATIONS:

The registrant should be informed of the following:

INERT INGREDIENT INFORMATION IS NOT INCLUDED

- a. There is not sufficient environmental fate data to support the proposed EUP for use of acetochlor and [REDACTED] on corn. The environmental fate data for acetochlor and [REDACTED] should be submitted simultaneously in order that a complete environmental fate assessment of acetochlor can be made.
- b. The status of the EUP Environmental Fate Data Requirements for acetochlor for terrestrial food use is as follows:

<u>Environmental Fate Data Requirements</u>	<u>Status of Data Requirement</u>	<u>MRID No.</u>
Degradation Studies-Lab		
161-1 Hydrolysis	Fulfilled (WGM;01/18/91)	41565144
Metabolism Studies-Lab		
162-1 Aerobic (Soil)	Not Fulfilled (WGM;01/18/91)	41565147
Mobility Studies		
163-1 Leaching, Adsorption/ Desorption	Fulfilled (WGM;01/18/91)	41565149
163-2 Volatility-lab	Not Required (PRD;04/24/89)	
Accumulation Studies		
165-1 Rotational crops-confined	Not Submitted ¹	
165-4 In fish	Not Submitted	

¹ Accumulation in confined rotational crops data is required when it is reasonably foreseeable that any food or feed crop may be subsequently planted on the site of pesticide application. However, the confined rotational crops data are not required for crop destruct EUP's.

- e. The status of the EUP Environmental Fate Data Requirements for [REDACTED] for terrestrial food use is as follows:

<u>Environmental Fate Data Requirements</u>	<u>Status of Data Requirement</u>	<u>MRID No.</u>
Degradation Studies-Lab		
161-1 Hydrolysis	In Review	
Metabolism Studies-Lab		
162-1 Aerobic (Soil)	In Review	

Con't--	<u>Environmental Fate Data Requirements</u>	<u>Status of Data Requirement</u>	<u>MRID No.</u>
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Mobility Studies

163-1	Leaching, Adsorption/ Desorption	In Review
163-2	Volatility-lab	In Review

Accumulation Studies

165-1	Rotational crops-confined	Not Submitted ¹
165-4	In fish	Not Submitted ²

¹ Accumulation in confined rotational crops data is required when it is reasonably foreseeable that any food or feed crop may be subsequently planted on the site of pesticide application. However, the confined rotational crops data are not required for crop destruct EUP's.

² The fish accumulation study is required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms.

NOTE TO PM: Attached is a status sheet of data requirements for registration of acetochlor and [REDACTED]

9. BACKGROUND:

ICIA5676 6.4 EC herbicide is the combination of acetochlor and the [REDACTED]. The acetochlor will be used to control many annual grasses, yellow nutsedge and certain broadleaf weeds in transplanted junipers and yews and corn while the [REDACTED] pesticide formulations to attenuate the phytotoxicity of the pesticide's active ingredient (acetochlor).

Acetochlor is toxic to aquatic life, but is less toxic to bees. There is no toxicity data available for [REDACTED]

10. DISCUSSION:

ADDENDUM TO EUP APPLICATION FOR USE OF ICIA5676 ON CORN

ICI submitted additional data for review in support of the EUP application reviewed in January 1991. The registrant, ICI Americas, stated that a new aerobic soil metabolism study and accumulation in fish studies have been submitted. These studies have not been received by EFGWB. Therefore, aerobic soil metabolism data and accumulation in fish data are needed to fully understand the environmental fate of acetochlor.

In addition, based on the label clearly stating "DO NOT ROTATE TO ANY CROP OTHER THAN CORN" the registrant stated that confined rotational crops data

INERT INGREDIENT INFORMATION IS NOT INCLUDED

5

is not required for an EUP. However, the guidelines state that accumulation in confined rotational crops data is required when it is reasonably foreseeable that any food or feed crop may be subsequently planted on the site of pesticide application. Confined rotational crops data are generally not required for crop destruct EUP's.

Additional data was submitted as a rebuttal to the aerobic soil metabolism study (MRID 41565147) review (WGM;01/18/91). Based on a review of the submitted data and the EFGWB review of the aerobic soil metabolism study, the aerobic soil metabolism data requirement is not fulfilled for the following reasons:

The registrant submitted data to identified only 3 of the 11 degradates which were present in concentrations of >0.01 ppm.

Sufficient data is needed to fully understand the environmental fate of acetochlor. Even though the registrant submitted addition HPLC data, the separation of degradates in analysis was not clarified. Therefore, the pattern of formation and decline of the degradates and acetochlor is not fully understood.

EUP APPLICATION

In meeting the objectives of the proposed experimental program, a total of up to 10,000 pounds will be applied on up to 5,000 acres across the United States (see Table I) over a two year period which begins 1 February 1992 and ending 31 January 1994. During 1992 there will be a total of up to 3,340 pounds applied on up to 1,670 acres. In 1993 there will be up to 6,600 pounds applied on up to 3,330 acres. The primary application season will be April, May, and June of each year.

Acetochlor, ICIA5676, will be applied at a rate of 0.75 to 2.5 lbs. ai/A (varying according to soil type and organic matter from site to site) with no more than one application per site per year. The application at a site could be make as early as 6 weeks prior to planting or as late as 1 day before emergence of the corn seedings.

ICIA5675 6.4 EC will be applied to the soil surface primarily using ground equipment. However, some material will be applied aerially. There will be no chemigation applications. If applied with dry bulk fertilizer, ICIA-5676 6.4 EC will be applied either as a liquid spray or impregnated on the dry fertilizer.

Although the primary application will be preplant surface, at some sites the material may be incorporated into the top 1 to 2 inches of soil. The incorporation will be done by using one of several implements such as a disk, field cultivator, rotary hoe, or other mechanical means to thoroughly distribute the ICIA5676 within the soil layer.

Two types of data will be collected. The first is efficacy or percent control versus a commercial standard and an untreated check. The percent may be arrived at by stand counts of weeds in each treatment compared to the standard and untreated check or it can be a visual estimation against the same criteria. The second type of data to be collected is phytotoxicity evaluations. This will be rating of hybrid lines by actual stand counts.

or percent stunting, seeding vigor, chlorosis, and epinasty versus commercial standards and untreated checks.

In general there will be two types of tests. The most numerous will be small scale plots with 3 to 4 replicates per treatment covering approximately 1 acre. The second type and less numerous, but covering more total acreage, is large scale plots. The large scale plots will be non-replicated and cover more than an acre. The larger plots will be primarily those done by air and with dry bulk fertilizer. Those types of applications require larger equipment and acreages for a minimal loading.

Food or feed items grown under this EUP containing residues which do not exceed the established temporary tolerances would be sold through the normal channels of trade. Those food or feed items from plots, such as the phytotoxicity studies, which receive a rate higher than 2.5 lbs. ai/acre will be destroyed or used for research purposes and not allowed to enter human or animal diets.

11: COMPLETION OF ONE-LINER:

One-liner is attached for Acetochlor. There is no one-liner for [REDACTED]

12: CBI APPENDIX:

N/A

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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THE STATUS OF THE ENVIRONMENTAL FATE DATA REQUIREMENTS FOR ACETOCHLOR AND [REDACTED] REGISTRATION FOR TERRESTRIAL NON-FOOD CROPS ARE SUMMARIZED BELOW

ACETOCHLOR

Environmental Fate Data Requirement	Status of Data Requirement	MRID No.	Status of Data Requirement	MRID No.
Degradation Studies-lab				
161-1 Hydrolysis	Fulfilled (WGM;01/18/91)	41565144	In Review	41561409
161-2 Photodegradation in water	Fulfilled (WGM;06/15/91)	41565145 (1)	In Review	41561410
161-3 Photodegradation on soil	Fulfilled (WGM;06/15/91)	41565146 (1)	In Review	41561411
Metabolism Studies-lab				
162-1 Aerobic soil	Not Fulfilled (WGM;1/18/91)	41565147 (2)	In Review	41561412
162-2 Anaerobic soil (2)			Not Submitted	
Mobility Studies				
163-1 Leaching, Adsorption/ Desorption	Fulfilled (WGM;01/18/91)	41565149	In Review	41561413
Dissipation Studies-field				
164-1 Soil	Not Fulfilled (WGM;06/15/91)	41565152 (1&2) 41565153 41592012 41592013	In Review	41561414 41561415 41561417
164-4 Combination tank mix	Not Submitted (3)			
Accumulation Studies				
165-1 Confined rotational crops	Not Submitted		Not Submitted	
165-4 in Fish	Not Fulfilled (WGM;06/15/91)	41565154 (1&2)	Not Submitted	

- 1 These studies are in secondary review.
- 2 Data for acetochlor was submitted with the new chemical screen.
- 3 A combination and tank mix study (164-4) is also required. Therefore, a terrestrial soil dissipation study on two soils using acetochlor, a terrestrial soil dissipation study on two soils using [REDACTED] and a terrestrial soil dissipation study on two soils using both acetochlor and [REDACTED] are required.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Environmental Fate & Effects Division
 PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
 ACETOCHLOR (ICI)

Last Update on November 13, 1991

[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

LOGOUT	Reviewer:	Section Head:	Date:
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Common Name: ACETOCHLOR (ICI)

PC Code # : 121601

CAS #: 34256-82-1

Caswell #:

Chem. Name : 2-CHLORO-N-(ETHOXYMETHYL)-N-(2-ETHYL-6-METHYL-PHENYL)-
 ACETAMIDE

Action Type: HERBICIDE

Trade Names: ICIA5676

(Formul'tn):

Physical State: STRAW COLOURED LIQUID

Use : POSTEMERGENCE BROADLEAVED WEED CONTROL

Patterns :

(% Usage) :

:

Empirical Form: $C_{14}H_{20}NO_2Cl$

Molecular Wgt.: 269.80

Melting Point : °C

Log Kow : 3.0

Henry's : E

Vapor Pressure: 4.40E -5 Torr

Boiling Point: °C

pKa: @ °C

Atm. M3/Mol (Measured) 7.00E -8 (calc'd)

Solubility in ...

Water	2.23E	2	ppm	@20.0 °C	Comments
Acetone	E		ppm	@ °C	
Acetonitrile	E		ppm	@ °C	
Benzene	E		ppm	@ °C	
Chloroform	E		ppm	@ °C	
Ethanol	E		ppm	@ °C	
Methanol	E		ppm	@ °C	
Toluene	E		ppm	@ °C	
Xylene	E		ppm	@ °C	

Hydrolysis (161-1)

[V] pH 5.0: STABLE

[V] pH 7.0: STABLE

[V] pH 9.0: STABLE

[] pH :

[] pH :

[] pH :

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ACETOCHLOR (ICI)

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Photolysis (161-2, -3, -4)

[V] Water:INSIGNIFICANT

[] :
[] :
[] :

[V] Soil :INSIGNIFICANT

[] Air :

Aerobic Soil Metabolism (162-1)

[S] SILTY CLAY LOAM:13.5 DAYS

[]
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Anaerobic Soil Metabolism (162-2)

[S] SANDY LOAM: RELATIVELY STABLE-230 DAYS

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Anaerobic Aquatic Metabolism (162-3)

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Aerobic Aquatic Metabolism (162-4)

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Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
ACETOCHLOR (ICI)

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[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

Soil Partition Coefficient (Kd) (163-1)

[V]	SOIL	%OM	Kd
[]	COARSE SAND	0.77	0.05 TO 0.026
[]	LOAMY SAND	1.9	0.53 TO 3.34
[]	SANDY LOAM	2.6	1.14 TO 3.02
[]	CLAY	5.4	3.77 TO 4.93
[]	SAND	1.5	0.93 TO 5.48

Soil Rf Factors (163-1)

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[]
[]

Laboratory Volatility (163-2)

[]
[]

Field Volatility (163-3)

[]
[]

Terrestrial Field Dissipation (164-1)

[S] SILT LOAM SOIL: 36 DAYS FROM UPPER 3.5"
[S] CLAY LOAM SOIL: 26 DAYS FROM UPPER 3.5"
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Aquatic Dissipation (164-2)

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[]
[]

Forestry Dissipation (164-3)

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[]

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
ACETOCHLOR (ICI)

Last Update on November 13, 1991

[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

Long-Term Soil Dissipation (164-5)

[]
[]

Accumulation in Rotational Crops, Confined (165-1)

[]
[]

Accumulation in Rotational Crops, Field (165-2)

[]
[]

Accumulation in Irrigated Crops (165-3)

[]
[]

Bioaccumulation in Fish (165-4)

[S] BIOCONCENTRATION FACTORS: 40X FOR EDIBLE 780X FOR NONEDIBLE
[] 150X FOR WHOLE FISH - 2 TO 33% AT 28 DAY DEPURATION REMAINED

Bioaccumulation in Non-Target Organisms (165-5)

[]
[]

Ground Water Monitoring, Prospective (166-1)

[]
[]
[]
[]

Ground Water Monitoring, Small Scale Retrospective (166-2)

[]
[]
[]
[]

Ground Water Monitoring, Large Scale Retrospective (166-3)

[]
[]
[]
[]

Ground Water Monitoring, Miscellaneous Data (158.75)

[]
[]
[]

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
ACETOCHLOR (ICI)

Last Update on November 13, 1991

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Field Runoff (167-1)

[]
[]
[]
[]

Surface Water Monitoring (167-2)

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Spray Drift, Droplet Spectrum (201-1)

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Spray Drift, Field Evaluation (202-1)

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Degradation Products

MULTIPLE DEGRADATES. MAJOR DEGRADATES WERE METHYL OXANILIC ACID,
SULFINYLACETIC ACID, AND SULFOACETANILIDE

Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
ACETOCHLOR (ICI)

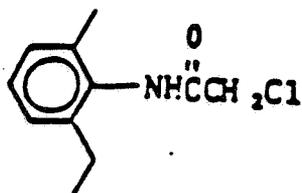
Last Update on November 13, 1991

[V] = Validated Study [S] = Supplemental Study [U] = USDA Data

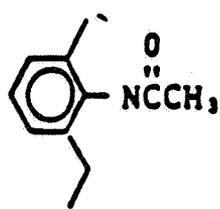
Comments

References: ENVIRONMENTAL FATE STUDIES; FARM CHEMICAL HANDBOOK
Writer : WGM

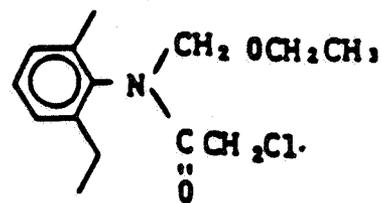
Figure 8. Structures of Compounds



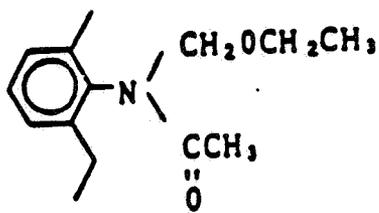
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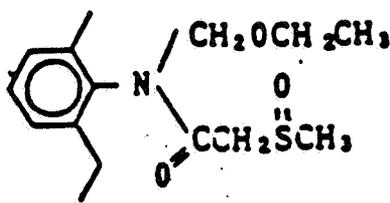
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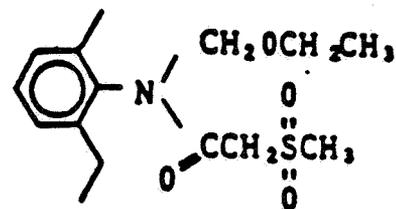
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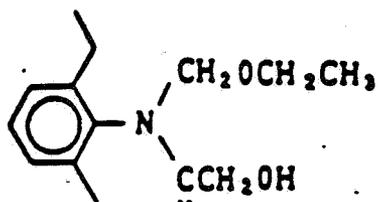
XI



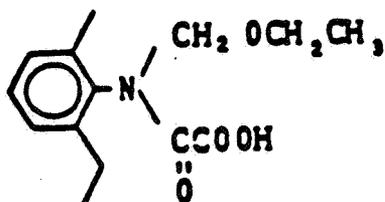
XIII



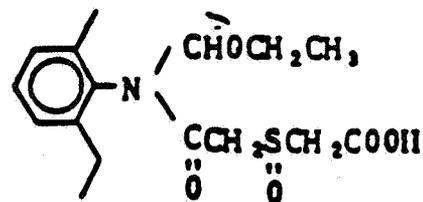
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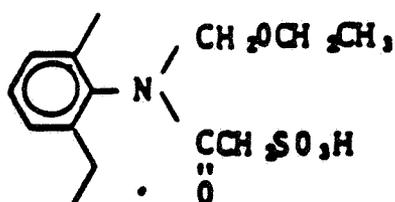
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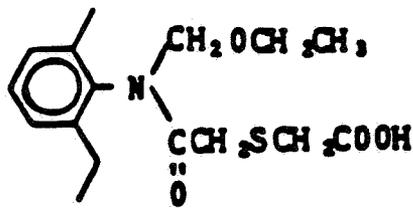
XVII



XVIII



XIX



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RIN 2556-94

ACETOCHLOR REVIEW (12/601)

Page 17 is not included in this copy.

Pages _____ through _____ are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
 - A draft product label.
 - The product confidential statement of formula.
 - Information about a pending registration action.
 - FIFRA registration data.
 - The document is a duplicate of page(s) _____.
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-

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