

FOSETYL-AL (ALIETTE)

Pesticide Registration Standard

(123301)

June 1983
Office of Pesticides and Toxic Substances

Environmental Protection Agency
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16. Abstract (Limit: 200 words)

This document contains information regarding reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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This registration standard was written by the EPA Office of Pesticide Programs (EPA/OPP) in cooperation with Rhone Poulenc, Inc. Further information is available from the Product Manager, Henry Jacoby, EPA/OPP, 401 M Street, S.W., Washington, DC 20460, telephone (703) 557-1900.

II. REGULATORY POSITION AND RATIONALE

A. Introduction

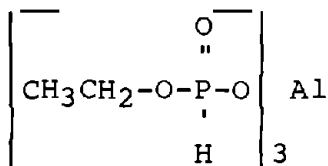
This Registration Standard presents the regulatory position of the Environmental Protection Agency (the Agency) on registration of manufacturing-use products (MP) containing the fungicide Fosetyl-Al, aluminum tris (O-ethyl phosphonate). The Agency's position is based on a consideration of available data. Registration requests for products containing Fosetyl-Al will be evaluated based on this standard.

This standard was developed with the cooperation of Rhone Poulenc, Incorporated. The topical discussions and data evaluation records (DER's) were written by Rhone Poulenc, Incorporated and submitted with each study to the Agency. The Agency reviewed and evaluated the data and critiqued and revised the DER's and topical discussions according to its findings. Although written by Rhone Poulenc, Incorporated, the DER's and topical discussion reflect the Agency's position on the subject.

B. Description of Chemical

Fosetyl-Al is the proposed American National Standards, Incorporated (ANSI) name for aluminum tris (O-ethyl phosphonate). The pesticidal uses of Fosetyl-Al are being developed by Rhone Poulenc, Inc.. It is marketed under the name Aliette™. The Chemical Abstracts Service (CAS) Registry Number is 39148-24-8. The OPP Internal Control Number (EPA Shaughnessy Number) is 123301. Fosetyl-Al is a white odorless powder. The empirical formula is C₆H₁₈AlO₉P₃. Fosetyl-Al melts with decomposition at temperatures greater than 200° celsius. The solubility of Fosetyl-Al in water at 20° celsius is 120 grams per liter.

The structural formula is:



Rhone Poulenc, Inc. is the sole producer of Fosetyl-Al. It is currently registered in ten foreign countries for use as a fungicide on fruits, vegetables, and ornamentals. Registration in the United States is pending for use as a pineapple seed piece (crowns) dip treatment and as a foliar spray on ornamentals.

C. Regulatory Position

Based on a scientific and technical evaluation of the available data, the Agency has made the following determinations:

1. The risk criteria found in section 162.11(a) of Title 40 Code of Federal Regulations were exceeded for Fosetyl-Al by exhibiting an oncogenic effect in rats fed Fosetyl-Al. However, based on the low level of exposure (i.e. mixer/loader, applicator, planter, and dietary) estimated to result from the two uses registerable under this Standard, a preplant dip for pineapple crowns and formulation for foliar application to field and greenhouse grown ornamentals, the Agency has determined that Fosetyl-Al is not likely to cause unreasonable adverse effects to either man or the environment.
2. Tolerances of 0.1 part per million (ppm) for pineapples and 0.1 ppm for pineapple forage must be established.
3. There is no need to establish reentry intervals for Fosetyl-Al.
4. Manufacturing-use pesticide products containing Fosetyl-Al as a sole active ingredient may be registered for sale, distribution, reformulation, and use, subject to the terms and conditions specified in this Standard.

D. Regulatory Rationale

The Agency has determined that it can allow the registration of Fosetyl-Al after considering the following:

1. Fosetyl-Al degrades in the environment through the hydrolysis of the ethyl ester bond with subsequent degradation of the ethanol into carbon dioxide. The phosphorous acid metabolite is expected to form precipitates with aluminum, calcium or iron in the soil. The half life of Fosetyl-Al under aerobic conditions in soil is approximately one and one-half hours. The intermediate metabolites in grapes, pineapple and the rat are ethanol and phosphoric acid. The environmental fate of Fosetyl-Al is sufficiently understood to conclude that little if any environmental accumulation of the chemical will result.
2. Residues of Fosetyl-Al remaining in/on harvested pineapples grown from treated pineapple seed pieces are undetectable by a method sensitive to 0.10 ppm. However, the data developed with C¹⁴ labeled Fosetyl-Al indicate that residues of Fosetyl-Al or its metabolites could remain in harvested pineapples at or below the level of detection.

3. No ecological hazards of concern resulting from the use of Fosetyl-Al on pineapple seed pieces or ornamentals have been identified in the studies reviewed.

4. Dietary and long term worker exposure to Fosetyl-Al and its degradates will be very low for pineapple crown treatment and for ornamental uses.

5. Positive oncogenic effects were observed in the rat two-year feeding study. An in-depth animal-by-animal review has been undertaken by the Agency and a provisional oncogenic risk assessment based on the rat feeding study was carried out. The provisional risks are shown below:

<u>Exposure</u>	<u>Pineapple Use</u>	<u>Ornamental Use</u>
Dietary	0.27-2.4 X 10 ⁻⁸	none
Applicator	Not applicable	0.20-2.0 X 10 ⁻⁸
Mixer/loader	0.50-4.0 X 10 ⁻⁷	1.0-9.0 X 10 ⁻⁹
Planters*	0.7-6.0 X 10 ⁻⁶	Not applicable

*Risk estimate for planters assumes planters will wear gloves that are impermeable to Fosetyl-Al.

Because of these low levels of risk, the Agency has determined that the potential adverse effects associated with the registrable uses are negligible and do not constitute an unreasonable adverse effect.

These risk estimates, low as they are, are nonetheless likely to be overestimates of any actual risk exposure since they represent linear risk models at the level of detection, and uncertainties in other inputs to the risk model were assumed at conservative levels.

E. Criteria for Registration Under This Standard

To be covered by this Standard, products must contain Fosetyl-Al as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in Section F of this document.

F. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be covered under this Standard, Manufacturing-use products must contain Fosetyl-Al as the sole active

ingredient. Each with an appropriate certification of limits.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade products and MPs containing Fosetyl-Al for any acute toxicity category, provided that the labeling of those products bears appropriate precautionary statements.

3. Use Patterns

To be registered under this Standard manufacturing-use products containing Fosetyl-Al may be labeled for formulation only into end-use products for:

- °Terrestrial, non-domestic, food uses on: pineapple crowns (seed pieces).
- °Terrestrial, non-domestic, non-food uses on: ornamentals (including azalea, boxwood, Japanese holly, juniper, Monterey pine, Pieris japonica, Pittosporium, rhododendron, and Schefflera).
- °Domestic, outdoor uses on: ornamentals (as specified above).
- °Greenhouse, non-food uses on: ornamentals (as specified above).

G. REQUIRED LABELING

All manufacturing-use products containing Fosetyl-Al must bear appropriate labeling as specified in 40 CFR 162.10. Other portions of the guidance package contain specific information regarding label requirements.

1. Use Pattern Statements

The ingredient statement for MPs must list the active as:

Aluminum tris (O-ethylphosphonate)..... _____%.

In addition, all MPs must state that they are intended only for formulation into end-use products for any of the use patterns listed above. (Specify those sites listed in Use Patterns in Section F. 3.) A limiting factor will be the data that support these use patterns.

2. Precautionary Statements

Labels for all MP products containing Fosetyl-Al must bear statements reflecting the acute human toxicity of the compound. Fosetyl is in Toxicity Category I for eye

irritation; Category III for oral, dermal and inhalation routes of exposure; and Category IV for dermal irritation. The required precautionary statements associated with these Toxicity Categories are specified in 40 CFR §162.10.

The following environmental hazard statement must appear on all manufacturing-use product labels:

Do not discharge into lakes, streams, ponds or public water unless in accordance with NPDES permit. For guidance contact your Regional Office of the EPA.

Labeling statements to end-use products are not required to be included in this standard; however, in order to reduce the oncogenic risks to pineapple seed piece planters, the following note to user must appear on the label for the pineapple use:

Note to User: Gloves impermeable to Fosetyl-Al must be worn during the handling and planting of pineapple crowns (seed pieces).

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>158.120 Product Chemistry</u>				
<u>Product Identity:</u>				
61-1 - Identity of Ingredients	TGAI	Yes	00098326	No
61-2 - Statement of Composition	TGAI	Yes	00098326	No
61-3 - Discussion of Formation of Ingredients	TGAI	Yes	00098326	No
<u>Analysis and Certification of Product Ingredients</u>				
62-1 - Preliminary Analysis	TGAI	Yes	00098326	No
62-2 - Certification of Limits	TGAI	Yes	00098326	No
62-3 - Analytical Methods for Enforcement of Limits	TGAI	Yes	00098327	No
<u>Physical and Chemical Characteristics</u>				
63-2 - Color	TGAI	Yes	00098325	No
63-3 - Physical State	TGAI	Yes	00098325	No
63-4 - Odor	TGAI	Yes	00098325	No
63-5 - Melting Point	TGAI	Yes	00098325	No
63-6 - Boiling Point	TGAI	Not applicable ^{2/}		

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<u>158.120 Product Chemistry</u>				
<u>Product Identity:</u>				
63-7 - Density, Bulk Density, or Specific Gravity (continued)	TGAI	Yes	00098325	No
63-8 - Solubility	TGAI OR PAI	Yes	00098325	No
63-9 - Vapor Pressure	TGAI OR PAI	Not applicable ^{3/}		
63-10- Dissociation constant	TGAI OR PAI	Yes	00098325	No
63-11- Octanol/water partition coefficient	PAI	Yes	00098325	No
63-12- pH	TGAI	Yes	00098325	No
63-13- Stability	TGAI	Yes	00098325	No ^{4/}
<u>Other Requirements:</u>				
64-1 - Submittal of samples	TGAI	Yes		No

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.

2/ Data are not needed as Fosetyl-Al is a powder, boiling point is not relevant.

3/ Data are not needed as Fosetyl-Al is a non-volatile.

4/ A three-month stability study was provided. The study is adequate to support registration of products for uses covered by this standard. Any additional uses will require a 12-month stability study.

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Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>158.125 Residue Chemistry</u>				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Yes	00103249 00103250	No ^{2/}
- Livestock	PAIRA and plant metabolites	Not applicable		
171-4 - Residue Analytical Method				
- Plant residues	TGAI and metabolities	Yes	00103250	No ^{2/}
- Animal residues	TGAI and metabolities	Not applicable		
171-4 - Storage Stability Data				
	TEP	Yes	GS-0260-061	No ^{2/}
171-4 - Magnitude of the Residue- Residue Studies for Each Food Use				
Crop 1 (Pineapples)				
-- Crop field trials	PAI	Yes	00103250 GS-0260-061	No ^{2/}
-- Processed Food/Feed	EP	Not applicable		
-- Meat/milk/poultry/eggs	TEP/EP	Not applicable		

Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.

Data support use on pineapple, additional crops or change in use pattern will require additional data.

TABLE A
 GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	1/ Composition	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>158.130 Environmental Fate</u>					
<u>DEGRADATION STUDIES-LAB:</u>					
161-1 - Hydrolysis	TGAI or PAIRA	A, B, F, H	Yes	00098370 or 00098325	No
<u>Photodegradation</u>					
161-2 - In water	TGAI or PAIRA	A, B	Yes	00098371	No
161-3 - On soil	TGAI or PAIRA	A,	Yes	00098371	No
161-4 - In air	TGAI or PAIRA	A,	Yes	00098731	No
<u>METABOLISM STUDIES-LAB:</u>					
162-1 - Aerobic Soil	TGAI or PAIRA	A, B, F, H	Yes	00106018 00098372	No
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		No ^{3/}
162-3 - Anaerobic Aquatic	TGAI or PAIRA		Not Applicable		No
162-4 - Aerobic Aquatic	TGAI or PAIRA		Not Applicable		No
<u>MOBILITY STUDIES:</u>					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A, B, F, H	Yes		No
Leaching				00098375	
Adsorption				00106019	

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Data Requirement	Composition ^{1/}	Use ^{2/} Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>158.130 Environmental Fate</u> (continued)					
163-2 - Volatility (Lab)	TEP	A, F	No		No ^{4/}
163-3 - Volatility (Field)	TEP	A, F	No		No ^{4/}
<u>DISSIPATION STUDIES-FIELD:</u>					
164-1 - Soil	TEP	A	No		No ^{5/}
164-2 - Aquatic (Sediment)	TEP		Not Applicable		No
164-3 - Forestry	TEP		Not Applicable		No
164-4 - Combination and Tank Mixes	TEP		Not Applicable		No
164-5 - Soil, Long-term	TEP	A	No		No ^{5/}
<u>ACCUMULATION STUDIES:</u>					
165-1 - Rotational Crops (Confined)	PAIRA	A	No		No ^{5/}
165-2 - Rotational Crops (field)	TEP	A	No		No ^{5/}
165-3 - Irrigated Crops	TEP	A	No		No ^{5/}

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Data Requirement	1/ Composition	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>158.130 Environmental Fate</u> (continued)					
165-4 - In Fish	TGAI or PAIRA	A,F	No		No ^{6/}
165-5 - In Aquatic Non-Target Organisms	TEP		Not Applicable		No
- Field exposure study	TEP	A	No		Yes ^{7/}

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ This requirement is waived based on the short half-life of Fosetyl-Al under aerobic conditions and the known fate of phosphates under anaerobic conditions. This waiver is for preplant pineapple dip only. Additional uses may require this study.

4 Not required because the active ingredient is a non-volatile salt.

5/ This requirement is waived based on the short half-life (1 1/2 hours) determined in the aerobic soil metabolism study.

6/ This requirement is waived because the octanol/water partition coefficient is low (ranges from 1.7×10^{-3} to 5.2×10^{-3}) and the short half-life.

7/ Field study to determine potential exposure to pineapple planters. Contact the Agency concerning protocol and conduct of this study.

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<u>158.135 Toxicology</u>					
<u>ACUTE TESTING:</u>					
81-1 - Oral LD ₅₀ Rat/rabbit ^{3/}	TGAI	A,B,F,H	Yes	00098330	No
81-2 - Dermal LD ₅₀	TGAI	A,B,F,H	Yes	00098331	No
81-3 - Inhalation LC ₅₀ - Rat	TGAI	A,B,F,H	Yes	00098332	No
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI		Not Applicable		
<u>SUBCHRONIC TESTING:</u>					
82-1 - 90-Day Feeding - Rodent, Non-rodent Rat Dog	TGAI	A	Yes ^{4/}	00098336 00098337	No
82-2 - 21-Day Dermal	TGAI	A,B,F,H	Yes	00098338	No
82-3 - 90-Day Dermal	TGAI		Not Applicable		No
82-4 - 90-Day Inhalation - Rat	TGAI		Not Applicable		No
82-5 - 90-Day Neurotoxicity- Hen/Mammal	TGAI		Not Applicable		No

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	Composition ^{1/}	Use ^{2/} Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>158.135 Toxicology</u> (continued)					
<u>CHRONIC TESTING:</u>					
83-1 - Chronic Toxicity - 2 species: Rodent (Rat) and Non-rodent (Dog)	TGAI	A,B,F,H	Yes	00098339 00098352 ^{5/} 00098340	No
83-2 - Oncogenicity Study - Rat and Mouse preferred	TGAI	A,B,F,H	Yes	00098339 ^{6/} 00098352 ^{5/} 00098353	No
83-3 - Teratogenicity - 2 species Rabbit and Rat	TGAI	A,B,F,H	Yes	00098347 00114091	No
83-4 - Reproduction, 2-generation	TGAI	A,B,F,H	Yes	00098348	No

TABLE A
 GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	Composition ^{1/}	Use ^{2/} Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>158.135 Toxicology</u> (continued)					
<u>MUTAGENICITY TESTING:</u>					
84-2 - Gene Mutation	TGAI	A,B,F,H	Yes		No
	Ames test/S. Typhimurium (unactivated & activated) and Yeast Assay (D7)/S. Cerevisiae.			00098343	
84-2 - Chromosomal Aberration	TGAI	A,B,F,H	Yes	00098345	No
	Induct. test/E. Coli.(unactivated & activated) and DNA Repair/E. Coli.			00098343	No
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B,F,H	Yes	00098345	No
	Micronucleus test/ mouse(oral route)			00098345	
<u>SPECIAL TESTING</u>					
85-1 - General Metabolism	PAI or PAIRA	A,B,F,H	Yes	00098358	No
85-2 - Domestic Animal Safety	Choice	Not Applicable			

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GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	1/ Composition	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
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158.135 Toxicology
(continued)

- 1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
- 2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.
- 3/ The rabbit oral LD₅₀ is used for support as it is the most sensitive species for the oral hazard.
- 4/ The 90-day feeding study requirements are superseded by the chronic feeding studies listed in 83-1.
- 5/ Study was conducted with phosphorous acid metabolite.
- 6/ The review of the rat study demonstrates a positive oncogenic effect at the 8,000 and 30,000-40,000 ppm dose levels.
- 7/ Any request for additional uses of Fosetyl-Al must be supported by (a) either an application exposure study or estimates of applicator exposure and (b) either a dermal penetration study or estimates of dermal penetration.

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<u>158.145 Wildlife and Aquatic Organisms</u>					
<u>AVIAN AND MAMMALIAN TESTING</u>					
71-1 - Avian Oral LD ₅₀	TGAI	A, B, F, H	Yes	00098360	No
71-2 - Avian Dietary LC ₅₀	TGAI	A, B, F, H	Yes		No
Bobwhite Quail				00098362	
Mallard Duck				00098363	
71-3 - Wild Mammal Toxicity	TGAI		No		No ^{3/}
71-4 - Avian Reproduction	TGAI		No		No ^{4/}
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP		No		No ^{4/}
<u>AQUATIC ORGANISM TESTING</u>					
72-1 - Freshwater Fish LC ₅₀	TGAI	A, B, F, H	Partial		No ^{5/}
Bluegill Sunfish				00119526	
Rainbow Trout					
72-2 - Acute LC ₅₀ Freshwater Invertebrates	TGAI	A, B, F, H	Partial		No ^{5/}
<u>Daphnia magna</u>					

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<u>158.145 Wildlife and Aquatic Organisms</u> (continued)					
72-3 - Acute LC ₅₀ Estuarine and Marine Organisms	TGAI	A,B,F,H	Partial		Yes ^{6/}
Grass Shrimp				00098368	
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI		Not Applicable		No
72-5 - Fish - Life-Cycle	TGAI		Not Applicable		No
72-6 - Aquatic Organism	TGAI, PAI or Degradation Product		Not Applicable		No
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP		Not Applicable		No

TABLE A
 GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	1/ Composition	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
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158.145 Wildlife and
 Aquatic Organisms
 (continued)

- 1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient, TEP = Typical end-use product.
- 2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.
- 3/ This requirement is waived since the mammalian toxicity data indicate that the chemical will pose a low potential risk to wild mammals.
- 4/ This data requirement is waived for pineapple crown dip and ornamental use based on the short half-life of Fosetyl-Al under aerobic conditions and the octanol/water coefficient that indicate persistence and accumulation are not expected. These data may be required for additional uses.
- 5/ The rainbow trout and Daphnia magna studies have been received, however they have not been reviewed.
- 6/ This study alone is not sufficient to meet this requirement. However, the uses covered in this standard do not warrant any additional data.

TABLE A
 GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	1/ Composition	2/ Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>158.150 Plant Protection</u>					
121-1 - <u>TARGET AREA</u> <u>PHYTOTOXICITY</u>	EP		No		No ^{3/}
<u>NONTARGET AREA PHYTOTOXICITY</u>					
<u>TIER I</u>					
122-1 - Seed Germination/ Seedling Emergence	TGAI		No		No ^{3/}
122-1 - Vegetative Vigor	TGAI		No		No ^{3/}
122-2 - Aquatic Plant Growth	TGAI		No		No ^{3/}
<u>TIER II^{3/}</u>					
123-1 - Seed Germination/ Seedling Emergence	TGAI				
123-1 - Vegetative Vigor	TGAI				
123-2 - Aquatic Plant Growth	TGAI				
<u>TIER III^{3/}</u>					
124-1 - Terrestrial Field	TEP				
124-2 - Aquatic Field	TEP				

TABLE A
 GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	<u>1/</u> Composition	Use <u>2/</u> Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
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158.150 Plant Protection
 (continued)

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
 EP = End-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop;
 D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor;
 I = Indoor.

3/ The requirement for submission of these data is being reserved.

TABLE A
 GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	1/ Composition	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>158.155 Nontarget Insect</u>					
<u>NONTARGET INSECT TESTING- POLLINATORS</u>					
141-1 - Honeybee acute contact LD ₅₀	TGAI		Not Applicable		No
141-2 - Honeybee - toxicity of residues on foliage	TEP		Not Applicable		No
141-3 - Wild bees important in alfalfa pollination - toxicity of residues on foliage	TEP		Not Applicable		No
141-4 - Honeybee subacute feeding study	(Reserved)				
141-5 - Field testing for pollinators	TEP		Not Applicable		No

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
 EP = End-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop;
 D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor;
 I = Indoor.

3/ The requirement for submission of these data is being reserved.

TABLE A
 PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FOSETYL-AL

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>158.120 Product Chemistry</u>				
<u>Product Identity:</u>				
61-1 - Identity of Ingredients	MP	Yes	00098325	No
61-2 - Statement of Composition	MP	Yes	00098325	No
61-3 - Discussion of Formation of Ingredients	MP	Yes	00098325	No
<u>Analysis and Certification of Product Ingredients</u>				
62-1 - Preliminary Analysis	MP	Yes	00098325	No
62-2 - Certification of Limits	MP	Yes	00098325	No
62-3 - Analytical Methods for Enforcement of Limits	MP	Yes	00098327	No
<u>Physical and Chemical Characteristics</u>				
63-2 - Color	MP	Yes	00098325	No
63-3 - Physical State	MP	Yes	00098325	No
63-4 - Odor	MP	Yes	00098325	No
63-7 - Density, bulk density, or specific gravity	MP	Yes	00098325	No

TABLE B
 PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FOSETYL-AL

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>158.120 Product Chemistry</u> (continued)				
63-12- pH	MP	Yes	00098325	No
63-14- Oxidizing or action	MP	Yes	00098325	No
63-15- Flammability	MP	Yes	00098328	No
63-16- Explodability	MP	Yes	00098328	No
63-17- Storage Stability	MP	Yes	00098325	No
63-18- Viscosity	MP	Not applicable		
63-19- Miscibility	MP	Not applicable		
<u>Other Requirements</u>				
64-1 - Submittal of Samples	Choice			

^{1/} Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product; MP = Manufacturing-use product. Choice = Choice of several test substances determined on a case-by-case basis. Required for all uses.

TABLE B
 PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FOSETYL-AL

Data Requirement	Composition ^{1/}	Use ^{2/} Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>158.135 Toxicology</u>					
<u>ACUTE TESTING</u>					
81-1 - Oral LD ₅₀	MP	A,B,F,H	Yes	00098330	No
81-2 - Dermal LD ₅₀	MP	A,B,F,H	Yes	00098331	No
81-3 - Inhalation LC ₅₀	MP	A,B,F,H	Yes	00098332	No
81-4 - Primary Eye Irritation - Rabbit	MP	A,B,F,H	Yes	00098333	No
81-5 - Primary Dermal Irritation	MP	A,B,F,H	Yes	00098334	No
81-6 - Dermal Sensitization	MP	A,B,F,H	Yes	00098335	No

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product; MP = Manufacturing-use product. Required for all uses.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, FoodCrop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food Crop; G = Forestry; H = Domestic Outdoor; I = Indoor.

Registration Standards Case 0260: Fosetyl-Al

BIBLIOGRAPHY OF STUDIES CONSIDERED IN SUPPORT OF REGISTRATION UNDER THE STANDARD

All studies in this bibliography are usable only with the permission of their submitter--Rhone-Poulenc--under the provisions of FIFRA §3(c)(1)(D)(i), for the ten-year period beginning with the date of first product registration under this standard.

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<u>MRID</u>	<u>CITATION</u>
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