

Pesticide Fact Sheet

Name of Chemical: Aminopyralid
Reason for Issuance: Conditional Registration
Date Issued: August 10, 2005

DESCRIPTION OF CHEMICAL

Generic Name: 2-pyridine carboxylic acid, 4-amino-3,6-dichloro-

Common Name: Aminopyralid

Trade Names: Aminopyralid Technical
Milestone™

EPA Chemical Code: 005100

Chemical Abstracts
Service (CAS)
Number: 150114-71-9

Year of Initial
Registration: 2005

Pesticide Type: Herbicide

Chemical Family: pyridine carboxylic acid

U.S. and Foreign
Producers: Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268

USE PATTERNS AND FORMULATIONS

Aminopyralid is a new pyridine carboxylic acid herbicide intended for use in rangeland, permanent grass pastures, non-cropland areas (rights-of-way, roadsides and non-irrigation ditch banks), natural areas (wildlife management areas, natural recreation areas, campgrounds, trailheads, and trails), and grazed areas in and around these sites, as well as wheat. Aminopyralid provides systemic postemergence broad-spectrum control of a number of key noxious and invasive annual, biennial and perennial weed species, as well as agronomic broadleaf weeds. Aminopyralid can also provide residual weed control activity controlling re-infestations and reducing the need for re-treatment depending on the rate applied and the target weeds. Aminopyralid Technical is a 95.3% manufacturing use product. The aminopyralid end-use product (Milestone) will be formulated as a soluble liquid containing 2 pounds acid equivalent per gallon and will be applied by ground or air at rates between 0.03 and 0.11 lb aminopyralid acid equivalents (a.e./A) (30 to 120 grams a.e./ha). The total amount of Milestone applied broadcast, as a re-treatment, and/or spot treatment, cannot exceed 7 fl oz per acre (0.11 lb a.e./A) per year in rangeland, permanent grass pastures and non-cropland areas. The total amount of Milestone used in wheat cannot exceed 0.57 fl oz per acre (0.009 lb a.e./A) per growing season.

SCIENCE FINDINGS

SUMMARY SCIENCE STATEMENTS

Acute toxicity data indicate that aminopyralid has low toxicity via oral, dermal and inhalation routes of exposure. The technical aminopyralid product is classified in toxicity category I [DANGER] based on an acute eye irritation study conducted with the free acid. The formulated end-use product (Milestone) has low toxicity and is classified in toxicity category IV [Caution].

In an acute neurotoxicity study in rats with aminopyralid, there were no treatment-related effects on Functional Observation Battery (FOB), motor activity, or neuropathological observations. The systemic No Observed Adverse Effect Level (NOAEL) was 1000 mg/kg based on transient clinical observations of fecal soiling in males and urine soiling in females observed at 2000 mg/kg bw, the highest dose tested [HDT]. In a chronic neurotoxicity study in rats the NOAEL was equal to or greater than 1,000 mg/kg/day [HDT].

Aminopyralid was negative in all mutagenicity studies, except for an in vitro chromosome aberration assay utilizing rat lymphocytes. In this assay, aminopyralid induced chromosome aberrations without S9 activation, but only at cytotoxic concentrations. The clastogenic response was induced secondary to toxicity.

In a rat developmental study the NOAEL for maternal and developmental toxicity was equal to or greater than 1,000 mg/kg/day [HDT]. In a developmental toxicity study in rabbits with aminopyralid, the NOAEL for maternal toxicity was 250 mg/kg/day and the

developmental NOAEL was equal or greater than 500 mg/kg/day. Maternal toxicity was observed at 500 and 750 mg/kg/day [HDT] in the form of decreased body weights and clinical observations of uncoordinated gait. Ulcers and erosions of the glandular mucosa of the stomach were observed in the 500 and 750 mg/kg/day dose groups. Similar toxic effects were also observed in a developmental study in rabbits with Milestone, the formulated triisopropanolamine (TIPA) salt of aminopyralid. Developmental toxicity could not be determined in aminopyralid rabbit study since the 750 mg/kg/day group was removed from the study due to the severity of the clinical signs (body weight changes, decreased food consumption and a decreased amount of feces). However, in the rabbit developmental study with Milestone, developmental toxicity was demonstrated by a decrease in fetal body weights at 520 mg acid equivalents (ae)/kg/day. In a 2-generation reproduction study in rats, there was no evidence of parental, reproductive, or offspring toxicity observed after exposure to aminopyralid up to 1000 mg/kg/day [HDT]. The developmental toxicity studies and the 2-generation reproduction study did not exhibit quantitative or qualitative susceptibility.

There were no systemic toxic effects observed at 1000 mg/kg/day [HDT] in a 28-day dermal toxicity study in rats with aminopyralid. However, dermal toxicity was indicated by slight epidermal hyperplasia in males at the HDT.

The database on aminopyralid indicates that the stomach, ileum and cecum are targets for this compound. In a 90-day toxicity study in dogs the NOAEL was 282 mg/kg/day for males and 232 mg/kg/day for females based on slight diffuse hyperplasia and hypertrophy of the mucosal epithelium of the stomach at 1070 mg/kg/day in males and 929 mg/kg/day in females. In the 1-year chronic toxicity study in dogs, the NOAEL was 99 mg/kg/day for males and 93 mg/kg/day for females based on thickening of the stomach, slight lymphoid hyperplasia of the gastric mucosa, and slight chronic mucosal inflammation at the HDT. In a 90-day mouse dietary study, no toxicity was observed at 1000 mg/kg/day [HDT]. In a 90-day rat feeding study the NOAEL was 1000 mg/kg/day [HDT] for females and 500 mg/kg/day for males based on hyperplasia of the mucosal epithelium of the ileum and the cecum at 1000 mg/kg/day [HDT].

In the mouse chronic feeding study the NOAEL was 1000 mg/kg/day [HDT] for males and 250 mg/kg/day for females. In the rat chronic feeding study the NOAEL was 50 mg/kg/day based on cecal enlargement, slight mucosal hyperplasia (males) and slightly decreased body weights at 500 mg/kg/day.

Aminopyralid has been classified as "not likely" to be carcinogenic to humans. No increases in any tumors were found in carcinogenicity studies in rats and mice.

In a metabolism study in rats, aminopyralid was rapidly absorbed, distributed, and excreted following oral administration. Tissue distribution and bioaccumulation were minimal; <0.73% of administered dose [AD] was recovered in tissues after 7 days for all dosing groups. The highest levels of radioactivity were found in the skin and carcass. Aminopyralid was excreted unchanged, indicating an absence of metabolism. The AD

was recovered as parent compound in 100% of the feces and = 96% of the urine. Three unknown components found in urine (= 4 %) were also detected in similar quantities in dose formulations, suggesting that they were trace impurities.

Based on aminopyralid's low toxicity, an acute Reference Dose (RfD) for the general population is not required.

The chronic RfD for aminopyralid is 0.5 mg/kg/day. This value is based on the NOAEL of 50 mg/kg/day in the rat combined chronic toxicity/carcinogenicity study with a 100-fold uncertainty factor to account for interspecies extrapolation (10X) and intraspecies variability (10X). An additional safety factor to protect infants and children is not required, due to the toxicity properties of the material and the conservative nature of the exposure estimates.

A DEEM chronic exposure analysis was conducted using the tolerance levels for wheat grain and meat commodities and assuming 100% of crops treated with aminopyralid. The estimated exposures to US-population and relevant sensitive sub-population groups were all at least 3 orders of magnitude below the RfD (< 1% RfD).

Based on the PRZM/EXAMS model, the estimated environmental concentrations (EECs) of for chronic exposures are estimated to be 1.937 parts per billion (ppb) for surface water and 0.630 ppb for ground water. The chronic estimated water concentrations derived from surface water modeling results were significantly higher than the modeled ground water concentrations, and therefore protective of potential exposures via ground water sources of drinking water when incorporated into aggregate exposure estimates. The aminopyralid EEC's were incorporated into LifeLine™ Version 2.0 to determine aggregate pesticide exposures from pesticide residues in **the diet**.

There are no requested uses for aminopyralid that are considered residential and neither handler nor post-application residential exposures from uses around homes are expected to occur. However, the use on campgrounds and other recreation areas to control vegetation has the potential to result in short-term post-application incidental oral exposures for infants and children via hand-to mouth transfer of residues and ingestion of aminopyralid-contaminated grass and soil. For children with a 15-kg body weight exposed via the hand-to-mouth route, the potential MOE was 150,000. Post-application exposure via inhalation is not expected to occur.

The source of human exposure results from dietary exposure from food and drinking water, and short term incidental oral exposure, a short term oral exposure of children to treated campgrounds.. Aggregating these exposure estimates gives a combined potential level of 0.0033 mg/kg/day, for the highest exposed group, children 1-2 years of age. The margin of exposure (MOE) associated with this Tier I exposure estimate is 32,000, greatly above the acceptable limit (MOE = 100). EPA thus concludes that there is reasonable certainty that no harm will come from aggregate exposure to aminopyralid residues.

Based on labeled uses, the occupational exposure is expected to be short- to intermediate-term and no long-term exposure is expected. Based on the available toxicological information, dermal exposures do not result in any adverse systemic effect; therefore, dermal exposures were not included into the estimation of occupational risk to workers. Short- and intermediate-term oral and inhalation exposures are being regulated based on the effects seen in the developmental rabbit toxicity study, which showed a NOAEL of 104 mg/kg/day.

The highest potential exposure was estimated to Mixer-Loaders working on aerial applications of 0.11 lb ae/A, for up to 1200 acres applied per day. The corresponding MOE is 40,000.

Dietary tolerances are established for free and conjugated residues in the following crop food/feed commodities:

Commodity	Parts per million
Grass, forage	25
Grass, hay	50
Wheat, bran	0.1
Wheat, forage	2.0
Wheat, grain	0.04
Wheat, hay	4.0
Wheat, straw	0.25
Aspirated grain fractions	0.2

Tolerances also listed for the parent aminopyralid in or on the following animal commodities:

Commodity	Parts per Million
Cattle, fat	0.02
Cattle, meat	0.02
Cattle, meat byproducts, excluding kidney	0.02
Cattle, kidney	0.3
Goat, fat	0.02

Goat, meat	0.02
Goat, meat byproducts, excluding kidney	0.02
Goat, kidney	0.3
Horse, fat	0.02
Horse, meat	0.02
Horse, meat byproducts, excluding kidney	0.02
Horse, kidney	0.3
Milk	0.03
Sheep, fat	0.02
Sheep, meat	0.02
Sheep, meat byproducts, excluding kidney	0.02
Sheep, kidney	0.3

In aquatic systems, the primary route of degradation is photolysis, where a laboratory experiment yielded a half-life of 0.6 days. In addition to CO₂, oxamic and malonic acid were identified as major degradates. Aminopyralid was stable to direct hydrolysis and in anaerobic sediment-water systems. In aerobic sediment-water systems, degradation proceeded slowly, with observed total system half-lives of 462 to 990 days. The degradation resulted in the formation of non-extractable residues and no other major products.

Under aerobic conditions, degradation of aminopyralid in five different soils resulted in the production of CO₂ and non-extractable residues. Half-lives ranged from 31.5 to 533.2 days in 5 soils. For risk assessment purposes, EPA used a half-life of 103.5 days.

Aminopyralid photolyzed moderately slowly on a soil surface. The half-life was 72 days and CO₂, non-extractable residues and small amounts of acidic volatiles were the degradates.

Aminopyralid is weakly sorbed to soil. A laboratory Freundlich adsorption isotherm study with 8 US and European soils yielded 48-hour K_d values of 0.03 to 0.72 mL/g; adsorption K_{oc} values were 1.05 to 24.3 mL/g.

Two field dissipation studies were performed (in California and Mississippi). The results indicate that aminopyralid is likely to be non-persistent and relatively immobile in the field. Half-lives of 32 and 20 days were determined, with minimal leaching below the 15 to 30 cm soil depth.

Aminopyralid has been shown to be practically non-toxic to birds, fish, honeybees, earthworms, and aquatic invertebrates. Aminopyralid is slightly toxic to eastern oyster, algae and aquatic vascular plants. The log Kow is less than 3 and thus aminopyralid is not expected to bioaccumulate in fish tissue.

There are no acute or chronic risks to non-target endangered or non-endangered fish, birds, wild mammals, terrestrial and aquatic invertebrates, algae or aquatic plants.

TECHNICAL CHEMICAL CHARACTERISTICS

Empirical Formula: $C_6H_4C_{12}N_2O_2$

Molecular Weight: 207.016 g/mole

Color; Off-white

Physical State: Powder

Odor: Odorless

Melting Point: 161.75 - 165.23° C

Density: 1.72 (20° C, relative to water at 4° C)

Solubility:

Water	212 g/L (pH 5) 205 g/L (pH 7) 203 g/L (pH 9) 2.48 g/L (unbuffered)
Acetone	29.2 g/L
Ethyl Acetate	4 g/L
Methanol	52.2 g/L
1,2-dichloroethane	0.189 g/L
Xylene	0.043 g/L
Heptane	less than 0.010 g/L

Vapor Pressure: 7.14×10^{-11} mm Hg at 20° C

1.92 x 10⁻¹⁰ mm Hg at 25° C

Dissociation
Constant: pK_a = 2.56 at 20° C

Octanol/Water
Partition
Coefficient: logP = 0.201 (Unbuffered at 20° C)
LogP = -1.75 (pH 5 at 20° C)
LogP = -2.87 (pH 7 at 20° C)
LogP = -2.96 (pH 9 at 20° C)

pH: 2.31 (1% w/w solution/suspension)

Oxidizing or
Reducing
Action: none

Mobility: K_d = 0.03 - 0.72

TOXICOLOGY CHARACTERISTICS

Milestone

(formulated end-use product)

Acute Oral
Toxicity
(rats):
Toxicity LD₅₀ Males and Females > 5000 mg/kg
Category: IV

Acute Dermal
Toxicity
(rats):
Toxicity LD₅₀ Males and Females > 5000 mg/kg
Category: IV

Acute Inhalation
Toxicity
(rats):
Toxicity LC₅₀ Males and Females > 5.79 mg/L
Category: IV

Primary Eye

Irritation
(rabbits):
Toxicity
Category: No irritation
IV

Primary Skin
Irritation
(rabbits):
Toxicity
Category: Slight erythema at 24 and 72 hours, resolving by day 7
IV

Dermal
Sensitization
(guinea pigs): Not a sensitizer

90-day dietary
(rats): NOAEL = 1000 mg (TIPA) salt of aminopyralid/kg/day (520 mg acid equivalents aminopyralid (ae)/kg/day)
LOAEL = not determined

Developmental
Toxicity
(rabbit): Maternal NOAEL = 200 mg TIPA salt of aminopyralid /kg/day (104 mg ae/kg/day)
Maternal LOAEL = 500 mg TIPA salt of aminopyralid /kg/day (260 mg ae/kg/day) based on severe inanition and body weight loss, decreased fecal output, and mild clinical observations of uncoordinated gait

Developmental NOAEL = 500 mg TIPA salt of aminopyralid /kg/day (260 mg ae/kg/day)
Developmental LOAEL = 1000 mg TIPA salt of aminopyralid/kg/day (520 mg ae/kg/day) based on decreased fetal body weights

Developmental
Toxicity
(rat): Maternal NOAEL = 1000 mg TIPA salt of aminopyralid/kg/day (520 mg ae/kg/day)
Maternal LOAEL = not determined

Developmental NOAEL = 1000 mg TIPA salt of aminopyralid/kg/day (520 mg ae/kg/day)
Developmental LOAEL = not determined

Mutagenicity: The mutagenicity studies submitted for Milestone satisfy the

mutagenicity test battery. Milestone was negative in all mutagenicity studies.

Metabolism

(Non-guideline): ¹⁴C-Aminopyralid and ¹⁴C-aminopyralid TIPA salt, when administered orally to rats, were bioequivalent in terms of absorption, distribution, metabolism, and excretion of the amino-dichloro-picolinate portion of the molecule(s).

Aminopyralid Technical

(manufacturing use product)

Acute Oral

Toxicity

(rats):

Toxicity LD₅₀ Males and Females > 5000 mg/kg

Category: IV

Acute Dermal

Toxicity

(rabbits):

Toxicity LD₅₀ Males and Females >5000 mg/kg

Category: IV

Acute Inhalation

Toxicity

(rats):

Toxicity LC₅₀ Males and Females >5.5 mg/L

Category: IV

Primary Eye

Irritation

(rabbits):

Toxicity Corneal opacity in 1/3 through day 35

Category: I

Primary Skin

Irritation

(rabbits):

Toxicity No irritation

Category: IV

Dermal

Sensitization

(guinea pigs): Not a sensitizer

Acute Neurotoxicity

Screening

Battery

(rat):

NOAEL = 1000 mg/kg

LOAEL = 2000 mg/kg based on fecal soiling in males and urine soiling in females

90-day dietary

(rats):

NOAEL Male = 500 mg/kg/day, Female = 1000 mg/kg/day

LOAEL Male = 1000 mg/kg/day based on hyperplasia of the mucosal epithelium of ileum and cecum, Female = not determined

90-day dietary

(dogs):

NOAEL Male = 282 mg/kg/day, Female = 232 mg/kg/day

LOAEL Male = 1070 mg/kg/day, Female = 929 mg/kg/day based on stomach histopathology (slight diffuse hyperplasia and hypertrophy of the mucosal epithelium)

28-day dermal

(rats):

Systemic NOAEL = 1000 mg/kg/day

LOAEL = not determined

Dermal NOAEL Male = 100 mg/kg/day, Female = 1000 mg/kg/day

LOAEL Male = 500 mg/kg/day based on histopathological changes (slight epidermal hyperplasia), Female = no

Developmental

Toxicity

(rabbit):

Maternal NOAEL = 250 mg/kg/day

Maternal LOAEL = 500 mg/kg/day based on decrease in body weight (GD 7-10), decreased food consumption, clinical observations of uncoordinated gait and ulcers and erosions of the stomach

Developmental NOAEL = 500 mg/kg/day

Developmental LOAEL = not determined

Developmental

Toxicity

(rat):

Maternal NOAEL = 1000 mg/kg/day

Maternal LOAEL = not determined

Developmental NOAEL = 1000 mg/kg/day

Developmental LOAEL = not determined

Two-Generation
Reproduction
(rat):

Paternal NOAEL = 1000 mg/kg/day
Paternal LOAEL = not determined

Reproductive NOAEL = 1000 mg/kg/day
Reproductive LOAEL = not determined

Offspring NOAEL = 1000 mg/kg/day
Offspring LOAEL = not determined

1 Year Chronic
Feeding
(dog):

NOAEL Male = 99 mg/kg/day, Female = 93 mg/kg/day
LOAEL Male = 967 mg/kg/day, Female = 1038 mg/kg/day based on thickening of stomach mucosa (females), and stomach histopathology in all animals (slight diffuse hyperplasia and hypertrophy of the mucosal epithelium, slight lymphoid hyperplasia of the gastric mucosa and very slight/slight chronic mucosal inflammation)

Chronic Neurotoxicity
(rat):

NOAEL = 1000 mg/kg/day
LOAEL = not determined

Chronic Feeding/
Carcinogenicity
(rat):

NOAEL = 50 mg/kg/day
LOAEL = 500 mg/kg/day based on cecal enlargement, slight mucosal hyperplasia (males) and slightly decreased body weights

Carcinogenicity
(mouse):

NOAEL Male = 1000 mg/kg/day, Female 250 mg/kg/day
LOAEL Male = not determined, Female = 1000 mg/kg/day based on increased mortality

Mutagenicity:

The mutagenicity studies submitted for aminopyralid satisfy the mutagenicity test battery. Aminopyralid was negative in all mutagenicity studies, except for an *in vitro* chromosome aberration assay utilizing rat lymphocytes. In this assay, aminopyralid induced chromosome aberrations, but only at cytotoxic concentrations. The clastogenic response was induced secondary to toxicity.

Metabolism: Low dose = 50 mg/kg
High dose = 1000 mg/kg
Repeated dose = 50 mg/kg/day (unlabeled) for 14 days, 50 mg/kg/day (labeled) on day 15
Recovery after 168 hrs: 96% in low dose (urine - 50%, feces - 43%, tissues - 0.1%, cage wash - 10%), and 95% in the repeated low dose (urine 59%, feces - 33%, tissues - 0.1%, cage wash - 3%).
Aminopyralid represented = 96% of administered dose (AD) in urine and 100% AD in feces. Three unknown components (= 4 %) found in urine were also found in dose formulations.

ECOLOGICAL CHARACTERISTICS

Avian Acute Toxicity:

Bobwhite Quail: LD₅₀>2250 mg a.e./kg bw

Avian Dietary Toxicity:

Bobwhite Quail: 5-day LC₅₀ >5556 mg a.e./kg diet

Mallard Duck: 5- day LC₅₀ >5496 mg a.e./kg diet

Avian Reproduction:

Bobwhite Quail: No Observed Effect Concentration (NOEC) = not determined
Lowest Observed Effect Concentration (LOEC) = 640 mg a.e./kg diet

Mallard Duck:

No Observed Effect Concentration (NOEC) = 2623 mg a.e./kg diet
Lowest Observed Effect Concentration (LOEC) > 2623 mg a.e./kg diet

Acute Mammalian Toxicity:

Rattus rattus: LD₅₀ >5000 mg a.e./kg bw

Chronic Mammalian Toxicity:

Rattus norvegicus: NOEL >1000 mg a.e./kg bw/day

Freshwater fish and amphibian

Acute Toxicity:

Bluegill Sunfish: 96-hour LC₅₀ >100 mg a.e./L

Rainbow Trout: 96-hour LC₅₀ >100 mg a.e./L

Northern leopard frog: 96-hour LC₅₀ >95.2 mg a.e./L

Estuarine/marine fish

Acute Toxicity:
Sheepshead minnow: 96-hour LC₅₀ >120 mg a.e./L

Freshwater Fish
Early life-stage
Toxicity:
Fathead Minnow: NOEC = 1.36 mg a.e./L
LOEC = 2.44 mg a.e./L
MATC** = 1.82 mg a.e./L

** Defined as the geometric mean of the NOEC and LOEC

Freshwater Invertebrate
Toxicity:
Daphnia magna: 48-hour EC₅₀ >98.6 mg a.e./L

Freshwater Invertebrate
Life-Cycle Toxicity:
Daphnia magna: NOEC = 102 mg a.e./L (highest concentration tested)
LOEC > 102 mg a.e./L

Estuarine/Marine
Invertebrate Acute
Toxicity:
Eastern Oyster: 48-hour EC₅₀ >89 mg a.e./L
Mysid: 96-hour LC₅₀ >100 mg a.e./L

Non-Target Insects
Toxicity:
Honey Bee
Acute Contact: LD₅₀ >100 µg a.e./bee
Acute Oral: LD₅₀ >117 µg a.e./bee

Seedling Emergency and Vegetative Vigor For Milestone:

Seedling Emergence:		
<u>Species</u>	<u>EC25 (g a.i./ha)</u>	<u>Most Sensitive Parameter</u>
Monocot - Barnyardgrass	>230.8	None
Monocot - Corn	>230.8	None
Monocot - Onion	29.0	Fresh weight (Most Sensitive Monocot)
Monocot - Wheat	>230.8	None
Dicot - Cucumber	>57.7	None
Dicot - Soybean	2.7	Fresh weight (Most Sensitive Dicot)
Dicot - Sugar Beet	14.0	Fresh weight
Dicot - Lettuce	20.0	Fresh weight

Dicot - Oilseed Rape	49.0	Fresh weight
Dicot - Radish	>230.8	None

Vegetative Vigor:

Species	EC25 (g a.i./ha)	Most Sensitive Parameter
Monocot - Barnyardgrass	>230.8	None
Monocot - Corn	>230.8	None
Monocot - Onion	53.0	Fresh weight
Monocot - Wheat	>230.8	None
Dicot - Cucumber	12.0	Shoot length
Dicot - Soybean	0.75	Shoot length
Dicot - Sugar Beet	8.4	Fresh weight
Dicot - Lettuce	3.3	Fresh weight
Dicot - Oilseed Rape	>230.8	None
Dicot - Radish	54.0	Fresh weight

Non-target Aquatic Plant Toxicity (Tier II):

Vascular Plants

Duckweed

Lemna gibba: $EC_{50} > 88$ mg a.e./L NOEC = 44 mg a.e./L

Nonvascular Plants

Green algae

Pseudokirchneriella subcapitata: $ErC_{50} = 30$ mg a.e./L NOEC = 23 mg a.e./L

Marine diatom:

Skeletonema costatum: $EbC_{50} = 70$ mg a.e./L NOEC = 13 mg a.e./L

Freshwater diatom:

Navicula pelliculosa: $EC_{50} = 18$ mg a.e./L NOEC = 6 mg a.e./L

Blue-green algae:

Anabaena

Flos-aquae: not determined

Aminopyralid has been shown to be practically non-toxic to birds, fish, honeybees, earthworms, and aquatic invertebrates. Aminopyralid is slightly toxic to eastern oyster, algae and aquatic vascular plants. The log Kow is less than 3, indicating that aminopyralid is not expected to bioaccumulate in fish tissue. Tier II seedling emergence and vegetative vigor studies were conducted using the formulated product, Milestone. Seedling emergence testing indicated that onion was the most sensitive monocot (fresh shoot weight $EC_{25} = 29$ g a.i./ha), while soybeans were the most sensitive dicot (fresh shoot weight $EC_{25} = 2.7$ g a.i./ha). Vegetative vigor testing indicated that onion was

again the most sensitive monocot (fresh shoot weight EC25 = 53 g a.i./ha). Similarly, soybeans were the most sensitive dicot (shoot length EC25 = 0.75 g a.i./ha). Grass species (barnyardgrass, corn and wheat) were among the least sensitive species tested in both the seedling emergence and vegetative vigor tests and had EC25 values that exceeded the maximum application rate tested. There are no acute or chronic risks to non-target endangered or non-endangered fish, birds, wild mammals, terrestrial and aquatic invertebrates, algae or aquatic plants.

ENVIRONMENTAL CHARACTERISTICS

In aquatic systems, the primary route of degradation is photolysis, where a laboratory experiment yielded a half-life of 0.6 days (corrected for natural sunlight conditions). In addition to CO₂, oxamic and malonic acid were identified as major degradates, along with a number of minor 2-3 carbon chain length acid amides. Aminopyralid was stable to direct hydrolysis and in anaerobic sediment-water systems. In aerobic sediment-water systems, degradation proceeded slowly, with observed total system half-lives of 462 to 990 days. The degradation resulted in the formation of non-extractable residues and no other major products.

Under aerobic conditions, degradation of aminopyralid in five different soils resulted in the production of no significant degradation products beyond CO₂ and non-extractable residues. Half-lives ranged from 31.5 to 533.2 days, although material balance criteria were not met for 4 of the 5 soils; the soil meeting these criteria yielded a half-life of 103.5 days. By the end of the study, CO₂ accounted for 66 to 73% of the applied (except in a Barnes Clay Loam soil at 27-30% of applied). Non-extractable residues were detected at 0 to 16% of applied radioactivity at the end of the study, except for the test with a Houston Black Clay soil, where the non-extractable residues were 23-24% of applied.

Aminopyralid photolyzed moderately slowly on a soil surface. The half-life was 72 days (corrected for natural sunlight and soil metabolism) and CO₂, non-extractable residues and small amounts of acidic volatiles were the degradates.

Aminopyralid is weakly sorbed to soil. A laboratory Freundlich adsorption isotherm study with 8 US and European soils yielded 48-hour K_d values of 0.03 to 0.72 mL/g; adsorption K_{oc} values were 1.05 to 24.3 mL/g.

Two field dissipation studies were performed (in California and Mississippi). The results indicate that aminopyralid is likely to be non-persistent and relatively immobile in the field. Half-lives of 32 and 20 days were determined, with minimal leaching below the 15 to 30 cm horizon depth.

The nature of the residue in plants and animals is well understood. Based on the nature of residue studies (NOR) on grass and wheat, the tolerance expression in or on grass forage, grass hay, wheat raw agricultural commodities and wheat processed products is

the total parent aminopyralid, both free and conjugated. Based on the NOR study on lactating goat, the tolerance expression in milk, meat and meat-byproducts is the unchanged parent, aminopyralid.

Tolerances are established for residues of aminopyralid as described in the Summary Science Statements of this Fact Sheet.

AGGREGATE EXPOSURES

As indicated by the Food Quality Protection Act (FQPA), 1996, the potential for concurrent exposure to aminopyralid via oral, dermal and inhalation routes must be assessed by EPA. This aggregate exposure considers every possible non-occupational exposure route, including residues in food, in drinking water and residential exposure from indoor/outdoor non-crop uses.

However, based on the available toxicological information, dermal exposures do not result in any adverse systemic effect; therefore, dermal exposures are not included into the estimation of aggregate risk for any duration of exposure. Short- and intermediate-term oral and inhalation exposures are being regulated based on the effects seen in the developmental rabbit toxicity study. However, the non-crop uses do not include any indoor uses; therefore, both handler and post-application inhalation exposures are expected to be negligible.

1. From Food and Feed Uses

Based on aminopyralid's low toxicity profile, an acute Reference Dose (RfD) for the general population or any of the population sub-groups is not required.

The chronic Reference Dose (RfD) for aminopyralid is 0.5 mg/kg/day. It is based on the NOAEL of 50 mg/kg/day from the rat combined chronic toxicity/ carcinogenicity study, the lowest NOAEL observed in any of the chronic studies. A 100-fold uncertainty factor to account for interspecies extrapolation (10X) and intraspecies variability (10X) was applied over the selected NOAEL in order to establish the RfD.

An extra safety factor (SF) to protect infants and children is not needed based on the following considerations:

- a) the toxicity data showed no increase in susceptibility in fetuses and pups with in-utero and post-natal exposure; b) the dietary food exposure assessment was done with tolerance-level residues and 100% crop treated for all commodities, which results in very high-end estimates of dietary exposure; c) the drinking water assessment was based on values generated by models which are designed to provide conservative, high-end estimates of water concentrations; d) exposures due to recreational activities are based on default EPA assumptions that result in high-end estimates of exposure.

A DEEM chronic exposure analysis was conducted using the tolerance levels for wheat

grain and meat commodities and assuming 100% of crops treated with aminopyralid. The estimated exposures to US-population and relevant sensitive sub-population groups were all at least 3 orders of magnitude below the level of the RfD (< 1% RfD).

2. From Potable Water

Drinking water estimated concentrations were estimated with the SCI-GROW model for ground water and with the Index Reservoir model for surface water. The set of assumptions included the maximum seasonal use rate of 0.11 lb a.e./A, K_{oc} of 1.05 and a half-life of 38.7 days. Aminopyralid does not have an acute RfD established; therefore, an acute assessment is not needed for drinking water. A chronic exposure assessment considering the highest chronic concentrations from surface drinking water has shown levels of exposure which are four orders of magnitude below the RfD of 0.5 mg/kg-bw/day, both for adults and children 1-6 years of age.

3. For Non-Dietary Uses

At this time, there are no requested uses for aminopyralid that are considered home uses and neither handler nor post-application residential exposures from uses around home are expected to occur. However, the use on campgrounds and other recreation areas to control vegetation has the potential to result in short-term post-application incidental oral exposures for infants and children via hand-to mouth transfer of residues and ingestion of aminopyralid-contaminated grass and soil. Post-application exposure via inhalation is not expected to occur.

Short-term residential exposure to children with 15 kg body-weight from the three routes mentioned above was estimated using the HED Draft Standard Operating Procedures (SOP's) for Residential Exposure Assessments (12/18/97) and the Revisions to the Standard Operating Procedures (SOP's) for Residential Exposure Assessment (Science advisory Council for Exposure Policy 12, Revised February 22, 2001) for Hand-to-Mouth Transfer, Ingestion of Turfgrass and Ingestion of Soil, from uses on lawn broadcast application. The lowest MOE was 150,000 for this tier-I post-application residential assessment and it corresponds to children exposed via the hand-to-mouth route.

AGGREGATE RISK CONCLUSIONS

Since the only source of residential exposure would result from oral exposure, an aggregate exposure assessment was performed adding the estimated chronic dietary exposure to the estimated short-term oral residential exposure. Totaling the two oral exposure estimates gives a combined potential level of 0.0033 mg/kg/day, for the highest exposed group, children 1-2 years of age. The margin of exposure (MOE) associated with this Tier I exposure estimate is 32,000 and it is much above the acceptable limit (MOE = 100). EPA thus concludes that there is reasonable certainty that no harm will come from aggregate exposure to aminopyralid residues.

CUMULATIVE EXPOSURE TO SUBSTANCES WITH COMMON MECHANISM OF TOXICITY

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for aminopyralid and any other substances. Furthermore, aminopyralid does not appear to have a toxic metabolite that is produced by other substances. For the time being, EPA has assumed that aminopyralid does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by the Office for Pesticides Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>

OCCUPATIONAL EXPOSURE

Based on labeled uses, the occupational exposure is expected to be short- to intermediate-term and no long-term exposure is expected. The application of Milestone to control weeds in wheat, rangeland, pastures, non-cropland areas and natural recreation areas is recommended by using broadcast treatment with ground and aerial equipment on wheat and also hand-spray and spot treatments for all other uses.

Based on the available toxicological information, dermal exposures do not result in any adverse systemic effect; therefore, dermal exposures were not included into the estimation of occupational risk to workers. Short- and intermediate-term oral and inhalation exposures are being regulated based on the effects seen in the developmental rabbit toxicity study, which showed a NOAEL of 104 mg/kg/day.

The highest potential exposure was estimated to Mixer-Loaders working on aerial applications of 0.11 lb ae/A, for up to 1200 acres applied per day. The corresponding MOE is 40,000.

SUMMARY OF DATA GAPS

No major data gaps have been identified with the registrant-submitted data, although uncertainties were noted in the determinations of soil half-life, chronic effects on birds and effects upon cyanobacteria.

1. Submit completed enforcement method of analysis to show that analytical method differentiates between aminopyralid, picloram and clopyralid.

2. The analytical method must be submitted to EPA Fort Meade Laboratory for validation.
3. Submit storage stability data for grass forage and hay reflecting up to approximately 15 months of frozen storage.
4. Submit a repeated Aerobic Soil Metabolism Study (EPA Guidelines No. 162-1).
5. Submit a repeated Avian Reproduction study in bobwhite quail (EPA Guideline No. 71-4(a)).
6. Submit a repeated Tier II Aquatic Plant Growth: Blue-Green Algae, *Anabaena flos aquae* (EPA Guideline No. 123-2).

PUBLIC INTEREST FINDING

Aminopyralid is a Reduced Risk herbicide that provides reliable control of a broad spectrum of difficult-to control noxious weeds and invasive plants on rangeland and pastures, rights-of-way, and wildlife habitat areas. Aminopyralid is particularly effective for the control of tropical soda apple, musk thistle, Canada thistle, spotted knapweed, diffuse knapweed, yellow starthistle and Russian knapweed. Aminopyralid has a favorable human health toxicity profile when compared to the registered alternatives for these use sites and will be applied at a lower rate. Its residual action should alleviate the need for repeat applications, resulting in a reduction in the amount of herbicides applied to the environment for the control of these weeds. Aminopyralid has been determined to be practically non-toxic to non-target animals at the registered application rates, compared to the alternatives, and is less likely to impact both terrestrial and aquatic plants.

GOVERNMENT PERFORMANCE AND RESULTS ACT (GPRA)

Registration of aminopyralid will meet the objectives of GRPA title 3.1.1 by assuring new pesticides that enter the market are safe for humans and the environment and title 4.1.2 by reducing environmental exposure to herbicides.

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Disclaimer: The information presented in this Pesticide Fact Sheet is for informational purposes only and may not be used to fill data requirements for pesticide registration and reregistration.

**Study Information For Ingredient
005100 / 150114-71-9 / Aminopyralid**

MRID	Citation	Receipt Date
46235600	Dow AgroSciences LLC (2004) Submission of Residue and Toxicity Data in Support of the Applications for Registration of Aminopyralid Technical and GF-871 and the Petition for Tolerance of Aminopyralid on Grass Forage, Grass Hay, Wheat Commodities, Milk, Cattle Meat and Meat By-Products. Transmittal of 37 of 108 Studies.	25-Mar-2004
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