



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Pesticide Fact Sheet

Name of Chemical: Mandipropamid
Reason for Issuance: New Chemical
Dated Issued January 2008

Description of Chemical

Generic Name: Mandipropamid [4-chloro-N-[2-[3-methoxy-4-(2-propynyloxy)phenyl]ethyl]a-(2-propynyloxy)-benzeneacetamide]
Common Name: Mandipropamid
Chemical Class: Mandelamide
EPA Chemical Code: 036602
CAS Number: 34726-62-2
Registration Status: New Chemical Registration
Pesticide Type: Fungicide
U.S. Producer: Syngenta Crop Protection
P.O. Box 18300
Greensboro, NC 27419

Tolerances Established

Tolerances were established for Mandipropamid in the 40 CFR 180.637 as summarized below:

Tolerances for combined residues of Mandipropamid:

<i>Brassica</i> , Head and Stem, Subgroup 5A	3 ppm
<i>Brassica</i> , Leafy Greens, Subgroup 5B	25 ppm
Vegetable, Cucurbit, Group 9	0.6 ppm
Vegetable, Fruiting, Group 8	1 ppm
Vegetable, Leafy, except <i>Brassica</i> , Group 4	20 ppm
Vegetable, Tuberous and Corm, Subgroup 1C	0.01 ppm
Grape	1.4 ppm

Grape, raisin	3 ppm
Onion, dry bulb	0.05 ppm
Onion, green	4 ppm
Okra	1 ppm
Potato, wet peel	0.03 ppm

Use Patterns and Formulations

Mandipropamid is a new fungicide in the mandelamide class developed by Syngenta Crop Protection, Inc. for the control of foliar oomycete pathogens in a range of crops including *Plasmopara viticola* in grapes, *Phytophthora infestans* in potatoes and tomatoes, and *Pseudoperonospora cubensis* in cucurbits. Mandipropamid is also proposed for uses on leafy vegetables to control downy mildew (*Bremia lactucae*) and blue mold (*Peronospora effuse*).

There is one technical and one end use product to be registered in the U.S. The end-use product (EP) associated with these petitions is Mandy Flowable Fungicide, which contains 23.3% active ingredient (2.08 lb ai/gal). The EP is proposed for multiple foliar applications using ground, irrigation, or aerial equipment at a maximum seasonal rate of 0.52 lb ai/acre for all crops except green onions for which a maximum seasonal rate of 0.39 lb ai/acre is proposed. The proposed preharvest intervals (PHIs) range from 0 day (cucurbits) to 14 days (grapes; tuberous and corm vegetables). No residential uses are proposed.

A tolerance for tomato paste was requested by Syngenta, however, the maximum expected residue in tomato paste and puree resulting from the proposed use will be covered by the recommended tolerance for vegetable, fruiting, crop group 8.

A separate tolerance is being established for potato, wet peel, even though it was not requested. The maximum expected residue in potato wet peel resulting from the use on potato is 0.03 ppm which was calculated by multiplying the Highest Average Field Trial (HAFT) <0.01 ppm by the observed concentration factor of >3x. Potatoes have a separate tolerance under the vegetable, tuberous and corm subgroup 1C.

Okra is listed on the proposed label as a member of the fruiting vegetables. However, a separate tolerance for okra is being established until the new crop group regulation is published.

Table 1. Details of Proposed Uses of 2.08 lb ai/gal flowable formulation (Mandy Flowable Fungicide).				
Application Timing, Type, and Equipment	Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications per Season	Maximum Seasonal Application Rate (lb ai/A)	PHI (days)
Brassica, Head and Stem Subgroup (Broccoli, Chinese broccoli (gai lon), Brussels sprouts, cabbage, Chinese cabbage (napa), Chinese mustard cabbage (gai choy), cauliflower, cavalo broccoli, and kohlrabi)				
Brassica, Leafy Greens, Subgroup (Broccoli raab, Chinese cabbage, collards, kale, mizuna, mustard greens, mustard spinach, and rape greens – including all cultivars and/or hybrids of these)				
Postemergence Foliar spray Ground, aerial, or chemigation	0.13	4 ¹	0.52	1
	Use Directions and Restrictions: For resistance management, do not apply more than two applications of Mandy before alternation with at least one application of a fungicide that is not in Group 40. Applications should begin prior to disease development and continue throughout the season on a 7-10 day schedule of fungicides, following the resistance management guidelines. A silicone-based adjuvant should be added at recommended rates.			
Dry Bulb (bulb onion, garlic, and shallot)				
Green Onion (green onions, leek, and Welch onion)				
Postemergence Foliar spray Ground, aerial, or Chemigation	0.13	4 ¹ for dry bulb vegetables; 3 ¹ for green onions	0.52 for dry bulb vegetables; 0.39 for green onions	7
	Use Directions and Restrictions: For resistance management, do not apply more than two applications of Mandy before alternation with at least one application of a fungicide that is not in Group 40. Applications should begin prior to disease development and continue throughout the season on a 7-10 day schedule of fungicides, following the resistance management guidelines. A silicone-based adjuvant should be added at recommended rates.			
Cucurbits (cantaloupe, chayote, Chinese waxgourd, cucumber, gourds, honeydew melons, <i>Momordica</i> spp. (bitter melon, balsam apple), muskmelon, watermelon, pumpkin, squash, and zucchini – including all cultivars and/or hybrids of these)				
Fruiting Vegetables (pepper [bell, non-bell, and sweet non-bell], eggplant, okra, groundcherry, and pepino; see below for specific proposed use on tomatoes)				
Postemergence Foliar spray Ground, aerial, or Chemigation	0.13	4 ¹	0.52	1
	Use Directions and Restrictions: For resistance management, do not apply more than two applications of Mandy before alternation with at least one application of a fungicide that is not in Group 40. Applications should begin prior to disease development and continue throughout the season on a 7-10 day schedule of fungicides, following the resistance management guidelines. When disease epidemics are severe, tank mix Mandy with another fungicide that is efficacious for disease control. For <i>Phytophthora</i> blight control, Mandy should always be tank mixed to provide adequate control. A non-ionic surfactant may be added at recommended rates.			
Tomato (including tomatillo)				
Postemergence Foliar spray Ground, aerial, or Chemigation	0.13	4 ¹	0.52	1
	Use Directions and Restrictions: For resistance management, do not apply more than two sequential applications of Mandy or any other Group 40 (CAA) fungicide before alternation with at least two applications of a fungicide that is not in Group 40			

Table 1. Details of Proposed Uses of 2.08 lb ai/gal flowable formulation (Mandy Flowable Fungicide).				
Application Timing, Type, and Equipment	Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications per Season	Maximum Seasonal Application Rate (lb ai/A)	PHI (days)
Applications should begin prior to disease development and continue throughout the season on a 7-10 day schedule of fungicides, following the resistance management guidelines. A non-ionic surfactant may be added at recommended rates.				
Grapes				
Postemergence Foliar spray Ground, aerial, or Chemigation	0.13	4 ¹	0.52	14
	Use Directions and Restrictions: For resistance management, do not apply more than two applications of Mandy before alternation with at least one application of a fungicide that is not in Group 40. Applications should begin prior to disease development and continue throughout the season on a 7-10 day schedule of fungicides, following the resistance management guidelines. A non-ionic surfactant may be added at recommended rates.			
Vegetables, Leafy, except <i>Brassica</i> (amaranth, arugula, cardoon, celery (Chinese), celtuce, chervil, chrysanthemum (edible-leaved and garland), corn salad, cress (garden and upland), dandelion, dock, endive, fennel (Florence), lettuce, orach, parsel, purslane (garden and winter), radicchio (red chicory), rhubarb, spinach (New Zealand and vine), Swiss chard.)				
Postemergence Foliar spray Ground, aerial, or Chemigation	0.13	4 ¹	0.52	1
	Use Directions and Restrictions: For resistance management, do not apply more than two applications of Mandy before alternation with at least one application of a fungicide that is not in Group 40. Applications should begin prior to disease development and continue throughout the season on a 7-10 day schedule of fungicides, following the resistance management guidelines. A non-ionic surfactant may be added at recommended rates.			
Vegetables, Tuberous and Corm, Subgroup (arracacha, arrowroot, artichoke (Chinese and Jerusalem), burdock, canna, cassava (edible, bitter, and sweet), chayote (root), chufa, dasheen (taro), ginger, leren, potato, sweet potato, taniel, turmeric, and yam (bean and true))				
Postemergence Foliar spray Ground, aerial, or Chemigation	0.13	4 ¹	0.52	14
	Use Directions and Restrictions: For resistance management, do not apply more than two sequential applications of Mandy or any other Group 40 (CAA) fungicide before alternation with at least two applications of a fungicide that is not in Group 40. Applications should begin prior to disease development and continue throughout the season on a 7-10 day schedule of fungicides, following the resistance management guidelines. A non-ionic surfactant may be added at recommended rates.			

¹. A maximum number of uses were not specified on the labels; however, based on the residue data, the application rate, and the seasonal maximum use rate, the number of applications specified in this table should be reflected on the labels.

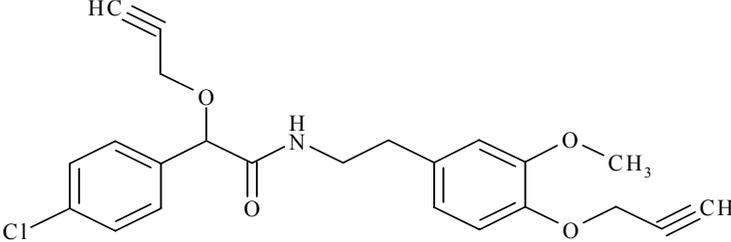
Science Findings

The toxicity data base for mandipropamid is adequate for risk assessment and tolerance setting. Mandipropamid has low or minimal acute toxicity via the oral (Category IV), dermal (Category IV), and inhalation routes of exposure (Category IV). It is minimally irritating to the eye (Category IV) and non-irritating to the skin (Category IV); however, it is classified as a skin sensitizer.

The database is adequate to characterize potential pre-and/or post-natal risk for infants and children. Acceptable/guideline developmental toxicity study in rats and rabbits and a reproduction study in rats, as well as acute and subchronic neurotoxicity studies in rats were available for FQPA assessment.

Available product chemistry and toxicology data supporting the proposed tolerance are summarized below:

Structure and Nomenclature

Table 2. Test Compound Nomenclature.	
Compound	
Common name	Mandipropamid 
Company experimental name	NOA 446510
IUPAC name	(<i>RS</i>)-2-(4-chloro-phenyl)- <i>N</i> -[2-(3-methoxy-4-prop-2-ynyloxy-phenyl)-ethyl]-2-prop-2-ynyloxy-acetamide
CAS name	4-chloro- <i>N</i> -[2-[3-methoxy-4-(2-propynyloxy)phenyl]ethyl]- α -(2-propynyloxy)-benzeneacetamide
CAS registry number	374726-62-2
End-use product (EP)	Mandy Flowable Fungicide (2.08 lb/gal; EPA Reg. No. 100-1254), (Alternate Brand Name: Revus)

Physical and Chemical Properties

Table 3. Physical and chemical Properties of the Technical Grade of Mandipropamid.		
Parameter	Value	Reference
Melting point/range	96.4-97.3°C	MRID 46800006
Molecular formula/weight	C ₂₃ H ₂₂ ClNO ₄ / 411.9	
pH	6-8 at 25°C (1% aqueous dispersion)	
Density	1.24 x 10 ³ kg/m ³ at 22°C	
Water solubility (25°C)	4.2 mg/L	
Solvent solubility (25°C)	n-hexane 42 mg/L n-octanol 4.8 g/L toluene 29 g/L methanol 66 g/L ethyl acetate 120 g/L acetone 300 g/L dichloromethane 400 g/L	
Vapor pressure	<9.4 x 10 ⁻⁷ Pa at 25°C or <7.0 x 10 ⁻⁹ mmHg	
Dissociation constant, pK _a	No dissociation constant in the pH range of 1 to 12	
Octanol/water partition coefficient, Log(P _{ow})	3.3 at 25°C	

Toxicological Characteristics

Mandipropamid has low or minimal acute toxicity via the oral (Category IV), dermal (Category IV), and inhalation routes of exposure (Category IV). It is minimally irritating to the eye (Category IV) and non-irritating to the skin (Category IV); it is a skin sensitizer.

Liver toxicity is the primary effect and was observed in rats, mice and dogs. In a 90-day rat dietary study, there was slight hepatotoxicity in both sexes at 260 mg/kg/day (NOAEL = 41/45 mg/kg/day, M/F). There was the suggestion of effects on the liver in the 90-day mouse dietary study (increased liver weights in both sexes and microscopic pathology) at 624/800 mg/kg/day (M/F), with the NOAEL = 248/316 mg/kg/day (M/F). The 90-day dog study showed (capsule) increased cholesterol, increased liver weights and liver enzymes (alkaline phosphatase activity, alanine aminotransferase) and increased pigment in hepatocytes and Kupffer cells in both sexes at 400 mg/kg/day. Additionally, centrilobular hepatocyte vacuolation in females was observed at 400 mg/kg/day with the NOAEL = 100 mg/kg/day.

In the combined chronic/carcinogenicity dietary rat study, no effects on the liver were noted at doses up to and including the HDT of 61/70 mg/kg/day (M/F); however, increased nephrotoxicity occurred in males. No liver effects were observed in the 18-month mouse dietary admix carcinogenicity study at doses up to 223/285 mg/kg/day (M/F). The following effects on the liver were present in the 1-year dog study (capsule) at 40 mg/kg/day (NOAEL = 5

mg/kg/day): increased incidence and severity of microscopic pigment in the liver and increased alkaline phosphatase activity in both sexes, as well as increased alanine aminotransferase activity in males. In the 24-month rat study, only nephrotoxicity was observed. In the 18-month mouse study, the only effects seen were decreases in body weight and food utilization.

There was no evidence of teratogenicity or indications of increased neonatal sensitivity in the developmental and reproduction toxicity studies. In the rat and rabbit developmental toxicity studies, no maternal or developmental effects were observed at the limit dose of 1000 mg/kg/day. In the two-generation rat reproduction study, the only parental/systemic effects were decreased body weights, body weight gains, food consumption and food utilization in males at the LOAEL of 146/148 mg/kg/day (M/F)(NOAEL = 23/25 mg/kg/day, M/F). No effects on reproduction were observed at any dose. There were decreased pup body weights in both sexes observed at the LOAEL of 146/148 mg/kg/day (M/F). In addition, there was a delay in prepuccial separation in F₁ males (group mean days: control = 43.7; 146 mg/kg/day = 44.8) which was considered to be the result of lower body weights.

Dermal exposure to mandipropamid for 28 days in the rat did not result in systemic or dermal toxicity up to the limit dose of 1000 mg/kg/day.

There was no evidence of neurotoxicity, mutagenicity or carcinogenicity after exposure to mandipropamid. In addition, there was no estrogen-, androgen-, and/or thyroid-mediated toxicity.

Table 4 Acute Toxicity Profile - Test Substance				
Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral rat	46800201	LD ₅₀ > 5000 mg/kg	IV
870.1200	Acute dermal rat	46800202	LD ₅₀ > 5050 mg/kg	IV
870.1300	Acute inhalation rat	46800204	LC ₅₀ > 5.19 ± 0.55 mg/L	IV
870.2400	Acute eye irritation rabbit	46800206	Iritis and positive signs of conjunctivitis clearing within 24 hours.	IV
870.2500	Acute dermal irritation rabbit	46800208	PDI = 0.33	IV
870.2600	Skin sensitization guinea pig	46800210	Sensitizer	N/A
870.2600	Skin sensitization mouse	46800212	Not acceptable	N/A

N/A -- not applicable.

Table 5. Subchronic, Chronic and Other Toxicity Profile for Mandipropamid				
Guideline No.	Study Type	MRID No. (year)/ Classification	Dose levels	Results
870.3100a	90-Day oral toxicity (rat)	46800216 (2005) Acceptable/ Guideline	ppm= 0, 100, 500, 3000, 5000 mg/kg/day= M: 0, 8, 41, 260, 435 F: 0, 9, 45, 260, 444	NOAEL = 41/45 mg/kg/day M/F LOAEL = 260 mg/kg/day both sexes, based on decreased body weights, weight gains and food utilization in males and slight hepatotoxicity in both sexes
30.3100	28-Day oral toxicity (rat)	46800214 (2005) Acceptable/ Guideline	ppm = 0, 1000, 3000, 10,000, 16,000 [10,000 & 16,000 died < day 4] mg/kg/day = M: 0, 135, 418, 624, 604 F: 0, 121, 381, 784, 1410	NOAEL = not established LOAEL = M=135, F=121 mg/kg/day, based on decreased food consumption in both sexes and decreased body weights and weight gains in males (liver changes at 418/381 mg/kg/day M/F).
870.3100a	90-Day oral toxicity (mouse)	46800213 46800217 (2005) Acceptable/ Guideline	ppm= 0, 300, 800, 2000, 5000 mg/kg/day= M: 0, 37, 98, 248, 624 F: 0, 47, 129, 316, 800	NOAEL = M/F = 248/316 mg/kg/day LOAEL = M/F = 624/800 mg/kg/day, based on decreased body weight gain in males and females (as well as the suggestion of effects on the liver: increased weights in both sexes and microscopic pathology).
870.3150	90-Day oral toxicity (dog)	46800218 46800219 46800220 (2005) Acceptable/ Guideline	mg/kg/day= 0, 5, 25, 100, 400 (capsule)	NOAEL = 100 mg/kg/day LOAEL = 400 mg/kg/day, based on liver toxicity (increased cholesterol, alkaline phosphatase activity, ALT activity, liver weights and microscopic pigment in hepatocytes and Kupffer cells in both sexes and centrilobular hepatocyte vacuolation in females).
870.3200	21/28-Day dermal toxicity (rat)	46800222 46800221 (2005) Acceptable/ Guideline	mg/kg/day= 0, 250, 500, 1000 (limit dose)	Systemic/Dermal NOAEL = 1000 mg/kg/day LOAEL = not determined
870.3700a	Prenatal developmental (rat)	46800224 46800223 (2005) 46800228 (2001) Acceptable/ Guideline	mg/kg/day= 0, 50, 200, 1000	Maternal NOAEL = 1000 mg/kg/day LOAEL = not determined Developmental NOAEL = 1000 mg/kg/day LOAEL = not determined

Table 5. Subchronic, Chronic and Other Toxicity Profile for Mandipropamid				
Guideline No.	Study Type	MRID No. (year)/ Classification	Dose levels	Results
870.3700b	Prenatal developmental (rabbit)	46800227 46800225 46800226 46800229 (2005) Acceptable/ Guideline	mg/kg/day= 0, 50, 250, 1000	Maternal NOAEL = 1000 mg/kg/day LOAEL = not determined Developmental NOAEL = 1000 mg/kg/day LOAEL = not determined
870.3800	Reproduction and fertility effects (rat)	46800230 46800231 (2005) Acceptable/ Guideline	ppm=(males/ females) 0, 50, 250, 1500 mg/kg/day= (mean of pre mating both sets of parents) = 0/0, 4.6/5.0, 22.9/24.5, 146.3/148.2	Parental/Systemic NOAEL = M/F = 22.9/24.5 mg/kg/day LOAEL = M/F = 146.3/148.2 mg/kg/day, based on decreased body weights, weight gains, food consumption and food utilization in males Reproductive NOAEL = M = 146.3/148.2 mg/kg/day LOAEL = not determined Offspring NOAEL = M/F = 22.9/24.5 mg/kg/day LOAEL = M/F = 146.3/148.2 mg/kg/day, based on decreased pup body weights in both sexes.
870.4100b	Chronic toxicity (dog)	46800232 (2005) Acceptable/ Guideline	mg/kg/day= 0, 5, 40, 400 (capsule)	NOAEL = 5 mg/kg/day LOAEL = 40 mg/kg/day, based on evidence of liver toxicity (increased incidence and severity of microscopic pigment in the liver and increased alkaline phosphatase activity in both sexes as well as increased alanine aminotransferase activity in males).
870.4300	Combined chronic toxicity/ carcinogenicity (rat)	46800234 (2005) Acceptable/ Guideline	ppm = 0, 50, 250, 1000 mg/kg/day= M/F = 0/0, 3.0/3.5, 15.2/17.6, 61.3/69.7	NOAEL = M/F = 15.2/17.6 LOAEL = 61.3/69.7mg/kg/day, based on decreased body weight gain and food utilization and increased nephrotoxicity in males. There was no evidence of carcinogenicity in rats.
870.4200b	Carcinogenicity (mouse)	46800233 (2005) Acceptable/ Guideline	ppm = 0, 100, 500, 2000 mg/kg/day= M/F = 0/0, 10.6/13.2, 55.2/67.8, 222.7/284.6	NOAEL = M/F = 55/68 mg/kg/day LOAEL = 223/285 mg/kg/day, based on decreased body weight gain in both sexes and decreased food utilization in males. There was no evidence of carcinogenicity in mice.
870.5100	Bacterial Reverse Mutation Assay	46800235 (2005) Acceptable/ Guideline	Tested up to limit dose of 5000 µg/plate	Negative

Table 5. Subchronic, Chronic and Other Toxicity Profile for Mandipropamid				
Guideline No.	Study Type	MRID No. (year)/ Classification	Dose levels	Results
870.5300	<i>In Vitro</i> Mammalian Cell Gene Mutation Test – Mouse Lymphoma	46800236 (2005) Acceptable/ Guideline	Tested up to limit dose (4119 µg/mL)	Negative
870.5375	<i>In Vitro</i> Chromosome Aberration test – Human Peripheral Blood Lymphocytes	46800237 (2002) Acceptable/ Guideline	Up to cytotoxic concentrations	Negative
870.5395	Micronucleus Assay in Rats	46800238 (2005) Acceptable/ Guideline	Limit dose of 2000 mg/kg	Negative
870.5550	<i>In Vivo/In Vitro</i> Unscheduled DNA Synthesis Assay in Primary Rat Hepatocytes	46800239 Acceptable/ Guideline	mg/kg = 0 or 2000	Negative
870.6200a	Acute neurotoxicity (rats)	46800242 (2005) 46800241 (2003) Acceptable/ Guideline	mg/kg = 0, 200, 600, 2000 (limit dose)	NOAEL = M/F = 2000 mg/kg LOAEL = M/F = not observed
870.6200b	Subchronic neurotoxicity (rats)	46800240 (2005) Acceptable/ Guideline	ppm = 0, 100, 500, 2500 mg/kg/day = M/F = 0/0, 7.4/8.4, 37.3/41.0, 192.5/206.7	NOAEL = M/F = 37/41 mg/kg/day LOAEL = M/F = 192/207 mg/kg/day, based on slightly decreased body weight, weight gain and food utilization in males.

Table 5. Subchronic, Chronic and Other Toxicity Profile for Mandipropamid				
Guideline No.	Study Type	MRID No. (year)/ Classification	Dose levels	Results
870.7485	Metabolism and pharmacokinetics (rat)	46800243-46800246 (2005) Acceptable/ Guideline	mg/kg/day = single oral 3 or 300 methoxy label repeated 3 methoxy label single oral 3 or 300 methoxy/chloro labels	After 48 hours, absorption was 67-74% at 3 mg/kg and 30-45% at 300 mg/kg. Blood T _{max} at 3 mg/kg was 8.5 hours for M and 4.5 hours for F; at 300 mg/kg was 24 hours for M and 10 hours for F (rate of resorption greater in F; extent and rate greater in low dose). Recoveries at 168 hours 88-99% (most eliminated by 48 hours). Excluding 3 mg/kg F, most excreted in feces; at 3 mg/kg F, feces and urine similar. Elimination after 48 hours in bile was high at 3 mg/kg (55-73%), but was 22-28% at 300 mg/kg. Liver had highest concentration at all measurements. More radioactivity in plasma than whole blood. Identified compounds 66-94% of administered dose in each group (168 hours). Parent and following metabolites at ≥5% at 3 and/or 300 mg/kg: NOA 458422, NOA 458422 glucuronide, SYN 534133 and CGA 380778. Differences in metabolic profile due to sex, dose and radiolabel position. Each unknown compound < 5%. Major metabolic transformations involved loss of one or both propargyl groups followed by glucuronidation and O-demethylation.
870.7600	Dermal Penetration (rat)	46800248 (2005) Acceptable/ Guideline	Nominal doses: mg/cm ² skin = 0.00152, 0.0076, 2.54. Spray strength dilutions of 1/333 and 1/1667 v/v.	Recovery was 96-112%. Minimal absorption (<0.17 to 3.44% of applied dose). 91-105% recovered from 6 hour skin wash. Greatest absorption in 1/1667 aqueous dilution 114 hours after 6 hours of exposure (3.44% absorbed).
Non-Guideline	Methods Development and Validation for Dietary Formulation Analyses	46800215 (2002) Acceptable/ Non-Guideline	N/A	Validation of analytical method for determining concentrations, stability and homogeneity of test article in dietary formulations.
Non-Guideline	<i>In Vitro</i> Dermal Penetration Study, Rat epidermis	46800247 (2003) Acceptable/ Non-Guideline	µg/cm ² skin = 2570 or 2510	Absorption rate greatest during first 30 minutes of exposure, 0.715-0.746 µg/cm ² /hour. Absorption rates over 24 hours were 0.077-0.091 µg/cm ² /hour.

Guideline No.	Study Type	MRID No. (year)/ Classification	Dose levels	Results
Non-Guideline	<i>In Vitro</i> Dermal Penetration Study, Rat epidermis	46800251 (2005) Acceptable/ Non-Guideline	$\mu\text{g}/\text{cm}^2$ skin = 1.35, 6.69, 2538	Absorption was poor (recovery of applied radioactivity 99-105%). Absorption rates over 24 hours were $<0.04 \mu\text{g}/\text{cm}^2/\text{hour}$ in concentrate formulation and $0.01 \mu\text{g}/\text{cm}^2/\text{hour}$ in aqueous spray dilutions.
Non-Guideline	<i>In Vitro</i> Dermal Penetration Study, Pig epidermis	46800249 (2003) Acceptable/ Non-Guideline	$\mu\text{g}/\text{cm}^2$ skin = neat: 38,600 in acetone: 39.9	Absorption was poor ($<0.01\%$). Absorption rate for neat was greatest during first 4 hours ($0.03 \mu\text{g}/\text{cm}^2/\text{hour}$) and was $0.02 \mu\text{g}/\text{cm}^2/\text{hour}$ over 24 hours. Absorption rate for acetone was 3.58% (first hour = 0.56 , 24 hours = $0.05 \mu\text{g}/\text{cm}^2/\text{hour}$). Absorption enhanced by acetone.
Non-Guideline	<i>In Vitro</i> Dermal Penetration Study, Human epidermis	46800250 (2005) Acceptable/ Non-Guideline	$\mu\text{g}/\text{cm}^2$ skin = 1.35, 6.69, 2538	Recovery of radioactivity was 95-102%. Absorption was minimal. Over 24 hours, absorption was $<0.04 \mu\text{g}/\text{cm}^2/\text{hour}$ in the concentrate formulation and $\leq 0.001 \mu\text{g}/\text{cm}^2/\text{hour}$ in the aqueous spray dilutions.

Exposure/ Scenario	Point of Departure	Uncertainty/ FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General Population, including Infants and Children)	N/A	N/A	N/A	<u>No appropriate endpoint was identified.</u>
Acute Dietary (Females 13-49 years of age)	N/A	N/A	N/A	<u>No appropriate endpoint was identified.</u>
Chronic Dietary (All Populations)	NOAEL = 5 mg/kg/day	$\text{UF}_A = 10\text{X}$ $\text{UF}_H = 10\text{X}$ FQPA SF = 1X	Chronic RfD = 0.05 mg/kg/day cPAD = 0.05 mg/kg/day	<u>Chronic toxicity – dogs</u> LOAEL = 40 mg/kg/day, based on evidence of liver toxicity (increased incidence and severity of microscopic pigment in the liver and increased alkaline phosphatase activity in both sexes as well as increased alanine aminotransferase activity in males).
Cancer (oral, dermal, inhalation)	“Not Likely to be Carcinogenic to Humans.” No treatment-related tumors observed in carcinogenicity studies in rats and mice. A cancer risk assessment is not needed.			

NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (c = chronic). RfD = reference dose. N/A = not applicable.

Table 7. Summary of Toxicological Doses and Endpoints for Mandipropamid for Use in Occupational Human Health Risk Assessments				
Exposure/ Scenario	Point of Departure	Uncertainty Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Dermal (1-30 days) and Intermediate-term (1-6 months)	N/A	N/A	N/A	<u>No appropriate endpoint was identified.</u> 28-day dermal toxicity study – rat, no systemic or dermal effect up to the limit dose of 1000 mg/kg/day; there were no neurotoxicity or developmental concerns.
Inhalation Short-(1-30 days) and Intermediate-term (1-6 months)	NOAEL = 41 mg/kg/day IAF=100%	UF _A = 10X UF _H = 10X	MOE = 100	<u>90-day oral toxicity – rats</u> LOAEL = 260 mg/kg/day, based on decreased body weights, body weight gains and food utilization in males and slight hepatotoxicity in both sexes.
Cancer (oral, dermal, inhalation)	“Not Likely to be Carcinogenic to Humans.” No treatment-related tumors observed in carcinogenicity studies in rats and mice. A cancer risk assessment is not needed.			

NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). MOE = margin of exposure. LOC = level of concern. N/A = not applicable. IAF=inhalation absorption factor.

Food Quality Protection Act Considerations:

The Agency recommends that the FQPA SF be reduced to 1X because there is no evidence of increased susceptibility, there are no/low concerns and no residuals uncertainties regarding pre- and/or postnatal toxicity, there is no evidence of neurotoxicity in the database and a DNT study is not required. In addition, the toxicological database is complete and there is no need for additional uncertainty factors. Furthermore, the exposure assessments are based on reliable data and reasonable worst-case assumptions and will not likely underestimate risks.

Exposure Assessment:

Acute Dietary Exposure and Risk: No acute dietary endpoint based on effects attributable to a single dose could be identified based on the toxicology data currently available for mandipropamid.

Chronic Dietary Exposure and Risk: A tolerance level (unrefined) chronic exposure assessment that assumes 100% crop treated was conducted for the proposed Section 3 uses of mandipropamid. The DEEM analysis incorporates estimates of drinking water concentration from the Environmental Fate and Effect Division directly into the analysis. The chronic dietary exposure analysis for mandipropamid results in dietary risk estimates for food

and water that are below the Agency's level of concern for chronic dietary exposure. For mandipropamid, the DEEM chronic dietary exposure estimate was 22% of the cPAD for the U.S. population and was 30% of the cPAD for the highest exposed population subgroup, children 1-2 years of age.

Cancer Exposure and Risk: Mandipropamid is classified as not likely to be a human carcinogen. Therefore, a cancer assessment was not performed.

Residential Exposure and Risk: Residential exposures were not assessed because the proposed uses of mandipropamid do not involve applications by homeowners or by commercial applicators in residential settings.

Aggregate Exposure and Risk: The chronic aggregate risk calculations include exposures only from food and water sources. Acute aggregate and cancer risks were not assessed due to the absence of an acute dietary endpoint and because mandipropamid is not likely to be carcinogenic to humans.

Cumulative Exposure and Risk: Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information concerning the cumulative effects" of a particular pesticide's residues and "other substances that have a 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 as to mandipropamid and any other substances, and mandipropamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that mandipropamid has 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 EPA's Office of Pesticide 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 and Risk: Mandipropamid is a fungicide to be applied as a foliar spray by aerial equipment, chemigation, groundboom equipment, and airblast equipment. Occupational exposure is expected to be short (1-30 days) and intermediate-term (1-6 months) in duration. No long-term (more than 6 months) exposure is expected from the proposed uses in mandipropamid due to the limited number of applications and fungicide rotation directions.

No chemical-specific exposure data were submitted. Therefore, occupational handler assessments for mandipropamid were based on surrogate unit exposures from the Pesticide Handlers Exposure Database (PHED).

Dermal handler exposure and risks were not assessed for mandipropamid, since no short- or intermediate-term dermal endpoints were identified. All inhalation scenarios were assessed. In all scenarios except aerial applicator (where adequate baseline or open cockpit data are not available), short- and intermediate-term inhalation risks resulted in MOEs greater than 100 (53,000-460,000) at the baseline level of personal protective equipment, (PPE) (i.e., no respirator) and were not of concern to the Agency. Inhalation risks to pilots in enclosed cockpits with no respirator (engineering control scenario) were not of concern. In this assessment the Agency assumed the maximum application rates that are on the labels, a 70 kg body weight for the handler, and an average workday of 8 hours. With respect to aerial applications by open cockpit, we are not aware of this type of application taking place. Therefore, a label statement prohibiting open cockpits is not warranted.

Occupational post application risks to agricultural workers following treatments to agricultural crops were not assessed, since dermal endpoints of concern were not identified.

Short-/Intermediate-Term Handler Risk: Short- and intermediate-term dermal exposures and risk were not assessed for mandipropamid, since no short- or intermediate-term dermal endpoint was identified.

Short-/Intermediate-Term Postapplication Risk: Occupational post-application exposures/risks were not quantified because no appropriate dermal endpoints were identified.

Environmental Fate Characteristics/Ecological Effects

Environmental Fate Summary: Mandipropamid is considered to be persistent in the environment based on its degradation in soil and water. The major route of dissipation is degradation under aerobic aquatic conditions. Mandipropamid degrades to several intermediary degradation products. The transformation products are ultimately degraded to non-extractable residues and carbon dioxide. Mandipropamid is moderately mobile and some of its metabolites are mobile to highly mobile in soils, and therefore have the potential to leach into ground water. Mandipropamid can reach surface waters via spray drift and rainfall events that cause runoff.

a. Hydrolysis/photolysis

Mandipropamid appears to be stable to hydrolysis in the environmental pH range of 5-9, but is susceptible to photolysis in soil and water. The environmental photolysis half-lives of mandipropamid in pH 7, 25°C aqueous solutions was estimated as 0.63-1.1 days. The soil

photolysis half-lives of mandipropamid was estimated as 16.4-23.9 days. Based on its vapor pressure and Henry's Law constant, volatilization from water and soil are not expected to be important environmental fate processes.

b. Soil/Water Degradation

The linear biodegradation half-life of mandipropamid in six European and one U.S. soils ranged from approximately 26 to 103 days under aerobic conditions. Based on results from the supplemental study, under anaerobic conditions the rate of biodegradation appears to be much slower. Mandipropamid degraded with linear half-lives of 151 days in a silt loam soil from Switzerland maintained under anaerobic conditions. The aerobic aquatic degradation half-lives of mandipropamid were 17.8-18.5 days in two river water/silt loam sediment systems from England and Germany.

c. Terrestrial Field Dissipation. Studies on mandipropamid were conducted in four bare plots cropped with field potatoes: in California (sandy loam soil), New York (loamy sandy soil), and Georgia (sandy loam soil). The field dissipation half-lives of mandipropamid were: 75.3 days (California site); 100.5 days (New York); 81.5 days (Georgia).

Ecological Effects Summary

a. Avian Acute Toxicity

Mandipropamid is practically nontoxic to birds on an acute oral and acute dietary basis.

b. Avian Chronic Toxicity

Mandipropamid did not cause any significant chronic effects on reproduction or growth and survival of chicks at 1060 ppm a.i. which was the highest concentration tested.

c. Mammalian Acute Toxicity

Mandipropamid is practically nontoxic to mammals on an acute oral toxicity basis.

d. Mammalian Chronic Toxicity

The results of the mammalian reproductive toxicity study demonstrated a parental system NOAEL and offspring NOAEL of 250 ppm a.i. based on decreased parental body weights,

decreased parental weight gains, decreased parental food consumption, decreased parental food utilization, decreased pup body weights in both sexes and delayed sexual maturation in offspring.

e. Fish Acute Toxicity

The registrant submitted a freshwater fish chronic toxicity study that demonstrates chronic exposure to technical mandipropamid causes significant decreases to fish growth at a NOAEC and LOAEC concentration of 0.21 ppm and 0.45 ppm respectively.

f. Aquatic Invertebrate Toxicity

The registrant submitted aquatic invertebrate acute toxicity studies demonstrating that technical mandipropamid is moderately toxic to freshwater invertebrates and very highly to moderately toxic marine/estuarine invertebrates.

g. Aquatic Invertebrate Chronic Toxicity

The registrant submitted aquatic invertebrate chronic toxicity data that are invalid. Thus, the Agency is uncertain about the chronic toxic effects of mandipropamid to aquatic invertebrates.

Ecological Risk Summary

Based on the available data, the Agency has determined that mandipropamid's proposed uses are not expected to pose significant acute or aquatic risk to birds; acute or chronic risk to mammals; acute risk to aquatic invertebrates; acute or chronic risk to fish; or acute risk to terrestrial or aquatic plants. The RQ values for acute risk to aquatic invertebrates, acute risk to plants, and chronic risk to fish are several orders of magnitude below the Agency LOC. Therefore, no additional risk mitigation measures are needed and LOCs were not exceeded.

Data Needs and Label Requirements

The registrant will be required to submit the following confirmatory data. All required label changes have been made. This chemical was found to be a reduced risk chemical, therefore no public interest finding statement is needed.

1. Invertebrate chronic toxicity: The submitted Daphnia study is invalid because reproduction of the daphnids in the solvent control were significantly lower than in the negative control.
2. Storage Stability Data: Storage stability data for SYN 500003 which covers the entire 32

months of storage (interim storage submitted).

stability data for six months were

Contact Person at USEPA

Rose Mary Kearns
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202
703-305-5611

DISCLAIMER: The information in this Pesticide Fact Sheet is for information only and is not to be used to satisfy data requirements for pesticide regulation. The information is believed to be accurate as of the date on the document.

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