

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: 2/18/05

Subject: Napropamide. Revised Residue Chemistry Considerations for Reregistration Eligibility Decision (Phase 2). Case No. 2450.

DP Barcode: D303455

PC Code: 103001

Chemical Class: Amide Herbicide

40 CFR: §180.328 (a) and (b)

From: Danette Drew, Chemist
Reregistration Branch 3
Health Effects Division (7509C)

Through: Catherine Edien, Branch Chief
Reregistration Branch 3
Health Effects Division (7509C)

To: Susan Stanton, Risk Assessor
Reregistration Branch 3
Health Effects Division (7509C)

This document has been revised to reflect, where appropriate, the registrant error-only (Phase 1) comments to the document "Napropamide. Residue Chemistry Considerations for Reregistration Eligibility Decision", D305600, dated 11/15/04.

Executive Summary

Napropamide [N,N-diethyl-2-(1-naphthalenyloxy)propionamide] is a selective preemergence herbicide registered to provide control of broadleaf weeds and annual grasses. Napropamide is currently registered for food/feed uses on almond, apple, apricot, artichoke, asparagus, avocado, blackberry, blueberry, boysenberry, broccoli, Brussels sprouts, cabbage, cauliflower, cherry, citrus fruits (grapefruit, lemon, orange, tangelo, and tangerine), cranberry, currant, eggplant, fig, filbert (hazelnut), grapes, kiwifruit, loganberry, mint, nectarine, olive, peach, pear, pecan, pepper, persimmon, pistachio, plum, pomegranate, prune, raspberry (black and red), rhubarb, strawberry, sweet potato, tomato, and walnut (black and English). Napropamide is also registered for use on tobacco.

End-use products containing napropamide as the active ingredient are sold under the trade name Devrinol®. Several formulation classes are registered for food/feed uses including the 10% granular (G), 50% dry flowable (DF), 2 lb/gal emulsifiable concentrate (EC), and 4 lb/gal flowable concentrate (FIC) formulations of napropamide. These formulations are typically applied as postemergence broadcast or soil applications using ground equipment. The maximum registered single application rates range from 2 lb ai/A for most vegetable crops and up to 15 lb ai/A for cranberries.

Tolerances are established under 40 CFR §180.328 (a) and (b) for negligible residues (0.1 ppm) of napropamide *per se* in/on various raw agricultural commodities. No meat/milk/egg/poultry tolerances are established for napropamide residues.

The qualitative nature of the residue in plants is understood. Acceptable metabolism studies with napropamide have been conducted on three dissimilar crops (apple, cabbage, and tomato). The results of these studies were presented on 3/16/93 to the HED Metabolism Committee. The committee concluded that the residue of concern in plants is napropamide *per se* and that the current tolerance expression is adequate; the tolerance is expressed in terms of residues of the parent compound only.

The qualitative nature of the residue in livestock is understood. HED has received and reviewed acceptable ruminant and poultry metabolism studies with napropamide. Based on the findings from these studies, HED has determined that 40 CFR §180.6(a)(3) is applicable to napropamide; there is no reasonable expectation of finite residues in ruminants or poultry. As a result of this determination, HED has recommended that waivers be granted from the requirements to: conduct a ruminant and poultry feeding study (860.1480), develop a residue analytical method for meat/milk/ poultry/eggs (860.1340), and conduct a storage stability study for meat/milk/poultry/eggs (860.1380). This recommendation is based on the low level of residues observed in the goat metabolism study where the test animals were dosed with [¹⁴C]napropamide at an average level of 9.9 ppm in the diet which is equivalent to 120x the maximum theoretical dietary burden of 0.083 ppm to dairy cattle (74x the MTDB of beef cattle). This recommendation is also based on the fact that there are no poultry and swine feedstuff associated with the raw agricultural commodities with established tolerances. A data-collection method and an enforcement method may be required if the registrants wish to register new food/feed uses in the future

Residue analytical methods for plant commodities are available for the purposes of tolerance enforcement and data collection. The Pesticide Analytical Manual, Volume I, indicates that napropamide is completely recovered (>80% recovery) using Multiresidue Method Sections 302 (Luke Method; Protocol D) and 401 (Krause N-methyl carbamate Method; Protocol A). In addition, PAM Volume II lists a GLC method as Method I (WRC 71-35) for the determination of napropamide *per se* in/on plant commodities.

The current PAM Volume II method uses benzene, a hazardous or toxic reagent. HED is recommending that the data-collection methods (GC/NPD methods with confirmation by GC/MSD), which were used in the analysis of samples from the magnitude of the residue studies, be subjected to method validations required for enforcement purposes.

There are adequate storage stability data to support the storage intervals and conditions of samples collected from the residue field studies. These data indicate that napropamide is reasonably stable under frozen storage conditions in/on: (i) alfalfa hay, almond nutmeat, apple, and soybean seed for >3 years; (ii) wheat grain and straw for up to 2.5 years, and; (iii) corn ear, orange, and pepper for up to ~2 years. There are also adequate storage stability data for representative processed commodities. These data indicate that residues of napropamide are reasonably stable under frozen storage conditions in orange juice, oil, dried pulp, apple juice, and apple pomace for up to 36-38 months.

There are adequate magnitude of the residue data to support the registered uses of napropamide on Brassica leafy vegetables and fruiting vegetables as well as on the individual crops of artichokes, asparagus, coffee, cranberry, mint, pistachio, pomegranate, rhubarb, strawberry, sweet potato, and tobacco. The available residue data for the above commodities indicate that residues of napropamide are mostly nondetectable (<0.05 ppm) following applications of representative formulations according to the maximum registered use patterns.

There are limited but adequate data to support the reinstatement of regional uses of napropamide on basil, marjoram, rosemary, and savory (summer and winter). The product label for the 50% DF formulation (EPA Reg. No. 70506-36) should be amended to reflect the parameters of use pattern for which residue data are available for the herb and spice crops.

Additional magnitude of the residue data are required for the crop groups of citrus fruits, pome fruits, stone fruits, berries, and tree nuts as well as the individual crops of avocado, fig, grape, kiwifruit, olives, and persimmon. There are presently no registered uses of napropamide on cucurbit vegetables. Unless the basic registrants of napropamide or other interested parties propose uses and submit supporting data, the established tolerance for cucurbit vegetables should be revoked.

Adequate processing studies with napropamide have been submitted for apples, figs, grapes, oranges, plums, and tomatoes. These studies indicate that residues of napropamide do not concentrate above the analytical method's LOQ of 0.05 ppm in the respective processed commodities of the above crops

except in citrus oil where a processing factor of 35x was reported. A coffee processing study and a mint processing study remain a reregistration requirement.

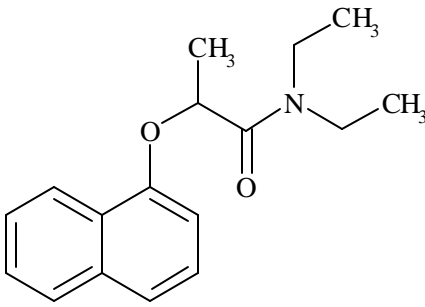
An acceptable confined rotational crop study has been submitted and reviewed. The metabolites identified in the various matrices of rotational crops corresponded to the metabolites identified in the plant metabolism studies and were found in approximately similar proportions. Napropamide and desethyl napropamide were found in all crops. HED has determined that limited/extensive field rotational crop data (OPPTS 860.1900) are not required provided the registrants accept the Agency's recommendation to establish a 60-day plantback interval (PBI) for leafy vegetables, a 180-day PBI for cereal grains, and a 365-day PBI for all other crops. Any labels that do not already specify the appropriate crop restrictions should be amended.

Regulatory Recommendations and Residue Chemistry Deficiencies

- " Label revision are required for the 50% DF formulation (EPA Reg. No. 70506-36) if the registrant, United Phosphorus Inc., proposes to reinstate regional uses of napropamide on basil, marjoram, rosemary, and savory (summer and winter).
- " It is recommended that the data-collection methods, GC/NPD methods with confirmation by GC/MSD (Method Nos. RR 92-073B, RR 92-006B, RR 92-072B, and RR 91-101B), that were used in the analysis of samples collected from the magnitude of the residue studies be subjected to method validations required for enforcement purposes.
- " Additional magnitude of the residue data are required for the crop groups of citrus fruits, pome fruits, stone fruits, berries, and tree nuts as well as on the individual crops of avocado, fig, grape, kiwifruit, olives, and persimmon (see Table 4 for specific deficiencies).
- " A mint processing study is required.
- " A coffee processing study (instant coffee) is required. If coffee beans treated at exaggerated rates equivalent to at least the maximum theoretical concentration factor due to processing do not show measurable residues, than processing studies will not be required.
- " Labels should be amended to include the appropriate preharvest intervals (PHIs). Not all crops have PHIs specified on the label. Minimum PHIs should reflect those used in the crop field trials.

Background

The PC code and nomenclature of napropamide are listed below in Table 1. The physicochemical properties of napropamide are listed in Table 2.

Compound	
Common name	Napropamide
Molecular Formula	C ₁₇ H ₂₁ NO ₂
Molecular Weight	271.4
IUPAC name	(<i>RS</i>)- <i>N,N</i> -diethyl-2-(1-naphthyloxy)propionamide
CAS name	<i>N,N</i> -diethyl-2-(1-naphthalenyloxy)propanamide
CAS #	15299-99-7

Parameter	Value	Reference
Melting point	68-70 °C	MRID 41610201; D303463; 9/30/04
pH	8.9 at 22 °C	MRID 41610201; D303463; 9/30/04
Density, bulk density, or specific gravity	0.584 g/mL at 22 °C	MRID 41610201; D303463; 9/30/04
Water solubility	74 mg/L at 25 °C	MRID 41610201; D303463; 9/30/04
Solvent solubility at 20 °C	Miscible with acetone, chlorobenzene, ethanol, and dichloromethane 4.5 g/100 mL in kerosene 17.7 g/100 mL in n-octanol 55.5 g/100 mL in xylene	D210989, 7/27/95, K. Dockter
Vapor pressure	1.7 x 10 ⁻⁷ torr or 2.3 x 10 ⁻⁵ Pa at 25 °C	MRID 41610201; D303463; 9/30/04
Dissociation constant, pK _a	Not applicable; napropamide is neither an acid nor a base.	
Octanol/water partition coefficient	2.1 x 10 ³ (log K _{OW} = 3.3)	MRID 41610201; D303463; 9/30/04

Parameter	Value	Reference
UV/visible absorption spectrum	Not available	Data Outstanding

860.1200 Directions for Use

Product List

A 1/27/05 product registration query of the USEPA/OPP Chemical Ingredients (OPPIN) database identified 12 active end-use products (EPs) containing napropamide (PC Code 103001) as the active ingredient, which are registered to United Phosphorus, Inc. (UPI) and Loveland Products, Inc. (formerly Platte Chemical Co.). These EPs are listed in Table 3.

EPA Reg. No.	Formulation	Product Name
United Phosphorus, Inc. (UPI)		
70506-27	21.8% EC 2 lb/gal EC	Devrinol 2-E Selective Herbicide
70506-28 ¹	21.8% EC 2 lb/gal EC	Devrinol 2-E Ornamental Selective Herbicide
70506-31	43.2% FIC 4 lb/gal FIC	Devrinol 4-F Selective Herbicide - Flowable
70506-33	2% G	Devrinol 2-G Ornamental Selective Herbicide
70506-34	10% G	Devrinol 10-G Selective Herbicide
70506-36	50% DF	Devrinol 50-DF Selective Herbicide
70506-37	43.2% FIC 4 lb/gal FIC	Devrinol 4-F Ornamental Selective Herbicide
70506-38	50% DF	Devrinol 50-DF Ornamental Herbicide
70506-39	2% G	Devrinol Lawn and Ornamental Selective Herbicide
70506-63	24.1% EC	Devrinol 2-EC Ornamental Herbicide
70506-64	24.2% EC	Devrinol 2-EC Selective Herbicide
Loveland Products, Inc. (formerly Platte Chemical Co.)		
34704-771	4% G	Napropamide-Oxadiazon 4-2 Granules

¹ cancellation requested 12/6/04

SRRD (Special Review and Reregistration Division) issued a Use Closure Memorandum for Napropamide Case No. 2450 on 4/29/04 in an attempt to provide use information that will be incorporated into the preliminary risk assessment for napropamide. The Napropamide Use Closure

Memo resulted from the 9/24/03 SMART meeting and subsequent discussions with the registrant, United Phosphorus, and review of product labels. The Closure Memo serves as the Agency's record of common understanding on the uses of napropamide to be used in risk assessments, including currently registered product information.

A tabular summary of the residue chemistry science assessments for reregistration of napropamide is presented in Table 4. The conclusions listed in Table 4 regarding the reregistration eligibility of napropamide food/feed uses are based on the use patterns to be supported by the basic producers. When end-use product DCIs are developed, RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer's labels.

SUMMARY OF RESIDUE CHEMISTRY DATA REQUIREMENTS

Table 4. Summary of Residue Chemistry Data Requirements for Napropamide (PC Code 103001).				
OPPTS Guideline No.	Guideline Description/Commodity	40 CFR Tolerances (ppm)	Must Additional Data Be Submitted?	MRID Nos. ¹
860.1200	Directions for Use	N/A = Not Applicable	Yes ²	See Table 3
860.1300	Nature of the Residue - Plants	N/A	No	00049481, 00113800, 00132824, 42349801 ³ , 42349802 ³ , 42393901 ³ , 42845901 ⁴
860.1300	Nature of the Residue - Animals	N/A	No	42775801 ⁵ , 42775802 ⁵
860.1340	Residue Analytical Method			
	- Plant Commodities	N/A	Yes ⁶	00032356, 00049482, 00049483, 00094087, 00126316, 00132824, 43345102 ⁷ , 43345105 ⁷ , 43345106 ⁷ , 43345108 ⁷
	- Livestock Commodities	N/A	No	00132824
860.1360	Multiresidue Method	N/A	No	PAM Vol. I
860.1380	Storage Stability Data			
	- Plant Commodities	N/A	Reserved ⁸	00049489, 00094488, 41575306 ⁹ , 41575307 ¹⁰ , 44020101 ¹¹ , 44020102 ¹¹
	- Livestock Commodities	N/A	No	
860.1400	Magnitude of the Residue - Water, Fish, and Irrigated Crops	N/A	N/A	
860.1460	Magnitude of the Residue - Food Handling	N/A	N/A	
860.1480	Magnitude of the Residue - Meat, Milk, Poultry, Eggs			
	- Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	None established	No	
	- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	None established	No	
860.1500	Crop Field Trials			
	Root and Tuber Vegetables Group (Crop Group 1)			
	- Potato, sweet	0.1, roots; [§180.328(a)]	No	42256501 ¹²
	Leafy Vegetables Group (except <i>Brassica</i> Vegetables) (Crop Group 4)			

Table 4. Summary of Residue Chemistry Data Requirements for Napropamide (PC Code 103001).				
OPPTS Guideline No.	Guideline Description/Commodity	40 CFR Tolerances (ppm)	Must Additional Data Be Submitted?	MRID Nos. ¹
	- Rhubarb	0.1; [§180.328(a)]	No	00126316
	<i>Brassica</i> (Cole) Leafy Vegetables Group (Crop Group 5)	0.1; [§180.328(a)]	No	00025888
	Fruiting Vegetables (Except Cucurbits) Group (Crop Group 8)	0.1(N); [§180.328(a)]	No	00023230, 00027319, 00027320, 00027321, 00028796, 00033961, 00035669, 00049483, 00049484, 00067872, 00067873, 00070786, 00070814, 00113800
	Cucurbits Vegetables Group (Crop Group 9)	0.1; [§180.328(a)]	No ¹³	00025886
	Citrus Fruits Group (Crop Group 10)	0.1(N); [§180.328(a)]	Yes ¹⁴	00023235, 00023883, 00035665, 00049485, 00070780, 00070784, 00113800, 00113821, 00115128
	Pome Fruits Group (Crop Group 11)	0.1(N); [§180.328(a)]	Yes ¹⁵	00035664, 00070780, 00070784, 00070785, 00113821, 00115128, 00118001
	Stone Fruits Group (Crop Group 12)	0.1(N); [§180.328(a)]	Yes ¹⁶	00023883, 00035663, 00049487, 00070784, 00113800, 00113821, 00115128, 00118001
	Berry Group (Crop Group 13)	0.1(N), fruit, small; [§180.328(a)]	Yes ¹⁷	00113821, 00118001, 00120304
	Tree Nuts Group (Crop Group 14)	0.1(N), almond hull and nut; [§180.328(a)]	Yes ¹⁸	00023883, 00032358, 00035666, 00049488, 00070780, 00113800, 00113821, 00115128, 00118001
	Herb and Spice Group (Crop Group 19)			
	- Basil	0.1; [§180.328(a)]	No ¹⁹	00094087, 41575308 ²⁰
	- Marjoram	0.1; [§180.328(a)]	No ²¹	

Table 4. Summary of Residue Chemistry Data Requirements for Napropamide (PC Code 103001).				
OPPTS Guideline No.	Guideline Description/Commodity	40 CFR Tolerances (ppm)	Must Additional Data Be Submitted?	MRID Nos. ¹
	- Rosemary	0.1; [§180.328(a)]	No ²²	00115110, 41575309 ²³
	- Savory (summer)	0.1; [§180.328(a)]	No ²⁴	00115110, 41575310 ²³
	- Savory (winter)	0.1; [§180.328(a)]	No ²⁵	
	Miscellaneous Commodities			
	- Artichoke	0.1, globe artichoke; [§180.328(a)]	No	00025883
	- Asparagus	0.1; [§180.328(a)]	No	00025884
	- Avocado	0.1; [§180.328(a)]	Yes ²⁶	00025885
	- Coffee beans	0.1(N); [§180.328(a)]	No	00113814
	- Cranberry	0.1, Fruit, small [§180.328(a)]	No ²⁷	00065363, 00113821, 00118001
	- Fig	0.1(N); [§180.328(a)]	Yes ²⁸	00035668, 00113821
	- Grape	0.1, Fruit, small [§180.328(a)]	Yes ²⁹	00023883, 00035667, 00049486, 00113800, 00113821, 00115128
	- Kiwifruit	0.1; [§180.328(a)]	Yes ³⁰	00025887
	- Mint	0.1; [§180.328(a)]	No	00025889
	- Olives	0.1; [§180.328(a)]	Yes ³¹	00030179
	- Persimmon	0.1; [§180.328(a)]	Yes ³²	00025890
	- Pistachio	0.1; [§180.328(a)]	No	00027550, 00035666
	- Pomegranate	0.1; [§180.328(b)]	No	00144964
	- Strawberry	0.1, Fruit, small [§180.328(a)]	No ³³	00027322, 00118001
	- Tobacco	N/A	No	00120304

Table 4. Summary of Residue Chemistry Data Requirements for Napropamide (PC Code 103001).				
OPPTS Guideline No.	Guideline Description/Commodity	40 CFR Tolerances (ppm)	Must Additional Data Be Submitted?	MRID Nos. ¹
860.1520	Processed Food/Feed			
	- Apple	None established	No	43249401 ⁷
	- Coffee bean	None established	Yes ³⁴	00140144
	- Fig	None established	No	00035668, 00113821
	- Grape	None established	No	43249402 ⁷
	- Mint	None established	Yes ³⁵	00025889
	- Orange	None established	No	43249403 ⁷
	- Plum	None established	No	43249404 ⁷
	- Tomato	None established	No	43249405 ⁷
860.1650	Submittal of Analytical Reference Standards	N/A	No	
860.1850	Confined Accumulation in Rotational Crops	N/A	No	42794501 ³⁶
860.1900	Field Accumulation in Rotational Crops	N/A	Reserved ³⁷	43419901 ³⁸

1. Unbolded references were discussed in the Residue Chemistry Science Chapter of the Napropamide Reregistration Standard dated 12/1/88. No references were reviewed in the Napropamide Phase 4 Reviews. All other references were reviewed as noted.
2. The registrant, United Phosphorus Inc., may include napropamide uses on basil, marjoram, rosemary, and savory (summer and winter) on the product label for the 50% DF formulation (EPA Reg. No. 70506-36) provided the label is amended to reflect the parameters of use pattern for which residue data are available.
3. DP Barcodes D179747 and D180815, 2/1/93, S. Knizner.
4. DP Barcode D193544, 5/4/94, C. Swartz.
5. DP Barcode D192158, 12/17/93, S. Knizner.
6. HED recommends that the data-collection methods, GC/NPD methods with confirmation by GC/MSD (Method Nos. RR 92-073B, RR 92-006B, RR 92-072B, and RR 91-101B), that were used in the analysis of samples collected from the magnitude of the residue studies, be subjected to method validations required for enforcement purposes.
7. DP Barcodes D204409 and D207610, 4/25/95, S. Knizner.
8. Provided that samples, that will be collected from additional field trials requested by this Chapter, are analyzed within the storage intervals for which napropamide has been found to be stable, no additional storage stability data are required for reregistration.
9. DER for MRID 41575306; DP Bacode D308147,10/4/04, D. Drew.
10. DER for MRID 4157530;DP Bacode D308147,10/4/04 , D. Drew.
11. DERs for 44020101 and 44020102; DP Barcode D226804, 10/4/04, D. Drew.
12. DP Barcode D176816, 8/11/92, J. Morales.
13. There are presently no registered uses of napropamide on any member of the cucurbit vegetables crop group. Unless the basic registrants of napropamide or other interested parties propose uses and submit supporting data, the established crop group tolerance for cucurbit vegetables should be revoked.
14. The following are required : Data depicting napropamide residues in/on lemons harvested 35 days following the last of two applications of the 50% DF formulations at 4 lb ai/A per application. The requested trials should be conducted in CA since this state represents the major lemon production area in the western U.S. where this use pattern is permitted.
15. The following are required: Data depicting napropamide residues in/on apples and pears harvested 35 days following the last of two applications of the 50% DF formulations at 4 lb ai/A per application. The requested trials should be conducted in CA, which is representative of the western U.S. where this use pattern is permitted.
16. The following are required: (i) Data depicting napropamide residues in/on cherries (sweet or tart), peaches, and plums (fresh prune) harvested 35 days following the last of two incorporated soil applications 50% DF formulation at 4 lb ai/A per application; the requested trials should be conducted in CA, which is representative of the western U.S. where this use pattern is registered; and (ii) Data depicting napropamide

- residues in/on cherries (sweet or tart), peaches, and plums (fresh prune) harvested at a suitable interval following a single side-by-side soil application of the 10% G and the 50% DF formulations at 4 lb ai/A. As specified in the Reregistration Standard, the requested trials must be conducted in: (a) MI and OR/WA for cherries; (b) GA, MI, NJ, PA, and SC for peaches; and (c) MI and OR for plums/fresh prunes.
17. The following are required: Data depicting napropamide residues in/on blueberries harvested at a suitable interval following a single side-by-side soil application of the 50% DF and 10% G formulation at 4 lb ai/A. The current OPPTS GLN 860.1500 requires a total of six trials for blueberry as part of the Berry Group, and HED notes that the registrants have already submitted data from three trials. Therefore, three additional trials on blueberry are required. The requested trials must be conducted in MI, NJ, and NC which were the test states identified in the Napropamide Reregistration Standard.
 18. The following are required: Data depicting napropamide residues in/on pecans and walnuts (or almonds) harvested 35 days following the last of two applications of the 50% DF formulation at 4 lb ai/A per application. For the purpose of continuity, the requested trials should be conducted in NM and TX (pecan only) and CA (walnut/almond only) which were the test states identified in the Napropamide Reregistration Standard because they represent the major nut growing areas in the western U.S. where this use pattern is registered.[It is noted that pecan and walnut were once considered the representative commodities of tree nut group; the current OPPTS GLN 860.1500 now lists almond and pecan as the representative commodities.]
 19. There are currently no registered uses of napropamide on basil. A registrant (United Phosphorus, Inc.) has indicated that they will propose the inclusion of basil on the product label for the 50% DF formulation (EPA Reg. No. 70506-36). Based on the available but limited data, HED has determined that the registrant may include basil on the product label for the 50% DF formulation (EPA Reg. No. 70506-36) provided use is limited to the state of CA for a single preplant broadcast or banded soil application at a maximum rate of 4 lb ai/A.
 20. Phase 3 Summary of MRID 00094087.
 21. There are currently no registered uses of napropamide on marjoram. A registrant (United Phosphorus, Inc.) has indicated that they will propose the inclusion of marjoram on the product label for the 50% DF formulation (EPA Reg. No. 70506-36). The available residue data for basil may be translated to marjoram provided the registrant proposes a use pattern for marjoram which is identical to basil.
 22. There are currently no registered uses of napropamide on rosemary. A registrant (United Phosphorus, Inc.) has indicated that they will propose the inclusion of rosemary on the product label for the 50% DF formulation (EPA Reg. No. 70506-36). Based on the available but limited data, HED has determined that the registrant may include rosemary on the product label for the 50% DF formulation (EPA Reg. No. 70506-36) provided use is limited to the state of CA for a single preplant broadcast or banded soil application at a maximum rate of 6 lb ai/A.
 23. Phase 3 Summary of MRID 00115110.
 24. There are currently no registered uses of napropamide on summer savory. A registrant (United Phosphorus, Inc.) has indicated that they will propose the inclusion of summer savory on the product label for the 50% DF formulation (EPA Reg. No. 70506-36). Based on the available but limited data, HED has determined that the registrant may include summer savory on the product label for the 50% DF formulation (EPA Reg. No. 70506-36) provided use is limited to the state of CA for a single preplant soil incorporated application at a maximum rate of 6 lb ai/A.

25. There are currently no registered uses of napropamide on winter savory. A registrant (United Phosphorus, Inc.) has indicated that they will propose the inclusion of winter savory on the product label for the 50% DF formulation (EPA Reg. No. 70506-36). The available residue data for basil may be translated to winter savory provided the registrant proposes a use pattern for winter savory which is identical to basil.
26. The following are required: Data depicting napropamide residues in/on avocados harvested 35 days following the last of two soil applications of 50% DF formulation at 4 lb ai/A per application. The requested trials should be conducted in CA which is the state identified by the Reregistration Standard and representative of the western U.S. where this use is registered. If the registrants have not initiated these trials, the registrants should refer to Table 5 of OPPTS GLN 860.1500 for the required number of field trials.
27. Existing data are adequate to support a tolerance of 0.1 ppm for residues of napropamide on cranberries.
28. The following are required: Data depicting napropamide residues in/on fresh figs harvested 35 days following the last of two applications of the 50% DF formulation at 4 lb ai/A per application. The requested trials should be conducted in CA, which is the state identified by the Reregistration Standard. If the registrants have not initiated these trials, the registrants should refer to Table 5 of OPPTS GLN 860.1500 for the required number of field trials.
29. The following are required: Data depicting napropamide residues in/on grapes harvested 35 days following the last of two applications of the 50% DF formulation at 4 lb ai/A per application. The requested trials should be conducted in CA, which is the state identified by the Reregistration Standard. If the registrants have not initiated these trials, the registrants should refer to Table 5 of OPPTS GLN 860.1500 for the required number of field trials.
30. The following are required: Data depicting napropamide residues in/on kiwifruit harvested 35 days following the last of two applications of the 50% DF formulation at 4 lb ai/A per application. The requested trials should be conducted in CA, which is the state identified by the Reregistration Standard. If the registrants have not initiated these trials, the registrants should refer to Table 5 of OPPTS GLN 860.1500 for the required number of field trials.
31. The following are required: Data depicting napropamide residues in/on olives harvested 35 days following the last of two applications of the 50% DF formulation at 4 lb ai/A per application. The requested trials should be conducted in CA, which is the state identified by the Reregistration Standard. If the registrants have not initiated these trials, the registrants should refer to Table 5 of OPPTS GLN 860.1500 for the required number of field trials.
32. The following are required: Data depicting napropamide residues in/on persimmon fruits harvested 35 days following the last of two applications of the 50% DF formulation at 4 lb ai/A per application. The requested trials should be conducted in CA, which is the state identified by the Reregistration Standard. If the registrants have not initiated these trials, the registrants should refer to Table 5 of OPPTS GLN 860.1500 for the required number of field trials.
33. Existing data are adequate to support a tolerance of 0.1 ppm for residues of napropamide on strawberries.
34. The following are required: A processing study depicting napropamide residues on coffee beans for instant coffee. A processing study was previously submitted (MRID 000140144) but was found to be unacceptable as an instant coffee processing study was not conducted. If coffee beans treated at exaggerated rates equivalent to at least the maximum theoretical concentration factor due to processing do not show measurable residues, than processing studies will not be required.

35. The following are required: A processing study depicting napropamide residues in mint oil. If residues concentrate sufficiently, appropriate tolerances must be proposed. A processing study was previously submitted (MRID 00025889) but the study was not performed at an exaggerated rate and there were no measurable napropamide residues on mint tops.
36. DP Barcode 192205, 7/16/93, S. Knizner.
37. Field accumulation studies with napropamide are not required provided all product labels specify a 60-day plantback interval (PBI) for leafy vegetable, a 180-day PBI for cereal grains, and a 365-day PBI for all other crops. Any labels that do not already specify these restrictions should be amended.
38. DP Barcode D210722, 2/15/95, R. Perfetti.

RESIDUE CHARACTERIZATION

General Discussion on Residue Chemistry of Napropamide

860.1300 Nature of the Residue - Plants

42349801 and 42845901 (Apple)

42349802 and 42845901 (Tomato)

42393901 and 42845901 (Cabbage)

HED Metabolism Committee Decision Memo of 4/7/93

The qualitative nature of the residue in plants is understood. Acceptable metabolism studies with napropamide have been conducted on three dissimilar crops (apple, cabbage, and tomato). The results of these studies were presented on 3/16/93 to the Metabolism Committee. The committee concluded that the residue of concern in plants is napropamide *per se* and that the current tolerance expression is adequate; the tolerance is expressed in terms of residues of the parent compound only. The Committee also concluded that the concentration of quionones detected in the metabolism studies were sufficiently low so as not to be of toxicological concern. The Committee additionally noted that other plant metabolites were also found in rat metabolism studies. These metabolites are present at low levels and would not likely be found if they were included in the plant analytical method. Brief summaries of the available plant metabolism studies are presented below.

Apple

Ring-labeled napropamide was applied to soil in a 4-sq. meter area around an apple tree. Two applications were made; the first at green cluster at a rate of 4.11 lb ai/A (1.03x), and the second approximately five months later at 4.04 lb ai/A (1.01x), to give a preharvest interval (PHI) of 35 days. Application rate and timings adequately reflected label directions. The first and second year's crop were harvested and analyzed for total radioactive residues (TRR).

In the first year's crop, the fruit TRR was 0.0032 ppm. The radioactivity was fractionated, and no fraction had a residue level greater than 0.002 ppm. Because of the low residues detected, additional analysis was not performed. In the second year's crop, the fruit TRR was 0.0098 ppm. The radioactivity was also fractionated, and no fraction had a residue level greater than 0.006 ppm. Because of the low residues detected, additional analysis was not performed.

Cabbage

Ring-labeled napropamide was applied to soil in a pot at a slightly exaggerated rate of 2.25 lb ai/A (1.125x). The PHI ranged from 55 to 63 days. The TRR found in the cabbage heart sample was 0.125 ppm. Of this, 94.5% was extractable and a total of 90.7% of the TRR was characterized and 59.9% of the TRR was identified. Natural incorporation into sugars accounted for

50.1% of the TRR. The major metabolites identified were: naphthoxypropionic acid (3.0% TRR); desethylnapropamide (2.5% TRR); and 5-hydroxy-napropamide (1.2% TRR). The parent compound accounted for 0.8% of the TRR.

In whole cabbage, the TRR found was 0.457 ppm. Of this amount, 89.1% was extractable and a total of 77.0% of the TRR was characterized and 35.2% of the TRR was identified. Natural incorporation into sugars accounted for 12.6% of the TRR. The major identified metabolites were: 5-hydroxy-napropamide (6.7% TRR); 1,4-naphthoquinone (4.9% TRR); naphthoxypropionic acid (2.9% TRR); and desethylnapropamide (2.3% TRR). The parent compound accounted for 0.9% TRR.

Tomato

Ring-labeled napropamide was applied to soil in a pot at a slightly exaggerated rate of 2.25 lb ai/A (1.125x). Fruits were harvested when ripe; PHI ranged from 67 to 122 days. The TRR found in/on tomatoes was 0.051 ppm. Of this amount, 92.3% was extractable, and a total of 83.7% of the TRR was characterized and 43.9% of the TRR was identified. Natural incorporation into sugars accounted for 21.2% of the TRR. The major metabolite found was o-phthalic acid (6.1% TRR), followed by 5-hydroxydesethyl-napropamide (4.5% TRR) and 5-hydroxynaphthoxypropionic acid (4.2% TRR).

860.1300 Nature of the Residue - Livestock

42775801 (Ruminant)

42775802 (Poultry)

The qualitative nature of the residue in livestock is understood. HED has received and reviewed acceptable ruminant and poultry metabolism studies with napropamide. Based on the findings from these studies, HED has determined that 40 CFR §180.6(a)(3) is applicable to napropamide; there is no reasonable expectation of finite residues in ruminants or poultry. As a result of this determination, HED has recommended that waivers be granted from the requirements to: conduct a ruminant and poultry feeding study (860.1480), develop a residue analytical method for meat/milk/ poultry/eggs (860.1340), and conduct a storage stability study for meat/milk/poultry/eggs (860.1380). This recommendation is based on the low level of residues observed in the goat metabolism study where the test animals were dosed with [¹⁴C]napropamide at an average level of 9.9 ppm in the diet which is equivalent to 120x the maximum dietary burden of 0.083 ppm to dairy cattle (74x the MTDB of beef cattle). This recommendation is also based on the fact that there are no poultry and swine feedstuff associated with the raw agricultural commodities with established tolerances. Brief summaries of the available animal metabolism studies are presented below.

Ruminants (MRID 42775801)

Two lactating goats were orally dosed with [¹⁴C]napropamide twice daily at levels equivalent to 11.2 ppm and 8.5 ppm in the diet (average of 9.9 ppm) for four consecutive days. During the testing period, milk was collected twice daily, in the morning and afternoon. The goats were sacrificed 23-24 hours after the last dose, and the following samples were collected: liver, kidney, omental fat, subcutaneous fat, perirenal fat, muscle from foreleg and rump, urine from bladder, bile, and gastrointestinal tract. For both goats, approximately 90% of the total administered dose was eliminated in the urine and feces. The mean excretion of radioactivity in milk was very small (0.084% of dose). The amount of radioactivity found in liver (0.170% of dose) and kidney (0.007% of dose) was also small.

The TRR in milk over each 24-hour period encompassed in the study ranged from 0.0068 ppm to 0.0089 ppm, and levels plateaued after 24 hours. The TRRs averaged 0.0031 ppm in muscle and 0.0066 ppm in fat. The identification and/or characterization of radioactive residues in milk, muscle, and fat was not necessary because TRR levels were less than 0.010 ppm.

The TRR in liver of Goat 2 was 0.165 ppm. Radioactive residues in liver were adequately identified and/or characterized. Napropamide and desethylnapropamide were determined in liver at 0.3% TRR. Approximately 40% of the TRR was associated with trichloroacetic acid precipitated proteins. Following extensive fractionation of solubilized radioactivity from liver debris, no components were present at >0.010 ppm.

The TRR in the kidney of Goat 2 was 0.034 ppm. Radioactive residues in kidney were adequately identified and/or characterized. The only identified metabolite in kidney was napropamide at 1.8% TRR. TLC analysis of various kidney fractions indicated the presence of 13 unknowns, the largest being 4.7% TRR. About 19.0% of the TRR remained associated with trichloroacetic acid precipitated proteins.

Poultry

Gelatin capsules containing [¹⁴C]napropamide were orally administered to 10 laying hens once daily for ten consecutive days. Each bird received an average of 8.3 ppm napropamide in the diet (range of 7.4 ppm to 10.1 ppm). Eggs were collected twice daily from each chicken. The hens were sacrificed 23-24 hours after the last dose, and the following samples were collected: skin plus subcutaneous fat, peritoneal fat, leg muscle, breast muscle, liver, kidney, and gastrointestinal tract and contents. Most of the administered dose was found in the excreta (average of 92.1%). Additionally, 2.51% of the administered dose was found in cage washings. Liver and kidney, the tissues with the highest TRR levels, contained only 0.046% and 0.006% of the administered dose, respectively.

The TRR levels in all tissues were low. Liver and kidney were the tissue with the highest TRR levels, with values of 0.105 ppm and 0.0455 ppm respectively. TRR levels in muscle were <0.0034 ppm, and levels in skin and fat were <0.0078 ppm. Radioactive residue levels in the egg whites were reasonably constant over the dosing period, and were always <0.010 ppm. Residue levels in egg yolks rose to a

plateau of between 0.0373 ppm to 0.0419 ppm on days 6-10 of the study.

Radioactive residues in poultry liver were adequately characterized. About 29.5% of the TRR in liver was solvent extractable. Napthoxypropionic acid accounted for a total of 13.7% TRR and desethylnapropamide accounted for 2.5% TRR. Following extensive fractionation, no other fractions had TRR levels >0.010 ppm.

Radioactive residues in egg yolk were also adequately characterized. About 83.6% of the TRR was solvent extractable. The following components were identified: napthoxypropionic acid (6.1% TRR), napropamide (5.2% TRR), desethylnapropamide (4.1% TRR), and 4-hydroxydesethyl-napropamide (3.9% TRR). No other fractions had TRR levels >0.010 ppm.

860.1340 Residue Analytical Methods

Plant commodities

PAM Vol. II

MRIDs 00032356, 00049482, 00049483, 00094087, 00126316, 00132824, 43345102, 43345105, 43345106, and 43345108

Enforcement method: A GLC method is listed as Method I (WRC 71-35) in the Pesticide Analytical Manual (PAM) Volume II for the determination of napropamide *per se* in/on plant commodities. In Method I, napropamide residues in/on crop samples are extracted with benzene, cleaned up on an alumina column, and determined by GLC with a Coulson electrolytic conductivity detector operated in the nitrogen-specific mode. The stated limit of detection (LOD) is 0.05 ppm.

According to the 1/16/91 Napropamide Phase 4 Review, the PAM Volume II method is unacceptable for tolerance enforcement because the method uses benzene, a hazardous or toxic reagent. HED is now recommending that the data-collection methods discussed below (GC/NPD methods with confirmation by GC/MSD) which were used in the analysis of samples collected from the magnitude of the residue studies, be subjected to method validations required for enforcement purposes.

Data collection methods: Samples from the magnitude of the residue and storage stability studies were analyzed for residues of napropamide using: (i) GC equipped with thermionic flame detection in the nitrogen/phosphorus mode (method in Report No. RRC 83-68), a modified version of Method I in PAM Vol. II which substitutes toluene for benzene; (ii) GLC method (modified WRC 73-56); (iii) GLC enforcement method (WRC 71-35); and (iv) GLC method (WRC 73-35).

Zeneca (now known as Syngenta) submitted adequate descriptions of and validation data for several (essentially similar) analytical methods for the determination of napropamide in/on: (i) apple processed commodities (Method No. RR 92-073B); (ii) orange processed commodities (Method No. RR92-

006B); (iii) pome fruits (Method No. RR 92-072B); and (iv) stone fruits and prunes (Method No. RR 91-101B). These methods are GC methods with nitrogen/phosphorus detection (NPD) with a quantitation limit of 0.05 ppm for each commodity. The registrant stated that Method Nos. RR 92-073B, RR92-006B, RR 92-072B, and RR 91-101B were updated from Method Nos. RR 90-160B, RR 90-173B, RR 90-175B, and RR 90-247B.

Briefly, samples (except orange molasses, oil, and dried pulp) were homogenized in toluene and filtered through anhydrous sodium sulfate. Orange molasses and dried pulp samples were homogenized in toluene and water, and then filtered through anhydrous sodium sulfate. Orange oil samples were homogenized in acetonitrile and then partitioned with hexane; the acetonitrile phases were combined, concentrated to dryness, and dissolved in toluene. For samples for which an emulsion forms during the homogenization step, the extract was centrifuged. Toluene extracts of orange dried pulp, molasses, and oil were cleaned up on an alumina column, and the eluates were concentrated to dryness and dissolved in toluene prior to analysis. Residues of napropamide in the extracts were determined by GC/NPD. Detectable residues of napropamide were confirmed by GC with mass selective detection (GC/MSD).

Livestock commodities

HED has determined that napropamide is a Category 40 CFR §180.6(a)(3) pesticide (i.e., no reasonable expectations of finite residues of concern in ruminants and poultry) and recommends that a waiver be granted from the requirement to develop a residue analytical method for meat/milk/poultry/eggs for the purpose of reregistration. A data-collection method and an enforcement method may be required in the future if the registrants wish to register new food/feed uses in the future.

860.1360 Multiresidue Methods

The FDA PESTDATA database dated 11/01 (PAM Volume I, Appendix I) indicates that napropamide is completely recovered (>80% recovery) using Multiresidue Method Sections 302 (Luke Method; Protocol D) and 401 (Krause N-methyl carbamate Method; Protocol A).

860.1380 Storage Stability

Plant commodities

MRIDs 00049489, 00094488, 41575306, 41575307, 44020101, and 44020102

Several studies, investigating the storage stability of napropamide in/on various raw agricultural commodities, are available. These studies indicate that napropamide is reasonably stable under frozen storage conditions in/on: (i) alfalfa hay, almond nutmeat, apple, and soybean seed for >3 years; (ii)

wheat grain and straw for up to 2.5 years, and; (iii) corn ear, orange, and pepper for up to ~2 years. Residues of napropamide appear to decline in/on oranges by >50% after 3 years of frozen storage. It is, however, noted that samples from the submitted orange trials were stored for about 18 months prior to analysis. Thus, corrections of residues need not be applied for the various residue studies including the study conducted for orange.

The available storage stability data are adequate to support the storage intervals and conditions of samples from the conducted residue field trials. Provided that RAC samples, that will be collected from additional field trials requested by this Chapter, are analyzed within the storage intervals for which napropamide has been found to be stable, no additional storage stability data are required for reregistration. A summary of the available storage stability data for napropamide is listed in Table 5.

Table 5. Summary of Available Freezer Storage Stability Data for Napropamide in Various Raw Agricultural Commodities.	
Crop Group Limit of Demonstrated Freezer Storage Data for Supporting Commodities	Max. Storage Intervals of Trial Samples Prior to Analysis
Root and tuber vegetables	
<u>Potato</u> : Residues of napropamide are reasonably stable in/on potato tubers for up to 1246 days (> 3 years) of frozen storage (MRID 41575307).	~8 months for sweet potato
Leafy vegetables	
<u>Alfalfa</u> : Residues of napropamide are reasonably stable in/on alfalfa hay for up to 1246 days (> 3 years) of frozen storage (MRID 41575307).	123 days (4.0 months) for rhubarb
Brassica vegetables	
<u>Alfalfa and wheat</u> : Residues of napropamide are reasonably stable in/on alfalfa hay for up to 1246 days (> 3 years), and wheat straw for up to 903 days (2.5 years) of frozen storage (MRID 41575307).	732 days (24 months) for broccoli 730 days (24 months) for Brussel sprouts 1348 days (44 months) for cabbage 1275 days (42 months) for cauliflower
Fruiting vegetables	
<u>Pepper</u> : Residues of napropamide are reasonably stable in/on pepper for up to 890 days (>2 years) of frozen storage (MRID 41575307).	~3 years for eggplant ~3 years for pepper 809 days (26.6 months) for tomato
Citrus fruits	
<u>Orange</u> : Residues of napropamide are reasonably stable in/on orange for up to 890 days (>2 years) of frozen storage, however, residues of napropamide appear to decline in oranges by >50% after 3 years of frozen storage (MRID 41575307).	storage interval not provided for grapefruit 404 days (13.3 months) for lemon 551 days (18.1 months) for orange 404 days (13.3 months) for tangerine
Pome fruits	
<u>Apple</u> : Residues of napropamide are reasonably stable in/on apple for up to 1246 days (>3 years) of frozen storage (MRID 41575307).	746 days (24.5 months) for apple 771 days (25.4 months) for pear
Stone fruits	
<u>Apple</u> : Residues of napropamide are reasonably stable in/on apple for up to 1246 days (>3 years) of frozen storage (MRID 41575307).	storage intervals not provided for apricot, cherry, nectarine, peach, and plum
Berries	
<u>Apple</u> : Residues of napropamide are reasonably stable in/on apple for up to 1246 days (>3 years) of frozen storage (MRID 41575307).	523 days (17.2 months) for blueberry storage interval not provided for caneberry
Tree nuts	

Table 5. Summary of Available Freezer Storage Stability Data for Napropamide in Various Raw Agricultural Commodities.	
Crop Group Limit of Demonstrated Freezer Storage Data for Supporting Commodities	Max. Storage Intervals of Trial Samples Prior to Analysis
<u>Almond</u> : Residues of napropamide are reasonably stable in/on almond nutmeat for up to 1237 days (>3 years) of frozen storage (MRID 41575307).	629 days (20.7 months) for almond 785 days (25.8 months) for filberts 909 days (29.9 months) for pecan 650 days (21.4 months) for walnut

Table 5. Summary of Available Freezer Storage Stability Data for Napropamide in Various Raw Agricultural Commodities.	
Crop Group Limit of Demonstrated Freezer Storage Data for Supporting Commodities	Max. Storage Intervals of Trial Samples Prior to Analysis
Herbs	
<u>Alfalfa and Wheat</u> : Residues of napropamide are reasonably stable in/on alfalfa hay for up to 1246 days (> 3 years) and wheat straw for up to 903 days (2.5 years) of frozen storage (MRID 41575307).	202 days (6.6 months) for basil and summer savory 88 days (2.9 months) for rosemary
Miscellaneous commodities	
<u>Pepper</u> : Residues of napropamide are reasonably stable in/on pepper for up to 890 days (>2 years) of frozen storage (MRID 41575307).	620 days (20.3 months) for artichoke
	1,368 days (45 months) for asparagus
<u>Apple</u> : Residues of napropamide are reasonably stable in/on apple for up to 1246 days (>3 years) of frozen storage (MRID 41575307).	624 days (20.5 months) for avocado
<u>Almond</u> : Residues of napropamide are reasonably stable in/on almond nutmeat for up to 1237 days (>3 years) of frozen storage (MRID 41575307).	237 days (7.8 months) for coffee beans
<u>Apple</u> : Residues of napropamide are reasonably stable in/on apple for up to 1246 days (>3 years) of frozen storage (MRID 41575307).	301 days (9.9 months) for cranberry
	461 days (15.2 months) for figs
	415 days (13.7 months) for grape
	413 days (13.6 months) for kiwifruit
<u>Alfalfa and Wheat</u> : Residues of napropamide are reasonably stable in/on alfalfa hay for up to 1246 days (> 3 years) and wheat straw for up to 903 days (2.5 years) of frozen storage (MRID 41575307).	278 days (9.1 months) for mint hay
<u>Almond</u> : Residues of napropamide are reasonably stable in/on almond nutmeat for up to 1237 days (>3 years) of frozen storage (MRID 41575307).	925 days (30.4 months) for olive
<u>Apple</u> : Residues of napropamide are reasonably stable in/on apple for up to 1246 days (>3 years) of frozen storage (MRID 41575307).	955 days (30.3 months) for persimmon
<u>Almond</u> : Residues of napropamide are reasonably stable in/on almond nutmeat for up to 1237 days (>3 years) of frozen storage (MRID 41575307).	341 days (11.2 months) for pistachio
<u>Apple</u> : Residues of napropamide are reasonably stable in/on apple for up to 1246 days (>3 years) of frozen storage (MRID 41575307).	718 days (23.6 months) for pomegranate
	714 days (23.5 months) for strawberry
Tobacco	

Crop Group Limit of Demonstrated Freezer Storage Data for Supporting Commodities	Max. Storage Intervals of Trial Samples Prior to Analysis
<u>Tobacco</u> : Residues of napropamide are reasonably stable in/on tobacco for up to 1191 days (>3 years) of frozen storage (MRID 41575306).	683 days (~23 month) for tobacco

Table 5. Summary of Available Freezer Storage Stability Data for Napropamide in Various Raw Agricultural Commodities.	
Crop Group Limit of Demonstrated Freezer Storage Data for Supporting Commodities	Max. Storage Intervals of Trial Samples Prior to Analysis
Processed commodities	
<u>Apple</u> : Residues of napropamide are reasonably stable in apple juice and dried apple pomace for up to 37 and 36 months, respectively, of frozen storage (MRID 44020101).	157 days (5.2 months) for apples and its processed commodities
<u>Grape</u> : No storage stability data available for grape processed commodities, however, additional storage stability data will not be required because of the demonstrated stability of napropamide in numerous RACs and processed apples and oranges (see D204409 and D207610, 4/25/95, S. Knizner).	104 days (3.4 months) for grapes and its processed commodities
<u>Orange</u> : Residues of napropamide are reasonably stable in orange juice, oil, and dried orange pulp for up to 36 months of frozen storage. Residues of napropamide are not stable in orange molasses; napropamide declined by ~56-63% in orange molasses after 3 months and by 75% in orange molasses after 12 months of frozen storage (MRID 44020102).	137 days (4.5 months) for oranges and its processed commodities
<u>Plum</u> : No storage stability data available for the plum processed commodity, however, additional storage stability data will not be required because of the demonstrated stability of napropamide in numerous RACs and processed apples and oranges (see D204409 and D207610, 4/25/95, S. Knizner).	51 days (1.7 months) for plums and its processed commodities
<u>Tomato</u> : No storage stability data available for tomato processed commodities, however, additional storage stability data will not be required because of the demonstrated stability of napropamide in numerous RACs and processed apples and oranges (D204409 and D207610, 4/25/95, S. Knizner). In addition, no storage stability data are required because sample were stored <1 month.	27 days (<1 month) for tomato and its processed commodities

Processed commodities

MRID 44020101 (Apple); MRID 44020102 (Orange)

Adequate storage stability data for the processed commodities of apple and orange are available. In addition, HED has previously determined (DP Barcodes D204409 and D207610, 4/25/95, S. Knizner) that no additional storage stability data are required for the processed commodities of grape, plum, or tomato because of the demonstrated stability of napropamide in/on numerous RACs.

The submitted storage stability data for the processed commodities of apples indicate that fortified residues of napropamide are reasonably stable under frozen storage conditions in apple juice and dried apple pomace for up to 37 and 36 months, respectively. It is noted that the processed commodities of apples, listed in Table 1 of OPPTS 860.1000, are juice and wet pomace; dried apple pomace has been removed. No storage stability data pertaining to wet pomace were submitted, however, based on the results of the apple processing study, residues of napropamide do not concentrate in wet pomace. The Agency will not require additional data for this processed commodity. The storage stability data of residues in the processed fractions of apples demonstrate stability over the storage period of the submitted apple processing study wherein samples were stored for up to 157 days (5.2 months) prior to analysis.

The submitted storage stability data for the processed commodities of oranges indicate that fortified residues of napropamide are reasonably stable under frozen storage conditions in orange juice, oil, and dried pulp for up to 36-38 months. Under frozen storage conditions, fortified residues of napropamide may decline in orange molasses (~56-63%) following frozen storage for 3 months and by 75% in orange molasses after 12 months of frozen storage. Orange molasses has been removed from Table 1 OPPTS 860.1000 as a processed commodity of orange. The storage stability data of residues in the processed fractions of oranges demonstrate stability over the storage period of the submitted orange processing study wherein samples were stored for up to 137 days (4.5 months) prior to analysis.

Livestock commodities

At this time, the Agency has determined that napropamide is a Category 3 pesticide (i.e., no reasonable expectations of finite residues of concern in ruminants and poultry) and has recommended that a waiver be granted from the requirement to conduct storage stability for meat/milk/poultry/eggs.

860.1400 Water, Fish, and Irrigated Crops

Napropamide is presently not registered for direct use on water and aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

860.1460 Food Handling

Napropamide is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

860.1480 Meat, Milk, Poultry, and Eggs

The HED review of the animal metabolism studies concluded that napropamide is a 40 CFR §180.6(a)(3) pesticide (i.e., no reasonable expectations of finite residues of concern in ruminants and poultry). The review recommended that a waiver be granted from the requirement to conduct ruminant and poultry feeding studies. A ruminant feeding study is not required for reregistration based on the low level of residues observed in the goat metabolism study at a feeding level of about 120x the maximum anticipated dietary burden (dairy cattle) for napropamide (74x the MTDB for beef cattle). A poultry feeding study is also not required because there are presently no poultry feedstuff associated with the currently registered uses of napropamide. The maximum theoretical dietary burden of napropamide to livestock is presented below in Table 6.

Table 6 Calculation of Maximum Dietary Burdens of Napropamide to Livestock.				
Feedstuff	% Dry Matter ¹	% Diet ¹	Established Tolerance (ppm)	Dietary Contribution (ppm) ²
Beef Cattle				
Almond hulls	90	10	0.1	0.011
Apple, pomace, wet	40	40	0.1 (pome fruits)	0.100
Citrus, pulp, dried	91	20	0.1 (citrus fruits)	0.022
Total Burden	–	70 ³	–	0.133
Dairy Cattle				
Almond hulls	90	10	0.1	0.011
Apple, pomace, wet	40	20	0.1 (pome fruits)	0.050
Citrus, pulp, dried	91	20	0.1 (citrus fruits)	0.022
Total Burden	–	50 ³	--	0.083
Poultry				
	There are no poultry feedstuff associated with RACs with established tolerances.			
Swine				
	There are no swine feedstuff associated with RACs with established tolerances.			

¹ Table 1 (OPPTS Guideline 860.1000).

² Contribution = ([tolerance /% DM] x % diet) for beef and dairy cattle.

³ The remainder of the diet will be composed of feedstuff derived from crops that do not have napropamide uses/tolerances proposed.

A ruminant and poultry feeding study may be required in the future if the registrants wish to register new food/feed uses in the future, and if these uses should result in significantly higher dietary burden.

860.1500 Crop Field Trials

There are adequate magnitude of the residue data to support the registered uses of napropamide on the crop groups of Brassica leafy vegetables and fruiting vegetables as well as on the individual crops of artichokes, asparagus, coffee, cranberry, mint, pistachio, pomegranate, rhubarb, strawberry, sweet

potato, and tobacco.

Pending submission of a revised label for the 50% DF formulation (EPA Reg. No. 70506-36), there are limited but adequate data to support the reinstatement of regional uses of napropamide on basil, marjoram, rosemary, and savory (summer and winter). The label for the above napropamide end-use product should be amended to reflect the parameters of use pattern for which residue data are available for herb and spice crops.

Additional magnitude of the residue data are required for the crop groups of citrus fruits, pome fruits, stone fruits, berries, and tree nuts as well as on the individual crops of avocado, fig, grape, kiwifruit, olives, and persimmon. There are presently no registered uses of napropamide on any member of the cucurbit vegetables crop group. Unless the basic registrants of napropamide or other interested parties propose uses and submit supporting data, the established tolerance for cucurbit vegetables should be revoked.

Root and Tuber Vegetable Group (Group 1)

Sweet Potato

MRID 42256501

A tolerance of 0.1 ppm has been established for residues of napropamide in/on sweet potato, roots [40 CFR §180.328(a)].

Currently, napropamide is registered for broadcast application to sweet potato at a maximum single rate of 2 lb ai/A. Application is to be made to the plant bed or posttransplant.

The sweet potato tolerance was established through a petition, PP#2E4108, submitted by IR-4. The residue data that were originally submitted in support of this petition remain adequate. Three sweet potato trials were conducted in CA, NC, and LA. A single post-transplant application of napropamide was made at 2 lb ai/A (1x the maximum single application rate) and at 4 lb ai/A (2x). Residues of napropamide were nondetectable (<0.05 ppm) in/on samples of sweet potato harvested within 133 days of treatment in CA, 116 days in NC, and 90 days in LA. Napropamide residues in/on sweet potato were determined using GC equipped with thermionic flame detection in the nitrogen/phosphorus mode (method in Report No. RRC 83-68) with a detection limit of 0.05 ppm. The method is a modified version of the method described in PAM Vol. II, in which toluene is substituted for benzene. Samples were stored under unspecified conditions for up to ~8.0 months prior to analyses.

Leafy Vegetables Group (except Brassica Vegetables) (Crop Group 4)Rhubarb

MRID 00126316

A tolerance of 0.1 ppm has been established for residues of napropamide in/on rhubarb [40 CFR §180.328(a)].

Currently, napropamide is registered for broadcast, chemigation, or soil broadcast application to rhubarb at a maximum single rate of 4 lb ai/A. Application is to be made when rhubarb is dormant, and use is limited to the Pacific Northwest region of the U.S.

Adequate rhubarb field trial data, submitted by IR-4, were discussed in the 12/1/88 Napropamide Reregistration Standard. These data showed that residues of napropamide were <0.05 ppm (nondetectable) in/on rhubarb samples harvested 50 or 88 days following a single soil surface application of the 50% WP formulation at 2-16 lb ai/A (0.5-4x the maximum single application rate) in seven tests conducted in OR(3) and WA(4). The data-collection method was a GLC method (modified WRC 73-56) with a limit of detection of 0.05 ppm. Samples were stored under unspecified conditions for up to 123 days (4.0 months) prior to analyses.

Brassica (Cole) Leafy Vegetables Group (Crop Group 5)

MRID 00025888

A tolerance of 0.1 ppm has been established for residues of napropamide in/on vegetable, brassica, leafy, group 5 [40 CFR §180.328(a)].

Currently, napropamide is registered on broccoli, Brussels sprouts, cabbage, and cauliflower for a single preplant or postplant broadcast, chemigation, or soil incorporated application at a maximum rate of 2 lb ai/A.

Crop field trial data for broccoli, Brussels sprouts, cabbage, and cauliflower were discussed in the 12/1/88 Napropamide Reregistration Standard and deemed inappropriate to support a crop group tolerance because at that time, there were no registered uses for the representative commodity mustard greens. However, the 1/16/91 Napropamide Phase 4 Review reexamined the available data as well as the registered uses of napropamide on Brassica vegetables. Considering the early use of the herbicide and the available field trial data generated on Brussels sprouts and cauliflower (which may substitute for mustard greens), the Phase 4 Review concluded that no additional data are required for Brassica vegetables. The submitted field trial data for broccoli, Brussel sprouts, cabbage, and cauliflower indicate that residues of napropamide were nondetectable (<0.02-<0.05 ppm) following treatment at

1x or at exaggerated rates. A summary of the available residue data for Brassica vegetables is presented below.

Broccoli: Five broccoli trials were conducted in CA(2), FL(1), MS(1), and OR(1). In the tests conducted in CA, residues of napropamide were <0.02 ppm (nondetectable) in/on one sample collected 78-126 days posttreatment and were <0.05 ppm (nondetectable) in/on one sample collected 71 days following treatment using the 50% WP formulation at 2 lb ai/A (1x the maximum single application rate). In the test conducted in OR, residues of napropamide were <0.03 ppm (nondetectable) in/on each of two samples harvested 122 days following a single soil incorporated application of the 50% WP formulation at 6 lb ai/A (3x rate permitted in the Pacific Northwest). In the test conducted in MS, residues of napropamide were <0.05 ppm (nondetectable) in/on one sample harvested 86 days following a single preplant soil incorporated application of the 50% WP formulation at 4 lb ai/A (2x the maximum single application rate permitted in the southeastern region). In the test conducted in FL, residues of napropamide were <0.05 ppm (nondetectable) in/on one sample collected 118 days following application using the 50% WP formulation at 2 lb ai/A (1x the maximum single application rate permitted in the southeastern region of the U.S.); one additional sample collected at 163 days following application at 2x bore <0.02 ppm (nondetectable) napropamide residues. In six additional tests, residues were <0.02 ppm (nondetectable) to <0.05 ppm (nondetectable) in/on five samples collected 71-126 days following application using the 2 lb/gal EC formulation (not registered for this use) at 2 lb ai/A. Napropamide residues in/on broccoli were determined using GLC methods (modified WRC 73-56, WRC 71-35, and unspecified methods) with detection limits of 0.02 ppm (WRC 71-35), 0.03 ppm (unspecified methods) and 0.05 ppm (WRC 73-56). Samples were stored under unspecified conditions for up to ~732 days (24 months) prior to analyses.

Brussels sprouts: Five Brussels sprout trials were conducted in CA(1), FL(1), MS(1), and OR(2). In the test conducted in FL, residues of napropamide were <0.02 ppm (nondetectable) in/on one sample collected 163 days following a single preplant soil incorporated application of the 50% WP formulation at 2 lb ai/A (1x the maximum single application rate permitted in the southeastern region of the U.S.). In the test conducted in MS, residues of napropamide were <0.03 ppm (nondetectable) in/on one sample harvested 86 days following a single preplant soil incorporated application of the 50% WP formulation at 4 lb ai/A (2x the maximum single application rate permitted in the southeastern region of the U.S.). In the tests conducted in OR, residues of napropamide were <0.03 ppm (nondetectable) in/on each of two samples harvested 111 or 115 days following a single preemergence or preplant broadcast soil incorporated application of the 50% WP formulation at 4 lb ai/A (2x the maximum single application rate permitted in the Pacific Northwest). In the test conducted in CA, residues of napropamide were <0.02 ppm (nondetectable) in/on one sample harvested 78-126 days following a single preplant broadcast soil incorporated application of the 50% WP formulation at 2 lb ai/A (1x the maximum single application rate). In two additional tests, residues were <0.02 ppm (nondetectable) to <0.05 ppm (nondetectable) in/on two samples harvested 86 or 78-126 days following a single preplant broadcast soil incorporated application of the 2 lb/gal EC formulation (not registered for this use) at 2 lb ai/A. Napropamide residues in/on Brussels sprouts were determined using GLC methods (WRC

71-35 and unspecified methods) with detection limits of 0.02 ppm (WRC 71-35) and 0.03 ppm (unspecified methods). Samples were stored under unspecified conditions for up to ~730 days (24 months) prior to analyses.

Cabbage: Eight cabbage trials were conducted in FL(4) and MS(4). In the tests conducted in FL, residues of napropamide were <0.05 ppm (nondetectable) in/on each of five samples collected 87-115 days following application of the 50% WP formulation at 2 lb ai/A (1x the maximum single application rate permitted in the southeastern region of the U.S.). In the tests conducted in MS, residues of napropamide were <0.03 ppm (nondetectable) in/on one sample harvested 96 days following a single preplant broadcast soil incorporated application of the 50% WP formulation at 2 lb ai/A (1x the maximum single application rate permitted in the southeastern region of the U.S.). Two additional samples harvested 86 or 96 days following application at 2x bore <0.03 ppm (nondetectable) or <0.05 ppm (nondetectable) of napropamide residues. In five additional tests, residues were <0.03 ppm (nondetectable) to <0.05 ppm (nondetectable) in/on eight samples harvested 86-115 days following a single preplant broadcast soil incorporated application of the 2 lb/gal EC formulation (not registered for this use) at 2 or 4 lb ai/A. Additional data were submitted from four tests conducted in CA pertaining to napropamide residue in/on cabbage. Cabbage received a single preplant or preemergence soil application of the 50% WP formulation or the 2 lb/gal EC formulation (not registered for this use) at 2 lb ai/A. Residues were <0.02 ppm (nondetectable) in/on each of four samples collected 78-126 days posttreatment. Napropamide residues in/on cabbage were determined using GLC methods (WRC 71-35, WRC 73-56, and unspecified methods) with detection limits of 0.02 ppm (WRC 71-35), 0.05 ppm (WRC 73-56), and 0.03 ppm (unspecified methods). Samples were stored under unspecified conditions for up to ~1348 days (44 months) prior to analyses.

Cauliflower: Five cauliflower trials were conducted in CA(1), FL(3), and MS(1). In the test conducted in MS, residues of napropamide were <0.05 ppm (nondetectable) in/on one sample harvested 106 days following a single preplant broadcast soil incorporated application of the 50% WP formulation at 4 lb ai/A (2x the maximum single application rate permitted in the southeastern region of the U.S.). In the test conducted in CA, residues of napropamide were <0.02 ppm (nondetectable) in/on one sample collected 78-126 days following a single preemergence soil application of the 50% WP formulation at 2 lb ai/A (1x the maximum single application rate). In the tests conducted in FL, residues were <0.05 ppm (nondetectable) in/on each of three samples harvested 69 or 97 days following a single preplant soil incorporated application of the 50% WP formulation at 2 lb ai/A (1x the maximum single application rate permitted in the southeastern region of the U.S.). In seven additional tests, residues were <0.02 ppm (nondetectable) to <0.05 ppm (nondetectable) in/on seven samples collected 78-126 days following a single preemergence or preplant soil incorporated application using the 2 lb/gal EC formulation (not registered for this use) at 2 lb ai/A. Napropamide residues in/on cauliflower were determined using GLC methods (WRC 71-35 and WRC 73-56) with detection limits of 0.02 ppm (WRC 71-35) and 0.05 ppm (WRC 73-56). Samples were stored under unspecified conditions for up to ~1275 days (42 months) prior to analyses.

Fruiting Vegetables (Except Cucurbits) Group (Crop Group 8)

MRID 00070786 (Eggplant)

MRIDs 00027321, 00033961, 00035669, 00049484, and 00113800 (Pepper)

MRIDs 00023230, 00027319, 00027320, 00028796, 00035669, 00049483, 00067872, 00067873, and 00070814 (Tomato)

A tolerance of 0.1 ppm has been established for residues of napropamide in/on fruiting vegetables [40 CFR §180.328(a)].

Currently, napropamide is registered on eggplant, pepper, and tomato for a single soil broadcast, soil banded, chemigation, or soil incorporated application made at preplant, pretransplant, or transplant (or posttransplant) at a maximum rate of 2 lb ai/A.

Crop field trial data reflecting preplant or preemergence treatment on eggplant, pepper, and tomato were discussed in the 12/1/88 Napropamide Reregistration Standard. It was concluded that the submitted data are inadequate to assess the adequacy of the established crop group tolerance because no data were submitted reflecting postemergence uses on eggplant and tomato which were then registered under EPA SLN Nos. FL780021 and SC780013. These SLN registrations have subsequently been cancelled, and no postemergence uses are currently registered for fruiting vegetables. Following a re-examination of available data, HED now concludes that adequate data are available to support the registered uses of napropamide on fruiting vegetables. These data, which are summarized below, indicate that residues of napropamide were <0.05 ppm (nondetectable) in/on samples of eggplant, pepper, and tomato harvested 51-164 days following a single preplant or preemergence broadcast application of the 50% WP, 2 lb/gal EC, or 4 lb/gal FIC formulation at 1-4x the maximum single application rate.

Eggplant: Ten eggplant trials were conducted in CA(4), FL(3), and MS(3). Residues of napropamide were <0.05 ppm (nondetectable) in/on samples of eggplant harvested 61-149 days following a single preplant soil incorporated or pretransplant soil surface application of the 50% WP, 2 lb/gal EC (not registered for this use), and 4 lb/gal FIC formulation at 1-4 lb ai/A (0.5-2x the maximum single application rate). Napropamide residues in/on eggplant were determined using GLC methods (WRC 73-35, WRC 73-56, or unspecified methods) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to ~3 years prior to analyses.

Pepper: In one study (MRID 00027321), ten pepper trials were conducted in FL(4), GA(1), LA(1), MS(2), and NC(2). Residues of napropamide were <0.05 ppm (nondetectable) in/on bell peppers harvested 51-154 days following a single preplant broadcast soil incorporated or preemergence soil surface application of the 50% WP or 2 lb/gal EC formulation at 2 or 4 lb ai/A (1x or 2x the maximum single application rate). Napropamide residues in/on bell peppers were determined using unspecified GLC methods with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to ~3 years prior to analyses.

In a second study (MRIDs 00033961 and 00049484), eight pepper trials were conducted in CA(7) and NC(1). Residues of napropamide were <0.05 ppm (nondetectable) in/on bell and chili peppers harvested 105-184 days following a single preplant broadcast soil incorporated or preemergence soil surface application of the 50% WP or 2 lb/gal EC formulation at 1-4 lb ai/A (0.5-2x). Napropamide residues in/on bell and chili peppers were determined using unspecified GLC methods with detection limits of 0.02 and 0.05 ppm. Samples were stored under unspecified conditions for up to ~3 years prior to analyses.

In the third study (MRID 00035669), four pepper trials were conducted in CA(2) and SC(2). Residues of napropamide were ≤0.05 ppm (nondetectable) in/on bell peppers harvested 105-120 days following a single preplant broadcast soil incorporated application of the 4 lb/gal FIC or 50% WP formulation at 1.5-4 lb ai/A (0.75-2x). Napropamide residues in/on bell peppers were determined using a GLC method (WRC 73-56) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 165 days (5.4 months) prior to analyses.

In the fourth study (MRID 00113800), two pepper trials were conducted in CA. Residues of napropamide were <0.05 ppm (nondetectable) in/on peppers harvested 145 or 155 days following a single preplant application of the 50% WP formulation at 4 lb ai/A (2x). Napropamide residues in/on pepper were determined using an unspecified GLC method with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to ~260 days (8.5 months) prior to analyses.

Tomato: In studies reported in MRIDs 00023230, 00027319, 00027320, 00028796, and 00070814, 62 tomato trials were conducted in CA(32), FL(4), IL(1), LA(4), MD(2), MS(11), MO(1), NY(1), NC(1), WA(1), and VA(4). Residues of napropamide were <0.05 ppm (nondetectable) in/on tomatoes harvested 67-179 days following a single preplant soil banded incorporated or preemergence soil surface application of the 50% WP or 2 lb/gal EC formulation at 1-6 lb ai/A (0.5-3x). Napropamide residues in/on tomato were determined using unspecified GLC methods with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to ~809 days (26.6 months) prior to analyses.

In the second study (MRIDs 00035669 and 00067873), 22 tomato trials were conducted in CA(13), FL(1), and SC(8). Residues of napropamide were <0.05 ppm (nondetectable) in/on tomatoes harvested 81-127 days following a single preplant soil incorporated or preemergence soil surface application of the 50% WP, 2 lb/gal EC, and 4 lb/gal FIC formulations at 1-4 lb ai/A (0.5-2x). Napropamide residues in/on tomato were determined using GLC methods (WRC 71-35 and WRC 73-56) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 184 days (6.1 months) or frozen for up to 62 days (2 months) prior to analyses.

In the third study (MRIDs 00049484 and 00067872), 36 tomato trials were conducted in CA(20), GA(4), MS(2), NY(1), SC(8), and VA(1). Residues of napropamide were <0.05 ppm (nondetectable) in/on tomatoes harvested 72-162 days following a single preplant, pretransplant, or

preemergence soil incorporated application of the 50% WP or 4 lb/gal FIC formulation at 0.5-8 lb ai/A (0.25-4x). Napropamide residues in/on tomatoes were determined using GLC methods (modified WRC 73-56 and unspecified) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 600 days (19.7 months) prior to analyses.

Cucurbits Vegetables Group (Crop Group 9)

A tolerance of 0.1 ppm has been established for residues of napropamide in/on cucurbit vegetables [40 CFR §180.328(a)].

There are presently no registered uses of napropamide on any member of the cucurbit vegetables crop group. Unless the basic registrants of napropamide or other interested parties propose uses and submit supporting data, the established crop group tolerance for cucurbit vegetables should be revoked.

Citrus Fruits Group (Crop Group 10)

MRIDs 00023883, 00035665, and 00113821 (Grapefruit)

MRIDs 00023883, 00035665, 00070780, and 00113821 (Lemon)

MRIDs 00023235, 00023883, 00035665, 00049485, 00070780, 00070784, 00113821, and 00115128 (Orange)

A tolerance of 0.1 ppm has been established for residues of napropamide in/on citrus fruits [40 CFR §180.328(a)].

Currently, napropamide is registered on citrus fruits (grapefruit, lemon, orange, and tangerine) for a single broadcast or directed spray application made at a maximum rate of 4 lb ai/A. In addition, napropamide is registered on citrus fruits (grapefruit, lemon, orange, tangelo, and tangerine) for up to two (split) broadcast, chemigation, or soil broadcast applications at 4 lb ai/A/application per growing season, for a total rate of 8 lb ai/A. A 35-day PHI has been established. The grazing of livestock is prohibited.

Crop field trial data for grapefruit (16 trials), lemon (21 trials), orange (22 trials), and tangerine (8 trials) were discussed in the 12/1/88 Napropamide Reregistration Standard. The submitted data were deemed insufficient to assess the adequacy of the established tolerance for citrus fruits because no data were submitted reflecting residues in/on grapefruit and lemon (the representative commodities of citrus fruits) following split seasonal applications in the western U.S. using the 50% WP or the 50% DF formulations. Although inadequate, the available data indicate that residues of napropamide were <0.05 ppm (nondetectable) in/on grapefruit, lemons, oranges, and tangerines following a single soil application of the 50% WP or 4 lb/gal FIC formulation made early in the season at rates up to 3x. The data also indicate that residues of napropamide were nondetectable in/on oranges harvested 121-346 days following the last of split applications at 1x.

To support the use pattern reflecting split applications in the western U.S., the Napropamide

Reregistration Standard required residue data only for lemon. No grapefruit data were required since virtually all U.S. grapefruit are produced in the state of FL. To date, the requested data have not been submitted. The following are required to support the registered uses of napropamide on citrus fruits:

- " Data depicting napropamide residues in/on lemons harvested 35 days following the last of two soil incorporated applications of the 50% DF formulation at 4 lb ai/A per application (total 8 lbai/A). The requested trials should be conducted in CA since this state represents the major lemon production area in the western U.S. where this use pattern is permitted.

A summary of the available data for citrus fruits is presented below.

Grapefruit: Sixteen grapefruit trials were conducted in AZ(4), CA(3), FL(1), and TX(6). Residues of napropamide were <0.05 ppm (nondetectable) in/on grapefruit harvested at various intervals following a single soil application of the 50% WP or 4 lb/gal FIC formulation at 4-8 lb ai/A (1-2x the maximum single application rate). Napropamide residues in/on grapefruit were determined using GLC methods (WRC 73-56 and unspecified methods) with a detection limit of 0.05 ppm. Sample storage conditions and intervals were not specified.

Lemon: Twenty one lemon trials were conducted in AZ(11), CA(8), and FL(2). Residues of napropamide were <0.05 ppm (nondetectable) in/on lemons harvested at various intervals following a single soil application of the 50% WP or 4 lb/gal FIC formulation at 4-8 lb ai/A (1-2x the maximum single application rate). Napropamide residues in/on lemons were determined using GLC methods (WRC 73-56 and unspecified methods) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 404 days (13.3 months) prior to analyses.

Orange: Twenty two orange trials were conducted in AZ(4), CA(12), FL(1), and TX(5). Residues of napropamide were <0.05 ppm (nondetectable) in/on oranges harvested at various intervals following a single soil application or split seasonal applications of the 50% WP or 4 lb/gal FIC formulation at 4-12 lb ai/A (1-3x the maximum single application rate). Napropamide residues in/on oranges were determined using GLC methods (modified WRC 73-56 and unspecified methods) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 551 days (18.1 months) prior to analyses.

Tangerine: Eight tangerine trials were conducted in AZ(3) and CA(5). Residues of napropamide were <0.05 ppm (nondetectable) in/on tangerine harvested 37-273 days following a single soil application of the 50% WP or 4 lb/gal FIC formulation at 8 lb ai/A (2x the maximum single application rate). Napropamide residues in/on tangerines were determined using GLC methods (modified WRC 73-56 and unspecified methods) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 404 days (13.3 months) prior to analyses.

Pome Fruits Group (Crop Group 11)

MRIDs 00070784, 00070785, 00113821, 00115128, and 00118001 (Apple)

MRIDs 00035664, 00070780, 00113821, and 00118001 (Pear)

A tolerance of 0.1 ppm has been established for residues of napropamide in/on pome fruits [40 CFR §180.328(a)].

Currently, napropamide is registered on apples and pears, the representative commodities of the pome fruits group, for a single postemergence broadcast spray application at a maximum rate of 4 lb ai/A. In addition, napropamide is registered on apples and pears for up to two broadcast, chemigation, or soil broadcast applications at 4 lb ai/A per application for a total seasonal rate of 8 lb ai/A. A 35-day PHI has been established; the grazing of livestock is prohibited.

Crop field trial data for apples and pears were discussed in the 12/1/88 Napropamide Reregistration Standard. These data indicate that residues of napropamide were nondetectable (<0.05 ppm) in/on apples and pears harvested 98-366 days following one or two soil applications at 0.5-2x the maximum single application rate. The Reregistration Standard, however, concluded that these data are insufficient to assess the adequacy of the established crop group tolerance for pome fruits because no data were submitted reflecting harvest of apples and pears 35 days after the last of two treatments of the 50% WP (has since been cancelled) or the 50% DF formulation at 4 lb ai/A (total 8lb a.i./A), the use permitted in the western U.S. To date, the requested data have not been submitted and examination of napropamide labels shows that this use pattern remains registered. The following are required to support the registered uses of napropamide on pome fruits:

- “ Data depicting napropamide residues in/on apples and pears harvested 35 days following the last of two soil incorporated applications of the 50% DF formulation at 4 lb ai/A per application. The requested trials should be conducted in CA, which is representative of the western U.S. where this use pattern is permitted.

A summary of the available residue data for pome fruits is presented below.

Apple: In the first study (MRIDs 00070784, 00070785, 00113821, and 00115128), a total of 37 apple trials was conducted in CA(24), IL(2), ME(1), MI(1), MO(1), VA(1), and WA(4). Residues of napropamide were <0.05 ppm (nondetectable) in/on apples harvested 98-177 days following a single soil application or split seasonal applications of the 50% WP, 4 lb/gal FIC, or 2 lb/gal EC formulation (not registered for this use) at 2-8 lb ai/A (0.5-2x the maximum single application rate) or two applications of the 50% WP formulation at 2-4 lb ai/A (0.5-1x). Napropamide residues in/on apples were determined using GLC methods (WRC 73-56, modified WRC 73-56, and unspecified methods) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 746 days (24.5 months) prior to analyses.

In the second study (MRID 00118001), seven trials were conducted in ID(1) and OR(6). Residues of napropamide were <0.05 ppm (nondetectable) in/on apples harvested 142-188 days following a single soil application of the 10% G formulation at 2 or 4 lb ai/A (0.5-1x). Napropamide residues in/on apples were determined using a GLC method (WRC 71-35) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 344 days (11.3 months) prior to analyses.

Pear: A total of 48 pear trials was conducted in CA(24), OR(8), and WA(16). Residues of napropamide were <0.05 ppm (nondetectable) in/on pears harvested 109-366 days following a single soil application of the 50% WP, 10% G, 4 lb/gal FIC, or 2 lb/gal EC formulation (not registered for this use) at 2-8 lb ai/A (0.5-2x). Napropamide residues in/on pears were determined using unspecified GLC methods with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 771 days (25.4 months) prior to analyses.

Stone Fruits Group (Crop Group 12)

MRIDs 00035663, 00049487, and 00113821 (Apricot)

MRIDs 00023883, 00035663, 00049487, and 00113821 (Cherry)

MRIDs 00023883, 00035663, and 00113821 (Nectarine)

MRIDs 00023883, 00035663, 00049487, 00113821, 00115128, and 00118001 (Peach)

MRIDs 00023883, 00035663, 00049487, 0113800, and 00115128 (Plum and Prune)

A tolerance of 0.1 ppm has been established for residues of napropamide in/on stone fruits [40 CFR §180.328(a)].

Currently, napropamide is registered on stone fruits (apricot, cherry, nectarine, peach, plum, and prune) for a single postemergence broadcast spray application at a maximum rate of 4 lb ai/A. In addition, napropamide is registered on stone fruits (apricot, cherry, nectarine, peach, plum, and prune) for up to two broadcast, chemigation, or soil broadcast applications at 4 lb ai/A per application for a total seasonal rate of 8 lb ai/A. A 35-day PHI has been established. The grazing of livestock is prohibited.

Crop field trial data for apricot (10 trials), cherry (10 trials), nectarine (7 trials), peach (45 trials), plum (24 trials), and prune (1 trial) were discussed in the 12/1/88 Napropamide Reregistration Standard. These data indicate that residues of napropamide were nondetectable (<0.05 ppm) in/on apricot, cherry, nectarine, peach, and plum/prune following one soil application of the 50% WP or 4 lb/gal FIC formulation made early in the season at 0.5-4x the maximum single application rate. The Reregistration Standard concluded that these data are insufficient to assess the adequacy of the established crop group tolerance for stone fruits because none of the data reflect harvest of cherry, peach, or plum 35 days after the last of two treatments at 4 lb ai/A, the use permitted in the western U.S. In addition, no data were submitted reflecting registered use of the 10% G formulation on cherries and plums. To date, the requested data have not been submitted and examination of napropamide labels shows that these use patterns remain registered. The following are required to support the registered uses of napropamide on stone fruits:

- " Data depicting napropamide residues in/on cherries (sweet or tart), peaches, and plums (fresh prune) harvested 35 days following the last of two incorporated soil applications of the 50% DF formulation at 4 lb ai/A per application. The requested trials should be conducted in CA, which is representative of the western U.S. where this use pattern is registered.
- " Data depicting napropamide residues in/on cherries (sweet or tart), peaches, and plums (fresh prune) harvested at a suitable interval following a single incorporated soil application of the 10% G and the 50% DF formulations at 4 lb ai/A. As specified in the Registration Standard, the requested trials should be conducted in: (i) MI and OR/WA for cherries; (ii) GA, MI, NJ, PA, and SC for peaches; and (iii) MI and OR for plums/fresh prunes.

A summary of the available data for stone fruit is presented below.

Apricot: Ten apricot trials were conducted in CA(9) and WA(1). Residues of napropamide were <0.05 ppm (nondetectable) in/on samples of apricot harvested 81-222 days following a single soil application of the 50% WP, 4 lb/gal FIC, or 2 lb/gal EC formulation (not registered for this use) at 4-8 lb ai/A (1-2x the maximum single application rate). Napropamide residues in/on apricots were determined using GLC methods (modified WRC 73-56 and unspecified methods) with a detection limit of 0.05 ppm. Sample storage conditions and intervals were not specified.

Cherry: Ten cherry trials were conducted in CA(6), OR(2), and WA(2). Residues of napropamide were <0.05 ppm (nondetectable) in/on cherries harvested 108-193 days following a single soil application of the 50% WP or 4 lb/gal FIC formulation at 4-8 lb ai/A (1-2x). Napropamide residues in/on cherries were determined using GLC methods (WRC 71-35, modified WRC 73-56, and unspecified methods) with a detection limit of 0.05 ppm. Sample storage conditions and intervals were not specified.

Nectarine: Seven nectarine trials were conducted in CA. Residues of napropamide were <0.05 ppm (nondetectable) in/on nectarines harvested 105-187 days following a single soil application of the 50% WP, 4 lb/gal FIC, or 2 lb/gal EC formulation (not registered for this use) at 4-8 lb ai/A (1-2x). Napropamide residues in/on nectarines were determined using GLC methods (modified WRC 73-56, and unspecified methods) with a detection limit of 0.05 ppm. Sample storage conditions and intervals were not specified.

Peach: A total of 45 peach trials was conducted in CA(35), FL(1), GA(1), IL(1), MD(1), NC(2), UT(1), VA(1), and WA(1). Residues of napropamide were <0.05 ppm (nondetectable) in/on peaches harvested 49-288 days following a single soil application of the 10% G, 50% WP, 4 lb/gal FIC, or 2 lb/gal EC formulation (not registered for this use) at 4-16 lb ai/A (1-4x). Napropamide residues in/on peaches were determined using GLC methods (modified WRC 73-56, and unspecified methods) with a detection limit of 0.05 ppm. Sample storage conditions and intervals were not specified.

Plum: Twenty plum trials were conducted in CA. Residues of napropamide were <0.05 ppm (nondetectable) in/on plums harvested 78-271 days following a single soil application of the 50% WP or 4 lb/gal FIC formulation at 2-8 lb ai/A (0.5-2x) or two split applications of the WP, FIC, or EC formulation at 4 lb ai/A (1x). Residues of napropamide were <0.05 ppm (nondetectable) in/on plums harvested 35 days following a single soil application of the 2 lb/gal EC formulation (not registered for this use) at 8 lb ai/A. Napropamide residues in/on plum were determined using GLC methods (modified WRC 73-56, WRC 71-35, and unspecified methods) with a detection limit of 0.05 ppm. Sample storage conditions and intervals were not specified.

Berry Group (Crop Group 13)

MRIDs 00113821 and 00120304 (Blueberry)

MRIDs 00113821, 00118001, and 00120304 (Caneberry)

A tolerance of 0.1 ppm has been established for residues of napropamide in/on the obsolete crop group “fruit, small” [40 CFR §180.328(a)]. According to the revised crop group regulation [40 CFR §180.41], the small fruits and berries group has been reclassified as “Berries Crop Group”. Cranberry, grape, and strawberry which used to be part of the obsolete crop group are now classified as “Miscellaneous Commodities”. The representative commodities of Crop Group 13 are any one blackberry (or any one raspberry) and blueberry.

Currently, napropamide is registered on: (i) berries (including blackberry, blueberry, boysenberry, currant, loganberry, and raspberry) for a single broadcast, chemigation, or soil broadcast application at a maximum rate of 4 lb ai/A; and (ii) caneberries (including blackberry, boysenberry, loganberry, and raspberry) for a single postemergence broadcast spray application at a maximum rate of 4 lb ai/A. No PHI has been established. The grazing of livestock is prohibited.

Crop field trial data for blueberries and caneberries were discussed in the 12/1/88 Napropamide Reregistration Standard. The residue data for blueberries indicate that residues of napropamide were nondetectable (<0.05 ppm) in/on treated samples harvested: (i) 96 or 176 days following a single soil application of the 50% WP formulation at 4 lb ai/A (1x the maximum single application rate); and (ii) 90-192 days following a single application of the 4 lb/gal FIC or 2 lb/gal EC formulation (not registered for this use) at 4 or 6 lb ai/A. The residue data for caneberries indicate that residues of napropamide were <0.02 and <0.05 ppm (nondetectable) in/on treated samples harvested 45-450 days following a single soil application of the 10% G or 50% WP formulation at 2-8 lb ai/A (0.5-2x). In addition, residues of napropamide were <0.05 ppm (nondetectable) in/on caneberries harvested 38-450 days following a single application of the 2 lb/gal EC formulation at 4 lb ai/A (1x).

The Reregistration Standard, however, deemed the available residue data as insufficient to assess the adequacy of the established tolerance for the berry group because geographic representation of the data for blueberry is inadequate. These data requirements remain outstanding. The following are required to satisfy reregistration requirements for the berries group:

- " Data depicting napropamide residues in/on blueberries harvested at a suitable interval following a single soil application of the 10% G and the 50%DF formulations at 4 lb ai/A. The current OPPTS GLN 860.1500 requires a total of six trials for blueberry as part of the Berry Group, and HED notes that the registrants have already submitted data from three trials. Therefore, three additional trials on blueberry are required. For the purpose of continuity, the requested trials must be conducted in MI, NJ, and NC which were the test states identified in the Napropamide Reregistration Standard.

A summary of the available data for berries is presented below.

Blueberry: Three blueberry trials were conducted in GA(1) and WA (2). Residues of napropamide were <0.05 ppm (nondetectable) in/on blueberries harvested: (i) 96 or 176 days following a single soil application of the 50% WP formulation at 4 lb ai/A (1x the maximum single application rate); and (ii) 90-192 days following a single application of the 4 lb/gal FIC or 2 lb/gal EC formulation (not registered for this use) at 4 or 6 lb ai/A. Napropamide residues in/on blueberries were determined using unspecified GLC methods with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 523 days (17.2 months) prior to analyses.

Caneberry: A total of 19 trials on caneberries was conducted in CA(2), FL(1), OR(13), and WA (3). Residues of napropamide were <0.02 and <0.05 ppm (nondetectable) in/on caneberries harvested 45-450 days following a single soil application of the 10% G or 50% WP formulation at 2-8 lb ai/A (0.5-2x the maximum single application rate). Residues of napropamide were <0.05 ppm (nondetectable) in/on caneberries harvested 38-450 days following a single application of the 2 lb/gal EC formulation at 4 lb ai/A (1x). Napropamide residues in/on caneberries were determined using GLC methods (WRC 71-35 and unspecified methods) with detection limits of 0.02 and 0.05 ppm. Sample storage conditions and intervals were not specified.

Tree Nuts Group (Crop Group 14)

MRIDs 00023883, 00032358, 00035666, 00049488, 00113800, 00113821, and 00115128 (Almond)

MRIDs 00032358, 00035666, and 00113821 (Filbert)

MRIDs 00032358, 00035666, 00113821, and 00118001 (Pecan)

MRIDs 00032358, 00035666, 00070780, and 00113821 Walnut)

Tolerances of 0.1 ppm each have been established for residues of napropamide in/on the obsolete crop group "nut" and in/on almond hulls [40 CFR §180.328(a)]. According to the revised crop group regulation [40 CFR §180.41], the nut group has been reclassified as "Nut, tree, group 14".

Currently, napropamide is registered on tree nuts (almond, pecan, filbert/hazelnut, and walnut) for a single postemergence broadcast spray application at a maximum rate of 4 lb ai/A. In addition, napropamide is registered on tree nuts for up to two broadcast, chemigation, or soil broadcast applications at 4 lb ai/A per application for a total seasonal rate of 8 lb ai/A. A 35-day PHI has been

established. The grazing of livestock is prohibited.

Crop field trial data for almonds (42 trials), pecans (18 trials), filberts/hazelnuts (9 trials), and walnuts (18 trials) were discussed in the 12/1/88 Napropamide Reregistration Standard. The available data indicate that residues of napropamide were <0.05 ppm (nondetectable) in/on almonds, filberts, pecans, and walnuts following one soil application of the 50% WP or 4 lb/gal FIC formulation made early in the season at rates up to 2x the maximum single application rate. The data also indicate that residues of napropamide were <0.05 ppm (nondetectable) in/on almonds and almond hulls harvested 90 days following the last of split applications at 1x the maximum single application rate.

The Reregistration Standard concluded that the available data for almond hulls are adequate and did not require additional data for this commodity. However, additional residue data were required for pecans and walnuts in order to assess the adequacy of the established crop group tolerance. The Reregistration Standard required the registrants to submit data reflecting residues in/on pecans and walnuts following split seasonal applications in the western U.S. of the 50% WP (has since been cancelled) or the 50% DF formulations. [It is noted that pecan and walnut were once considered the representative commodities of tree nut group; the current OPPTS GLN 860.1500 now lists almond and pecan as the representative commodities.] These data requirements remain outstanding, and the following are required to satisfy reregistration requirements for tree nuts:

- " Data depicting napropamide residues in/on pecans and almonds (or walnuts) harvested 35 days following the last of two soil applications of the 50% DF at 4 lb ai/A per application. For the purpose of continuity, the requested trials should be conducted in NM and TX (pecan only) and CA (almond/walnut only) which were the test states identified in the Napropamide Reregistration Standard because they represent the major nut growing areas in the western U.S. where this use pattern is registered.

A summary of the available data for tree nuts is presented below.

Almond: A total of 42 almond trials, reflecting single application (36 trials) and split seasonal applications (6 trials), was conducted in CA. Residues of napropamide were <0.05 ppm (nondetectable) in/on almond nuts and hulls harvested: (i) 91-134 days following the last of two soil applications of either the 50% WP or 4 lb/gal FIC formulation at 4-8 lb ai/A/application (1-2x the maximum single application rate); (ii) 290 days following split applications with the 50% WP formulation at 2 and 8 lb ai/A/application (0.5-2x); or (iii) 91-334 days following a single application of the 50% WP or 4 lb ai/gal FIC formulation at 4 lb ai/A (1x) or 6-8 lb ai/A (1.5-2x). Napropamide residues in/on almond commodities were determined using GLC methods (WRC 71-35, WRC 73-56, and other unspecified methods) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 629 days (20.7 months) prior to analyses.

Filbert: Filbert crop field trial data were discussed in the 12/1/88 Napropamide Reregistration

Standard. A total of nine trials were conducted in OR in/on filberts. Residues of napropamide were <0.05 ppm (nondetectable) in/on filberts harvested: (i) 144-324 days following a single application of the 50% WP or 4 lb ai/gal FIC formulation at 6-8 lb ai/A (1.5-2x the maximum single application rate); and (ii) 201-265 days following a single application of the 2 lb ai/gal EC formulation (not registered for this use) at 4-6 lb ai/A. Napropamide residues in/on filberts were determined using GLC methods (WRC 73-56 or an unspecified method) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 785 days (25.8 months) prior to analyses.

Pecan: A total of 18 pecan trials was conducted in AZ(6), CA(2), FL(1), GA(7), and SC(2). Residues of napropamide were <0.05 ppm (nondetectable) in/on pecans harvested: (i) 26-273 days following a single application of the 50% WP or 4 lb ai/gal FIC formulation at 4 lb ai/A (1x the maximum single application rate); (ii) 161-220 days following a single application of the 50% WP or 4 lb ai/gal FIC formulation at 6-8 lb ai/A (1.5-2x); (iii) 50 days following the last of two applications of the 10% G formulation at 6 lb ai/A (1.5x); and (iv) 63-209 days following a single application of the 2 lb ai/gal EC formulation (not registered for this use) at 4-6 lb ai/A. Napropamide residues in/on pecans were determined using GLC methods (WRC 73-56 or an unspecified method) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 909 days (29.9 months) prior to analyses.

Walnut: A total of 18 walnut trials was conducted in CA(17) and OR(1). Residues of napropamide were <0.05 ppm (nondetectable) in/on walnuts harvested: (i) 216-344 days following a single application of the 50% WP or 4 lb ai/gal FIC formulation at 4 lb ai/A (1x the maximum single application rate); (ii) 187-329 days following a single application of the 50% WP or 4 lb ai/gal FIC formulation at 6-8 lb ai/A (1.5-2x); (iii) 190 days following a single application of the 2 lb ai/gal EC formulation (not registered for this use) at 8 lb ai/A. Napropamide residues in/on walnuts were determined using GLC methods (WRC 73-56 or an unspecified method) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 650 days (21.4 months) prior to analyses.

Herb and Spice Group (Crop Group 19)

There are currently no registered uses of napropamide on basil, marjoram, rosemary, summer savory, and winter savory. United Phosphorus, Inc. has indicated [email correspondence dated 6/22/04 between Demson Fuller, EPA and Ann Tillman, UPI] that they will propose the reinstatement of the above crops on the product label for the 50% DF formulation (EPA Reg. No. 70506-36).

Basil

MRID 00094087

A tolerance of 0.1 ppm has been established for residues of napropamide in/on basil [40 CFR

§180.328(a)].

Limited residue data are available for basil. These data, which were submitted by IR-4 and discussed in the 12/1/88 Napropamide Reregistration Standard, may be used to reinstate use on basil. In three trials conducted in CA, residues of napropamide were <0.05 ppm (nondetectable) in/on: (i) basil (fresh and dried) harvested 59 days following a single preplant soil incorporated application of the 50% WP or 2 lb/gal EC formulation at 2 or 4 lb ai/A; and (ii) dried basil harvested 128 days following a single application at 2 lb ai/A. Samples were analyzed for napropamide residues using GLC methods (modified WRC 73-56 or an unspecified method) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 202 days (6.6 months) prior to analyses.

Based on the available but limited data, HED has determined that the registrant may include basil on the product label for the 50% DF formulation (EPA Reg. No. 70506-36) provided use is limited to the state of CA for a single preplant broadcast or banded soil application at a maximum rate of 4 lb ai/A.

Marjoram

A tolerance of 0.1 ppm has been established for residues of napropamide in/on marjoram [40 CFR §180.328(a)].

No residue data are available for marjoram. The available residue data for basil may be translated to marjoram provided the registrant (United Phosphorus, Inc.) proposes a use pattern for marjoram which is identical to basil.

Rosemary

MRID 00115110

A tolerance of 0.1 ppm has been established for residues of napropamide in/on rosemary [40 CFR §180.328(a)].

Limited residue data are available for rosemary. These data, which were submitted by IR-4 and discussed in the 12/1/88 Napropamide Reregistration Standard, may be used to reinstate use on rosemary. In one trial conducted in CA, residues of napropamide were <0.05 ppm (nondetectable) in/on rosemary (12 samples, 4 samples/rate) harvested 85 days following a single preplant soil incorporated application of the 2 lb/gal EC formulation at 2-6 lb ai/A. Samples were analyzed for napropamide residues using an unspecified GLC method with a detection limit of 0.05 ppm. Samples were stored under frozen conditions (temperature unspecified) for ~88 days (2.9 months) prior to analyses.

Based on the available but limited data, HED has determined that the registrant may include rosemary

on the product label for the 50% DF formulation (EPA Reg. No. 70506-36) provided use is limited to the state of CA for a single preplant broadcast or banded soil application at a maximum rate of 6 lb ai/A.

Summer Savory

MRID 00115110

A tolerance of 0.1 ppm has been established for residues of napropamide in/on summer savory [40 CFR §180.328(a)].

Limited residue data are available for summer savory. These data, which were submitted by IR-4 and discussed in the 12/1/88 Napropamide Reregistration Standard, may be used to reinstate use on summer savory. In five trials conducted in CA, residues of napropamide were <0.05 ppm (nondetectable) in/on fresh (n=5) and dried (n=4) samples of summer savory harvested 71 or 128 days following a single preplant soil incorporated application of the 50% WP formulation at 2-6 lb ai/A. Samples were analyzed for napropamide residues using GLC methods (WRC 73-56 or an unspecified method) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 202 days (6.6 months) prior to analyses.

Based on the available but limited data, HED has determined that the registrant may include summer savory on the product label for the 50% DF formulation (EPA Reg. No. 70506-36) provided use is limited to the state of CA for a single preplant soil incorporated application at a maximum rate of 6 lb ai/A.

Winter Savory

A tolerance of 0.1 ppm has been established for residues of napropamide in/on winter savory [40 CFR §180.328(a)].

No residue data are available for winter savory. Consistent with the previous HED's recommendation in the Reregistration Standard, the available residue data for basil may be translated to winter savory provided the registrant (United Phosphorus, Inc.) proposes a use pattern for winter savory which is identical to basil.

Miscellaneous Commodities

Artichoke

MRID 00025883

A tolerance of 0.1 ppm has been established for residues of napropamide in/on globe artichoke [40 CFR §180.328(a)].

Napropamide is currently registered on artichokes for a single broadcast, chemigation, or soil broadcast application at 4 lb ai/A. No PHI has been established. The grazing of livestock is prohibited.

Adequate residue data, which were discussed in the 12/1/88 Napropamide Reregistration Standard, are available to support the established globe artichoke tolerance. In 30 trials conducted in CA, residues of napropamide were <0.05 ppm (nondetectable) in/on fresh artichokes harvested at 14-117 days following a single postemergence application of the 50% WP and 2 lb/gal EC formulations at 2-12 lb ai/A (0.5-3x the maximum application rate). Napropamide residues in/on artichokes were determined using a GLC method (WRC 73-56) with a detection limit of 0.03-0.05 ppm. Samples were stored under unspecified conditions for up to 620 days (20.3 months) prior to analyses.

Asparagus

MRID 00025884

A tolerance of 0.1 ppm has been established for residues of napropamide in/on asparagus [40 CFR §180.328(a)].

Currently, napropamide is registered on asparagus for a single broadcast, chemigation, or soil broadcast application at 4 lb ai/A. No PHI has been established. The grazing of livestock is prohibited.

Adequate residue data, which were discussed in the 12/1/88 Napropamide Reregistration Standard, are available to support the established tolerance for residues of napropamide in/on asparagus. A total of 55 asparagus trials was conducted in AZ(6), CA(35), DE(1), MI(2), and WA(11). Residues of napropamide were <0.05 ppm (nondetectable) in/on asparagus harvested 6-173 days following a single preemergence broadcast application of the 10% G, 50% WP, and 2 lb/gal EC formulations at 2-16 lb ai/A (0.5-4x the maximum single application rate). Samples were analyzed using a GLC method (WRC 73-56) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 1,368 days (45 months) prior to analyses.

Avocado

MRID 00025885

A tolerance of 0.1 ppm has been established for residues of napropamide in/on avocado [40 CFR §180.328(a)].

Napropamide is currently registered on avocados for up to two broadcast, chemigation, or soil broadcast applications at 4 lb ai/A per application for a total seasonal rate of 8 lb ai/A. A 35-day PHI has been established. The grazing of livestock is prohibited.

Residue data for avocados were discussed in the 12/1/88 Napropamide Reregistration Standard. These data indicate that residues of napropamide were <0.05 ppm (nondetectable) in/on avocados following a single postemergence broadcast application of the 40% WP, 50% WP, and 2 lb/gal EC formulation, made early in the season, at rates up to 2x the maximum single application rate. However, the Reregistration Standard concluded that these data are insufficient to assess the adequacy of the established tolerance for avocado because no data were submitted reflecting harvest of avocado 35 days following the last of two treatments at 4 lb ai/A. To date, the requested data have not been submitted, and the following are required for reregistration:

- “ Data depicting napropamide residues in/on avocados harvested 35 days following the last of two postemergence broadcast or banded incorporated soil applications of the 50% DF formulation at 4 lb ai/A per application. The requested trials should be conducted in CA, which is the state identified by the Reregistration Standard and is representative of the western U.S. where this use is registered. If the registrants have not initiated these trials, the registrants should refer to Table 5 of OPPTS GLN 860.1500 for the required number of field trials.

Coffee bean

MRID 00113814

A tolerance of 0.1 ppm has been established for residues of napropamide in/on coffee bean [40 CFR §180.328(a)].

There are currently no registered uses of napropamide on coffee grown in the U.S. However, the registrant (United Phosphorus, Inc.) has indicated [email correspondence dated 6/22/04 between Demson Fuller, EPA and Ann Tillman, UPI] that napropamide is registered on coffee grown in Mexico. The registrant has provided English translation of the registered product label from Mexico which includes directions for use of napropamide on coffee grown for importation in the U.S. The 20.49% EC (240 g ai/L) formulation [Devrinol 240-E; Reg. RSCO-HEDE-0241-304-009-020] of napropamide is registered on coffee grown in Mexico as a soil incorporated application at a maximum

rate of 18.75 L product/ha (4.0 lb ai/A).

Adequate residue data, which were discussed in the 12/1/88 Napropamide Reregistration Standard, are available to support the established tolerance for residues of napropamide in/on coffee bean. A total of 37 trials was conducted in Brazil (8) and Columbia (29). Residues of napropamide were <0.05 ppm (nondetectable) in/on green and roasted coffee beans harvested 27-190 days following a single postplant application (surface spray or broadcast) to established coffee orchards of the 50% WP formulation at 2.2-4.3 lb ai/A (0.55-1.1x the maximum single application rate). Data were collected using a GLC method with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 237 days (7.8 months) prior to analyses.

Cranberry

MRIDs 00065363, 00113821, and 00118001

A tolerance of 0.1 ppm has been established for residues of napropamide in/on the obsolete crop group “fruit, small” [40 CFR §180.328(a)]. According to the revised crop group regulation [40 CFR §180.41], cranberry which used to be part of the obsolete crop group is now classified as a “Miscellaneous Commodity”. A separate tolerance for cranberry has not been established.

Currently, napropamide is registered on cranberry for: (i) a single broadcast application made in early spring at 9 lb ai/A; (ii) a single broadcast application made at a maximum rate of 15 lb ai/A; (iii) a postharvest broadcast application made at 9 lb ai/A; and (iv) a single postplant broadcast application made at 3 lb ai/A. The grazing of livestock is prohibited.

Residue data from 17 cranberry trials were discussed in the 12/1/88 Napropamide Reregistration Standard. These data indicate that residues of napropamide are nondetectable (<0.02 or <0.05 ppm depending on the method used) in/on cranberries following application of the 10% G or 50% WP formulation made early in the season at rates up to 2x the maximum single application rate. These data are adequate to support a tolerance of 0.1 ppm for residues of napropamide on cranberries.

Fig

MRIDs 00035668 and 00113821

A tolerance of 0.1 ppm has been established for residues of napropamide in/on fig [40 CFR §180.328(a)].

Napropamide is presently registered on figs for a single postemergence broadcast spray application at a maximum rate of 4 lb ai/A. In addition, napropamide is registered for up to two broadcast, chemigation, or soil broadcast applications at 4 lb ai/A per application for a total seasonal rate of 8 lb

ai/A. A 35-day PHI has been established. The grazing of livestock is prohibited.

Residue data for figs were discussed in the 12/1/88 Napropamide Reregistration Standard. These data were generated from 16 fig trials conducted in CA(12) and GA(4). Residues of napropamide were nondetectable (<0.05 ppm) in/on fresh, dried, and immature figs harvested 35-696 days following a single broadcast, banded, or directed spray application of the 50% WP, 2 lb/gal EC, or 4 lb/gal FIC formulation to established fig orchards at 4-8 lb ai/A (1-2x the maximum single application rate). The Reregistration Standard concluded that these data are insufficient to assess the adequacy of the established tolerance for fresh fig because no data were submitted depicting residues following two applications at 1x and a 35-day posttreatment interval. The Reregistration Standard deemed that a single sample collected at 35 days following application at 2x is insufficient for tolerance assessment. To date, the requested data have not been submitted, and the following are required for reregistration:

- “ Data depicting napropamide residues in/on fresh figs harvested 35 days following the last of two applications of the 50% DF formulation at 4 lb ai/A per application. The requested trials should be conducted in CA, which is the state identified by the Reregistration Standard. If the registrants have not initiated these trials, the registrants should refer to Table 5 of OPPTS GLN 860.1500 for the required number of field trials.

Grape

MRIDs 00023883, 00035667, 00049486, 00113821, and 00115128

A tolerance of 0.1 ppm has been established for residues of napropamide in/on the obsolete crop group “fruit, small” [40 CFR §180.328(a)]. According to the revised crop group regulation [40 CFR §180.41], grape which used to be part of the obsolete crop group is now classified as a “Miscellaneous Commodity”. A separate tolerance has not been established for napropamide residues in/on grape.

Napropamide is presently registered for use on grapes for: (i) a single postemergence broadcast spray application at a maximum rate of 4 lb ai/A; and (ii) up to two broadcast, chemigation, or soil broadcast applications at 4 lb ai/A per application for a total seasonal rate of 8 lb ai/A. A 35-day PHI has been established. The grazing of livestock is prohibited.

Residue data for grapes were discussed in the 12/1/88 Napropamide Reregistration Standard. A total of 36 grape trials was conducted in CA(30), OR(1), and WA(5). Residues of napropamide were nondetectable (<0.05 ppm) in/on grapes harvested 35-289 days following a single soil application of the 50% WP, 4 lb/gal FIC, or 10% G formulation at 1.3-8 lb ai/A (0.33-2x the maximum single application rate) or following two applications of the 50% WP formulation at 4 lb ai/A (1x the maximum seasonal rate). The Reregistration Standard concluded that these data are inadequate for the purpose of tolerance reassessment because only two samples of grape reflecting harvest 35 days following the latter of two treatments at 4 lb ai/A were submitted. To date, the requested data have not

been submitted, and the following are required for reregistration:

- " Data depicting napropamide residues in/on grapes harvested 35 days following the last of two soil incorporated applications of the 50% DF formulation at 4 lb ai/A per application. The requested trials should be conducted in CA, which is the state identified by the Reregistration Standard. If the registrants have not initiated these trials, the registrants should refer to Table 5 of OPPTS GLN 860.1500 for the required number of field trials.

Kiwifruit

MRID 00025887

A tolerance of 0.1 ppm has been established for residues of napropamide in/on kiwifruit [40 CFR §180.328(a)].

Napropamide is currently registered for use on kiwifruit for up to two broadcast, chemigation, or soil broadcast applications at 4 lb ai/A per application for a total seasonal rate of 8 lb ai/A. A 35-day PHI has been established. The grazing of livestock is prohibited.

Residue data for kiwifruit were discussed in the 12/1/88 Napropamide Reregistration Standard. A total of 16 kiwifruit trials was conducted in CA. Residues of napropamide were <0.05 ppm (nondetectable) in/on kiwifruit harvested 97-340 days following one or two soil applications of the 50% WP, 2 lb/gal EC, and 4 lb/gal FIC formulations at 4-8 lb ai/A (1-2x the maximum single application rate). Napropamide residues in/on kiwifruit were determined using a GLC method (WRC 73-56) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 413 days (13.6 months) prior to analyses.

The Reregistration Standard concluded that the above-summarized data are insufficient to assess the adequacy of the established tolerance for kiwifruit because no data reflecting harvest 35 days following the last of two treatments at 4 lb ai/A were submitted. To date, the requested data have not been submitted, and the following are required for reregistration:

- " Data depicting napropamide residues in/on kiwifruit harvested 35 days following the last of two postemergence broadcast or banded soil incorporation applications of the 50% DF formulation at 4 lb ai/A per application. The requested trials should be conducted in CA, which is the state identified by the Reregistration Standard. If the registrants have not initiated these trials, the registrants should refer to Table 5 of OPPTS GLN 860.1500 for the required number of field trials.

Mint

MRID 00025889

A tolerance of 0.1 ppm has been established for residues of napropamide in/on mint [40 CFR §180.328(a)].

Napropamide is currently registered on mint for a single broadcast or chemigation application at a maximum rate of 4 lb ai/A. No PHI has been established. The grazing of livestock is prohibited.

The 12/1/88 Napropamide Reregistration Standard concluded that the established tolerance for mint is supported by the available residue data on mint hay and spent hay. A total of 33 mint (peppermint and spearmint) trials was conducted in ID(8), OR(15), and WA(10). Residues of napropamide were <0.05 ppm (nondetectable) in/on mint hay and spent hay harvested 116-256 days following a single broadcast or surface spray application to established mint crops using the 10% G, 50% WP, and 2 lb/gal EC formulations at 2-4 lb ai/A (0.5-1x the maximum single application rate). Samples were analyzed using a GLC method (WRC 73-56) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 278 days (9.1 months) prior to analyses.

According to Table 1 of OPPTS 860.1000, the raw agricultural commodity of peppermint and spearmint is "tops (leaves and stems)". HED concludes that the submitted data for mint hay and spent hay may be used to satisfy data requirements peppermint tops and spearmint tops.

Olive

MRID 00030179

A tolerance of 0.1 ppm has been established for residues of napropamide in/on olive [40 CFR §180.328(a)].

Napropamide is presently registered on olives for up to two broadcast, chemigation, or soil broadcast applications at 4 lb ai/A per application for a total seasonal rate of 8 lb ai/A. A 35-day PHI has been established. The grazing of livestock is prohibited.

Residue data for olives were discussed in the 12/1/88 Napropamide Reregistration Standard. These data indicate that residues of napropamide were nondetectable (<0.05 ppm) in/on olives harvested 110-244 days following a single broadcast application of the 50% WP and 2 lb/gal EC formulations at 4-8 lb ai/A (1-2x the maximum single application rate). The Reregistration Standard concluded that these data are insufficient to assess the adequacy of the established olive tolerance because no data reflecting harvest 35 days following the last of two treatments at 4 lb ai/A per application were submitted. To date, the requested data have not been submitted, and the following are required for reregistration:

- " Data depicting napropamide residues in/on olives harvested 35 days following the last of

two postemergence broadcast or banded soil incorporation applications of the 50% DF formulation at 4 lb ai/A per application. The requested trials should be conducted in CA, which is the state identified by the Reregistration Standard. If the registrants have not initiated these trials, the registrants should refer to Table 5 of OPPTS GLN 860.1500 for the required number of field trials.

Persimmon

MRID 00025890

A tolerance of 0.1 ppm has been established for residues of napropamide in/on persimmon [40 CFR §180.328(a)].

Napropamide is currently registered on persimmon for up to two broadcast, chemigation, or soil broadcast applications at 4 lb ai/A per application for a total seasonal rate of 8 lb ai/A. A 35-day PHI has been established. The grazing of livestock is prohibited.

Residue data for persimmon were discussed in the 12/1/88 Napropamide Reregistration Standard. These data, which were generated from 5 trials conducted in CA, indicate that residues of napropamide were nondetectable (<0.05 ppm) in/on persimmons harvested 104-304 days following a single broadcast application of the 50% WP formulation at 4-8 lb ai/A (1-2x the maximum single application rate). The Reregistration Standard concluded that these data are insufficient to assess the adequacy of the established tolerance for persimmon because no data reflecting harvest 35 days following the last of two treatments at 4 lb ai/A per application were submitted. To date, the requested data have not been submitted, and the following are required for reregistration:

- “ Data depicting napropamide residues in/on persimmon fruits harvested 35 days following the last of two postemergence broadcast or banded soil incorporation applications of the 50% DF formulation at 4 lb ai/A per application. The requested trials should be conducted in CA, which is the state identified by the Reregistration Standard. If the registrants have not initiated these trials, the registrants should refer to Table 5 of OPPTS GLN 860.1500 for the required number of field trials.

Pistachio

MRIDs 00027550 and 00035666

A tolerance of 0.1 ppm has been established for residues of napropamide in/on pistachio [40 CFR §180.328(a)].

Napropamide is currently registered on pistachio for a single postemergence broadcast spray application at a maximum rate of 4 lb ai/A. A 35-day PHI has been established. The grazing of

livestock is prohibited.

Residue data for pistachio were discussed in the 12/1/88 Napropamide Reregistration Standard. These data indicate that residues of napropamide were nondetectable (<0.05 ppm) in/on pistachio nuts following one broadcast or directed spray application of the 50% WP, 2 lb/gal EC, or 4 lb/gal FIC formulation, made early in the season, at 1-4x the maximum single application rate. Almond data may also be translated to pistachio. Based on the current use pattern, these data are adequate to support the established tolerance for residues of napropamide on pistachios.

Pomegranate

MRID 00144964

A tolerance with regional registration of 0.1 ppm has been established for residues of napropamide in/on pomegranate [40 CFR §180.328(b)].

Napropamide is currently registered on pomegranate for one broadcast, chemigation, or soil broadcast applications at 4 lb ai/A. A 180-day PHI has been established. The grazing of livestock is prohibited.

The 12/1/88 Napropamide Reregistration Standard concluded that adequate residue data are available to support the registered uses and the established tolerance for pomegranate. These data were submitted by IR-4 from five trials conducted in CA. Residues of napropamide were <0.05 ppm (nondetectable) in/on pomegranate harvested 188-341 days following a single hand spray or tractor-mounted spray application using the 50% WP and 2 lb/gal EC formulations at 4-8 lb ai/A (1-2x the maximum single application rate). Napropamide residues in/on pomegranate were determined using a GLC method (WRC 73-56) with a detection limit of 0.05 ppm. Samples were stored under unspecified conditions for up to 718 days (23.6 months) prior to analyses.

For the purpose of reregistration, no additional data are required. The available data indicate that residues of napropamide were <0.05 ppm (nondetectable) in/on treated samples of pomegranate following one treatment at 8 lb ai/A (2x the maximum rate).

Strawberry

MRIDs 00027322 and 00118001

A tolerance of 0.1 ppm has been established for residues of napropamide in/on the obsolete crop group “fruit, small” [40 CFR §180.328(a)]. According to the revised crop group regulation [40 CFR §180.41], strawberry which used to be part of the obsolete crop group is now classified as a “Miscellaneous Commodity”. A separate tolerance has not been established for napropamide residues in/on strawberry.

Napropamide is currently registered on strawberry for a single broadcast, banded, strip, or soil application made to established plantings at posttransplant or prebloom at a maximum rate of 4 lb ai/A. In addition, napropamide is registered on strawberry for up to two broadcast, chemigation, or soil broadcast applications at 4 lb ai/A per application for a total seasonal rate of 8 lb ai/A. The grazing of livestock is prohibited.

The available residue data for strawberries were presented in the 12/1/88 Napropamide Reregistration Standard as part of the obsolete crop group. Residue data from 32 trials indicate that residues of napropamide were nondetectable (<0.05 ppm) in/on strawberry harvested 31-392 days following a single soil application of the 10% G, 50% WP, 4 lb/gal FIC, or 2 lb/gal EC formulation at 1-8 lb ai/A (0.25-2x the maximum single application rate). These data are adequate to support a tolerance of 0.1 ppm for residues of napropamide on strawberries.

Tobacco

MRID 00120304

The use of pesticides on tobacco does not require a tolerance or an exemption from a tolerance. Nonetheless, it is the Agency policy to require data in order to assess the exposure of humans to residues on tobacco.

Napropamide is currently registered on tobacco for: (i) application of the 10% G formulation at 1.36 lb ai/A; (ii) application of the 50% DF, 43.2% FIC, 21.8% EC and 24.1% EC formulations at 2 lb ai/A.

Residue data for tobacco were presented in the 12/1/88 Napropamide Reregistration Standard. A total of 12 tobacco trials was conducted in GA(2) and TN (10); in addition, 43 trials were conducted in NC (17) and TN (26). Residues of napropamide were <0.05 ppm (nondetectable) in/on samples of green leaf tobacco, flue-cured tobacco, and dark fired tobacco following: (i) a single preplant application at 1x using WP and FIC formulations; and (ii) a single posttransplant application at 1x using the WP, EC, and FIC formulations.

The Reregistration Standard, however, concluded that the available tobacco data are inadequate to assess the exposure of humans to residues of napropamide in/on tobacco and its products because the registered uses of the 1 lb/gal EC (MAI) and 50% DF formulations were not represented. Consequently, the Reregistration Standard required additional data. The need for additional tobacco data was re-iterated by the 1/16/91 Napropamide Phase 4 Review (J. Smith). However, the Agency (DP Barcode D172822, 2/24/92, A. Aikens) later reversed this requirement and concluded that the reviewed napropamide metabolism studies on cabbage, tomato (foliage portion), and apples would be adequate to determine the terminal residues of concern for the RAC tobacco. Therefore, no additional data for tobacco are required for reregistration. HED now concludes that napropamide residues are not likely to exceed 0.1 ppm in/on green leaf tobacco, flue cured tobacco, and dark-fired tobacco

when registered formulations of napropamide are applied to tobacco plants according to the maximum registered use pattern.

860.1520 Processed Food and Feed

Adequate processing studies with napropamide have been submitted for apples, figs, grapes, oranges, plums, and tomatoes. These studies indicate that residues of napropamide do not concentrate above the analytical method's LOQ of 0.05 ppm in the respective processed commodities of the above crops except in citrus oil where a processing factor of 35x was reported.

A coffee processing study and a mint processing study remain a reregistration requirement. Summaries of the available processing studies with napropamide are presented below.

Apple

MRID 43249401

An acceptable apple processing study is available. Residues of napropamide do not concentrate above the analytical method's LOQ of 0.05 ppm in wet mash, raw juice, clarified and pasteurized juice, wet pomace, and dry pomace processed from apples bearing nondetectable residues following treatment at 2x the maximum single application rate. According to Table 1 of OPPTS 860.1000, apple juice and wet pomace are the processed commodities of apples. Based on the results of the apple study, tolerances for apple juice and wet pomace are not needed.

Coffee

MRID 000140144

A processing study depicting napropamide residues on coffee beans for instant coffee is required. A processing study was previously submitted (MRID 000140144) but was found to be unacceptable as an instant coffee processing study was not conducted. If coffee beans treated at exaggerated rates equivalent to at least the maximum theoretical concentration factor due to processing do not show measurable residues, then processing studies will not be required.

Figs

MRIDs 00035668 and 00113821

Limited residue data are available for dried figs, the recognized processed commodity of figs. The 12/1/88 Napropamide Reregistration Standard reported that residues of napropamide were <0.05 ppm (nondetectable) in dried figs harvested 35 days (n= 1 sample) or 237 days (1 sample) following treatment at 1x using the WP formulation. The 1/16/91 Napropamide Phase 4 Review concluded that these fig data may be considered adequate pending submission of supporting storage stability data. The

available storage stability data for dried apple pomace may be used to satisfy this requirement. Residues of napropamide have been found to be reasonably stable in dried apple pomace for up to 36 months under frozen storage conditions.

Grape

MRID 43249402

An acceptable grape processing study is available. The results of the grape study indicate that residues of napropamide concentrate at least 3.1x in wet pomace, at least 6.9x in dried pomace, and at least 8.6x in raisin waste processed from grapes bearing nondetectable residues (<0.05 ppm) of napropamide following treatment at 5x the maximum seasonal rate. The data also indicate that residues of napropamide do not concentrate above the analytical method's LOQ of 0.05 ppm in juice or raisins processed from grapes bearing nondetectable residues.

According to Table 1 of OPPTS 860.1000, the recognized processed commodities of grapes are grape juice and raisins; wet and dry pomace and raisin waste have been deleted as significant livestock feedstuff. Based on the results of the grape processing study, tolerances for grape juice and raisins are not needed.

Mint

MRID 00025889

The submitted mint study was performed at 0.5x and 1x the maximum label rate. Residues were nondetectable on mint (peppermint and spearmint) tops and in mint oil. A mint processing study, performed at exaggerated rates, is required.

Orange

MRID 43249403

An acceptable orange processing study is available. The results of the study indicate that residues of napropamide concentrate at least 35x in citrus oil but do not concentrate above the LOQ (0.05 ppm) in juice, dried pulp, or molasses processed from oranges bearing nondetectable residues following treatment at 2x the maximum seasonal rate. The registrant noted that applications were not made at a rate greater than 2x because of phytotoxicity concerns. A tolerance for citrus oil will be determined when the highest average field trial (HAFT) value for all representative members of the citrus fruits group has been determined.

Plum

MRID 43249404

An acceptable plum processing study is available. The reviewed study shows that residues of napropamide do not concentrate above the LOQ (0.05 ppm) in prunes processed from plums bearing nondetectable residues following treatment at 2x the maximum seasonal rate. Based on the results of the plum processing study, a tolerance for prune is not needed.

Tomato

MRID 43249405

An acceptable tomato processing study is available. The results of the study indicate that residues of napropamide do not concentrate above the LOQ (0.05 ppm) in tomato juice, puree, wet pomace, or dry pomace processed from tomatoes bearing nondetectable residues following treatment at 2x the maximum seasonal rate. Since issuance of the Napropamide Phase 4 Review, the Agency has updated Table 1 of OPPTS 860.1000 and has added tomato paste as a processed commodity of tomato. No data pertaining to tomato paste were included in the reviewed study. However, based on nondetectable residues in tomato puree, the Agency does not anticipate that residues will concentrate in tomato paste and will not require additional data for this processed commodity. Tolerances for the processed commodities of tomatoes need not be established.

860.1650 Submittal of Analytical Reference Standards

As of 7/2/04, an analytical reference standard for napropamide is available at the EPA National Pesticide Standards Repository.

860.1850 Confined Accumulation in Rotational Crops

MRID 42794501

An acceptable confined rotational crop study with napropamide has been submitted and reviewed. In this study, wheat, carrots, and lettuce were planted at intervals of 60, 180, and 364 days in pots containing sandy clay loam soil. The soil was treated with [¹⁴C] napropamide at 4.4 lb ai/A (2.2x the maximum registered rate on annual crops). TRR accumulated ≥ 0.01 ppm in/on wheat forage (0.08-0.41 ppm), wheat straw (0.50-1.85 ppm), wheat grain (0.04-0.11 ppm), carrot root (0.04-0.14 ppm), carrot tops (0.08-0.16 ppm), and lettuce (0.04-0.08 ppm) at all plantback intervals (PBI). All samples of 60-day PBI as well as 180- and 364-day PBI wheat forage and wheat straw were subjected to extraction/characterization of residues. The metabolites identified in the various matrices of rotational crops corresponded to the metabolites identified in the plant metabolism studies and were found in approximately similar proportions. Napropamide and desethyl napropamide were found in all crops.

860.1900 Field Accumulation in Rotational Crops

Based on the results of the confined rotational crop study, HED initially concluded that field rotational crop studies are required for cereal grains and root/tuber vegetables to support the current uses of napropamide. In lieu of conducting the studies, the registrant submitted a request for a data waiver (D210722, R. Perfetti, 2/15/95) from OPPTS 860.1900 because the application rate used in the confined rotational crop study reflected 2.2x and not 1.1x as originally calculated. The Agency granted the waiver provided the registrant accepts the 60-day PBI for leafy vegetables, 180-day PBI for cereal grains, and a 365-day PBI for all other crops.

TOLERANCE REASSESSMENT SUMMARY

Tolerance Reassessments for Napropamide

The napropamide tolerances listed under 40 CFR §180.328(a) and (b) are expressed in terms N,N-diethyl-2-(1-naphthalenyloxy) propionamide. The tolerance expression is adequate. The HED Metabolism Committee has determined that the current tolerance expression (napropamide *per se*) is adequate based on the results of plant metabolism studies. A summary of the tolerance reassessment and recommended modifications in commodity definitions for napropamide is presented in Table 7.

Tolerances Established Under CFR §180.328(a)

Adequate residue data have been submitted to reassess the established tolerances for almond, hulls; artichoke, globe; asparagus; coffee bean; mint; rhubarb; sweet potato, roots; vegetable, brassica, leafy, group 5; and vegetable, fruiting. The available residue data for the above commodities indicate that residues of napropamide are mostly nondetectable (<0.05 ppm) following applications of representative formulations according to the maximum registered use patterns. The established tolerances for the above commodities are reassessed at the same level (0.1 ppm).

The available data are insufficient to allow reassessment of the established tolerances for: avocado; fig; fruit, citrus; fruit, pome; fruit, small; fruit, stone; kiwifruit; nut; olive; and persimmon. Additional crop field trial data are required.

Although tolerances are established for basil, rosemary, summer savory, and winter savory, there are presently no registered uses on these crops. A registrant (United Phosphorus, Inc.) has expressed interest in supporting these uses. Pending submission of a revised label for the 50% DF formulation (EPA Reg. No. 70506-36), there are limited but adequate data to support the reinstatement of napropamide uses on these crops. The label for the above end-use product should be amended to reflect the parameters of use pattern for which residue data are available. We recommend that the tolerances for the above commodities be transferred or reassigned under CFR §180.328(c) since the available data would only support regional registration.

There are presently no registered uses of napropamide on cucurbit vegetables. Unless the basic registrants of napropamide or other interested parties propose uses and submit supporting data, the established tolerance for cucurbit vegetables should be revoked.

The established group tolerance for residues of napropamide on "fruit, small" is based on an obsolete crop grouping. Therefore, the Agency is recommending that when the requested data become available, the tolerance for "fruit, small" should be revoked concomitant with establishing tolerances for: Berry group 13, cranberry, grape, and strawberry.

Tolerances to be Proposed Under 40 CFR §180.328(a)

Tolerances must be proposed for citrus oil, cranberry, grape, and strawberry. Adequate crop field trial data must be submitted before the appropriate tolerance levels may be determined.

Tolerances Established Under CFR §180.328(b)

Adequate residue data have been submitted to reassess the established regional tolerance for pomegranate. The tolerance is reassessed at the same level. We recommend that this tolerance be reassigned under 40 CFR §180.328(c) which is the appropriate designation for tolerances with regional registration.

A summary of tolerance reassessments is presented in Table 7.

Table 7. Tolerance Reassessment Summary for Napropamide .			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm) ¹	Comment/ [Correct Commodity Definition]
Tolerances Listed Under 40 CFR §180.328(a)			
Almond, hulls	0.1 (N)	0.1	
Artichoke, globe	0.1	0.1	
Asparagus	0.1	0.1	
Avocado	0.1	TBD	
Basil	0.1	0.1	Pending submission of a revised label for the 50% DF formulation (EPA Reg. No. 70506-36), there are limited but adequate data to support the reinstatement of napropamide uses on basil, marjoram, rosemary, summer savory, and winter savory. HED recommends that the tolerances for the above commodities be transferred or reassigned under CFR §180.328(c) since the available data would only support regional registration.
Marjoram	0.1	0.1	
Rosemary	0.1	0.1	
Savory, summer	0.1	0.1	
Savory, winter	0.1	0.1	
Coffee bean	0.1 (N)	0.1	[Coffee, green bean]
Fig	0.1 (N)	TBD	
Fruit, citrus	0.1 (N)	TBD	[Fruit, citrus, group 10]
Fruit, pome	0.1 (N)	TBD	[Fruit, pome, group 11]
Fruit, small	0.1 (N)	TBD	The established group tolerance on "fruit, small" is based on an obsolete crop grouping. HED is now recommending that when adequate data become available, the tolerance for "fruit, small" should be revoked concomitant with the establishment of separate tolerances for Berry group 13, cranberry, grape, and strawberry. [Berry, group 13]

Table 7. Tolerance Reassessment Summary for Napropamide .			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm) ¹	Comment/ [Correct Commodity Definition]
Fruit, stone	0.1 (N)	TBD	[Fruit, stone, group 12]
Kiwifruit	0.1	TBD	
Mint	0.1	0.1	[peppermint, tops and spearmint, tops]
Nut	0.1 (N)	TBD	[Nut, tree, group 14]
Olive	0.1	TBD	
Persimmon	0.1	TBD	
Pistachio	0.1	0.1	
Rhubarb	0.1	0.1	
Sweet potato, roots	0.1	0.1	
Vegetable, brassica, leafy, group 5	0.1	0.1	
Vegetable, cucurbit, group 9	0.1	Revoke	There are presently no registered uses of napropamide on cucurbit vegetables. Unless the basic registrants or other interested parties propose uses and submit supporting data, the established tolerance should be revoked.
Vegetable, fruiting	0.1 (N)	0.1	[Vegetable, fruiting, group 8]
Tolerances to be Established Under CFR §180.328(a)			
Citrus oil	--	TBD	
Cranberry	--	0.1	The established tolerance on “fruit, small” is based on an obsolete crop grouping. HED is recommending that when adequate data become available, the tolerance for “fruit, small” should be revoked concomitant with establishing tolerances for: Berry group 13, cranberry, grape, and strawberry.
Grape	--	TBD	
Strawberry	--	0.1	
Tolerances Listed Under 40 CFR §180.328(b)			
Pomegranate	0.1	0.1	This tolerance should be reassigned to §180.328(c).

¹ TBD = To be determined. Additional data are required for tolerance reassessment.

Codex/International Harmonization

No Codex or Canadian MRLs have been established for residues of napropamide; therefore, issues of compatibility do not exist. The following Mexican MRLs have been established for residues of napropamide:

coffee	0.1 ppm
apricot	0.1 ppm

chile pepper	0.1 ppm
plum	0.1 ppm
strawberry	0.1 ppm
tomato	0.1 ppm
apple	0.1 ppm
orange	0.1 ppm
walnut	0.1 ppm
pear	0.1 ppm
grape	0.1 ppm

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Agency Memoranda Citations

Table 7. Agency Memoranda Citations.						
Date	DP Barcode	CB No.	From	To	MRID Nos.	Subject
10/04/04	D308147	None	D. Drew		41575306	Napropamide. Storage Stability Data for Tobacco.
10/04/04	D308147	None	D. Drew		41575307	Napropamide. Storage Stability Data for Various Crops.
4/29/04	None	None	D. Fuller	Napropamide Team	None	Use Closure Memorandum for Napropamide Case No. 2450
4/25/95	D204409 and D207610	13860 and 14385	S. Knizner	B. Sidwell	43249401, 43345101, 43345102, 43345103, 43345104, 43345105, 43345106, 43345107, 43345108, 43345109	Napropamide. Plant Analytical Methods and Processing (Apples, Grapes, Prunes, Tomatoes) Studies. Reregistration Case No. 2450. Chemical No. 103001.
2/15/95	D210722	14915	R. Perfetti	E. Saito	43419901	Response to the Napropamide Reregistration Standard: Data Waiver Request.
5/4/94	D193544	12304	C. Swartz	B. Sidwell	42845901	Napropamide. List B Reregistration Case No.2450/ Chemical ID No. 103001. Supplemental Information to Upgrade Nature of the Residue Studies on Apples, Tomatoes and Cabbage.

Table 7. Agency Memoranda Citations.						
Date	DP Barcode	CB No.	From	To	MRID Nos.	Subject
12/17/93	D192158	12063	S. Knizner	K. Scanlon	42775801 and 42775802	Napropamide. Nature of the Residue in Ruminants and Poultry. Reregistration Case No. 2450. Chemical No. 103001.
7/16/93	D192205	12061	S. Knizner	K. Scanlon	42794501	Napropamide. Guideline 165-1. "Napropamide: Uptake and Metabolism in Confined Rotational Crops". Reregistration Case No. 2450. Chemical No. 103001.
4/7/93	None	None	S. Knizner	Files and HED Metabolism Committee	None	Napropamide. Reregistration Case No. 2450. Outcome of the 3/16/93 meeting of the HED Metabolism Committee.
3/2/93	None	None	S. Knizner	HED Metabolism Committee	None	Napropamide. Reregistration Case No. 2450. Issues to be presented at the 3/16/93 meeting of the HED Metabolism Committee.
2/1/93	D180815 and D179747	10244 and 10126	S. Knizner	K. Scanlon	42393901, 42349801, 42349802	Napropamide. Studies to Fulfill Guideline 171-4(a)(2) - Nature of the Residue in Cabbage, Apples, and Tomatoes. ICI Americas Inc. Project ID Nos. 90JH142, and 90JK193. Reregistration Case No. 2450. Chemical No. 103001.
8/11/92	D176816	9741	J. Morales	H. Jamerson and Tox Branch I	42256501	Napropamide on Sweet Potato. Evaluation of residue data and analytical methodology.
2/24/92	D172822	9169	A. Aikens	C. Rice/ P. Klinger	None	Napropamide. Registrant's Response to Phase IV DCI, Tobacco Crop Field Trial/Tobacco Uses Requirements. Case # 815847.
1/16/91	None	None	J. Smith		None	Napropamide Phase 4 Reviews.
12/1/88	None	None	C. Trichilo	R. Engler/ C. Kent	None	Product and Residue Chemistry Chapters for the Napropamide Reregistration Standard.