



Primary Evaluator

Date:

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This DER was originally prepared under contract by Dynamac Corporation (2275 Research Boulevard, Suite 300; Rockville, MD 20850; submitted 07/18/2006). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

### **STUDY REPORTS:**

46531301 Pensyl J.W. (1993) Magnitude of the Residues of Lactofen and its Metabolites in Green Peppers. Lab Project number: 1714/91/1027. Unpublished study prepared by Valent U.S.A. Corporation, 239 p.

46597201 Pensyl J.W. (1996) Magnitude of the Residue of Lactofen and its Metabolites in Tomatoes. Project number: VP-11576. Unpublished study prepared by Valent U.S.A. Corporation, 241 p.

46597202 Kowalsky J. (2003) Magnitude of the Residues of Lactofen on Peppers. Lab Project Number: V-03-25304. Unpublished study prepared by Valent U.S.A. Corporation, 84 p.

46597203 Kowalsky J. (2003) Magnitude of the Residues of Lactofen on Tomatoes. Lab Project Number: V-03-25291. Unpublished study prepared by Valent U.S.A. Corporation, 75 p.

### **EXECUTIVE SUMMARY:**

Valent U.S.A. Corporation has submitted field trial data for lactofen on the representative crops, pepper and tomato, of the fruiting vegetables group, crop group 8. A total of three pepper trials were conducted in Zone 3 (FL) during the 1991 (one bell pepper trial) and 2003 (one bell and one nonbell pepper trial) growing seasons. A total of four tomato field trials were conducted in Zone 3 (FL) during the 1990 (three trials) and 2003 (one trial) growing seasons. We note that both tomato varieties used in the crop field trials produce medium to large fruits.

For the pepper field trials, the 2 lb/gal emulsifiable concentrate (EC) formulation of lactofen was applied at each test location as one pre-transplant and one postemergence directed soil application to row middles at 0.49-0.51 lb ai/A/application for a total seasonal application rate of 0.98-1.1 lb ai/A. Shielded spray equipment was used in the 2003 trials. The first applications were made one or 12 days prior to transplanting, and the second applications were made at 46- to 67-day retreatment intervals. First applications were made in spray volumes of 31-33 gal/A, and second applications were made in spray volumes of 55-59 gal/A; nonionic surfactant (NIS) or crop oil concentrate (COC) adjuvants were added to the spray mixtures for second applications. Mature peppers were harvested 30 days following the second application.



For the tomato field trials, the 2 lb/gal EC formulation of lactofen was applied at each test location as one pre- or early post-transplant application and one to two postemergence directed soil applications to row middles at ~0.5 lb ai/A/application for total seasonal application rates of 0.96 lb ai/A (2003 field trial) or 1.5 lb ai/A (1990 trials); the 2003 trial included a treatment plot with two applications at an exaggerated rate of ~2.5 lb ai/A/application for a total seasonal application rate of ~5 lb ai/A. Shielded spray equipment was used for all trials. The first applications were made one or 12 days prior to transplanting or 5 days post-transplant; second applications were made at 30- to 37-day retreatment intervals; and third applications were made at 14- to 16-day retreatment intervals. First applications were made in spray volumes of 31-34 gal/A, and second and third applications were made in spray volumes of 55-60 gal/A; NIS or COC adjuvants were added to the spray mixtures for all applications, except the pre-transplant applications at the 2003 trial. Mature tomatoes were harvested 28-30 days following the last application.

Soil characteristics data were not provided for two pepper field trials and one tomato trial; however, these data are not required at this time because most of the relevant information is available from a reliable public source. For future submissions, the petitioner is advised that soil characteristics data must be provided for field trials reflecting applications to soil.

The maximum storage intervals of samples from harvest to analysis were 60 days for peppers and 56 days for tomatoes. A freezer storage stability study was conducted in conjunction with the 1990 magnitude of the residue study on tomatoes. Residues of lactofen and metabolites PPG-847, PPG-947, and PPG-2597 appeared to be relatively stable in/on tomatoes stored frozen for up to 68 days. Residues of PPG-1576 were found to decline in tomatoes, to ~60% of original value after 68 days of storage. These data are adequate to support the storage intervals and conditions of samples from the fruiting vegetable crop field trials. Because residues of PPG-1576 were found to be below the LOD in/on all tomato samples and below the LOQ in/on all pepper samples that were analyzed for residues of PPG-1576, no correction for potential decline during storage is needed.

Samples from the pepper and tomato field trials were analyzed using established gas chromatography with electron capture detection (GC/ECD) enforcement methods or modified versions of established enforcement methods. Pepper samples from the 1991 trial and tomato samples from the 1990 trials were analyzed for residues of lactofen and its metabolites PPG-1576, PPG-2597, PPG-847, and PPG-947 using method RM-28 (Method B of PAM Vol. II). The method was performed essentially as written for analysis of tomatoes, but was modified significantly for analysis of peppers. Samples of peppers and tomatoes from the 2003 trials were analyzed for residues of lactofen *per se* using method RM-28D-2 (rev. 8/12/03); method RM-28D is listed in the U.S. EPA Index of Pesticide Analytical Methods. The validated limits of quantitation (LOQs) were 0.01 ppm for peppers from the 1991 trial, and 0.02 ppm for samples from all other trials. The methods are adequate for data collection based on acceptable method validation and concurrent recovery data.

Residues of lactofen and metabolites were each below the LOQ (<0.01 ppm for the 1991 pepper field trials and <0.02 ppm for remaining pepper and tomato field trials) in/on all samples of



pepper and tomato harvested ~30 days following a single pre- or early post-transplant and one to two postemergence directed soil applications to row middles at ~0.5 lb ai/A/application for total seasonal application rates of ~1-1.5 lb ai/A.

No residue decline data were included in the submission; however, because residues were below the LOQ in/on all samples, these data are not required.

### **STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:**

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document DP Barcode D333151.

### **COMPLIANCE:**

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.

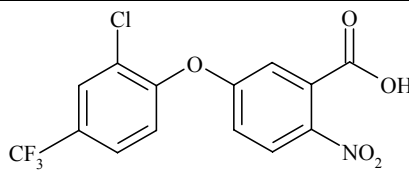
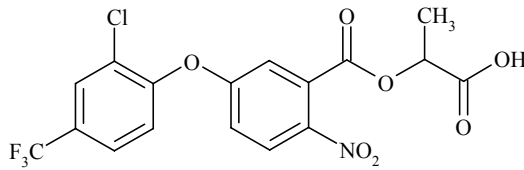
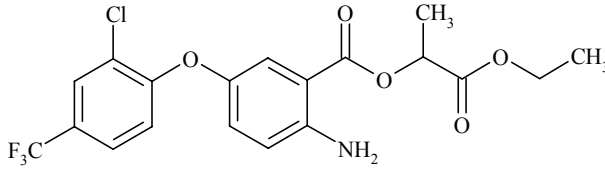
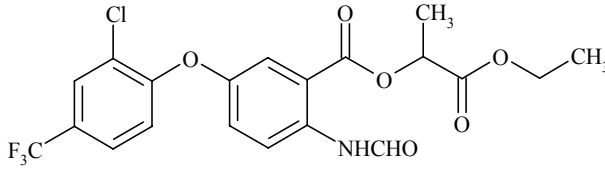
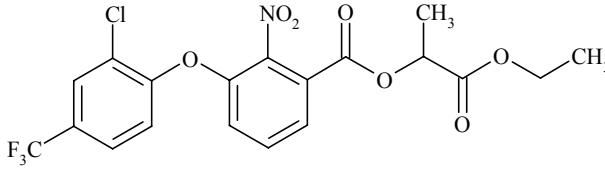
### **A. BACKGROUND INFORMATION**

Lactofen [1-(carboethoxy)ethyl-5-[2-chloro-4-(trifluoromethyl) phenoxy]-2-nitrobenzoate] is a selective contact, diphenyl ether herbicide (Group 14) that is structurally related to acifluorfen and is classified as a threshold carcinogen by EPA. Lactofen, formulated as an EC, is currently registered by Valent U.S.A. Corporation for preemergence and/or postemergence use on soybeans, snap beans, and cotton for the control of broadleaf weeds, such as nightshades, morning glories, pigweed, and ragweed. Tolerances are currently established for residues of the herbicide lactofen (1-(carboethoxy)ethyl-5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate) on snap bean, cotton seed, peanut and soybean seed at 0.01 ppm and on cotton gin products at 0.02 ppm [40 CFR §180.432(a)].

Valent has submitted a petition (PP# 5E6930) proposing the use of Cobra<sup>®</sup> herbicide (EPA Reg. No. 59639-34) on fruiting vegetables.

<b>TABLE A.1. Lactofen Nomenclature.</b>	
Chemical structure	
Common name	Lactofen
Company experimental name	PPG-844
IUPAC name	1-(carboethoxy)ethyl-5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate
CAS name	2-ethoxy-1-methyl-2-oxoethyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate
CAS registry number	77501-63-4



<b>TABLE A.1. Lactofen Nomenclature.</b>	
End-use product (EP)	2 lb/gal EC (Cobra <sup>®</sup> Herbicide; EPA Reg. No. 59639-34)
Chemical structure of acifluorfen (PPG-847)	 <p>5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoic acid</p>
Chemical structure of desethyl lactofen (PPG-947)	 <p>1-(carboxy)ethyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate</p>
Chemical structure of amino lactofen (PPG-1576)	 <p>1-(carboethoxy)ethyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-aminobenzoate</p>
Chemical structure of N-formyl lactofen (PPG-2597)	 <p>1-(carboethoxy)ethyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-formamidobenzoate</p>
Chemical structure of PPG-1530; Isomer A (internal standard)	 <p>1-(carboethoxy)ethyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-6-nitrobenzoate</p>

<b>TABLE A.2. Physicochemical Properties of Lactofen</b>		
Parameter	Value	Reference
Melting point/range	>250°C	44447003 <sup>1</sup>
pH	7.2 (on Pure Active Ingredient, 1% solution) at 25°C	44447003 <sup>1</sup>
Density (specific gravity)	1.34 at 24°C	44447003 <sup>1</sup>
Water solubility	0.97 ppm at 25°C 0.945 ± 0.131 ppm (column elution method at 20 ± 1 °C)	44447003 <sup>1</sup> 44460902 <sup>2</sup>



Parameter	Value	Reference
Solvent solubility	<u>g/100 g at 23 °C</u>	44447003 <sup>1</sup>
	kerosene 15.6 2-ethyl-1-hexanol 18.4 N-decanol 10.1 lactic acid 0.9  Lactofen is miscible at all proportions with the following solvents at -18°C or higher: DMSO, monochlorotoluene, dipropylene glycol dibenzoate, isophorone, cyclohexanone, mixed xylene, ethylene dichloride, acetone, DMF, amyl acetate, methyl isobutyl ketone.	
Vapor pressure	3.69 ± 1.73 x 10 <sup>-5</sup> Pa (2.8 x 10 <sup>-7</sup> mm Hg)	44460901 <sup>2</sup>
Dissociation constant, pK <sub>a</sub>	Not required	D241826, 1/16/98, H. Podall
Octanol/water partition coefficient, Log(K <sub>OW</sub> )	1 x 10 <sup>5</sup> at ambient temperature, estimated value	44460903 <sup>2</sup>
UV/visible absorption spectrum	In Review <sup>3</sup>	44447003 <sup>3</sup>

<sup>1</sup> RD Memorandum, D241826, 1/16/98, H. Podall.

<sup>2</sup> RD Memorandum D242241, 2/5/98, S. Mathur.

<sup>3</sup> D332587, C. Olinger, In Review.

## B. EXPERIMENTAL DESIGN

A total of three pepper trials were conducted in Zone 3 (FL) during the 1991 (one bell pepper trial) and 2003 (one bell and one nonbell pepper trial) growing seasons. A total of four tomato field trials were conducted in Zone 3 (FL) during the 1990 (three trials) and 2003 (one trial) growing seasons.

The study use pattern is detailed in Table B.1.2. For the pepper field trials, the 2 lb/gal EC formulation of lactofen was applied at each test location as one pre-transplant and one postemergence directed soil application to row middles at 0.49-0.51 lb ai/A/application for a total seasonal application rate of 0.98-1.1 lb ai/A; shielded spray equipment was used in the 2003 trials. The first applications were made one or 12 days prior to transplanting, and the second applications were made at 46- to 67-day retreatment intervals. First applications were made in spray volumes of 31-33 gal/A, and second applications were made in spray volumes of 55-59 gal/A; NIS or COC adjuvants were added to the spray mixtures for second applications. Mature peppers were harvested 30 days following the second application.

For the tomato field trials, the 2 lb/gal EC formulation of lactofen was applied at each test location as one pre- or early post-transplant application and one to two postemergence directed soil applications to row middles at ~0.5 lb ai/A/application for total seasonal application rates of 0.96 lb ai/A (2003 field trial) or 1.5 lb ai/A (1990 trials); the 2003 trial included a treatment plot with two applications at an exaggerated rate of ~2.5 lb ai/A/application for a total seasonal application rate of ~5 lb ai/A. Shielded spray equipment was used for all trials. The first applications were made one or 12 days prior to transplanting or 5 days post-transplant; second applications were made at 30- to 37-day retreatment intervals; and third applications were made at 14- to 16-day retreatment intervals. First applications were made in spray volumes of 31-34



gal/A, and second and third applications were made in spray volumes of 55-60 gal/A; NIS or COC adjuvants were added to the spray mixtures for all applications, except the pre-transplant applications at the 2003 trial. Mature tomatoes were harvested 28-30 days following the last application.

Trial site conditions are presented in Table B.1.1. The crop varieties grown are identified in Table C.3. Soil characteristics data were not provided for the trials conducted at Citra, FL. These data would generally be required because the submitted crop field trials reflect directed application to the soil. However, these data will not be required at this time because most of the relevant information is available from a reliable public source. For future submissions, the petitioner is advised that soil characteristics data must be provided for field trials reflecting applications to soil. We note that both tomato varieties used in the crop field trials produce medium to large fruits.

The petitioner provided acceptable daily, monthly, and/or historical weather data (temperature and rainfall) for all field trial sites, as well as descriptions of cultural procedures; maintenance chemicals and fertilizers used at each site were identified. Irrigation was used at all sites. The weather was reported to be normal for all field trials except the 1990 tomato field trials, where 10” of rain were received due to a tropical storm 3 days before the third application. The petitioner stated that this event was not believed to have significantly affected the results of the study.

### B.1. Study Site Information

<b>TABLE B.1.1. Trial Site Conditions.</b>				
Trial Identification (City, State; Year; Trial ID #); MRID	Soil characteristics <sup>1</sup>			
	Type	%OM	pH	CEC (meq/g)
<b>Pepper</b>				
Myakka City, FL 1991; 46531301	Fine sand	0.8	7.0	4.2
Citra, FL 2003; V25304-A; 46597202	NR [Fine sand]	NR [1%]	NR [6.4]	NR
Citra, FL 2003; V25304-B; 46597202	NR [Fine sand]	NR [1%]	NR [6.4]	NR
<b>Tomato</b>				
Immokalee, FL, 1990; T-7554; 46597203	Sand	1.8	6.8	3.8
Bradenton, FL, 1990; T-7555; 46597203	Sand	1.6	6.7	5.1
Bradenton, FL, 1990; T-7556; 46597203	Sand	1.9	7.0	5.3
Citra, FL, 2003; V-25291-A; 45697201	NR [Fine sand]	NR [1%]	NR [6.4]	NR

<sup>1</sup> NR = Not reported; these data are required because the submitted crop field trials reflect directed application to the soil. The [bracketed] information was obtained by the study reviewer from several University of FL Internet listings.



<b>TABLE B.1.2. Study Use Pattern.</b>							
Location (City, State; Year) Trial ID	EP <sup>1</sup>	Application					Tank Mix/ Adjuvants <sup>4</sup>
		Method; Timing	Volume (GPA) <sup>2</sup>	Rate (lb ai/A)	RTI <sup>3</sup> (days)	Total Rate (lb ai/A)	
<b>Pepper</b>							
Myakka City, FL 1991; 46531301	2.0 lb/gal EC	1. Directed to soil; one day before transplant	30	0.5	--	1.0	--
		2. Directed to soil; crown fruit 2" diameter; plant height 13"	60	0.5	46		NIS
Citra, FL 2003; V25304-A; 46597202	2.0 lb/gal EC	1. Directed to soil, shielded; 12 days before transplant	31	0.50	--	1.1	--
		2. Directed to soil, shielded; fruiting, small to med-small fruit	59	0.51	67		COC
Citra, FL 2003; V25304-B; 46597202	2.0 lb/gal EC	1. Directed to soil, shielded; 12 days before transplant	31	0.49	--	0.98	--
		2. Directed to soil, shielded; fruiting, small to med-small fruit	56	0.49	67		COC
<b>Tomato</b>							
Immokalee, FL, 1990; T- 7554; 46597203	2.0 lb/gal EC	1. Directed to soil; shielded; one day before transplant	34	0.5	--	1.5	NIS
		2. Directed to soil; shielded; early bloom; plant height 20-26"	60	0.5	35		NIS
		3. Directed to soil; shielded; early fruit-set; plant height 28-34"	60	0.5	14		NIS
Bradenton, FL, 1990; T-7555; 46597203	2.0 lb/gal EC	1. Directed to soil; shielded; 5 days post-transplant	32	0.5	--	1.5	NIS
		2. Directed to soil; shielded; 1 <sup>st</sup> bloom cluster open; plant height 20"	52	0.5	37		NIS
		3. Directed to soil; shielded; 1 <sup>st</sup> hand fruit 2" diam.; plant height 28"	55	0.5	16		NIS
Bradenton, FL, 1990; T-7556; 46597203	2.0 lb/gal EC	1. Directed to soil; shielded; 5 days post-transplant	32	0.5	--	1.5	NIS
		2. Directed to soil; shielded; 1 <sup>st</sup> bloom cluster open; plant height 24"	52	0.5	37		NIS
		3. Directed to soil; shielded; 1 <sup>st</sup> hand fruit 1 3/4 -2" diam.; plant height 28-30"	55	0.5	16		NIS
Citra, FL, 2003; V- 25291-A; 45697201	2.0 lb/gal EC	1. Directed to soil, shielded; 12 days before transplant	30.5	0.49	--	0.96	--
		2. Directed to soil, shielded; small green fruit; plant height 2-3'	54.6	0.47	30		COC
	2.0 lb/gal EC	1. Directed to soil, shielded; 12 days before transplant	31.3	2.50	--	4.9	--
		2. Directed to soil, shielded; small green fruit; plant height 2-3'	56.3	2.40	30		COC

<sup>1</sup> EP = End-use Product

<sup>2</sup> GPA = Gallons per acre



<sup>3</sup> RTI = Retreatment Interval

<sup>4</sup> NIS = Nonionic surfactant; COC = crop oil concentrate

NAFTA Growing Zones	Pepper			Tomato		
	Submitted	Requested <sup>1</sup>		Submitted	Requested <sup>1</sup>	
		Canada	U.S.		Canada	U.S.
1						1
1A						
2			1 (bell)			1
3	3 (2 bell and 1 non-bell)		1 (bell)	4		2
4						
5			1 (bell)			1
5A						
5B						
6			1 (bell)			
7						
7A						
8						
9						
10			2 (bell)			7
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
<b>Total</b>	<b>3</b>		<b>6 bell + 3 nonbell <sup>2</sup></b>	<b>4</b>		<b>12</b>

<sup>1</sup> As required by OPPTS 860.1500, Tables 2 and 5, for peppers and tomatoes as representative members of the fruiting vegetables crop group. The number of trials for each represents a 25% reduction due to the crop being a representative commodity used to obtain a crop group tolerance, or due to the pesticidal use resulting in no quantifiable residues.

<sup>2</sup> Specific regions are not recommended for non-bell peppers, because only 3 trials are required; however, according to Table 6 of OPPTS 860.1500, U.S. production of non-bell peppers occurs in Zones 2 (4%), 3 (3%), 5 (4%), 8 (50%), 9 (15%), and 10 (18%).

## B.2. Sample Handling and Preparation

Single control and duplicate treated samples of peppers and tomatoes were harvested from each site at commercial maturity, 28-30 days following the second or third application. For the 1990 tomato field trials, the petitioner reported that mature green tomatoes were harvested according to commercial agricultural practices. Pepper samples were placed in frozen storage at the field sites within 30 minutes of harvest. Tomato samples from the 2003 trial and green tomatoes from



the 1990 trials were placed in frozen storage at the field sites within 3.5 hours of harvest; additional samples from the Bradenton, FL sites were placed in a ripening room (temperature unspecified) immediately following harvest, and were held there for 6 days until they had been degreened; degreened tomatoes were then placed in frozen storage until shipment. Samples were shipped frozen within 1-15 days of harvest to the analytical laboratories: the Bioanalytical Laboratory; Oregon State University (Corvallis, OR) for the 1991 pepper trial; Chevron Technical Center (Richmond, CA) for the 1990 tomato trials; or Valent Technical Center (Dublin CA) for the 2003 pepper and tomato trials. Samples were stored frozen (~-20 °C) at the analytical laboratories until preparation for analysis via chopping or macerating with dry ice.

### B.3. Analytical Methodology

Samples from the pepper and tomato field trials were analyzed using established GC/ECD enforcement methods or modified versions of established enforcement methods. Pepper samples from the 1991 trial and tomato samples from the 1990 trials were analyzed for residues of lactofen and its metabolites PPG-1576, PPG-2597, PPG-847, and PPG-947 using method RM-28 (Method B of PAM Vol. II). The method was performed essentially as written for analysis of tomatoes, but was modified significantly for analysis of peppers. Modifications to the analytical method for peppers included: (1) conducting the acetonitrile (ACN):hexane partitioning earlier in the procedure; (2) separation of the acid metabolites (PPG-847 and PPG-947) from lactofen and the ester metabolites (PPG-1576 and PPG-2597) for analysis; and (3) addition of a two-column clean-up procedure for the acid metabolites. Samples of peppers and tomatoes from the 2003 trials were analyzed for residues of lactofen *per se* using method RM-28D-2 (rev. 8/12/03); method RM-28D is listed in the U.S. EPA Index of Pesticide Analytical Methods.

Using the modified version of method RM-28, samples from the 1991 pepper field trial were extracted 2x with ACN containing 1% triethylamine (TEA):hexane (2:1, v:v) and filtered, and the extracts were combined. Following phase separation, the ACN phase was extracted with two additional aliquots of hexane; all hexane phases were discarded. The ACN extract was combined with 5% NaCl solution and partitioned 3x with hexane. The resulting extracts were combined to yield an aqueous ACN extract and a hexane extract. The hexane extracts, containing lactofen and the ester metabolites, were concentrated and applied to a silica gel column for clean-up. Residues were eluted with dichloromethane (DCM):hexane (70:30, v:v), and the eluate was concentrated, combined with an internal standard mixture of CGA-1530 (lactofen Isomer A) and CGA-1827 (standard was not identified), and reserved for GC analysis. The aqueous ACN extract, containing the acid metabolites, was acidified with 6 N HCl and extracted 3x with toluene. The combined toluene extracts were applied to a basic alumina column, and residues were eluted with 1% sodium bicarbonate solution. The eluate was acidified with 6 N HCl and extracted 3x with DCM. Diazomethane was added to the combined DCM extracts to methylate the acid metabolites, and the mixture was reduced to dryness and re-dissolved in benzene, then applied to a second alumina column. Residues were eluted with benzene, concentrated, combined with the internal standard mixture, and reserved for GC analysis. Lactofen and the ester metabolites were determined using an SPB-5 column, and the acid metabolites were determined using a DB-1701 column. The validated LOQ was 0.01 ppm



(lowest limit of method validation; LLMV), and the reported limit of detection (LOD) was 0.005 ppm for lactofen and each metabolite.

Using method RM-28, samples from the 1990 tomato field trials were extracted 2x with ACN containing 1% TEA and filtered. The resulting extract was evaporated to dryness, re-dissolved in 5% NaCl solution, then partitioned with DCM (3x). The resulting DCM phases were combined, reduced to dryness, dissolved in ACN, and combined with diazomethane to methylate the acid metabolites. The methylated extract was dissolved in DCM:hexane (70:30, v:v), and applied to a silica gel column. Residues were eluted with DCM:hexane (70:30, v:v), and the eluate was concentrated, combined with an internal standard of CGA-1530 (lactofen Isomer A) in toluene, and reserved for GC analysis using a DB-5 or DB-1701 column. We note that the method included modified instructions for analysis of residues of PPG1576 alone to improve recoveries; the petitioner did not indicate whether these procedures were followed. The validated LOQ (LLMV) was 0.02 ppm, and the LOD was 0.01 ppm for lactofen and each metabolite.

Using method RM-28D-2, samples of peppers and tomatoes from the 2003 trials were extracted 2x with ethanol and filtered. The combined extracts were reduced by rotary evaporation and sonicated with ACN saturated with hexane, followed by 5% NaCl solution, and hexane. The resulting ACN:water phase was re-extracted 2x with hexane, and the hexane extracts were combined with the original hexane phase. The combined hexane phase was evaporated to dryness and redissolved in toluene:hexane (1:2, v:v), then applied to a silica gel column for clean-up. Residues were eluted with hexane:diethyl ether (60:40, v:v), and the eluate was evaporated to dryness and dissolved in toluene for analysis by GC/ECD on a DB-17 column. The validated LOQ was 0.02 ppm (LLMV), and the reported LOD was 0.01 ppm for lactofen in both matrices.

### **C. RESULTS AND DISCUSSION**

Sample storage conditions and intervals are summarized in Table C.2.1. The maximum storage intervals of samples from harvest to analysis were 60 days for peppers and 56 days for tomatoes. A freezer storage stability study was conducted in conjunction with the 1990 magnitude of the residue study on tomatoes. Untreated samples of tomato were fortified with lactofen, PPG-847, PPG-947, PPG-1576, and PPG-2597 at 0.1 ppm each, and stored frozen. Stored samples were analyzed at 0-day and following frozen storage for 32 and 68 days. Residues of lactofen, and all metabolites except PPG-1576 appeared to be relatively stable (Table C.2.2) in/on tomatoes stored frozen for up to 68 days. Residues of PPG-1576 were found to decline in tomatoes, to ~60% of original value after 68 days of storage. These data are adequate to support the storage intervals and conditions of samples from the fruiting vegetable crop field trials. Because residues of PPG-1576 were found to be below the LOD in/on all tomato samples and below the LOQ in/on all pepper samples that were analyzed for residues of PPG-1576, no correction for potential decline during storage is needed.

Method validation and concurrent recovery data are presented in Table C.1. Samples from the pepper and tomato field trials were analyzed using established GC/ECD enforcement methods or



modified versions of established enforcement methods. Pepper samples from the 1991 trial and tomato samples from the 1990 trials were analyzed for residues of lactofen and its metabolites PPG-1576, PPG-2597, PPG-847, and PPG-947 using method RM-28 (Method B of PAM Vol. II). The method was performed essentially as written for analysis of tomatoes, but was modified significantly for analysis of peppers. Samples of peppers and tomatoes from the 2003 trials were analyzed for residues of lactofen *per se* using method RM-28D-2 (rev. 8/12/03); method RM-28D is listed in the U.S. EPA Index of Pesticide Analytical Methods. The validated LOQ and LOD were 0.01 ppm and 0.005 ppm, respectively, for peppers from the 1991 trial, and 0.02 ppm and 0.01 ppm, respectively, for samples from all other trials. The methods are adequate for data collection based on acceptable method validation and concurrent recovery data. Method validation was conducted for method RM-28D-2 using tomato during method development; recoveries were 103-104% for tomato fortified at 0.02 ppm. Concurrent recoveries of lactofen ranged 90-93% for pepper fortified at 0.01 ppm and 93-117% for pepper and tomato fortified at 0.02 ppm. Recoveries of the lactofen metabolites ranged 73-114% from samples of pepper fortified at 0.01 ppm and tomato fortified at 0.02 ppm. Apparent residues of lactofen and metabolites were nondetectable in/on all samples of untreated pepper and tomato.

The results of the fruiting vegetable crop field trials are reported in Table C.3. A summary of the residue data is presented in Table C.4. Residues of lactofen and metabolites were each below the LOQ (<0.01 ppm for the 1991 pepper field trials and <0.02 ppm for remaining pepper and tomato field trials) in/on all samples of pepper and tomato harvested ~30 days following a single pre- or early post-transplant and one to two postemergence directed soil applications to row middles at ~0.5 lb ai/A/application for total seasonal application rates of ~1-1.5 lb ai/A.

No residue decline data were included in the submission; however, because residues were below the LOQ in/on all samples, these data are not required.

<b>TABLE C.1. Summary of Method Validation and Concurrent Recoveries of Lactofen Residues from Pepper and Tomato.</b>					
Matrix (Method)	Analyte	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± std dev (%) <sup>1</sup>
<b>Method validation</b>					
Tomato <sup>2</sup> (RM-28D-2; DB-17 column)	Lactofen	0.02	3	103, 105, 105	104 ± 1
Tomato (RM-28D-2; DB-5 column)	Lactofen	0.02	3	101, 103, 104	103 ± 2
<b>Concurrent recovery</b>					
Pepper (RM-28)	Lactofen	0.01	2	90, 93	92
	PPG-847	0.01	1	97	--
	PPG-947	0.01	1	107	--
	PPG-1576	0.01	2	81, 86	84
	PPG-2597	0.01	2	100, 114	107
Pepper (RM-28D-2)	Lactofen	0.02	2	103, 117	110
		0.1	2	98, 108	103



**TABLE C.1. Summary of Method Validation and Concurrent Recoveries of Lactofen Residues from Pepper and Tomato.**

Matrix (Method)	Analyte	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± std dev (%) <sup>1</sup>
Tomato <sup>2</sup> (RM-28)	Lactofen	0.02	5	93, 93, 95, 96, 100	95 ± 3
	PPG-847	0.02	5	89, 99, 104, 106, 113	102 ± 9
	PPG-947	0.02	5	97, 98, 102, 104, 105	101 ± 4
	PPG-1576	0.02	5	73, 75, 75, 78, 86	77 ± 5
	PPG-2597	0.02	5	76, 81, 87, 89, 93	85 ± 7
Tomato (RM-28D-2)	Lactofen	0.02	2	108, 112	110
		0.10	1	87	--

<sup>1</sup> Standard deviations were only calculated for samples sizes ≥3.

<sup>2</sup> Including green and greened tomatoes.

**TABLE C.2. Summary of Storage Conditions.**

Matrix	Storage Temperature (°C)	Actual Storage Duration <sup>1</sup> (days)	Interval of Demonstrated Storage Stability
Pepper	-20	39-60	Residues of lactofen and metabolites were relatively stable in/on tomato stored frozen for up to 68 days
Tomato	-20	22-56	

<sup>1</sup> Interval from harvest to analysis; samples were analyzed within 2-9 days of extraction.

**TABLE C.2.2 Stability of Lactofen Residues in Frozen Tomatoes.**

Analyte	Spike Level (ppm)	Storage interval (days)	Freshly Fortified Recovery (%)	Stored Sample Residues (%) [Average]	Average Corrected Stored Recovery (%) <sup>1</sup>
Lactofen	0.1	0	101	97, 102 [100]	99
		32	96	91, 95 [93]	97
		68	101	79, 86 [83]	82
PPG-847	0.1	0	109	119, 121 [120]	110
		32	110	103, 109 [106]	96
		68	121	97, 101 [99]	82
PPG-947	0.1	0	101	99, 100 [100]	99
		32	94	91, 98 [95]	95
		68	107	89, 97 [93]	87
PPG-1576	0.1	0	55	55, 57 [56]	102
		32	92	69, 73 [72]	78
		68	86	48, 52 [50]	58
PPG-2597	0.1	0	94	88, 94 [91]	97
		32	76	70, 73 [72]	95
		68	96	85, 89 [87]	91

<sup>1</sup> Residues were corrected for recovery from freshly fortified samples.



Trial ID (City, State; Year); MRID	Zone	Variety	Commodity or Matrix	Total Rate (lb ai/A)	PHI (days)	Residues (ppm) <sup>1</sup>				
						Lactofen	PPG-847	PPG-947	PPG-1576	PPG-2597
<b>Pepper</b>										
Myakka City, FL 1991; 46531301	3	Memphis	Bell pepper	1.0	30	<0.01, <0.01	<0.01, <0.01	<0.01, <0.01	<0.01, <0.01	<0.01, <0.01
Citra, FL 2003; V25304-A; 46597202	3	Camelot	Bell pepper	1.1	30	ND, ND	NA	NA	NA	NA
Citra, FL 2003; V25304-B; 46597202	3	Hot Beauty	Nonbell Pepper	0.98	30	ND, ND	NA	NA	NA	NA
<b>Tomato</b>										
Immokalee, FL, 1990; T-7554; 46597203	3	Solar Set	Tomato (green)	1.5	28	ND, ND	ND, ND	ND, ND	ND, ND	ND, ND
Bradenton, FL, 1990; T-7555; 46597203	3	Solar Set	Tomato (green)	1.5	30	ND, ND	ND, ND	ND, ND	ND, ND	ND, ND
			Tomato (degreened)			ND, ND	ND, ND	ND, ND	ND, ND	ND, ND
Bradenton, FL, 1990; T-7556; 46597203	3	Sunny	Tomato (green)	1.5	30	ND, ND	ND, ND	ND, ND	ND, ND	ND, ND
			Tomato (degreened)			ND, ND	ND, ND	ND, ND	ND, ND	ND, ND
Citra, FL, 2003; V-25291-A; 46597203	3	FLA47	Tomato	0.96	30	ND, ND	NA	NA	NA	NA
				4.9	30	ND, ND	NA	NA	NA	NA

<sup>1</sup> ND = Nondetectable. NA = Not analyzed. The reported LOQs were 0.01 ppm for the 1991 pepper field trial, and 0.02 ppm for all other field trials, and the reported LODs were 0.003 ppm for the 1991 pepper field trial, and 0.01 ppm for all other trials; we note that values were reported by the petitioner as <0.01 ppm for all samples analyzed.

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm) <sup>1</sup>							
			n	Min.	Max.	HAFT <sup>2</sup>	Median (STMdR)	Mean (STMR)	Std. Dev.	
<b>Lactofen</b>										
Pepper	0.98-1.1	30	6	<0.01	<0.02	<0.02	<0.02	<0.01	<0.01	0.0
Tomato	0.96	28-30	2	<0.02	<0.02	<0.02	<0.02	<0.01	<0.01	0.0
	1.5	30	10	<0.02	<0.02	<0.02	<0.02	<0.01	<0.01	0.0
	4.9	30	2	<0.02	<0.02	<0.02	<0.02	<0.01	<0.01	0.0

<sup>1</sup> The reported LOQs were 0.01 ppm for the 1991 pepper field trial, and 0.02 ppm for all other field trials. For calculation of the median, mean, and standard deviation, a value of 0.01 ppm (½ the LOQ for the majority of residue results) was used for samples with residues <LOQ.

<sup>2</sup> HAFT = Highest Average Field Trial.

## D. CONCLUSION

The submitted field trial data are adequate and reflect a single pre- or early post-transplant and one to two postemergence directed soil applications to row middles at ~0.5 lb ai/A/application



for a total seasonal application rate of ~1-1.5 lb ai/A. Residues were below the LOQ in/on samples of mature peppers and tomatoes harvested ~30 days following the last application. Acceptable methods were used for quantitation of residues in/on peppers and tomatoes, and the data are supported by acceptable storage stability data.

## E. REFERENCES

DP Barcode: RD D241826  
Subject: TGAI Product Chemistry Review/Action: 345. Reg. File Symbol No.: 59639-94. Chemical: Lactofen—76.7% pure. Company: Valent U.S.A. Corp.  
From: H. Podall  
To: S. Stanton  
Date: 1/16/98  
MRIDs: 44447001-44447003

DP Barcode: RD D242241  
Subject: Product Chemistry Review of TGAI. Reg./File Symbol No.: 59639-94. Product Name: Lactofen Technical.  
From: S. Mathur  
To: J. Miller  
Date: 2/5/98  
MRIDs: 44460901-44460903

## F. DOCUMENT TRACKING

RDI: Colinger (10/16/06)  
Petition Number(s): 5E6930  
DP Barcode(s): D333151  
PC Code: 128888

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