

#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

May 4, 2000

### MEMORANDUM

Subject:	Tolerance Reassessment of <b>Lactofen</b> : Product and Residue Chemistry Considerations; PC Code: 128888; DP Barcode: D263857
From:	Christine L. Olinger, Chemist Reregistration Branch I Health Effects Division (7509C)
Through:	Whang Phang, Ph.D., Branch Senior Scientist Reregistration Branch I Health Effects Division (7509C)
	and
	William J. Hazel, Ph.D., Chemist Reregistration Branch I Health Effects Division (7509C)
То:	Susan Stanton Herbicide Branch Registration Division (7503C) and
	Christina Scheltema, Chemical Review Manager Reregistration Branch 3 Special Review and Reregistration Division (7508W)

Attached are product chemistry and residue chemistry considerations for the tolerance reassessment of the herbicide lactofen. Reregistration is not yet required as it was registered after 1984. The following studies remain as data gaps:

- ! The following physical/chemical properties studies are required for the for the 76%T (EPA Reg. No. 59639-94): 830.6317, 830.6320, 830.7050, and 830.7100.
- Interpretation of the following physical/chemical properties studies are required for the for the 60% FI (EPA Reg. No. 59639-70): 830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.7000, 830.7050, 830.7100, 830.7200, 830.7220, and 830.7300. These data are required because the product composition has changed significantly as a result of a change in the manufacturing process.
- ! Confined Rotational Crop Study (860.1850)

cc:CLOlinger (RRB1), Reg Std. File 7509C:RRB1:CLOlinger:clo:CM#2:Rm 722J:305-5406: 4/27/00 RDI: VDobozy: 5/1/00; ChemSAC 4/26/00 PC Code 128888

Case Name: Lactofen Registrant: Valent U.S.A. Corporation Product(s): 76.7% T (EPA Reg. No. 59639-94)

PRODUCT	CHEMISTRY	DATA	SUMMARY
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		SUMMARI	
Guideline Number	Requirement	Are Data Requirements Fulfilled? <sup>1</sup>	MRID Number <sup>2</sup>
830.1550	Product identity and composition	Y	44447001
830.1600	Description of materials used to produce the product	Y	44447001
830.1620	Description of production process	Y	44447001
830.1670	Discussion of formation of impurities	Y	44447001
830.1700	Preliminary analysis	Y	44447002
830.1750	Certified limits	Y	44447002, CSF 9/25/97
830.1800	Enforcement analytical method	Y	44447002
830.6302	Color	Y	44447003
830.6303	Physical state	Y	44447003
830.6304	Odor	Y	44447003
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	44447003
830.6314	Oxidation/reduction: chemical incompatability	N/A <sup>3</sup>	
830.6315	Flammability	Y	44447003
830.6316	Explodability	N/A <sup>3</sup>	
830.6317	Storage stability	Ν	
830.6319	Miscibility	N/A <sup>3</sup>	
830.6320	Corrosion characteristics	Ν	
830.7000	рН	Y	44447003
830.7050	UV/Visible absorption	N $^4$	
830.7100	Viscosity	Ν	
830.7200	Melting point/melting range	N/A <sup>5</sup>	44447003
830.7220	Boiling point/boiling range	Y	44447003
830.7300	Density/relative density/bulk density	Y	44447003
830.7370	Dissociation constants in water	Y	PP#5F3299 6
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	PP#5F3299 <sup>6</sup>
830.7840	Water solubility: column elution method; shake flask method	Y	<b>44447003</b> , 44460902 <sup>7</sup> , 44460903 <sup>7</sup>
830.7950	Vapor pressure	Y	44460901 7

 $^{1}$  Y = Yes; N = No; N/A = Not Applicable. The database summarized above reflects amended registration in support of a change in the product composition resulting from a new manufacturing process. These data supercede all previously submitted product chemistry data, which reflected use of a different manufacturing process. Based on these data, the manufacturing process for the technical product differs significantly from the manufacturing process for the 60% FI (EPA Reg. No. 59639-70). In addition we note, that although REFS identifies this product as a 71.7% formulation, it is correctly identified as a 76.7% formulation. <sup>2</sup> **Bolded** references were reviewed by the Registration Division under D241826, 1/16/98, H. Podall and D242411, 1/22/98, A. Smith; and all other references were reviewed as noted.

<sup>3</sup> Data are not required according to RD Memorandum D241826, 1/16/98, H. Podall.

<sup>4</sup> The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

<sup>5</sup> Data are not required because the TGAI is a liquid at room temperature.

<sup>6</sup> PP#5F3299, CB No. 1492, 12/27/85, M. Firestone; physical/chemical data for the PAI.

<sup>7</sup> RD Memorandum, D242241, 2/5/98, S. Mathur.

PC Code 128888

Case Name: Lactofen Registrant: Valent U.S.A. Corporation Product(s): 60% FI (EPA Reg. No. 59639-70)

#### PRODUCT CHEMISTRY DATA SUMMARY

		Are Data	
Guideline		Requirements	
Number	Requirement	Fulfilled? <sup>1</sup>	MRID Number <sup>2</sup>
830.1550	Product identity and composition	Y	<b>43303501</b> , 43712901 <sup>3</sup>
830.1600	Description of materials used to produce the product	Y	<b>43303501</b> , 43712901 <sup>3</sup>
830.1620	Description of production process	Y	<b>43303501</b> , 43712901 <sup>3</sup>
830.1670	Discussion of formation of impurities	Y	<b>43303501</b> , 43712901 <sup>3</sup>
830.1700	Preliminary analysis	Y	<b>43303502</b> , 43712902 <sup>3</sup>
830.1750	Certified limits	Y	<b>43303502</b> , 43712902 <sup>3</sup> , CSF 7/6/95 <sup>3</sup>
830.1800	Enforcement analytical method	Y	<b>43303502</b> , 43712902 <sup>3</sup>
830.6302	Color	N $^4$	
830.6303	Physical state	N $^4$	
830.6304	Odor	N <sup>4</sup>	
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	N <sup>4</sup>	
830.6314	Oxidation/reduction: chemical incompatability	N <sup>4</sup>	
830.6315	Flammability	N $^4$	
830.6316	Explodability	N $^4$	
830.6317	Storage stability	N $^4$	
830.6319	Miscibility	N $^4$	
830.6320	Corrosion characteristics	N $^4$	
830.7000	pH	N <sup>4</sup>	
830.7050	UV/Visible absorption	N <sup>5</sup>	
830.7100	Viscosity	N $^4$	
830.7200	Melting point/melting range	N $^4$	
830.7220	Boiling point/boiling range	N $^4$	
830.7300	Density/relative density/bulk density	N $^4$	
830.7370	Dissociation constants in water	Y	PP#5F3299 <sup>6</sup>
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	PP#5F3299 <sup>6</sup>
830.7840	Water solubility: column elution method; shake flask method	N <sup>4</sup>	
830.7950	Vapor pressure	Y	PP#5F3299 6

 $^{1}$  Y = Yes; N = No; N/A = Not Applicable. The database summarized above reflects amended registration in support of a change in the product composition resulting from a new manufacturing process. These data supercede all previously submitted product chemistry data, which reflected use of the original manufacturing process. We note that, based on these data, the manufacturing process for the FI differs significantly from the manufacturing process for the 76.7% T (EPA Reg. No. 59639-94). <sup>2</sup> **Bolded** references were reviewed under CBTS No. 14171, D206354, 11/1/94, G. Otakie; and all other references were reviewed as noted.

<sup>3</sup> RD Memorandum, D217832, 8/14/95, S. Mathur.

<sup>4</sup> Because the product composition has changed significantly as a result of the change in the manufacturing process, updated data pertaining to the physical and chemical characteristics of the TGAI and MP are required.

<sup>5</sup> The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

<sup>6</sup> PP#5F3299, CB No. 1492, 12/27/85, M. Firestone; physical/chemical data for the PAI.

Agency	Memoranda	Citations
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Date	DP Barcode	CB No.	From	То	MRID Nos.	Subject
12/27/85	None	1492	M. Firestone	R. Mountfort and Toxicology Branch	Acc. Nos. 073855, 073853, 073843, and 073858	PP#5F3299 - Lactofen (Cobra) Herbicide on Soybeans. Evaluation of Analytical Methods and Residue Data.
11/1/94	D206354	14171	G. Otakie	J. Miller	43303501, 43303502	PP#8F3978 - Lactofen Manufacturing Concentrate - Evaluation of Product Chemistry Data/Change in Manufacturing Process.
8/10/95	D217832	None	S. Mathur	J. Miller	43712901, 43712902	Product Chemistry Review of MP; Reg./File Symbol No.: 59639-70; Product Name: Lactofen Manufacturing Concentrate (RD Memorandum).
1/16/98	D241826	None	H. Podall	S. Stanton	44447001-44447003	TGAI Product Chemistry Review/Action: 345; Reg. File Symbol No.: 59639-94; Chemical: Lactofen–76.7% pure; Company: Valent U.S.A. Corp. (RD Memorandum).
1/22/98	D242411	None	A. Smith	S. Stanton	44447001-44447003	Product Chemistry Review of Lactofen Technical (RD Memorandum).
2/5/98	D242241	None	S. Mathur	J. Miller	44460901-44460903	Product Chemistry Review of TGAI; Reg./File Symbol No.: 59639-94; Product Name: Lactofen Technical (RD Memorandum).

# LACTOFEN PC Code 128888 DP Barcode 263857

# Tolerance Reassessment Eligibility Decision Residue Chemistry Considerations

March 3, 2000

Contract No. 68-W-99-053

Submitted to: U.S. Environmental Protection Agency Arlington, VA

> Submitted by: Dynamac Corporation 1910 Sedwick Road Building 100, Suite B Durham, NC 27713

# LACTOFEN

## TOLERANCE REASSESSEMENT ELIGIBILITY DECISION

## **RESIDUE CHEMISTRY CONSIDERATIONS**

### PC Code 128888

## (DP BARCODE D263857)

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# LACTOFEN

#### TOLERANCE REASSESSMENT ELIGIBILITY DOCUMENT

#### **RESIDUE CHEMISTRY CONSIDERATIONS**

#### PC Code 128888

#### A. INTRODUCTION

Lactofen [1-(carboethoxy)ethyl-5-[2-chloro-4-(trifluoromethyl) phenoxy]-2-nitrobenzoate] is a selective contact, diphenyl ether herbicide that is structurally related to acifluorfen and is classified as a B2 carcinogen. Lactofen, formulated as an emulsifiable concentrate (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. Two pesticide petitions for establishing permanent tolerances for lactofen residues in/on cotton (PP#9F3798) and peanut (PP#8F3591) commodities are currently under consideration by the Agency. A request for a Section 18 Emergency Exemption for use of lactofen on tomatoes has also been previously considered by the Agency (DP Barcodes D194843 and D195248, N. Dodd, 9/29/93); however, no pesticide petition for use on tomatoes has been submitted.

The nature of the residue in plants is adequately understood based on plant metabolism studies on cotton, peanut, soybean, and tomato. Currently the tolerance expression for plant commodities includes the parent compound and metabolites that contain the diphenyl ether moiety. The HED Metabolism Assessment Review Committee (MARC) met on April 4, 2000, considered all of the metabolism studies submitted to date (including the subject study) and concluded that only the parent compound needs to0 be regulated for plant commodities, provided that pre-harvest intervals exceed 45 days. Based on goat and hen metabolism studies, lactofen residues in animals have been tentatively determined to include PPG-2838 in addition to parent and the four diphenyl ether metabolites currently regulated in plants (DP Barcode D195308 and D208336, G. Otakie, 2/2/95; and C. Olinger, 4/26/00). At this time tolerances for livestock and processed commodities are not needed.

#### **B. USE PATTERN SUMMARY**

### 1. Product List

A search of the Agency's Reference Files System (REFS) on 2/11/00 indicates that there are two lactofen end-use products (EPs) registered to Valent U.S.A. Corporation that have uses on food and/or feed crops (Table 1). The 2.4 lb/gal EC formulation of lactofen (EPA Reg. No. 59639-92) is a

multiple active ingredient (MAI) product, which contains 0.7 lb/gal of flumiclorac pentyl ester in addition to lactofen.

There are eight SLN Labels associated with the 2 lb/gal EC: two for use on succulent beans (SLN Nos. NM980003 and TX980006); three that are for non-food/non-feed uses (SLN Nos. AR960005, FL890032 and MS960001); and three (SLN Nos. IA890002, TX930007, and TX960001) that are listed in REFS as non-food/non-feed uses, but which are for use on soybeans or cotton. The one SLN label (MO960009) associated with the 2.4 lb/gal EC is also listed as a non-food/feed use, but is for the use of this product in tank mixes.

	Label Acceptance	Formulation	
EPA Reg No.	Date	Class	Product Name
59639-34 ª	9/99	2 lb/gal EC	Cobra <sup>®</sup> Herbicide
59639-92 <sup>b</sup>	11/99	2.4 lb/gal EC	Stellar <sup>®</sup> Herbicide

Table 1. Lactofen EPs with Uses on Feed/Food Crops Registered to Valent U.S.A. Corporation

<sup>a</sup> Includes SLNs for food/feed uses on succulent beans (SLN Nos. NM980003 and TX980006) along with non-food/feed uses (SLN Nos. AR960005, FL890032, IA890002, MS960001, TX930007, and TX960001).

<sup>b</sup> This EP is a multiple active ingredient (MAI) product that contains 0.7 lb/gal of flumiclorac pentyl ester in addition to 2.4 lb/gal of lactofen; Includes SLN No. MO960009 for a non-food/feed use.

## 2. Use Pattern Table

A comprehensive summary of the registered use patterns of lactofen, based on the product labels registered to Valent U.S.A., is presented in Table 2. A tabular summary of the residue chemistry science assessments for reregistration of lactofen is presented in Table 3. The conclusions listed in Table 3 regarding the tolerance reassessment eligibility are based on the use patterns registered by the basic producer, Valent U.S.A. Corporation. 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 producers labels.

A review of the above EP labels and the supporting residue data indicate that the following label amendment is required:

The use directions for cotton on the label for the 2 lb/gal EC (EPA Reg. No. 59639-34) are unclear on the maximum number of applications allowed per season. One section of the label states that "Cobra Herbicide may <u>also</u> be applied as a layby application", while Table 1C of the use directions implies that the product may be applied to cotton when plants are \$6 inches tall <u>or</u> at layby when plants are \$12 inches tall. The label must be amended to specify a maximum seasonal

application rate. The available cotton field trial data support a maximum of two applications per season, totaling 0.4 lb ai/A.

Site Application Type <sup>a</sup> Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ai/A)	Max. # Apps./seaso n	Minimum Retreatment Interval (Days)	Use Limitations <sup>b, c</sup>
Cotton Postemergence directed ground applications to plants at least 6 inches in height Ground equipment	2 lb/gal EC [59639-34]	0.2	2 <sup>d</sup>	Not specified (NS)	A 70-day PHI is specified. Applications may include crop oil concentrate at up to 2 pt/A or a non-ionic surfactant at 2 pt/100 gal of spray solution. A maximum seasonal application rate is not specified. Do not graze animals on forage or stubble or utilize hay or straw for animal feed or bedding.
Peanuts (Use pattern proposed under Broadcast applications at cracking (preemergence) and at 6-leaf stage (postemergence) Ground equipment	er PP#8F3591) 2 lb/gal EC [59639-34]	0.25 + 0.20	2	NS	A 90-day PHI is proposed, along with a restriction on the feeding of treated vine or hay to livestock.
Soybeans Broadcast and banded, pre- and postemergence applications Ground or aerial equipment	2 lb/gal EC [59639-34]	0.3 - preemergence 0.2 - postemergence	2	NS	Do not apply within 45 days of harvest or after growth stage R6 (full seed); 90-day PHI is specified in NY. Do not graze animals on forage or stubble or utilize hay or straw for animal feed or bedding. Do not apply more than 0.3 lb ai/A preemergence per season and more than a total of 0.4 lb ai/A/season. (0.2 lb ai/A/season in NY) Minimum application volumes of 5 and 10 gal/A are specified for aerial and ground applications, respectively. Applications may include 0.125-2% (v/v) of a crop oil concentrate or 0.25% of a non-ionic surfactant.

Table 2.Food/Feed Use Patterns Subject To Reregistration for Lactofen (PC Code 128888).

#### Table 2.(continued).

Site Application Type <sup>a</sup> Application Timing Application Equipment Soybeans (continued)	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ai/A)	Max. # Apps./seaso n	Minimum Retreatment Interval (Days)	Use Limitations <sup>b, c</sup>
Postemergence broadcast or banded applications Ground equipment	2.4 lb/gal EC [59639-92]	0.13	2	NS	A 60-day PHI is specified. Do not graze animals on forage or stubble or utilize hay or straw for animal feed or bedding. Do not apply more than 0.13 lb ai/A/application and more than 0.19 lb ai/A/season. A minimum application volume of 15 gal/A is specified. Applications may include 1-2 pts./A of crop oil concentrate or methylated seed oil. Do not apply by air.
Snap beans (in OR and TN only)					
Preemergence broadcast application within 48 hours of planting. Ground equipment	2 lb/gal EC [59639-34]	0.22 - OR 0.25 - TN	1	NA	Restricted to use in OR and TN. A 55-day PHI is specified. Apply no later than 48 hours after planting. Apply only one application per season, and do not apply to soils with high sand contents (sandy loams, loamy sands, and gravelly sandy loams)

<sup>a</sup> For banded applications, reduce the application volume and the broadcast rate in proportion to the area actually being treated.

<sup>b</sup> Labels for both the 2 and 2.4 lb/gal ECs include the following general restrictions: (1) a restricted entry interval of 12 hours; and (2) do not apply through any type of irrigation system.

<sup>c</sup> The label for Stellar<sup>®</sup> has the following rotational crop restrictions: do not rotate to crops other than soybeans or field corn within 30 days of the last application, and do not rotate to small grains for a least 120 days after the last application.

<sup>d</sup> A maximum of 2 applications/season is implied for the use on cotton; however, the label directions are unclear.

# C. SUMMARY OF RESIDUE CHEMISTRY DATA REQUIREMENTS

Guideline No.	Guideline Description / Commodity	§180.432 Tolerances (ppm)	Must Additional Data Be Submitted?	MRID Nos.	Comments
860.1200	Directions for Use	NA	Yes		Use directions for cotton must be amended.
860.1300	Nature of the Residue - Plants	NA	No	40436601 40436606 41297601 42508101 44166701 44411701	Adequate studies are available on soybean, peanuts, and tomatoes.
860.1300	Nature of the Residue - Animals	NA	No	41709501 41709502 42183001 43095001 43095002	Ruminant and poultry studies are adequate.
860.1340	Residue Analytical Method				
	Plant commodities	NA	No	40059402 40436603 41297604 42925301 44176601 44514701	An adequate GC/ECD method (RM-28D) is available for determining residues in plant commodities.
	Animal commodities	NA	No	42183003 42925301	An adequate GC/ECD method (RM-28C) is available for determining residues in animal commodities.
860.1360	Multi-Residue Method	NA	No	40026603 41297604 42183004	
860.1380	Storage Stability Data	NA	No	41297603 42925301 43379201 44194301 44411901	Crop field trials and processing studies are supported by adequate storage stability data.
860.1400	Magnitude of the Residue - Water, Fish, and Irrigated Crops	NA	NA		
860.1460	Magnitude of the Residue - Food Handling	NA	NA		
860.1480	Magnitude of the Residue - Meat, Milk, Poultry, Eggs	None	No	42263801 42925301	Tolerances are not required for residues in livestock commodities.

## Table 3. Summary of Residue Chemistry Data Requirements for Lactofen (PC Code 128888).

(continued)

# Table 3.Continued.

Guideline No.	Guideline Description / Commodity	§180.432 Tolerances	Must Additional Data Be Submitted?	MRID Nos.	Comments
860.1500	Crop Field Trials	(ppm)	Be Sublitted?	MIKID NOS.	Comments
800.1300	1				
	<u>Legume Vegetables Crop Group</u> Soybean	0.05	No	42934501 43638601	Residues of each analyte are <0.01 ppm in soybeans from 1x and 5x treatments.
	Bean, snap	0.05	No	43379201	Residues of each analyte are <0.01 ppm in snap beans from a 2x treatment.
860.1500	Miscellaneous Commodities				
	Cottonseed	0.05 (expired)	No	41069801 42494901	Residues of each analyte are <0.01 ppm in cottonseed from 1x and 2x treatments.
	Cotton gin byproducts	None	No	41709503 44411901	In gin trash from a 1x treatment, residues of lactofen <i>per se</i> are <0.01-0.03 ppm, and residues of each metabolite are <0.01ppm.
	Peanuts	None	No	40436604 41297602 42508102	Residues of each analyte are <0.01 ppm in peanut nutmeats from 1x and 3x treatments.
860.1520	Processed Food/Feed				
	Cottonseed		No	41209101 41709503	Residues do not concentrate in cottonseed processed commodities.
	Peanut		No	40436605 42508103	Residues do not concentrate in soybean processed commodities.
	Soybean		No	42934501 43638602	Residues do not concentrate appreciably in soybean processed commodities.
860.1850	Confined Accumulation in Rotational Crops	None	Yes	00117578 00117580	
860.1900	Field Accumulation in Rotational Crops	None	Reserved	00117579	

#### **D. RESIDUE CHARACTERIZATION**

#### **General Discussion on Residue Chemistry of Lactofen**

#### 1. Nature of the Residue in Plants

Adequate studies are available depicting the metabolism of [<sup>14</sup>C]lactofen in soybeans, peanuts, and tomatoes. Although the quantities of individual metabolites vary between crops, the data indicate that the metabolic pathway is similar between crops. The metabolism of lactofen initially involves reduction of the nitro group to an amino group, with or without loss of the ethyl ester side chains to form the preliminary diphenyl ether metabolites: amino lactofen (PPG-1576), N-formyl lactofen (PPG-2597), desethyl lactofen (PPG-947), acifluorfen (PPG-847), and amino acifluorfen (PPG-2053). Subsequent conjugation of these primary metabolites through their carboxyl and amino groups results in the formation of complex soluble and insoluble polar components. Data from the recent peanut metabolism study indicates that following formation of acifluorfen, the diphenyl ether bond may be cleaved in a glutathione-mediated reaction to form a glutathione conjugate with the 2-nitrobenzoic acid moiety. Subsequent degradation of the glutathione moiety to cysteine forms S-(carboxy-4-nitrophenyl)cysteine (CNPC), which was the most abundant metabolite detected in peanut hay. Free and conjugated 5-hydroxy-2-nitrobenzoic acid (HNBA) detected in nutmeats and hay may result from either loss of the cysteine moiety or from direct cleavage of the acifluorfen metabolite. The chemical names and structure of the lactofen residues of concern in plants and animals are presented in Figure 1.

In tomatoes, total radioactive residues (TRRs) were low (0.002 ppm) in/on ripe tomatoes harvested 25 days following the last of four soil-directed applications of [<sup>14</sup>C]lactofen totaling 1.5 lb ai/A (2.5x). <sup>14</sup>C-Residues were higher in/on ripe tomatoes (0.082 ppm) and foliage (1.389 ppm) from the same plants that were directly exposed to the spray treatment; however, these fruits and leaves also showed signs of severe phytotoxicity. Analysis of damaged fruit directly exposed to the spray treatment detected lactofen (5.5% TRR, 0.005 ppm) and N-formyl lactofen (2.9% TRR, 0.002 ppm), along with trace amounts (#1.4% TRR, #0.001 ppm) of amino CTBL, desethyl lactofen, and amino NCTBA; but the majority of <sup>14</sup>C-residues were characterized as being comprised of unknown polar compounds (42.6% TRR, 0.035 ppm). The metabolite profile in/on sprayed foliage was similar. As in fruit, the majority of solvent extractable <sup>14</sup>C-residues were comprised of unknown polar compounds (48.8% TRR, 0.679 ppm). The principal <sup>14</sup>C-residues identified in foliage were lactofen (7.6% TRR, 0.106 ppm) and N-formyl lactofen (4.3% TRR, 0.059 ppm), along with trace amounts (#2.0% TRR, 0.106 ppm) of amino CTBL, desethyl lactofen (4.3% TRR, 0.059 ppm).

In the most recent peanut metabolism study, TRRs were 0.046 and 0.216 ppm in/on peanut nutmeats and hay, respectively, harvested at maturity (127 days post-treatment) following two early-season broadcast applications of [<sup>14</sup>C]lactofen at -2x the proposed seasonal rate. The majority of <sup>14</sup>C-residues in nutmeats (70% TRR, 0.034 ppm) were characterized as unknown polar components,

with the largest single fraction accounting for 27.6% of the TRR (0.012 ppm). Minor amounts of conjugated HNBA (7.3% TRR) and CNPC (8.4% TRR) were detected in nutmeats, but lactofen and its diphenyl ether metabolites were not detected (<0.001 ppm). However in peanut hay, trace amounts of lactofen (0.8% TRR) were detected along with minor amounts of the following diphenyl ether metabolites: N-formyl lactofen (0.4% TRR), desethyl lactofen (0.7% TRR), acifluorfen (3.6% TRR) and amino acifluorfen (0.5% TRR). The principal <sup>14</sup>C-residue identified in hay was CNPC which accounted for 25.1% of the TRR (0.056 ppm). Minor levels of HNBA (4.4% TRR) and S-(carboxy-4-nitrophenyl) glutathione (CNPG; 1.2% TRR) were also identified in peanut hay. As in nutmeats, unknown polar components accounted for a largest portion of the <sup>14</sup>C-residues in hay (40.7% TRR, 0.090 ppm), although individual polar components or fractions each accounted for #8.9% of the TRR (0.020 ppm).

In a soybean metabolism study conducted at rates ranging from 0.5x to 1.25x, residues of lactofen, acifluorfen, amino lactofen, N-formyl lactofen, and desethyl lactofen were less than 0.01 ppm at preharvest intervals reflecting the registered use. Residues were generally non-detectable at a limit of quantitation of 0.005 ppm, with the exception of amino lactofen. One study showed residues of approximately 0.008 ppm at a preharvest interval of 89 days. Percent of total radioactive residue could not be determined from the information presented in the review or the study.

The current tolerance expression includes lactofen and metabolites containing the diphenyl ether linkage. Specifically, the enforcement method is capable of analyzing lactofen, acifluorfen, des-ethyl lactofen, amino lactofen, and N-formyl lactofen. The HED Metabolism Assessment Review Committee (MARC) met on April 4, 2000 to discuss the metabolism of lactofen in plants and livestock. The MARC concluded that only the parent compound need be included in the tolerance expression and risk assessment for plant commodities, assuming the pre-harvest interval is 45 days or greater (C. Olinger, 4/26/00, D265469).

Figure 1. Chemical name and structure of lactofen residues of concern in plants and animals.

Common names/(Codes) Chemical name	Chemical Structure
	Chemical Structure
Lactofen <sup>a</sup> (PPG-844, PG-1)	
1-(Carboethoxy)ethyl-5-[2-chloro-4- (trifluoromethyl)phenoxy]-2-nitrobenzoate	F <sub>3</sub> C NO <sub>2</sub>
Amino lactofen; amino CTBL <sup>a</sup> (PPG-1576, PG-74)	Cl O CH <sub>3</sub> O CH <sub>3</sub>
1-(Carboethoxy)ethyl 5-[2-chloro-4- (trifluoromethyl)phenoxy]-2-aminobenzoate	F <sub>3</sub> C NH <sub>2</sub>
<b>N-formyl lactofen</b> <sup>a</sup> (PPG-2597, PG-73)	CI O CH <sub>3</sub> O CH <sub>3</sub>
1-(Carboethoxy)ethyl 5-[2-chloro-4- (trifluoromethyl)phenoxy]-2-formamidobenzoate	F <sub>3</sub> C NHCHO
<b>Desethyl lactofen</b> <sup>a</sup> (PPG-947, PG-11)	CI O CH <sub>3</sub> O OH
1-(Carboxy)ethyl 5-[2-chloro-4- (trifluoromethyl)phenoxy]-2-nitrobenzoate	F <sub>3</sub> C NO <sub>2</sub> O
Acifluorfen (PPG-847, PG-5) <sup>a</sup>	
5-[2-chloro-4-(trifluoromethyl) phenoxy]-2- nitrobenzoic acid	CF <sub>3</sub> On NO <sub>2</sub>
Amino acifluorfen <sup>b</sup> ; amino NCTBA (PPG-2053, PG-75)	
2-amino-5-[2-chloro-4-(trifluoromethyl)phenoxy]- benzoic acid	F <sub>3</sub> C NH <sub>2</sub>
<b>PPG-2828</b> <sup>b</sup> (PPG-A947)	CI O CH <sub>3</sub> OH
1-(carboxy)ethyl-5-[2-chloro-4- (trifluoromethyl)phenoxy]-2-aminobenzoate	F <sub>3</sub> C NH <sub>2</sub>
PPG-1530 (Internal Standard)	
1-(Carboethoxy)ethyl 5-[2-chloro-4- (trifluoromethyl)phenoxy]-6-nitrobenzoate	F <sub>3</sub> C <sup>1</sup>

<sup>&</sup>lt;sup>a</sup> The residues of lactofen in plants formerly regulated for lactofen include: lactofen, desethyl lactofen, amino lactofen, N-formyl lactofen, and acifluorfen. <sup>b</sup>PPG-2053 and PPG-2828 are residues of concern in animal commodities, along with lactofen and the four plant metabolites.

#### 2. Nature of the Residue in Livestock

Adequate studies are available depicting the metabolism of [<sup>14</sup>C]lactofen in ruminants and poultry. In a ruminant metabolism study, a dairy goat was dosed orally with [<sup>14</sup>C]lactofen for four days at a level equivalent to 25 ppm in the diet (5,000x the maximum level of residues estimated in the diet, 0.005 ppm). TRR levels in tissues were 6.96 ppm in kidney, 4.39 ppm in liver, 0.110-0.143 ppm in fat, and 0.087-0.101 ppm in muscle. TRR levels in milk were 0.014-0.109 ppm and plateaued by Day 4. The principal <sup>14</sup>C-residue detected in tissues was PPG-2828, which accounted for 34% of the TRR in kidney (1.49 ppm) and 38% of the TRR in liver (2.65 ppm). PPG-2828 was also detected in muscle (#20% TRR, #0.02 ppm) and fat (#14% TRR, #0.02 ppm). Minor amounts (#2% TRR, #0.05 ppm) of PPG-1576, PPG-2597, and PPG-2053 were detected in liver and/or kidney. <sup>14</sup>C-Residues identified in milk from Days 4 and 5 included PPG-2828 (0.01-0.05 ppm), PPG-1576 (0.01 ppm), and PPG-847 (0.01 ppm). Lactofen was not detected in any tissues or milk.

In a poultry metabolism study, hens were dosed orally with [<sup>14</sup>C]lactofen for eight days at a level equivalent to 14.3 ppm in the diet (3,575x the maximum level of residues estimated in the diet, 0.004 ppm). TRR levels in tissues were 1.47 ppm in liver, 0.057 ppm in fat, 0.060-0.090 ppm in muscle, and 0.151 ppm in skin. TRR levels in eggs were 0.018-0.166 ppm in yolks and 0.008-0.047 ppm in whites. <sup>14</sup>C-Residues in yolks increased throughout the dosing period attaining a maximum of 0.166 ppm on Day 7; whereas, <sup>14</sup>C-residues in egg whites plateaued by Day 4 at 0.044 pm. The principal residues in poultry liver were PPG-847 (15.7% TRR, 0.230 ppm), PPG-947 (20.6% TRR, 0.303 ppm), and PPG-2828 (36.3% TRR, 0.534 ppm). In muscle, the major <sup>14</sup>C-residue was PPG-947 (59.7-77.0% TRR, 0.002-0.006 ppm); minor levels of lactofen (#14.2% TRR, #0.013 ppm), PPG-847 (3.6-7.3% TRR, 0.002-0.006 ppm), and PPG-2828 (#1.4% TRR, #0.001 ppm) were also detected. In fat and skin, the major <sup>14</sup>C-residue was PPG-947 (58.6-60.6% TRR, 0.033-0.091 ppm), along with PPG-847 (8.7-15.1% TRR, 0.005-0.023 ppm). In eggs (Day 7), PPG-947 was the principal <sup>14</sup>C-residue in both yolk (29.7% TRR, 0.049 ppm) and whites (46.8% TRR, 0.015 ppm), followed by PPG-847 (yolk - 5.7% TRR, 0.010 ppm; whites - 23.3% TRR, 0.008 ppm)

The residues of concern in animals include lactofen and its diphenyl ether metabolites, which would include PPG-847, PPG-947, PPG-1576, PPG-2053, PPG-2597, and PPG-2828 in animals (G. Okatie, 6/19/91, C. Olinger, 4/26/2000).

#### 3. Residue Analytical Methods

The Pesticide Analytical Manual (PAM) Vol. II, Pesticide Regulation Section 180.432 lists three GC/electron capture detection (ECD) methods (Methods I, A, and B) for determining residues of lactofen in plant commodities. For Method I, residues of lactofen are extracted with acetonitrile:triethylamine (ACN:TEA, 99:1, v/v), followed by partitioning with hexane for oily matrices. Lactofen residues are then purified by silica gel column chromatography and analyzed by GC/ECD using a DB-5 column. The Agency validated this method down to a limit of 0.01 ppm using soybeans.

Method A is similar to Method I, except that the extracted residues are base (NaOH) hydrolyzed converting lactofen to acifluorfen, which is then methylated with diazomethane. The derivatized residues are then purified by silica gel column chromatography and analyzed by GC/ECD using a DB-1701 column. Method B (Chevron Method RM-28, 3/12/90) is essentially identical to Method I, except that it allows for the use of an alternative column (DB-1701) with GC/ECD analysis for confirmation of residues.

In conjunction with the petitions for use of lactofen on cotton and peanuts, Method RM-28 was revised changing the extraction solvent from ACN:TEA to ethanol:water:TEA (94:5:1, v/v/v) and adding a water:dichloromethane (DCM) partitioning step after solvent extraction. The modified method (RM-28B) was rewritten to clarify the procedures and renamed Method RM-28D.

The proposed GC/ECD enforcement method (Method RM-28D) has been successfully radiovalidated in conjunction with a recent tomato metabolism study and has undergone a successful independent laboratory validation trial. In an initial petition method validation (PMV) trial, the Agency was able to validate the method only down to a limit of quantitation (LOQ) of 0.05 ppm for each analyte (DP Barcode D213094, G. Okatie, 5/9/95). However, after clarification of the procedures, the method was successfully validated (DP Barcode D229065, G. Otakie, 9/19/97) by the Agency using peanut nutmeats and cottonseed down to a LOQ of 0.01 ppm. Method RM-28D (revised 1/13/98) was subsequently revised to incorporate changes suggested by the Analytical Chemistry Branch and has been resubmitted to the Agency (DP Barcodes D244081, D244082 and D244635, C. Olinger, 4/27/00).

An adequate GC/ECD method (Valent Method RM-28C) is available for determining residues of lactofen and its six diphenyl ether metabolites (PPG-847, PPG-947, PPG-1576, PPG-2053, PPG-2597, and PPG-2828) in animal commodities. This method is essentially the same as Method B (RM-28B) in PAM Vol. II. Residues are extracted from animal matrices with ACN:TEA (99:1, v/v) and are partitioned with hexane. Residues are then methylated using diazomethane, purified by silica gel column chromatography, and analyzed GC/ECD using an internal standard (PPG-1530). The method LOQ and LOD is 0.01 and 0.005 ppm, respectively, for each analyte. The method was radiovalidated in conjunction with the goat and poultry metabolism studies using samples of milk, kidney, liver (goat and poultry), and egg yolks.

#### 4. Multiresidue Method Testing

Adequate data are available on the recovery of lactofen and its plant metabolites through Multiresidue Method Testing Protocols. The FDA PESTDATA database indicates that residues of lactofen *per se* are completely recovered through Method 304, PAM Vol. I (3<sup>rd</sup> ed., revised 10/97); however, no data are available on the recovery of lactofen through Methods 302 and 303.

### 5. Storage Stability Data

Adequate storage stability data are available to support the existing crop field trials and processing studies. The data indicate that lactofen is stable in cottonseed stored at 0 C for least 1 year and in cotton gin byproducts stored at -20 C for at least 5.4 months. Recoveries from cottonseed, corrected for recoveries from freshly fortified samples, were 80-105% for lactofen, and corrected recoveries from cotton gin byproducts were 71-110% at 5.4 months. Data for snap beans also indicate that residues are stable at -15 C for up to 9.6 months. In peanut nutmeats, residues of lactofen are stable in frozen nutmeats for at least 25 months. In soybeans, lactofen is stable for up to 154 days (recoveries of 67-97%), but residues declined moderately by 820 days (47-81% recoveries).

For animal commodities, lactofen and its metabolites were stable in milk at -20 C for at least 131 days (69-119% recoveries). In tissue samples, PPG-847 and PPG-947 were stable at -20 C for up to 154 days (74-164% recoveries). Lactofen and PPG-2597 were stable at -20 C in muscle, fat, and kidney for up to 152 days (73-114% recoveries), but declined in liver after 62 days (recoveries: lactofen, 8%; PPG-2597, 27%). The metabolites PPG-1576 and PPG-2828 stable in frozen tissues for up to 62 days (83-140% recoveries), but showed moderate declines from 90-154 days (48-85% recoveries). The metabolite PPG-2053 was the least stable analyte in frozen tissues with recoveries declining to 71-82% by 33 days and 12-65% by 62 days.

#### 6. Magnitude of the Residue in Crop Plants

Adequate lactofen residue data are available for cotton, peanuts, snap beans, and soybeans. An adequate number of field trials have been conducted on these crops depicting lactofen residues resulting from the application of lactofen at the maximum labeled or proposed use rate.

For cotton, residues of lactofen and its four regulated metabolites were each <0.01 ppm in/on cottonseed (n=14) harvested 59-127 days following a single postemergence soil-directed application of lactofen (2 lb/gal EC) at 0.4 lb ai/A (2x the single application rate) and in/on cottonseed (n=10) harvested 23-108 days following the last of two postemergence directed applications at 0.4 lb ai/A/application (0.8 lb ai/A/season; 2x the maximum seasonal rate). With one exception, residues of lactofen and its metabolites were also each <0.01 ppm in/on cotton gin byproducts (n=11) derived from cotton harvested 69-108 days following two applications at 0.2 lb ai/A (1x). One gin trash sample bore residues of lactofen *per se* at 0.03 ppm, but confirmatory analyses of this sample detected lactofen at <0.01-0.02 ppm and residues of lactofen were <0.01 ppm in the duplicate treated sample from the same trial.

In soybeans treated at 0.4 lb ai/A (1x the maximum seasonal rate) and harvested 44-50 days posttreatment, residues of lactofen *per se* in/on seeds were <0.005 ppm for 7 samples and 0.007 ppm for one sample (LOQ=0.01 ppm); residues of all four metabolites were nondetectable (<0.005 ppm) in/on all eight samples. In addition, residues of lactofen *per se* were #0.007 ppm in/on soybeans (n=4) from 4 trials conducted at 5x the maximum application rate, and residues of the four metabolites were <0.005 ppm. In five trials, residues of lactofen and its metabolites were each <0.01 ppm in/on snap beans harvested 53-59 days following a single application of lactofen at 0.5 lb ai/A (2x the maximum label rate).

In the 8 field trials conducted in conjunction with the petition for use on peanuts (PP#8F3591), residues of lactofen and its metabolites were each <0.01 ppm in/on 16 samples each of peanut nutmeats and hulls harvested 65-71 days following the last of two broadcast applications of lactofen (2 lb/gal EC) totaling 0.45 lb ai/A (1x the maximum proposed rate). Residues of each analyte were also <0.01 ppm in/on peanut nutmeats and hulls from two trials conducted at 2x and 5x the maximum seasonal rate.

#### 7. Magnitude of the Residue in Processed Food/Feed

Adequate processing studies are available for cottonseed, peanuts, and soybeans. These studies indicate that separate tolerances for processed commodities are not required for these crops. Residue data on aspirated grain fractions are not needed as the use is not likely to result in higher residues in/on these fractions.

In a single trial, residues of lactofen and its four metabolites were each <0.01 ppm in/on cottonseed harvested 76 days following the last of two directed applications of lactofen at 0.6 lb ai/A/application, (1.2 lb ai/A/season; 3x rate). Residues of each analyte were also <0.01 ppm in samples of meal, hulls, oil (crude and refined) and soapstock processed from 3x-treated cottonseed. The maximum theoretical concentration factor for processed cotton commodities is 6.3x (oil).

In four tests conducted at 5x the maximum use rate for soybeans, residues of lactofen *per se* were #0.007 ppm and in/on soybeans, and residues of each of the four metabolites were <0.005 ppm. In one trial, residues of lactofen *per se* in seeds averaged 0.006 ppm and concentrated by 3x in hulls (0.018 ppm); no concentration of metabolites was noted. Based on the level of residues of lactofen (#0.007 ppm) and its metabolites (each <0.005 ppm) in seeds and the observed 3x concentration factor for hulls, a separate tolerance for residues in hulls is not required.

Residues of lactofen and its metabolites were each <0.01 ppm in/on peanut nutmeats harvested 70 days following the last of two applications totaling 1.35 and 2.25 lb ai/A (3x and 5x the maximum seasonal use rate). Residue of each analyte were <0.01 ppm in meal, oil (crude and refined), and soapstock processed from nutmeats treated at 3x and 5x.

#### 8. Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Reregistration requirements for magnitude of the residue in meat, milk, poultry, and eggs are fulfilled. A ruminant feeding study is available depicting residues of lactofen and its residues of concern in animals (PPG-847, PPG-947, PPG-1576, PPG-2053, PPG-2597, and G-2828) in meat and milk.

Because residues of lactofen and its metabolites have been below the LOQ (<0.01 ppm) in essentially all samples of animal feed items from crops treated with lactofen, even at exaggerated rates, the dietary burden for livestock has been calculated using estimated residue levels rather than the tolerances. In the available animal feed items, only lactofen *per se* has ever been detected at quantifiable levels and only at 0.03 ppm in 1 out of 12 samples of cotton gin trash. Using an estimated maximum residue level of 0.01 ppm for livestock feed items (DP Barcode D228848, G. Otakie, 11/6/96) and a realistic animal diet, the calculated maximum dietary burdens for lactofen residues in livestock diets are 0.005 ppm for dairy and beef cattle, 0.004 ppm for poultry, and 0.0025 ppm for swine (see table below).

Feed Commodity	% Dry Matter <sup>a</sup>	% Diet <sup>a</sup>	Estimated Residues Levels (ppm) <sup>b</sup>	Dietary Contribution (ppm) <sup>c</sup>
Beef and Dairy Cattle				
Cottonseed	88	25	0.01	0.0028
Cotton gin- byproducts	90	20	0.01	0.0022
TOTAL BURDEN				0.005
Poultry				
Soybean, meal	NA	40	0.01	0.004
TOTAL BURDEN				0.004
Swine				
Soybean, meal	NA	25	0.01	0.0025
TOTAL BURDEN				0.0025

Calculation of maximum dietary burdens of livestock animals for lactofen

<sup>a</sup> Table 1 (OPPTS Guideline 860.1000, August 1996).

<sup>b</sup> Estimated residues based on data from field trials.

<sup>c</sup> Contribution = [tolerance / % DM (if cattle)] X % diet).

In the available ruminant feeding study, four groups of dairy cows (3 animals/dose group) were dosed with lactofen at levels equivalent to 0.025, 0.075, 0.25 and 2.5 ppm in the diet for 28 consecutive days. These dose levels are equivalent to 5x, 15x, 50x, and 500x the maximum estimated dietary burden for cattle (0.005 ppm). Milk was collected twice daily on days -1, 1, 4, 7, 10, 14, 21, 28, and 29 (day of slaughter). Cows were sacrificed within 24 hours for the final dose and samples of liver, kidney, fat, and muscle were collected. Duplicate samples of each matrix were collected and analyzed for each treated cow.

With the exceptions of the samples indicated in the table below, residues of lactofen and its six metabolites were nondetectable (<0.005 ppm) in ruminant tissues and milk.

Dose level	Summary of detectable (\$0.005 ppm) residues from cow feeding study
0.025 ppm (5x)	In liver, PPG-1576 was detected in three out of six samples at 0.005-0.006 ppm. No residues were detected in kidney; and samples of fat, muscle and milk were not analyzed.
0.075 ppm (15x)	In liver, PPG-1576 was detected in one sample at 0.005 ppm. In kidney, PPG-2828 was detected five samples at 0.005-0.008 ppm. No residues were detected in fat; and muscle and milk were not analyzed.
0.25 ppm (50x)	In liver, PPG-2828 was detected in all six samples at 0.008-0.014 ppm. In kidney, PPG-2828 also was detected in all six samples at 0.011-0.029 ppm, and PPG-1576 was detected at 0.007 ppm in one sample. No residues were detected in muscle and fat. In milk, PPG-2053 was detected at 0.008 ppm in one sample on Day 1, and PPG-1576 was detected at 0.005-0.007 ppm in a total of five samples over Days 1 through 21.
2.50 ppm (500x)	In liver, PPG-2053 and PPG-2828 were detected in all six samples at 0.005- 0.011 ppm and 0.093 to 0.214 ppm, respectively, and PPG-1576 was detected at 0.006 ppm in one sample. In kidneys, PPG-2828 was detected in all six samples at 0.131-0.233 ppm; PPG-2053 was detected in three samples at 0.006-0.008 ppm; and lactofen was detected at 0.005 ppm in one sample. In fat, PPG-1576 was detected in all six samples at 0.019-0.023 ppm. No residues were detected in muscle. In milk from days 1 through 28, PPG-2053 was detected in three samples, PPG-1576 in five samples, and PPG-2828 in 21 samples. The highest residue level for any moiety was PPG-2828 at 0.012 ppm in Day 10 milk.

As residues of lactofen and its six metabolites were each <LOQ (0.01 ppm) in liver, kidney and fat from the 0.075 ppm (15x) dose group and in milk and muscle from the 0.25 ppm (50x) dose group, there is no reasonable expectation of finding quantifiable lactofen residues in livestock tissues or milk [40 CFR 180.6(a)(3)]. Accordingly, tolerances for lactofen residues in livestock (cattle, goats, horses, and sheep) commodities not required at the present time. These data also indicate that tolerances are not required for hog commodities, given that the maximum dietary burden is lower for swine than ruminants. If additional feed items are registered, this decision will be revisited.

Based on the results of the poultry metabolism study, in which hens were dosed for 7 days at 14.3 ppm (3,575x dose level), a poultry feeding study and tolerances for lactofen residues in poultry and eggs are not required, as quantifiable levels of lactofen residues are unlikely to occur in poultry.

### 9. Confined and Field Accumulation in Rotational Crops

There are currently no plant-back restrictions on the COBRA® label. A confined rotational crop study in root crops indicated that there was minimal uptake of radioactivity in carrots and radishes planted between 42 and 119 days after treatment of soil with <sup>14</sup>C-lactofen. A confirmatory confined rotational crop study with a leafy vegetable and small grain is required.

## E. TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues of lactofen in or on raw agricultural commodities for plants are currently expressed in terms of lactofen and its metabolites (PPG-847, PPG-947, PPG-1576, and PPG-2597) containing the diphenyl ether linkage, expressed as lactofen. Permanent tolerances for lactofen residues have been established on snap beans and soybeans at 0.05 ppm [40 CFR §180.432(a)]. A time-limited tolerance was previously established for residues in/on cottonseed at 0.05 ppm [40 CFR §180.432(b)]; however, this tolerance expired on 12/31/96. There are currently no tolerances for lactofen in processed commodities or animal commodities, and the available processing studies and ruminant feeding study indicate that tolerances for processed and animal commodities are not required at the present time.

A summary of the lactofen tolerance reassessment and recommended modifications in commodity definitions are presented in Table 5. It is noted that the HED MARC has recommended that the tolerance expression for plant commodities should only include the parent compound.

#### **1.** Tolerance Reassessment Table

Commodity	Current Tolerance (ppm) <sup>a</sup>	Range of residues (ppm) <sup>b</sup>	Tolerance Reassessmen t (ppm)	Comment/Correct Commodity Definition		
	Toleran	ces listed under 40	CFR §180.432(a)	:		
Beans, snap	0.05	<0.01	0.01	Beans, snap, succulent (excluding Limas)		
Cottonseed	0.05 °	<0.01	0.01	Cotton, undelinted seed		
Soybean	0.05	<0.005-0.007 °	0.01	Soybean, seed		
Tolerances needed under 40 CFR §180.432(a):						
Cotton, gin byproducts	None	<0.01-0.03	0.02			
Peanut	None	<0.01	0.01			

Table 5.Tolerance Reassessment Summary for Lactofen.

<sup>a</sup> Expressed in terms of lactofen.

<sup>b</sup> Refer to section on Magnitude of Residues in Crop Plant for detailed discussion of residues in crops.

<sup>c</sup> Time limited tolerance for cottonseed expired on 12/31/96.

## 2. Codex/International Harmonization

No maximum residue limits (MRLs) for lactofen have been established or proposed by Codex for any agricultural commodity. Therefore, no compatibility questions exist with respect to U.S. tolerances.

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# 2. Agency Memoranda Citations

# Table 7. Agency Memoranda Citations.

Date	DP Barcode	CB No.	From	То	MRID Nos.	Subject
12/27/85	None	1492	M. Firestone	R. Mountfort and Toxicology Branch	Acc. Nos. 073855, 073853, 073843, and 073858	PP#5F3299 - Lactofen (Cobra) Herbicide on Soybeans. Evaluation of Analytical Methods and Residue Data.
9/29/86	None	1111	M. Firestone	R. Mountfort and Toxicology Branch	Acc. Nos. 263517- 263519	PP#5F3299 - Lactofen (Cobra) Herbicide on Soybeans. Evaluation of Amendment Dated June 23, 1986
9/30/86	None	None	S. Simko	Unknown	Acc. Nos. 073854, 071228	Environmental Fate and Exposure Assessment for Lactofen
2/24/87	None	1779 and 1897	C. Deyrup	R. Mountfort and Toxicology Branch	40026601-40026603, 40059401-40059403	PP#5F3299 - Lactofen on Soybeans. Amendments of 12/12/86 and 1/23/87
3/10/87	None	None	M. Law	C. Trichilo	None	PP#5F3299 - Lactofen Method Trial on Soybeans
3/25/87	None	None	C. Deyrup	R. Mountfort and Toxicology Branch	None	PP#5F3299 - Lactofen on Soybeans. Evaluation of Method Trial Report dated 3/10/87
3/1/88	None	3098, 3099	G. Otakie	R. Mountfort	40436601-40436606	PP#8F3591 - Lactofen (Cobra) Herbicide on Peanuts - Evaluation of Analytical Methods and Residue Data.
2/22/90	None	5741	G. Otakie	J. Miller	41209101 and 41209102	PP#9F3798 - Lactofen (Cobra <sup>®</sup> ) Herbicide on Cotton - Evaluation of Analytical Methods, Residue and Processing Data Dated July 24, 1989.
3/14/90	None	5952, 6054	G. Otakie	J. Miller	41297601-41297604	PP#8F3591 - Lactofen (Cobra) Herbicide on Peanuts - Evaluation of Amendments Dated May 8, 1989 and November 8, 1989.

# Table 7.Continued.

Date	DP Barcode	CB No.	From	То	MRID Nos.	Subject
4/5/90	None	None	G. Otakie	J. Miller	41297604	PP#8F3591 - Lactofen (Cobra <sup>®</sup> ) Herbicide on Peanuts - Multiresidue Protocol Testing.
8/14/90	None	6699	G. Otakie	J. Miller	None	PP#8F3591 - Lactofen (Cobra) Herbicide on Peanuts - Supplemental Submission and Request for Clarification Dated May 8, 1989.
6/19/91	None	None	G. Otakie	J. Stewart and M. Copley	None	Toxicological Significance of Lactofen Animal Metabolites.
6/20/91	None	7488	G. Otakie	J. Miller	41709501-41709503	PP#8F3798 - Lactofen (Cobra) Herbicide on Cotton - Evaluation of Amendments Dated November 19, 1990.
5/14/92	D177126	9735	G. Otakie	J. Miller and E. Wilson	42263801	PP#8F3798 - Lactofen (Cobra) Herbicide on Cotton - Evaluation of Feeding Study Protocol and Proposed Worst Case Dairy Cattle Diet - Amendment Dated April 1, 1992.
7/13/92	None	None	G. Otakie	H. Hundley	42183004	Multi-Residue Method Testing of Lactofen Metabolites.
9/30/92	D175379	9514	G. Otakie	J. Miller	42183001-42183003	PP#9F3798 - Lactofen (Cobra) Herbicide on Cotton - Evaluation of Amendments Dated January 17, 1992.
3/23/93	D183428	10730	G. Okatie	J. Miller	42494901	PP#8F3798 - Lactofen (Cobra) Herbicide on Cotton - Evaluation of Analytical Method and Residue Data.
4/7/93	D183793	10764	G. Otakie	J. Miller and J. Mayes	42508101, 42508102, 42508103	PP#8F3591 - Lactofen (Cobra) Herbicide on Peanuts - Evaluation of Analytical Method and Residue Data.
5/10/94	D195440	12627	G. Otakie	F. Sanders, J. Miller, F. Liem, and D. Bradway	42934501	PP#3299 - Response to Agency 6/18/93 Lactofen Data Call- In (i.e. Additional Residue Data to Support the Existing Registration of Lactofen on Soybeans) Dated 9/23/93 - Evaluation of Field Trial and Processing Residue Data.

# Table 7.Continued.

Date	DP Barcode	CB No.	From	То	MRID Nos.	Subject
2/2/95	D195308, D208336	12579, 14544	G. Otakie	J. Miller	42925301, 42925302	PP#9F3798 - Lactofen (Cobra) Herbicide on Cotton - Evaluation of Amendments Dated September 13, 1993 and September 28, 1994.
5/9/95	D213094	15249	G. Otakie	C. Parker and J. Smith	None	PP#9F3798 and 8F3591 - Lactofen on Cottonseed, Peanut Nutmeat and Peanut Hulls. Results of EPA Method Validation.
5/22/95	D199043	13259	G. Otakie	J. Miller	43095001, 43095002	PP#3798 - Lactofen (Cobra) Herbicide on Cotton - Evaluation of Amendments Dated January 21, 1994.
9/18/95	D207879	11450	N. Dodd	H. Jamerson and W. Hazel	43379201	PP#4E04418. Lactofen on Snap Beans. Review of Analytical Methods and Residue Data.
2/20/96	D217263	15862	G. Otakie	J. Miller and D. Kenny	43638601, 43638602	PP#3299 - Lactofen on Soybeans. Evaluation of Residue Data and Amended Use Request.
11/6/96	D228848	17494	G. Otakie	D. McCall	None	PP#3798 - Lactofen (Cobra) Herbicide on Cotton - Evaluation of Lactofen Position Document Dated July 26, 1996.
9/19/97	D229065	17493	G. Otakie	J. Miller	None	PP#9F3798 and 8F3591 - Lactofen on Cottonseed and Peanut Nutmeats - Results of Petition Method Validation Request for Revised Methods.
3/23/00	D264367	None	C. Olinger	G. Kramer	None	Lactofen: Issues to be presented to the Metabolism Assessment Review Committee
4/26/00	D265469	None	C. Olinger	G. Kramer	None	Lactofen: HED Metabolism Assessment Review Committee Decision Memorandum
5/3/00	D231841, D232696	None	C. Olinger	S. Stanton and C. Scheltema	44166701, 44176601	Lactofen - Evaluation of Tomato Metabolism Study and Radiovalidation Data.

# Table 7.Continued.

Date	DP Barcode	CB No.	From	То	MRID Nos.	Subject
5/3/00	D241039	None	C. Olinger	S. Stanton and C. Scheltema	44411901	PP#3798 - Lactofen (Cobra) Herbicide on Cotton - Evaluation of Residue Data for Cotton Gin Byproducts.
5/3/00	D244081, D244082, D244635	None	C. Olinger	S. Stanton and C. Scheltema	44176602, 44194301, 44411701, 44411702	PP#8F3591 - Lactofen (Cobra) Herbicide on Peanuts - Evaluation of Peanut Metabolism Study, Analytical Methodology, Storage Stability Data, and Response to Agency Review of April 7, 1993.