DATA EVALUATION RECORD

SODIUM FERRIC EDTA
(Slugkil 5)

STUDY TYPES: Product Identity and Composition (OPPTS 880.1100)
Description of Starting Materials, Production and Formulation Process (OPPTS 880.1200)
Discussion of Formation of Impurities (OPPTS 880.1400)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

MRIDs 47942001-03

Prepared for
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Task Order No. 10-006

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EPA Secondary Reviewer:

STUDY TYPE:	Product Identity and Composition (OPPTS 880.1100) Description of Starting Materials, Production and Formulation Process (OPPTS 880.1200) Discussion of Formation of Impurities (OPPTS 880.1400) Preliminary Analysis (OPPTS 830.1700) Certified Limits (OPPTS 830.1750) Enforcement Analytical Method (OPPTS 830.1800) Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)
MRID NO:	47942001-03
DECISION NO:	425380
DP BARCODE:	DP373925
TEST MATERIAL:	Slugkil 5 (a.i., 5.00% w/w sodium ferric EDTA)
PROJECT STUDY NO:	MRIDs 47942001-03: Not provided
SPONSOR:	W. Neudorff GmbH KG, An der Muhle 3, 31860 Emmerthal, Germany
TESTING FACILITY:	MRIDs 47942001-03: Eco-Care Technologies, Inc., 8233 Thomson Place, Saanichton, BC V8M 1S1, Canada
TITLE OF REPORT:	MRID 47942001: Slugkil 5 End Use Product. Product Chemistry. Product Identity and Composition MRID 47942002: Slugkil 5 End Use Product. Product Chemistry. Preliminary Analysis, Certified Limits and Enforcement Analytical Method MRID 47942003: Slugkil 5 End Use Product. Product Chemistry. Physical and Chemical Characteristics
AUTHORS:	MRID 47942001: Almond, D. and C. Stewart MRIDs 47942002-03: Stewart, C. and D. Almond
STUDY COMPLETED:	MRID 47942001: October 19, 2009 MRID 47942002: September 10, 2009 MRID 47942003: October 13, 2009
CONFIDENTIALITY CLAIMS:	MRIDs 47942001-02: Confidential material is contained in a confidential appendix. MRID 47942003: None.
GOOD LABORATORY PRACTICE:	MRID 47942001: A signed and dated GLP statement was included. The study is not subject to the requirements of 40 CFR Part 160. MRIDs 47942002-03: A signed and dated GLP statement was included. The study was conducted in accordance with the requirements of 40 CFR Part 160.
CONCLUSION:	Slugkil 5 is an end use product to be used as a molluscicide in home and garden, commercial, and agricultural applications. CSFs were submitted for a basic formulation and 13 alternate formulations. The active ingredient in each formulation is 5.00% w/w sodium ferric EDTA. In alternate formulations #1, #2, #5, #6, #8, #10, and #12, the active ingredient is supplied by 7.00% w/w Slugkil MP (EPA Reg. No. 67002-GR, purity 71.42%), which is being registered concurrently as a manufacturing use product. The purity of Slugkil MP is not given on the CSFs. The

Inert ingredient information may be entitled to confidential treatment

active ingredient is identified as ferric sodium EDTA on the CSFs and sodium ferric EDTA on the product label. The CSFs give the active ingredient content as 5.00%, while the product label gives the content as 5.0%. The inert ingredients in the basic formulation and alternate formulation #4 are [redacted] and [redacted] The inert ingredients in alternate formulations #1 and #5 are [redacted] and [redacted] The inert ingredients in alternate formulations #2, #6, #8, #10, and #12 are [redacted] and [redacted] The inert ingredients in alternate formulations #3, #7, #9, #11, and #13 are [redacted] and [redacted] There are discrepancies between the suppliers for [redacted] and [redacted] given on pp. 6-8 of 20 of MRID 47942001 and on the CSFs. The registrant has submitted a petition for an exemption from the requirement of a tolerance for sodium ferric EDTA. [redacted] and [redacted] are exempt under 40 CFR 180.950. Slugkil 5 is formulated using a non-integrated process, and no impurities are formed. Acceptable results of a five-batch preliminary analysis were provided. The lower and upper certified limits for the active ingredient are given incorrectly on the CSFs and in MRID 47942002. The enforcement analytical method is inductively coupled plasma mass spectrometry. The mean and relative standard deviation for results of the repeated analysis to determine precision of the method are incorrect in MRID 47941902. The physical and chemical characteristics were adequately described, with the exception that oxidation/reduction:chemical incompatibility was not addressed.

CLASSIFICATION: **Unacceptable**, but upgradeable if 1) the name of the active ingredient is made consistent on the CSFs and product label; 2) the purity of Slugkil MP is added to the CSFs for alternate formulations #1, #2, #5, #6, #8, #10, and #12; 3) the discrepancies between the CSFs and MRID 47941901 concerning the suppliers of the inert ingredients is resolved; 4) an MSDS or specification sheet is provided for each inert ingredient; 5) the certified limits for the active ingredient are corrected on the CSFs and in MRID 47941902; 6) the mean and relative standard deviation for the repeated analysis to determine precision of the enforcement analytical method are corrected in MRID 47941902; and 7) oxidation/reduction:chemical incompatibility is addressed.

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Test Material: Slugkil 5 (a.i., 5.00% w/w sodium ferric EDTA)

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Manufacturing process information may be entitled to confidential treatment

I. **PRODUCT IDENTITY AND COMPOSITION:** Slugkil 5 is an end use product to be used as a molluscicide in home and garden, commercial, and agricultural applications. CSFs were submitted for a basic formulation and 13 alternate formulations. The active ingredient in each formulation is 5.00% w/w sodium ferric EDTA. In alternate formulations #1, #2, #5, #6, #8, #10, and #12, the active ingredient is supplied by 7.00% w/w Slugkil MP (EPA Reg. No. 67002-GR, purity 71.42%), which is being registered concurrently as a manufacturing use product. The purity of Slugkil MP is not given on the CSFs. The active ingredient is identified as ferric sodium EDTA on the CSFs and sodium ferric EDTA on the product label. The CSFs give the active ingredient content as 5.00%, while the product label gives the content as 5.0%. The inert ingredients in the basic formulation and alternate formulation #4 are [redacted] and [redacted] The inert ingredients in alternate formulations #1 and #5 are [redacted] and [redacted] The inert ingredients in alternate formulations #2, #6, #8, #10, and #12 are [redacted] and [redacted] The inert ingredients in alternate formulations #3, #7, #9, #11, and #13 are [redacted] and [redacted] There is a discrepancy between the suppliers for [redacted] and [redacted] given on pp. 6-8 of 20 of MRID 47942001 and on the CSFs. The registrant has submitted a petition for an exemption from the requirement of a tolerance for sodium ferric EDTA. [redacted] are exempt under 40 CFR 180.950.

Deficiencies: The name of the active ingredient must be made consistent on the CSFs and product label for Slugkil 5. The purity of Slugkil MP must be added to the CSFs for alternate formulations #1, #2, #5, #6, #8, #10, and #12. The discrepancy between the CSFs and MRID 47942001 concerning the suppliers of the inert ingredients must be resolved.

II. **DESCRIPTION OF STARTING MATERIALS AND FORMULATION PROCESS:**

The starting materials for the basic formulation and alternate formulation #4 of Slugkil 5 are sodium ferric EDTA, [redacted], and [redacted] The starting materials for alternate formulations #1 and #5 are Slugkil MP, [redacted], and [redacted] The starting materials for alternate formulations #2, #6, #8, #10, and #12 are Slugkil MP, [redacted] and [redacted]. The starting materials for alternate formulations #3, #7, #9, #11, and #13 are sodium ferric EDTA, [redacted] and [redacted]. An MSDS was provided for Slugkil MP. No MSDS, specification sheet, or food grade certificate was provided for any of the remaining starting materials.

Slugkil 5 is formulated using [redacted] Flow charts for each type of formulation are provided on pages 10-11 of MRID 47942001.

[redacted]

Inert ingredient information may be entitled to confidential treatment
Manufacturing process information may be entitled to confidential treatment

[redacted]

[redacted]

[redacted]

After each formulation is completed, the final product is tested using the enforcement analytical method to quantify the amount of iron in the product.

Deficiencies: An MSDS or specification sheet must be provided for [redacted] and [redacted]

III. **DISCUSSION OF FORMATION OF IMPURITIES:** Slugkil 5 is produced by a non-integrated process, and no impurities are formed.

Deficiencies: None.

IV. **PRELIMINARY ANALYSIS:** Results of a five-batch preliminary analysis for Slugkil 5 using the enforcement analytical method are provided in Table 1. The mean content of active ingredient was [redacted] This is within the OPPTS 830.1750 recommended certified limits of [redacted]

[redacted]

Deficiencies: None.

V. **CERTIFIED LIMITS:** Tables 2-5 list the nominal concentrations and certified limits for the ingredients in Slugkil 5 as given on the CSFs. The lower and upper certified limits for the active ingredient are given incorrectly on the CSFs and on p. 4 of 4 of the confidential attachment to MRID 47942002 as [redacted] respectively. The correct limits based on OPPTS 830.1750 are [redacted] respectively. The certified limits for the inert ingredients are within the OPPTS 830.1750-recommended ranges.

TABLE 2. Nominal concentrations and certified limits for Slugkil 5 (basic formulation and alternate formulation #4)[a]

Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient					
Sodium ferric EDTA (15708-41-5)	139114	Active ingredient	5.00	4.75[b]	5.25[c]
Inert Ingredients					
[redacted]					

[a]Data from CSFs
[b]Calculated by reviewer; given incorrectly as 4.56 on CSFs
[c]Calculated by reviewer; given incorrectly as 5.44 on CSFs

TABLE 3. Nominal concentrations and certified limits for Slugkil 2 (alternate formulations #1 and #5)[a]

Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient					
Slugkil MP (71.42%)[b] (Sodium Ferric EDTA) (15708-41-5)	139114	Active ingredient	7.00 (5.00)	6.65 (4.75)[c]	7.35 (5.25)[d]
Inert Ingredients					
[redacted]					

[a]Data from CSFs
[b]Purity not included on CSFs
[c]Calculated by reviewer; given incorrectly as 4.56 on CSFs
[d]Calculated by reviewer; given incorrectly as 5.44 on CSFs

Inert ingredient information may be entitled to confidential treatment

TABLE 4. Nominal concentrations and certified limits for Slugkil 5 (alternate formulations #2, #6, #8, #10, and #12)[a]

Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient					
Slugkil MP (71.42%)[b] (Sodium Ferric EDTA) (15708-41-5)	139114	Active ingredient	7.00 (5.00)	6.65 (4.75)[c]	7.35 (5.25)[d]
Inert Ingredients					
[redacted]					

[a]Data from CSFs
[b]Purity not included on CSFs
[c]Calculated by reviewer; given incorrectly as 4.56 on CSFs
[d]Calculated by reviewer; given incorrectly as 5.44 on CSFs

TABLE 5. Nominal concentrations and certified limits for Slugkil 2 (alternate formulations #3, #7, #9, #11, and #13)[a]

Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient					
Sodium Ferric EDTA (15708-41-5)	139114	Active ingredient	5.00	4.75[b]	5.25[c]
Inert Ingredients					
[redacted]					

[a]Data from CSFs
[b]Calculated by reviewer; given incorrectly as 4.56 on CSFs
[c]Calculated by reviewer; given incorrectly as 5.44 on CSFs

Inert ingredient information may be entitled to confidential treatment

Deficiencies: The upper and lower certified limits for the active ingredient must be corrected on the CSFs and on p. 4 of 4 of the confidential attachment to MRID 47942002.

VI. **ENFORCEMENT ANALYTICAL METHOD:** The enforcement analytical method to determine the amount of iron in Slugkil 5 is inductively coupled plasma mass spectrometry (EPA Analytical Method 6010). Details are provided in MRID 47942003. The instrument is a Thermo Intrepid II XSP. The samples are digested according to EPA Analytical Method 3050 prior to analysis.

Precision of the method was demonstrated by repeated analysis of the same batch of Slugkil 5. The iron EDTA content ranged from 4.48 to 4.65%. The mean and relative standard deviation for the repeated analysis are given incorrectly as 1.96% and 1.43%, respectively, on p. 16 of 25 of MRID 47942003. The reviewer calculates these as 4.57% and 0.06%, respectively. Recovery from prepared iron standards ranged from 99.7 to 100.4%. There were no interferences, and the spectra demonstrated a mass resolution of 1 a.m.u. or better.

Deficiencies: The mean and relative standard deviation for the repeated analysis to determine precision must be corrected in MRID 47942003.

VII. **PHYSICAL AND CHEMICAL CHARACTERISTICS:**

1. **Methods**: Methods for determining the applicable physical and chemical characteristics of Slugkil 5 are provided in Table 6.

2. **Results**: The physical/chemical characteristics of Slugkil 5 are provided in Table 6. Oxidation/reduction:chemical compatibility was not addressed.

3. **Deficiencies:** Results must be provided for oxidation/reduction:chemical compatibility.

TABLE 6. Physical and Chemical Properties for Slugkil 5[a]			
Guideline Reference No./Property		**Description of Result**	**Methods**
830.6302	Color	Light brown	Visual inspection
830.6303	Physical State	Compressed noodle/pellet	Visual inspection
830.6304	Odor	Odorless	Olfactory inspection
830.6313	Stability	Not required for EP.	
830.6314	Oxidation/Reduction: Chemical Incompatibility	**Not addressed**	
830.6315	Flammability	The product does not contain any combustible ingredients.	Product knowledge
830.6316	Explodability	The product does not contain any combustible ingredients.	Product knowledge
830.6317	Storage Stability	Stable when stored for two years at 20°C.	Lab study No. 1182-2YAMB-070413
830.6319	Miscibility	Not applicable, the product is not to be diluted with petroleum solvents.	
830.6320	Corrosion Characteristics	No evidence of corrosiveness towards polyethylene bags when stored at 20°C for up to two years. Not expected to be corrosive to any materials it would normally contact.	Lab study No. 1182-2YAMB-070413
830.6321	Dielectric Breakdown Voltage	Not applicable, the product is not for use around electrical equipment.	
830.7000	pH	5.42 ± 0.03 when ground up and added to water.	CIPAC MT 75
830.7100	Viscosity	Not applicable, the product is a dry granular material.	
830.7200	Melting Range	Not required for EP.	
830.7220	Boiling Range	Not required for EP.	
830.7300	Density/Relative Density/Bulk Density	Pour density: 0.80 ± 0.03 g/mL. Tap density: 0.82 ± 0.03 g/mL.	CIPAC MT 159
830.7370	Dissociation Constant in Water	Not required for EP.	
830.7550	Partition Coefficient	Not required for EP.	
830.7840	Water Solubility	Not required for EP.	
830.7950	Vapor Pressure	Not required for EP.	

[a]Data from MRID 47942003

VIII. ADDITIONAL REVIEWER'S COMMENTS: None.