Date: January 13, 2004

SUBJECT: Revised Product Chemistry Review of Nations AG II Abamectin Technical

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TO: Meredith Laws / Thomas Harris, PM 04
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DP BARCODE: D285181
EPA REG. NO.: 72167-EN
PC CODE : 122804
REGISTRANT: Nations AG II, LLC
USE: Insecticide

INTRODUCTION:

The registrant has submitted the product chemistry data to support the registration of the Nations AG II IAbamectin technical, produced by [redacted] The abamectin B_1 which consists of B_{1a} and B_{1b} compounds is the biologically active ingredient. The product chemistry data have been submitted under MRID Nos. 455440-01, 455440-02, and 457475-01. The registrant has claimed that the proposed technical is substantially similar to the registered product with Reg. No. 100-895. The TRB has been asked to evaluate the product chemistry data submitted on the proposed Nations AG II Abamectin Technical.

SUMMARY OF FINDINGS:

1. The registrant has submitted the Confidential Statement of Formula for basic formulation (dated 11-05-01), for Abamectin technical. The nominal concentration (97.6%) of the AI agrees with the product label claim nominal concentration. The product chemistry data submitted corresponding to guideline reference 830.1550 (Product identity & Composition), and 830.1750 (Certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175 respectively.

2. The product chemistry data submitted corresponding to guideline reference 830.1600 (Description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.160. The registrant has provided the product specifications data on all the starting materials used for the production of this insecticide. [MRID No. 455440-01]

3. The product chemistry data submitted corresponding to guideline reference 830.1620 (Description of production process) satisfy the data requirements for 40CFR§158.162. The registrant has provided the details of the manufacturing process. [MRID No. 455440-01]

4. The product chemistry data submitted corresponding to guideline reference 830.1670 (Discussion on the formation of impurities)satisfy the data requirements for 40CFR§158.167. [MRID No. 455440-01]

5. The data submitted corresponding the guideline reference 830.1700 (Preliminary analysis) satisfy the data requirements of 40CFR§158.170. Five representative lots of the technical were analyzed for percent active ingredient, and other impurities present at levels of 0.1% or greater by method of HPLC/UV (245 nm). The HPLC-MS method was used to quantitate the AI and impurities. The methods were validated for accuracy, linearity, and precision. [MRID No. 455440-02].

6. The data submitted corresponding the guideline reference 830.1800 (Enforcement Analytical method) satisfy the data requirements of 40CFR§158.180. The HPLC / UV (245 nm) method was used to assay the active ingredient in the technical. The method was validated for accuracy, linearity, and precision. [MRID No. 455440-02].

7. The registrant has submitted product chemistry data corresponding to guideline reference 830 Series Subgroup B (Physical/Chemical properties)for the technical . The data submitted satisfy the data requirements of 40CFR 158.190. [MRID Nos. 457475-01]

8. No data have been submitted corresponding to guideline reference 830.6317 (one year storage stability), 830.6320 (Corrosion characteristics), and solubility of the TGAI in organic solvents.

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the Nations AG II Abamectin technical and has concluded that:

1. All the product chemistry data submitted corresponding to 830 Series Subgroup A and Subgroup B satisfy the data requirements of 40CFR§158.155 to 158.190 and are acceptable, except for one year storage stability (830.6317), corrosion characteristics (830.6320) studies, and solubility in organic solvents (830.7840).

2. The CSF for basic formulation (dated 11-05-01) is filled out correctly and completely. It is in compliance with PR Notice 91-2. The nominal concentration of the active ingredient (97.6%) concurs with the product label claim nominal concentration. The CSF for basic formulation is acceptable.

3. The applicant must generate and submit the results of one year storage stability (830.6317) and corrosion characteristics (830.6320) studies conducted under warehouse conditions in commercial containers to the Agency on completion.

4. The registrant has submitted solubility of the AI in water but no data have been submitted for the solubility of the AI in organic solvents. The registrant must submit this data.

5. The proposed technical / MP was determined not to be substantially similar to the registered product with Reg. No. 100-895 from the product chemistry view point.

(A). There are significant difference in the density and pH for the two products.

Product	pH	Density	NC (%)
100-895	8-9	73.70 lbs/cu. ft.	90.0
72167-EN	7.2	36.52 lbs/cu. ft.	97.6

(B). The nominal concentration and the impurity profile for the registered and proposed technical are not the same.

Page 3 is not included in this copy.

Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

√ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

Chemical Name (IUPAC, CAS)	Abamectin
Chemical Number (CAS; PC Code)	CAS No. 71751-41-2 PC Code: 122804
Registration/Symbol No.	72167-EN
Type of Product (T, MP, EP)	97.6% TGAI/ MP
DP Barcode	D285181
Reviewer	Shyam B. Mathur
Branch Chief	Deborah McCall

Table 1: Manufacturing and Impurity Data for the Abamectin Technical

GLN	Requirement	MRID	Status[1]	Details and/or Deficiency[2]
830.1550	Product identity and composition	Basic CSF (11-05-01)	A	The NC of AI (97.6%) is supported by 5 batch analysis & concurs with the product label claim 97.6%.
830.1600	Description of materials used to produce product	455440-01	A	The product specification sheets(MSDS) for all the starting materials have been provided by registrant.
830.1620	Description of production process	455440-01	A	Abamectin is not produced by traditional chemical synthesis, but is produced by fermentation using culture of microorganism Streptomyces avermitilis. Details of the fermentation and purification process are provided.
830.1670	Discussion of formation of impurities	455440-01	A	The registrant has provided required information on the formation of impurities during the fermentation process. It is theorized that all of the potential impurities in abamectin technical are either isomers of the AI, other avermectin molecules, or degradation products of the AI and other impurities.
830.1700	Preliminary analysis	455440-02	A	Registrant has provided 5 batch analysis for the TGAI. The AI was assayed by using HPLC / UV(245 nm). The impurities were identified by using HPLC - MS method.
830.1750	Certified limits	Basic CSF (11-05-01) 455440-02	A	The proposed certified limits for the TGAI were with in standard certified limits. The registrant has provided the explanation for the proposed limits.
830.1800	Enforcement analytical method	455440-02	A	The HPLC / UV (245 nm) method was used for the assay of the AI in abamectin technical

A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable.; G = Data gap; I = In progress or need upgrade;

Table 2: Physical and Chemical Properties f the Abamectin Technical. *See Note for acceptance condition

GLN	Requirement	MRID	Status[1]	Result[2] or Deficiency
830.6302	Color	457475-01	A	white
830.6303	Physical state	" "	"	Micro crystals (,0.1 mm)
830.6304	Odor	" "	"	odorless
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	" "	A	stable to elevated temperatures (54C, 14 days); stable to Cu & Fe and the corresponding sulfate ions at RT and 54C for two weeks.
830.6314	Oxidation/reduction: chemical incompatibility	" "	A	None
830.6315	Flammability	" "	A	Not flammable
830.6316	Explodability	" "	A	Not explosive
830.6317	Storage stability	" "	G	No data submitted
830.6319	Miscibility		NA	
830.6320	Corrosion characteristics		G	No data submitted
830.7000	pH	" "	A	7.2 at 20C
830.7050	UV/Visible absorption	" "	A	See Note 1
830.7100	Viscosity	NA		
830.7200	Melting point/ Melting range	457475-01	A	157 - 161C
830.7220	Boiling point/ Boiling range	NA		
830.7300	Bulk Density	457475-01	A	0.584
830.7370	Dissociation constants in water	"	A	No well established value in literature. Does not dissociate in various pH ranges
830.7550	Partition coefficient (n-octanol/water), shake flask method	"	A	Log Ko/w Avermectin B1a = 6.0 Log Ko/w Avermectin B1b = 5.5
830.7840	Water solubility: column elution method; shake flask method	"	U	water = 7 - 10 ug / l at 20C No data submitted for the solubility in organic solvents.
830.7950	Vapor pressure	"	A	2.0 x 10(-7) kPa at 25C

A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable ; G = Data gap W = waiver request
I = Incomplete or in progress; U = Needs upgrading

Note 1. UV/Vis 830.7050.

Solution	Conc (mol/l)	Lambda max (nm)	Log e	Absorbance	Bandwidth (nm)
MeOH	3.55 x 10(-5)	245	4.52	1.173	29
MeOH	3.55 x 10(-5)	245	4.52	1.166	30
(scanned at 25 nm/min)		237	4.47	1.048	Shoulder
		254	4.32	0.739	Shoulder
1NHCl:MeOH(1:9 v/v)	3.55 x 10(-5)	245	4.53	1.199	29
1NNaoH:MeOH(1:9 v/v)	3.55 x 10(-5)	246	4.41	0.909	
		350	3.30		