FEE

DATE OUT: 17/ JUN/ 2005

SUBJECT: FEE: PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]
DP BARCODE No.: 309348 **File Symbol No.:** 100-RERT
PRODUCT NAME: Gramoxone Inteon
COMPANY: Syngenta Crop Protection, Inc.
FOOD USE [X] INTEGRATED FORMULATION [ ]
PCC: 061601 **Decision No.** 348898

Debra M. Rate 6/17/05
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FROM: Debra Rate
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Technical Review Branch/RD (7505C)

TO: James Tompkins / Hope Johnson RM 25
Herbicide Branch / RD (7505C)

INTRODUCTION:

The registrant has submitted for review a basic formulation CSF (dated 26/JUL/2004) and an alternate formulation CSF (dated 10/JAN/2005) for the proposed end-use product, Gramoxone Inteon. The end-use product has paraquat dichloride (30.1%) as its active ingredient (AI). The registrant has submitted product chemistry studies under the MRID No. 463774-01 and 463645-02. The Technical Review Branch (TRB) has been asked to review the submitted CSFs and studies.

SUMMARY OF FINDINGS

1. The proposed end-use product, Gramoxone Inteon, contains paraquat dichloride (EPA Reg. 100-1067, 45.6%, Current Status: Registration Rejected), as its active ingredient (AI) with a product label claim of 30.1%.

2. The registrant has submitted a CSF for basic formulation (dated 26/JUL/2004) for the proposed end-use product, Gramoxone Inteon. The basic formulation CSF is filled out correctly and completely. The nominal concentration of the AI concurs with the product label claim nominal concentration. The CSF is in compliance with PR Notice 91-2. However, all of the inert ingredients have not been cleared by the Agency for this use. The data submitted corresponding to guideline 830.1550(product identity and composition) and guideline 830.1750 (certified limits) does not satisfy the requirements of 40§CFR158.155 and 158.175, respectively. See Confidential Appendix for the details of the uncleared inert ingredients.

3. The registrant has submitted a CSF for alternate formulation (dated 10/JAN/2005) for the proposed end-use product, Gramoxone Inteon. The alternate formulation CSF is filled out correctly and completely. The nominal concentration of the AI concurs with the product label claim nominal concentration. The CSF is in compliance with PR Notice 91-2. However, all of the inert ingredients have not been cleared by the Agency for this use. The data submitted corresponding to guideline 830.1550 (product chemistry and composition) and guideline 830.1750 (certified limits) does not satisfy the requirements of 40§CFR158.155 and 158.175, respectively. See the Confidential Appendix for the details of the uncleared inert ingredients.

4. The data submitted corresponding to the guideline reference 830.1600 (description of materials used to produce the product) satisfies the data requirements of 40§CFR158.160. [MRID No. 463774-01]

5. The data submitted corresponding to guideline references 830.1650 (description of formulation process) and 830.1670 (discussion on the formation of impurities) satisfy the data requirements of 40CFR§158.165 and 158.167, respectively. No impurities of toxic concern were reported to be

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carried-over from the technical sources, or produced in the formulation of the end-use product. [MRID No. 463774-01]

6. The registrant has submitted an adequate method of enforcement to fulfill the guideline requirements of 830.1800 (Enforcement Analytical Method). The submitted study satisfies the requirements of 40§CFR158.180. The methodology used to determine the %AI in the subject product is ion-pair high performance liquid chromatography (HPLC) with UV/Vis detector (300 nm). This method has been validated for linearity, accuracy and precision. [MRID No. 463774-01]

7. The data submitted corresponding to 830 Series Subgroup B (physical-chemical properties) satisfy the data requirements of 40CFR§158.190, except for storage stability (830.6317) and corrosion characteristics (830.6320). [MRID No. 463645-02]

8. The registrant has submitted a statement of Self-Certification (dated 02/APR/2004) for the Physical / Chemical properties corresponding to the 830 Series Subgroup B to fulfill the requirements of 40CFR§158.190. [MRID No. 463645-02]

9. The ingredient and storage and disposal statement on the proposed label meet label requirements from a product chemistry point of view. However, the label language must also comply with 40CFR180.1065.

CONCLUSIONS:

The TRB has reviewed the submitted basic formulation CSF (dated 26/JUL/2004) and alternate formulation CSF (dated 10/JAN/2005) for the proposed end-use product, Gramoxone Inteon and has concluded that:

1. The product chemistry data submitted corresponding to 830 Series Subgroup A are acceptable.

2. The CSF for basic formulation (dated 26/JUL/2004) will be acceptable, only if the following conditions are met. The inert ingredient in question (See Confidential Appendix) must be cleared for use by the Agency at the concentration specified on the CSF. See the Confidential Appendix for the details.

3. The CSF for alternate formulation (dated 10/JAN/05) will be acceptable, only if the following conditions are met. The inert ingredient in question (See Confidential Appendix) must be cleared for use by the Agency at the concentration specified on the CSF. See the Confidential Appendix for the details.

4. The product chemistry data submitted corresponding to 830 Series Subgroup B (physical/chemical properties) are acceptable, except for those pertaining to storage stability (830.6137) corrosion characteristics (830.6320).

5. The registrant must submit the results of the storage stability (830.6317) and the corrosion characteristics (830.6320) studies to the Agency on completion.

6. The language on the label concerning the inert ingredient (listed in the Confidential Appendix) must comply with 40CFR180.1065.

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Product Chem Review MRID#s 463[illegible]

Page 3 is not included in this copy.

Pages ____ through ____ are not included.

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.

BARCODE No.: 309348 **File Symbol No.:** 100-RERT **PRODUCT NAME:** Gramoxone Inteon
PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B)

Subgroup A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (Basic CSF / Alternate CSF)	N	26/JUL/2004 / 10/JAN/2005
830.1600. Beginning Materials	Y	463774-01
830.1650. Formulation Process	Y	463774-01
830.1670. Discussion of Impurities	Y	463774-01
830.1700. Preliminary Analysis	NA	
830.1750. Certified Limits (Basic CSF)	Y	26/JUL/2004 / 10/JAN/2005
830.1800. Enforcement Analytical Method	Y	463774-01

Subgroup B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	Y	Dark green (Munsell 7.5 G / 5.2 /2.0)	463645-02
830.6303. Physical State	Y	liquid	463645-02
830.6304. Odor	Y	Slightly fruity, pungent	463645-02
830.6314. Oxidation/Reduction Action	Y	Non-Ox or Red	463645-02
830.6315. Flammability	Y	>217 °F (>103 °C)	463645-02
830.6316. Explodability	Y	Not explosive	463645-02
830.6317. Storage stability	I	Stable two weeks at 54°C, one year study is in progress.	463645-02
830.6319. Miscibility	NA	Not intended to be mixed with petroleum solvents when used as directed.	463645-02
830.6320. Corrosion Characteristics	I	No corrosion seen after one month, one year study is in progress.	463645-02
830.6321. Dielec. Bkd. Vltg.	NA	Not intended to be used around electrical equipment.	463645-02
830.7000. pH	Y	pH = 5 – 7 (1% dispersion in water @ 25 °C)	463645-02
830.7100. Viscosity	Y	65.1 mPas @ 20 °C (10 s^{-1} shear rate)	463645-02
830.7300. Density/Bulk Density	Y	9.36 lbs / gal or 1.122 g / ml @ 20 °C	463645-02

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable;
G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

BARCODE No.: 309348 **File Symbol No.:** 100-RERT **PRODUCT NAME:** Gramoxone Inteon

830.1800 Enforcement Analytical Method: (MRID No. 463774-01)

The method used to determine the % AI in the proposed end-use product is ion-pair high performance liquid chromatography (HPLC).

Apparatus and Operating Conditions:

Instrument:	Agilent 1100 series HPLC system		
Column:	150 mm X 3.2 mm i.d. stainless steel packed with 5 μm Hichrom RPB (ex Hichrom Ltd.)		
Column Temperature:	40 °C		
Mobile Phase:	Prepare a 20 mM solution of 1-octane sulphonic acid sodium salt in water (e.g. dissolve 3.89 g of 1-octane sulphonic acid sodium salt in 900 ml of AST Type II water). Mix in the following ratio: 900 2 mM 1-octane sulphonic acid sodium salt solution 100 acetonitrile 16 orthophosphoric acid 10 ddiethylamine		
Flow Rate:	0.5 ml min-1		
Detector wavelength:	300 nm	Band width:	4 nm
Reference wavelength:	550 nm	Band width:	100 nm
Injection volume:	10 μl		
Data handling system:	Atlas		
Wash Solution I:	10% acetonitrile (in water)		
Wash Solution II:	10% acetonitrile (in water) with 0.16% orthophosphoric acid		
Retention Times:			
Paraquat:	~7.8 min.		