29/JAN/2001

SUBJECT: Product Chemistry Review of Sipcan Metolachlor Technical (MUP)

FROM: Shyam B. Mathur Ph.D
Product Chemistry Team
Technical Review Branch/RD (7505C)

SBmathur 01-29-01

TO: Joanne Miller, PM 23
Herbicide Branch / RD (7505C)

DP BARCODE: D270203
EPA REG. NO.: 60063-RT
REGISTRANT: Sipcam Agro, USA, Incorporation
USE: Herbicide

INTRODUCTION:

The registrant has submitted an application, in accordance with FIFRA Sec.3, for the registration of Sipcam Metolachlor technical, containing the herbicide active ingredient metolachlor. The Sipcam Agro USA, Inc., intend to register this material as a manufacturing use product, which will be used to formulate end-use products that will be applied to agricultural and horticulture crops , including turf grass. The applicant has submitted the product chemistry data for Subgroup A under MRID No. 452391-01 and 452391-02 and Subgroup B (Physical/Chemical Properties) under MRID NO. 452469-01.

SUMMARY OF FINDINGS:

1. The data submitted corresponding to guideline reference 830.1550 (Product identification) and 830. 1750 (certified limits) satisfy the data requirements of 40CFR§158.155 & 158.175 respectively.

2. The data submitted corresponding to guideline reference 830.1600 (Description of materials used to produce the product), 830.1620 (description of production process), and 830.1670 (Discussion on the formation of impurities) satisfy the data requirements of 40CFR§158.160, 158.162, and 158.167 respectively.

3. The data submitted corresponding to guideline reference 830. 1700 (Preliminary analysis) satisfy the data requirements of 40CFR§158.170.

4. The data submitted corresponding to guideline reference 830.1800 (Enforcement analytical method) satisfy the data requirements of 40CFR§158.180

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CONCLUSION:

1. The data submitted corresponding to guideline reference 830.1550 (Product identification) and 830. 1750 (certified limits) satisfy the data requirements of 40CFR§158.155 & 158.175 respectively, and are acceptable. [The impurity profile listed in the CSF for basic formulation dated 10-10-00 concurs with the analytical results of the batches obtained from amended process. The nominal concentration, the upper and lower certified limits for the AI are same. All the impurities are same, their nominal concentrations and upper certified limits are same. No new impurities are formed]. The CSF for basic formulation dated 10-10-00 is acceptable.

2. The data submitted corresponding to guideline reference 830.1600 (Description of materials used to produce the product), 830.1620 (description of production process), and 830.1670 (Discussion on the formation of impurities) satisfy the data requirements of 40CFR§158.160, 158.162, and 158.167 respectively and are acceptable.

3. The data submitted corresponding to guideline reference 830. 1700 (Preliminary analysis) satisfy the data requirements of 40CFR§158.170 and are acceptable.

4. The data submitted corresponding to guideline reference 830.1800 (Enforcement analytical method) satisfy the data requirements of 40CFR§158.180 and are acceptable.

5. The proposed technical was determined not be substantially similar to the registered product with Reg.No. 100-587 form the product chemistry point of view, since the impurity profile for the two products are entirely different.

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REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

Chemical Name (IUPAC, ANSI, etc.)	2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)-acetamide.
Chemical Numbers (CAS; PC Code)	Reg. No. 60063-RT CAS No. 51218-45-2 PC Code 108801
Registration/Symbol No.	60063-RT
Type of Product (T, FI, MP, EP)	97% T
DP Barcode	D270203
Reviewer	Shyam B. Mathur, Ph.D

The Sipcam Agro, USA Incorporation has submitted the product chemistry data corresponding to guideline reference Series 830 Subgroup A and Subgroup B under MRID Nos. 452391-01, 452391-02 and 452469-01 to support its registration.

Table 1: Manufacturing and Impurity Data for the cga-279202, Trifloxystrobin

GLN	Requirement	MRID	Status[1]	Details and/or Deficiency[2]
830.1550	Product Identity & Disclosure of Ingredients	452391-01	A	the NC, UCL and LCL of the AI are in compliance with regulations. All the impurities are identified and are quantitated. CSF dated 10-10-00
830.1600 830.1620 830.1650	Starting Materials & Manufacturing Process	452391-01	A	provided MSDS for all the starting materials. The production process is described in details with chemical equations and the apparatus used and the reaction parameters in each steps.
830.1670	Discussion of Impurities	452391-01	A	The *full discussion on the formation of impurities* is described and also for the theoretical possible impurities. All the impurities are identified and quantitated by GC/MS.
830.1700	Preliminary Analysis	452392-02	A	Five batches are analyzed under OECD Good laboratory practice. The AI was analyzed by using HPLC method. The organic by-products were analyzed by HPLC and GC/MS methods.
830.1750	Certification of Limits	452392-02	A	certified limits for the AI were in compliance with 40CFR15.175. CSF dated 10-10-00
830.1800	Analytical Methods	452392-02	A	the analytical method was validated for precision, accuracy, and linearity.

[1] A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable.
[2] Refer to CDI Appendix A for details.

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Table 2: Physical and Chemical Properties for the				
GLN	Requirement	MRID	Status[1]	Result[2] or Deficiency
830.6302	Color	452469-01	Y	Brown
830.6303	Physical State	" "	Y	Liquid
830.6304	Odor	" "	Y	None
830.6313	Stability	" "	Y	Stable under normal and elevated temps; stable with ions of Zn,Fe,Al and Cu and corresponding metals. Was also found stable to stainless steel wire and galvanized wire.
830.6314	Oxidation/Reduction	" "	Y	None
830.6315	Flammability		NA	
830.6316	Explodability		NA	
830.6317	Storage Stability	" "	I	Results will besubmitted on completion of studies.
830.6319	Miscibility		NA	
830.6320	Corrosion Characteristics	" "	I	1 month no-corrosion. One year is in progress.
830.7000	pH	" "	Y	4.02 at 25 deg. C
830.7050	UV/Visible Absorption	" "	Y	See Note 1
830.7100	Viscosity	" "	Y	69.51 mm^2 / s at 25 deg C
830.7200	Melting Point/ Melting Range		NA	
830.7220	Boiling Point/ Boiling Range	" "	Y	> 280 deg C
830.7300	Density/ Relative Density/ Bulk Density	" "	Y	1.1149 g/ml at 25 deg C
830.7370	Dissociation Constant in Water	" "	Y	The sample does not dissociate readily
830.7550 830.7560 830.7570	Partition Coefficient (Octanol/Water)	" "	Y	log P = 2.9 at 25 deg C
830.7840 830.7860	Solubility	" "	Y	488 mg/L at 25 deg C
830.7950	Vapor Pressure	" "	Y	4.2 mPa at 25 deg C

[1] A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable.
[2] For example, "brown" for 830.6302; "155° C" for 830.7200.

Note 1. 830.7050, UV-Visible: 0.1N HCl λ_{max} 266 nm, ε_{max} 515.6
λ_{max} 274 nm, ε_{max} 427.5
Water λ_{max} 266 nm, ε_{max} 533.1
λ_{max} 274 nm, ε_{max} 443.9
0.01N NaOH λ_{max} 218 nm, ε_{max} 13841
λ_{max} 266 nm, ε_{max} 535.5
λ_{max} 274 nm, ε_{max} 444.9

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ATTACHMENT: CONFIDENTIAL APPENDIX

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METOLACHLOR 01-29-2001

Page 6 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.

X 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.

COMMENTS:

The sources and specifications were provided for each of the starting materials. A detailed description including the relative amounts of starting materials and intermediates, types of equipment used, regulated conditions (temperature, pressure, and pH), duration of procedures, and flow charts of the chemical reactions of the manufacturing process of the 97% T was included.

The registrant stated that on the basis of chemical structure, Metolachlor is not prone to the formation of chlorinated dioxins, dibenzofuranes, or HCBs even after extreme conditions. None of the starting materials have precursor character, and the process chemistry as a potential source of chlorinated dioxins, dibenzofuranes and other HCB, can be ruled out with high probability.

BAR CODE: D270203; Reg. No.: 60063-RT; Chemical: Metolachlor Technical

830.1650, Product identity (MRID No. 452391-01)

The registrant provided the following information on this topic:

Common name: Metolachlor

CAS No.: 51218-45-2

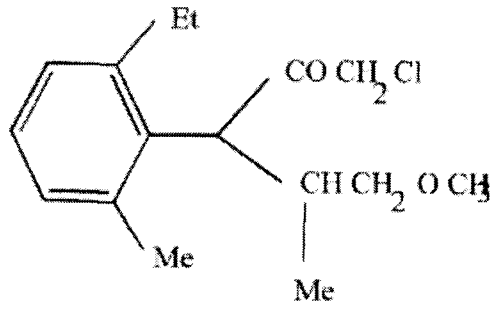
Empirical formula: C_{15} H_{22} Cl N O_2

CAS Name: 2-Chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide

IUPAC Name: 2-Chloro-6 '-ethyl-N-(2-methoxy-1- methylethyl)acet-o-toluidide

Mol. Wt.: 283.8

Structural formula:



[Metolachlor]

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Page _____ is not included in this copy.

Pages 9 through 12 are not included in this copy.

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_____ Identity of product impurities.

X Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

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