



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

OCT 6 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Ciba-Geigy Corporation's Response to the Product Chemistry Chapter - Metolachlor Registration Standard (MRID Nos. 402766-00, 402766-01, and 402766-02) - RCB No. 2641

FROM: Gobind P. Makhijani, Chemist *G. Makhijani*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Richard F. Mountfort, PM 23
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Amy Rispin, Ph.D, Chief
Science Integration Staff
Hazard Evaluation Division (TS-769C)

THRU: William J. Boodee, Section Chief *WJ*
Reregistration Section
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

In response to the Metolachlor Reregistration Guidance Document issued in September 1986, Ciba-Geigy Corporation has submitted partial product chemistry data (consisting of three volumes), dated July 24, 1987 (MRID Nos. 402766-00, 402766-01, and 402766-02).

Revised tables A and B are provided at the end of this report.

61-1: Product Identity and Disclosure of Ingredients

The registrant has submitted the required information (MRID No. 402766-01) on the identity of the product as well as a revised Confidential Statement of Formula (CSF), which contains certain process-related impurities not previously identified for metolachlor, technical. This is discussed under 62-2.

61-2: Description of Beginning Materials and Manufacturing Process

The registrant has submitted the names and addresses of suppliers of beginning materials and their specifications along with detailed manufacturing process (MRID No. 402766-01).

A summary of the manufacturing process is discussed in Confidential Appendix A.

61-3: Discussion of Formation of Impurities

The registrant has provided a theoretical discussion of the impurities formed during the production of metolachlor (MRID No. 402766-01).

No further information is required for this topic.

62-2: Certification of Ingredient Limits

The registrant has submitted a CSF (EPA Form 8750, Rev. 2-85) in which the lower and upper limits have been certified for the active ingredient and the upper limits have been certified for the impurities present at > 0.1 percent by weight (MRID No. 402766-01).

This certification of ingredient limits will be reviewed after the receipt of the preliminary analysis of product sample data.

A summary of the certification is given in Confidential Appendix B.

We defer to Toxicology Branch regarding the toxicological significance of the possible impurities formed during the manufacturing process of metolachlor.

Physical and Chemical Characteristics

The physical and chemical characteristics, previously not reported by the registrant, are as follows:

63-7 - Density - 1.12 g/cm³ at 20 °C.

63-10 - Dissociation Constant - No dissociation between pH 2 and 10.

63-11 - Octanol/Water Partition Coefficient - 850 (Log P = 2.9).

63-12 - pH - 5.66 at 25 ± 1 °C (Saturated solution).

2

- 63-13 - Stability - The stability of metolachlor to containers fabricated from carbo-zinc, carbon steel, and stainless steel was studied at temperatures of 52 °C for a period of 2 weeks. The percentage decomposition of metolachlor was < 1 percent and the metal ion level detected (Zn^{++} , Fe^{++} , and Fe^{+++}) was less than 10 ppm.
- 63-14 - Oxidizing and Reducing Action - None.
- 63-15 - Flammability - Flashpoint > 110 °C.
- 63-16 - Explodability - NFPA Code classified as a Class IIIb-combustible liquid.
- 63-17 - Storage Stability - Stable when stored at:
 - (a) Room temperature for a period of 12 months.
 - (b) 50 °C for a period of 28 weeks.
- 63-18 - Viscosity - 118 centipoises at 20 °C.
- 63-19 - Miscibility - Miscible with organic solvents.
- 63-20 - Corrosion Characteristics - Carbon steel at 50 °C--corrosion rate: 0.015 mil/yr. No corrosion or pitting detected.

Attachment I - Tables A and B (4 pages)
Metolachlor Registration Standard, S.F., Reviewer, RBP,
PMSD/ISB (E. Eldredge), Mountfort (PM 23), TOX (Coberly)

Attachment II - Confidential Appendices (3 pages)
Metolachlor Registration Standard, S.F., Reviewer, RBP,
PMSD/ISB (E. Eldredge), Mountfort (PM 23), TOX (Coberly)

cc: Metolachlor Registration Standard, S.F., R.F., Reviewer,
PMSD/ISB (E. Eldredge), Mountfort (PM 23), Circu., RBP,
TOX (Coberly)

Table A
Generic Data Requirements for Technical Metolachlor (EPA Registration No. 100-587)

Baseline Citation and e of Test	Test Substance	Guidelines Status	Are Additional Data Required?		Reference Citation
			[Yes]	[No]	
8.120 Product Chemistry					
<u>duct Identity and Composition</u>					
1 - Identity of Ingredients	TGAI	R	☐	☒	MRID No. 402766-01
2 - Materials and Process	TGAI	R	☐	☒	MRID No. 402766-01
3 - Formation of Impurities	TGAI	R	☐	☒	MRID No. 402766-01
<u>lysis and Certification of duct Ingredients</u>					
1 - Preliminary Analysis	TGAI	R	☒	☐	
2 - Certification of Ingredient Limits	TGAI	R	☐	☒	MRID No. 402766-01
3 - Analytical Methods to Verify Certified Limits	TGAI	R	☒	☐	
<u>sical and Chemical Characteristics</u>					
2 - Color	TGAI	R	☐	☒	MRID No. 402766-02
3 - Physical State	TGAI	R	☐	☒	MRID No. 402766-02
4 - Odor	TGAI	R	☐	☒	MRID No. 402766-02
5 - Melting Point	TGAI	N/A	☐	☐	
6 - Boiling Point	TGAI	R	☐	☒	MRID No. 402766-02
7 - Bulk Density	TGAI	R	☐	☒	MRID No. 402766-02
8 - Solubility	TGAI or PAI	R	☐	☒	MRID No. 402766-02

A

Table A
Generic Data Requirements for Technical Metolachlor (EPA Registration No. 100-587) (cont'd)

define Citation and e of Test	Test Substance	Guidelines Status	Data Required?		Reference Citation
			[Yes]	[No]	
8.120 Product Chemistry (cont'd)					
<u>Physical and Chemical Characteristics (cont'd)</u>					
9 - Vapor Pressure	PAI	R	☐	☒	MRID No. 402766-02
10 - Dissociation Constant	PAI	R	☐	☒	MRID No. 402766-02
11 - Octanol/Water Partition Coefficient	PAI	R	☐	☒	MRID No. 402766-02
12 - pH	TGAI	R	☐	☒	MRID No. 402766-02
13 - Stability	TGAI	R	☐	☒	MRID No. 402766-02
14 - Submittal of Samples	TGAI or PAI	R	☒ *	☐	
.....					

PAI = Technical Grade Active Ingredient; PAI = Purified Active Ingredient; R = Required; N/A = Not Applicable.
If samples are needed, the Agency will request them.

5

Table B
Product Specific Data Requirements for Manufacturing-Use Products Containing Metolachlor
EPA Registration No. 100-587

Define Citation and Use of Test	Test Substance	Guidelines Status	Data Required? [Yes] [No]	Reference Citation
<u>8.120 Product Chemistry</u>				
<u>Product Identity and Composition</u>				
1 - Product Identity and Disclosure of Ingredients	MUP	R	☐ ☒	MRID No. 402766-01
2 - Description of Beginning Materials and Manufacturing Process	MUP	R	☐ ☒	MRID No. 402766-01
3 - Discussion of Formation of Impurities	MUP	R	☐ ☒	MRID No. 402766-01
<u>Analysis and Certification of Product Ingredients</u>				
1 - Preliminary Analysis	MUP	CR	☐ ☒	
2 - Certification of Ingredient Limits	MUP	R	☐ ☒	MRID No. 402766-01
3 - Analytical Methods to Verify Certified Limits	MUP	R	☐ ☒	
<u>Physical and Chemical Characteristics</u>				
2 - Color	MUP	R	☐ ☒	MRID No. 402766-02
3 - Physical State	MUP	R	☐ ☒	MRID No. 402766-02
4 - Odor	MUP	R	☐ ☒	MRID no. 402766-02
7 - Density, Bulk Density, or Specific Gravity	MUP	R	☐ ☒	MRID No. 402766-02

Product Specific Data Requirements for Manufacturing-Use Products Containing Metolachlor
EPA Registration No. 100-587 (cont'd)

Outline Citation and Name of Test	Test Substance	Guidelines Status	Are Additional		Reference Citation
			Data Required? [Yes]	[No]	
8.120 Product Chemistry (cont'd)					
Physical and Chemical Characteristics (cont'd)					
12 - pH	MUP	CR	☐	☒	MRID No. 402766-02
14 - Oxidizing or Reducing Action	MUP	CR	☐	☒	MRID No. 402766-02
15 - Flammability	MUP	CR	☐	☒	MRID No. 402766-02
16 - Explodability	MUP	R	☐	☒	MRID No. 402766-02
17 - Storage Stability	MUP	R	☐	☒	MRID No. 402766-02
18 - Viscosity	MUP	CR	☐	☒	MRID No. 402766-02
19 - Miscibility	MUP	CR	☐	☒	MRID No. 402766-02

1 - Submittal of Samples	EP, TGAI, PAI	CR	$\bar{X}^*$	$\bar{X}$

: Required; CR - Conditionally Required; EP = End-Use Product; MUP = Manufacturing-Use Product; TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient.
: samples are required, the Agency will request them.

7

Page ____ is not included in this copy.

Pages 8 through 10 are not included in this copy.

The material not included contains the following type of information:

- ☒ Identity of product inert ingredients.
- ☐ Identity of product inert 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.
