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**DATE OUT: 03/SEP/2003**

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF: A TECHNICAL GRADE TGAI [X]**
**DPBARCODE #: D289789 EPA RECEIVED DATE: 11/APR/2003 FILE SYMBOL/REG NO: 11603-33 PRODUCT NAME: Diuron Technical Herbicide, 98.5 Diuron FOOD USE [X]**
**COMPANY NAME: Makhteshim Agan of North America MRID NO: 458753-01 & -02 + 459072-01**
**PPC NUMBER OF THIS TGAI: 035505 ACTION CODE: 306 CASE NO.: 003300**

**FROM:** Sami Malak, Chemist
Technical Review Branch/RD (7505C)

**TO:** 25 Jim Tompkins/Vickie Walters
Herbicide Branch/RD (7505C)

## INTRODUCTION:

With this re-submission, which is a first submission to TRB, the applicant in a letter dated 03/MAR/2003 requested the addition of an alternate manufacturing site to allow manufacturing in Israel in lieu of the current site in England. In support of this application, the applicant included product chemistry data, a basic CSF dated 03/MAR/2003, and a label received on 11/MAR/2003.

## FINDINGS:

1. The subject product, 98% pure, was transferred from Aceto Agricultural Chemical Corporation, Reg. No. 2749-58 by a letter dated 06/JUN/1990 to MTM Agrochemicals Ltd., Reg. No. 46120-01. It was again transferred from the latter to Makhteshim Agan of North America, by a letter dated 26/APR/2002, Reg. No. 11603-33 with the same purity of 98%. During the two transfers, the product was manufactured in England.

2. Adequate analytical method for the TGAI is available for enforcement. The method was previously submitted and reviewed in connection with registration of Diuron Technical, Reg.No. 11603-33. A HPLC analytical method, included in MRID #458753-01, was used in the preliminary analysis. The method is equipped with a UV detector and utilizes phenacetin as an internal standard. The method is reviewed in this memorandum.

3. The submitted product chemistry data pertaining to product's manufacturing, composition & labeling are adequate and support the new manufacturing site in Israel.

4a. The submitted product's label received on 11/MAR/2003 is substantially similar to the current label except that the nominal concentration was changed from 98% to 98.5%. The 98.5% reflects five batch analysis from th new manufacturing site in Israel.

4b. The label ingredient statement of 98.5% Diuron is consistent with that in the CSF, both are in compliance with the regulations of PR Notice 91-2. Further, the storage and disposal statement and the physical or chemical hazards statement are in compliance with the regulations of 40CFR§156.10.

5a. Product's composition as stated in the submitted basic CSF dated 03/MAR/2003 is substantially similar in composition to the current basic CSF dated 26/JAN/1998. Exceptions: the current CSF listed [redacted]

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

5b. The proposed basic CSF dated 03/MAR/2003, was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2). All ingredients claimed on the CSF are cleared for use in pesticide formulations intended for food uses.

**CONCLUSIONS:**

The applicants has satisfied product chemistry data requirements to allow manufacturing Diuron Technical in Israel. The submitted basic CSF dated 03/MAR/2003 and label received on 11/MAR/2003 are acceptable (Findings 4-b & 5-b). They must supersede the current basic CSF dated 26/JAN/1998 and label.

**EVIEW OF PRODUCT CHEMISTRY DATA (MRID #460585-01:**

1. A statement of data confidentiality dated 10/APR/2000 was included with this submission claiming confidentiality of any of the submitted data on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of this data was moved to Confidential Appendix A.

2. A GLP statement dated 28/FEB/2003 was included with this submission to the effect that the submitted studies were conducted in compliance with the GLP requirements of 40CFR§160.

830-1800 Enforcement Analytical Method:

Adequate analytical method for the TGAI is available for enforcement. The method was previously submitted and reviewed in connection with registration of Diuron Technical, Reg.No. 11603-33.

A HPLC analytical method, included in MRID #458753-01, was used in the preliminary analysis. The method is equipped with a UV detector and utilizes phenacetin as an internal standard. In this method, samples of diuron technical and standards were dissolved in acetonitrile then filtered and injected into the HPLC. The separation conditions included ODS(3) column and a UV detector.
Determination of associated impurities was accomplished by the use of a HPLC equipped with a UV using external standards.

Validation data for the analytical method regarding recovery, accuracy, precision, and linearity are adequate. Sample calculations and chromtograms were included with this submission.

**Table 2: Physical and Chemical Properties of Diuron Technical; 40CFR158.190**

| GRN | Requirement | MRID | Status[1] | Result[2] or Deficiency |
|---|---|---|---|---|
| 830.6302 | Color | 458753-02 | A | White |
| 830.6303 | Physical State | 458753-02 | A | Very fine powder |

| Table 2: Physical and Chemical Properties of Diuron Technical; 40CFR158.190 | | | | |
|---|---|---|---|---|
| GRN | Requirement | MRID | Status[1] | Result[2] or Deficiency |
| 830.6304 | Odor | 458753-02 | A | None |
| 830.6313 | Stability | | | |
| 830.6314 | Oxidation/Reduction | 458753-02 | A | The test substance is not an oxidizing agent, buts is a slight reducing agent. |
| 830.6315 | Flammability | | | |
| 830.6316 | Explodability | | | |
| 830.6317 | Storage Stability | 459072-02 | A | Stable for a period of two years. |
| 830.6319 | Miscibility | | | |
| 830.6320 | Corrosion Characteristics | 459072-02 | A | No changes were reported to the test substance or the packaging containers during the two year study. |
| 830.7000 | pH | 458753-02 | A | 5.34 |
| 830.7050 | UV/Visible Absorption | | | |
| 830.7100 | Viscosity | | | |
| 830.7200 | Melting Point/ Melting Range | | | |
| 830.7220 | Boiling Point/ Boiling Range | | | |
| 830.7300 | Density/ Relative Density/ Bulk Density | 458753-02 | A | 0.5114 |
| 830.7370 | Dissociation Constant in Water | | | |
| 830.7550/7560/7570 | Partition Coefficient (Octanol/Water) | | | |
| 830.7840 830.7860 | Water Solubility | | | |
| 830.xxxx | Solubility in Organic Solvents | | | |
| 830.7950 | Vapor Pressure | | | |

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

Only 9 properties were submitted as shown in the above table.

| Table 1: Manufacturing and Impurity Data for Diuron: 3-(3,4-dichlorophenyl)-1,1-dimethylurea | | | | |
|---|---|---|---|---|
| GRN | Requirement | MRID | Status[1] | Details and/or Deficiency[2] |
| 830.1550 | Product Identity & Disclosure of Ingredients | 459072-01 | A | For product identity refer to text below. For product's composition refer to Confidential Appendix A for details. |
| 830.1600<br>830.1620 | Starting Materials & Manufacturing Process | 459072-01 | A | Refer to Confidential Appendix A for details. |
| 830.1670 | Discussion of Impurities | 459072-01 | A | Refer to Confidential Appendix A for details. |
| 830.1700 | Preliminary Analysis | 459072-01 | A | Refer to Confidential Appendix A for details. |
| 830.1750 | Certification of Limits | 459072-01 | A | Refer to Confidential Appendix A for details. |
| 830.1800 | Analytical Methods | 459072-01 | A | Refer to text for details |

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

## GRN 830.1550 Product Identity:

Chemical Name: 3-(3,4-dichlorophenyl)-1,1-dimethylurea.

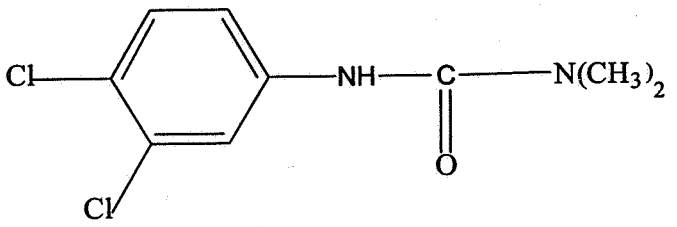
Common Name: Diuron

Product Name: Diuron Technical Herbicide.

Chemical Abstract Number: 330-54-1

Empirical Formula: $C_9H_{10}Cl_2N_2O$

Molecular Weight: 233.1

Structural Formula

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