



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DP BARCODE: D277268

SUBJECT: Mesotrione (PC Code: 122990)
Mesotrione (ZA1296) Prospective Groundwater (PGW) Study - Michigan,
USA (MRID: 454789-01)

TO: Joanne Miller
James Stone
Herbicide Branch, Registration Division (7505C)

FROM: James Lin, Environmental Engineer
Alex Clem, Environmental Scientist
Environmental Risk Branch III, EFED (7507C) *[Signature]* 11/28/01

THRU: Thomas Steeger *[Signature]* 11/28/01
Acting Branch Chief, Environmental Risk Branch III, EFED (7507C)

DATE: November 28, 2001

Background Information. The registrant, Syngenta Crop Protection, Inc., apparently anticipated possible groundwater concerns for mesotrione. Therefore, to test their concern and to avoid possible unfavorable Agency registration response, delay, or imposition of special requirements/restrictions, such as a precautionary groundwater label advisory, Syngenta conducted a prospective groundwater (PGW) monitoring study.

PGW studies provide a strong measure of the likelihood of pesticides or their transformation products leaching to ground water. Syngenta conducted this study on their own initiative, and without Agency consultation or imposition. From the registrant's perspective, in addition to allaying any Agency concern for ground water pollution, not having a groundwater advisory on their product label also apparently provides marketing advantage.

Syngenta conducted their PGW study in Michigan. They submitted two interim reports on the study previously. EFED discussed the interim reports in our Section 3 assessment. In the meantime, RD and EFED have met, exchanged e-mail, and had telephone conversations about

the mesotrione PGW study. Syngenta's current submission (MRID 454789-01) is their final report on the study.

Conclusions. This PGW study appears valid. Neither parent nor metabolites were detected. However, due to the relatively low rainfall amounts and possible frozen ground during the winter at this Michigan site, the study did not represent a reasonable upper-bound case for assessing the potential for leaching to ground water, for example, at a Southern USA site.

Results and Discussion. The principal study features listed below support our conclusions. Additional analysis of the study data would provide other potentially useful information, but would not alter the major study limitations or our conclusions.

1. Slow movement of bromide due to the slow water recharge:

Significant concentrations of bromide tracer (> 360 ug/L) were detected in three shallow groundwater monitoring wells at 8 MAT (month after treatment), providing an indication of the first water recharge event since the trial commenced. By the 11-MAT sampling event, significant bromide residues were observed in eight monitoring wells (up to 4,110 ug/L). By the 22-MAT sampling event, significant bromide residues (up to 13,160 ug/L) were observed in 15 of the 16 monitoring wells. Compared to soil metabolism rates for mesotrione residues, eight months is a relatively long time for bromide tracer to first reach shallow ground water.

2. Possible frozen ground conditions:

Sub-zero mean air temperatures (Table 3 data) during the winter months suggest frozen ground conditions that would effectively reduce or stop infiltration.

3. Less rainfall in Michigan than in the Southern USA:

The average annual rainfall at the study site is 35.7 inches, whereas the average rainfall in the Mississippi Delta region ranges from 45 to 65 inches.

Possible Alternative to a PGW Study in the Southern USA. Because of the apparent insufficiency of the Michigan study, the registrant and the Agency have been contemplating a PGW study in the Southern USA. However, the Agency is aware that Syngenta has conducted a soil lysimeter study (or studies) for the purpose of registration in Europe. Lysimeter studies are invaluable as a strong indicator of leaching potential. If analysis, interpretation, and inferences from the registrant's lysimeter results show minimal likelihood of significant leaching, then another PGW study or further action by the registrant or Agency would not be needed. Donald Stubbs and Philip Errico of RD have recently informed us that RD is requesting that Syngenta submit their lysimeter study data for review. After review, the Agency would consider the need for any further action.

DP BARCODE: D277268

CASE: 063670
SUBMISSION: S602216

DATA PACKAGE RECORD
BEAN SHEET

DATE: 08/22/01
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 575 CON REG FLW-UP DAT REQ HE
RANKING : 10 POINTS ()
CHEMICALS: 122990 Mesotrione (Proposed common name) 40.0000%

ID#: 000100-01131 ZA1296 4SC HERBICIDE
COMPANY: 000100 SYNGENTA CROP PROTECTION, INC.
PRODUCT MANAGER: 23 JOANNE MILLER 703-305-6224 ROOM: CM2 237
PM TEAM REVIEWER: JAMES STONE 703-305-7391 ROOM: CM2 257
RECEIVED DATE: 08/16/01 DUE OUT DATE: 02/12/02

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 277268 EXPEDITE: N DATE SENT: 08/22/01 DATE RET.: / /
CHEMICAL: 122990 Mesotrione (Proposed common name)
DP TYPE: 001 Submission Related Data Package

CSF: N LABEL: N
ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 01/09/02
DIV : EFED 08/23/01 / / NEGOT DATE: / /
BRAN: EAB III 08/23/01 / / PROJ DATE: / /
SECT: FO 08/23/01 / /
REVR : Pat Jennings 08/23/01 / /
CONTR: Jim Lin 10/5/01 / /

* * * DATA REVIEW INSTRUCTIONS * * *

Attention: ~~Skee Jones and Alex Clem~~ *Jim Lin*
Final Report of Michigan Prospective Groundwater Monitoring Study that company did on their own initiative. A Prospective Grounwater Study in Southern USA was a condition of registration [See attached Mesotrione Fact Sheet]. Does this study fulfill this requirement? Note: Sygenta will not intiate a site search on the new PGM until this study is reviewed.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

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MEMORANDUM

5 Dec 2001

Subject: Addendum to D277268 for mesotrione (PC 122990) regarding review of prospective groundwater monitoring (PGM) study conducted in Michigan

From: Alex Clem, Environmental Scientist, ERB 3/EFED (7507C) *Alex Clem 12/5/01*

Thru: Thomas Steeger, Acting Chief, ERB 3/EFED (7507C) *Thomas M. Steeger 12/7/01*

To: Joanne Miller, PM 23, and James Stone, PM Team Reviewer
Herbicide Branch, Registration Division (7505C)

As background for this addendum, EFED quotes the final paragraph from our review last week (28 Nov 2001) for the subject action (D277268):

“Possible Alternative to a PGW Study in the Southern USA. Because of the apparent insufficiency of the Michigan study, the registrant and the Agency have been contemplating a PGW study in the Southern USA. However, the Agency is aware that Syngenta has conducted a soil lysimeter study (or studies) for the purpose of registration in Europe. Lysimeter studies are invaluable as a strong indicator of leaching potential. If analysis, interpretation, and inferences from the registrant’s lysimeter results show minimal likelihood of significant leaching, then another PGW study or further action by the registrant or Agency would not be needed. Donald Stubbs and Philip Errico of RD have recently informed us that RD is requesting that Syngenta submit their lysimeter study data for review. After review, the Agency would consider the need for any further action.”

Philip Errico of RD has subsequently informed Alex Clem of EFED that there was misinformation or mis-communication about a lysimeter study. A Syngenta representative has since averred to Philip Errico that there is no such lysimeter study. Based on chemical characteristics, this is somewhat surprising to EFED. In case there has been an inadvertent mistake, EFED suggests to RD that they confirm from our European counterparts or in writing from the registrant that there are, in fact, no lysimeter data.

Assuming there are no lysimeter studies available, EFED falls back on our original new chemical review recommendation (DP Barcodes: D253844, D259964, D268681). As given in our transmittal memo at the time (3 May 2001), we quote the following recommendation for a generic groundwater label advisory for end-use products:

“This chemical has properties and characteristics associated with chemicals detected in ground water. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.”

If RD is committed to requiring the registrant to conduct another PGM study instead of requiring a precautionary statement on the product label, EFED will consider any forthcoming proposals the registrant submits.