

US EPA ARCHIVE DOCUMENT

DP Barcode : D233184
 PC Code No : 108800
 EEB Out : 4/11/97

To: Joanne Miller PM 23
 Product Manager

From: Daniel D. Rieder, Acting Chief
 Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 100-815
 Chemical Name : CGA-77102, Chiral Metolachlor
 Type Product : Herbicide
 Product Name : _____
 Company Name : Novartis
 Purpose : Review toxicity data on CGA-77102, chiral metolachlor, an isomer of metolachlor (108801). Determine if chiral metalochlor is similar toxicologically, to metolachlor (108801)
 Action Code : 101 Date Due : _____
 Reviewer : A. Yamhure Date In EEB: _____

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
 P=Partial (Study partially fulfilled Guideline but additional information is needed)
 S=Supplemental (Study provided useful information but Guideline was not satisfied)
 N=Unacceptable (Study was rejected)/Nonconcur



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

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MEMORANDUM D223753 / D223769 / D233184

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SUBJECT: The Ecological Effects Branch's (EEB) response to two different DP Barcodes - D223753 and D223769 - for the new chemical CGA 77102 (a metolachlor isomer-Chemical code 108800). Originally this action was a new chemical data screen. EEB proceeded to conduct full evaluation of the thirteen studies as well as making a preliminary estimate of the validity of these tests for use as bridging data for the apparently similar pesticides metalochlor and its isomer metalochlor CGA 77102. The thirteen studies reviewed are MRID numbers: 439289-06/07/08/09/10/11/12/13/29/30/31/32/33). **D233184**

FROM: Dan Rieder, Acting Chief
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

Dan Rieder 4/11/97

TO: Joanne Miller, Product Manager 23
(Product Reviewer Eugene Wilson)
Special Review and Reregistration Division (7508W)

The Ecological Effects Branch (EEB) has reviewed the above mentioned registration actions. The corresponding MRID numbers for the thirteen studies reviewed, as well as the determinations made by EEB on these two actions are presented in the Table 1 below.

Of the thirteen studies evaluated by EEB, ten were found to meet guideline requirements and to be scientifically sound. These studies therefore have been categorized as core. Of the three remaining studies two were categorized as supplemental and one as invalid.

Studies with (see data Table 1), MRIDs No. 439289-32 and 439289-33 were categorized as supplemental because only six, rather than the ten test plants required, were used. These tests could be upgraded to core when and if the missing plants are tested under similar conditions as the original six plants already tested.

Table 1

MRID	GUIDELINE	TYPE OF TEST	RESULTS	CATEGORY
439289-06	71-1	Acute oral mallard duck	LD50 > 2194 ai mg/kg NOEL 2194 ai mg/kg	Core
439289-07	71-1	Acute oral bobwhite quail	LD50 > 2194 ai mg/kg NOEL 874 ai mg/kg	Core
439289-08	71-2	8-day dietary bobwhite quail	LC50 > 4912 ppm ai NOEC 2762 ppm ai	Core
439289-09	71-2	8-day dietary mallard duck	LC50 > 4912 ppm ai NOEC 1556 ppm ai	Core
439289-10	72-1	Acute toxicity to bluegill sunfish	LC50 3.2 ppm ai NOEC 1.5 ppm ai	Core
439289-11	72-1	Acute toxicity to rainbow trout	LC50 11.9 ppm ai NOEL 2.5 ppm ai	Core
439289-12	72-2	Acute toxicity to <i>Daphnia magna</i>	48-hours EC50 26 ppm ai NOEL 4.8 ppm ai	Core
439289-13	72-3	Acute toxicity to <i>Mysidopsis bahia</i> (bay shrimp)	96-hour LC50 1.41 ppm ai NOEC not determined	Invalid (see rationale below)
439289-29	123-2 (tier II)	5-day toxicity to fresh water green algae (<i>Selenastrum c.</i>)	EC50 0.0080 ppm ai NOEC 0.0015 ppm ai	Core
439289-30	123-2 (tier II)	5-day toxicity to the marine diatom (<i>Skeletonema c.</i>)	EC50 0.11 ppm ai NOEC 0.021 ppm ai	Core
439289-31	123-2 (tier II)	Toxicity to duckweed (<i>Lemna gibba</i>)	EC50 0.021 ppm ai NOEC 0.0076 ppm ai	Core
439289-32	123-1 (tier II)	Seedling emergence - nontarget plants	Dry weight EC25 0.0057 lb ai/A NOEL 0.0003 lb ai/A	Supplemental (see rationale below)
439289-33	123-1 (tier II)	Vegetative vigor - nontarget plants	Phytotoxicity EC25 0.27 lb ai/A NOEL 0.01 lb ai/A	Supplemental (see rationale below)

The bay shrimp (*Mysidopsis bahia*) study, MRID 439289-13 was found to be scientifically unsound and did not meet guideline requirements. This test was therefore categorized as invalid. The reason for this assessment has to do with the age of the mysids at test initiation, which according to guidelines should be ≤ 24 hours and as uniform as possible among individuals. The mysids used were of variable age and older than 24 hours at test initiation. This study, in spite of the fact that it was conducted prior to the issuance of the corresponding guideline, is considered to be invalid mainly because the individual test organisms used were of variable age. Organisms of the same species but different age are likely to display different sensitivity to the same toxicant at equal dose. The endpoint obtained under these testing conditions would not be representative of the test species as a whole tested.

The following observations are made regarding the issue of the possible use of bridging data between these two related chemicals (CGA 77102 or metalochlor isomer - chemical code 108800 and metalochlor - chemical code 108801:

1. There are no valid (core) avian reproduction studies [(71-4 (a) and (b))] available for either chemical. These data gaps must be fulfilled. The registrant has already agreed to do so.
2. The vegetative vigor and seed germination/seed emergence studies that have been categorized as supplemental are acceptable for risk assessment purposes. EEB will use the lowest EC25 values obtained to estimate risk.
3. Generally speaking, a comparison of the toxicity of these two chemicals to the various test group organisms (invertebrates, fish, birds and plants - please see data Table 2) suggests that their toxicities are somehow similar and therefore that the acceptance of the use of bridging data between these two chemicals may be a viable alternative to the usual complete toxicological data set for each chemical.
4. The available data suggest that the risks to nontarget organisms from CGA 77102 (a metalochlor isomer (chemical code 108800), would not be significantly different from that of the original metalochlor (chemical code 108801).

Should you need further assistance on this matter, please contact Alvaro Yamhure of the EEB staff at (703) 305-6179.

Guideline	MRIID	Type test/Test organism	% ai	Results	Test date	Category	METAL OCHLOR ISOMER (00880) TESTS IN FEEB FILES AS OF 3/20/97
71-1(a)	00015517	Acute oral mudflat	Tech.	LD50 4640 mg/kg	1977	core	439289 06 87.4% LD50 > 2510 mg/kg 1983 (NOEL2510)
71-1 (b)							439289-07 87.4% LD50 > 2510 mg/kg 1983 (NOEL1000)
71-2(a)	00016125	Dietary mudflat	Tech.	LC50 > 1X10 ⁶ ppm	1977	core	439289-09 87.4% LC50 > 5620 mg/kg 1983 (NOEL1780)
71-2(a)	00016126	Dietary quail	Tech.	LC50 > 1X10 ⁶	1977	core	439289-08 87.4% LC50 > 5620 mg/kg 1983 (NOEL3160)
71-3(a)(b)	DC1						
72-1(a)	00015534	Acute fish fillet/gill	Tech.	LC50 15 ppm	1977	core	439289-10 Tech.(?) LC50 3.2 ppm 1983 (NOEC 1.5)
72-1(a)	00018723	Acute fish fillet/gill	Tech.	LC50 10 ppm	1978	core	
72-1(c)	0018722	Acute fish rainbow trout	Tech.	LC50 3.9 ppm	1978	core	439289 11 97.6% LC50 11.9 ppm ai 1995 (NOEC2.5)
72-2(a)	226955	Acute freshwater invertebrate - Daphnia	Tech.	EC50 25.1 ppm NOEL 5.6 ppm	1978	core	439289 12 97.6% EC50 26.0 ppm ai 1995 (NOEC4.8)
72-3(a)	434871-01	Acute fish sheephead minnow	97.3	LC50 9.8 mg ai/l	1994	core	
72-3(a)	430446-02	Acute fish sheephead minnow	97.0	LC50 7.9 ppm MATC 1.48 ppm	1980	Suppl.	
72-3(a)	434871 01	Acute fish sheephead minnow	97.3	LC50 1.8 mg ai/l	1994	core	
72-3(b)	434871 02	Acute mollusk - C. virginica	97.3	EC50 1.7 ppm	1994	core	
72-3(c)	434871-03	Acute mysid shrimp (M. tubia)	97.3	LC50 4.9 ppm	1994	core	439289 13 Tech.(?) LC50 1.41 ppm ai (NOEC)INVALID 1983
72-4(b)	430446-03	Daphnia life cycle				invalid	
72-4(b)	438026-01	Daphnia 21-day flow-thru	97.0	MATC 4.7-LOEC 6.9 NOEC 3.2ppm	1995	suppl.	
72-5	470257-23	Fish-fathead life cycle/early life-stage	97.4	MATC1.17LOEC1.6 NOEC 0.78ppm	1978	suppl.	
123-2	435113-01	Aquatic plant growth (algae)	97.3	EC50 10 ppb NOEL 0.7 ppb	1995	core	439289 29 97.6% EC50 0.0080 ppm ai (NOEC0.0015) 1995
123-2	435113 02	Aquatic plant growth (diatom)	97.3	EC50 0.38 ppm NOEL 0.00037 ppm	1995	core	439289 30 97.6% EC50 0.11 ppm ai (NOEC 0.021) 1995
123 2	434871-05	Aquatic plant growth (duckweed)	97.3	EC50 0.048 NOEC 0.0060 ppm	1994	core	439289 11 97.6% EC50 0.021 ppm ai (NOEC 0.0076) 1995
123 2	434871-04	Aquatic plant growth (A. fluviatilis)	97.3	EC50 1.2 mg ai/l	1994	core	
123 (a)	434871-07	Seed germ./seed emergence.	97.3	EC25 0.02 lb ai/A (monocot) 0.09 lb ai/A (dicot)	1994	core	Seed emerg: 439289 32 97.6% EC25(D) 0.0037 (MONO)0.048 lb ai/A 1995 NOEL(D) 0.0001 (MONO)0.010 lb ai/A
123 1(b)	434871 08	Vegetative vigor	97.3	EC25 0.030 lb ai/A (dicot) 0.0016 lb ai/A (monocot)	1994	core	439289 33 97.6% EC25(D) 0.27 (ND) 0.021 lb ai/A NOEL(D) 0.01 (ND) 0.011 lb ai/A
123-2	434871-06	Aquatic plant growth (diatom- S. costatum)	97.3	EC50 0.061 mg ai/l	1994	core	