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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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Memorandum

Subject: Novartis Response Regarding Outstanding Ecological Effects Data requirements for *s*-Metolachlor and Proposed Timetable for Completion.
Submission Number: S551205 DP Barcode: D250840

To: Joanne Miller, Product Manager 23
Registration Division (7505C)

From: Brian Montague, ERB I *Brian Montague* 12/16/98
Environmental Fate and Effects Division (7507C)

Through: Arnet Jones, Branch Chief *Arnet Jones* 01/20/99
ERB I, Environmental Fate and Effects Division (7507C)

The Environmental Fate and Effects Division has completed our review of the Novartis response regarding data gaps in *s*-metolachlor ecological testing requirements as discussed at our October 28 meeting. Novartis has responded with a commitment to conduct avian reproduction (with quail), chronic mysid, and fish early life stage studies with *s*-metolachlor to fulfill 71-4 and 72-4 guideline gaps along with a timetable that they estimate will be possible for submission of study results to the Agency. An existing honeybee acute contact study (guideline 141-1) will be forwarded by December 1998. Upon receipt and acceptance of these studies committed to by Novartis the Agency will be able to more accurately assess the risk potential from proposed uses of *s*-metolachlor and present data requirements will be considered fulfilled. Certain studies that they have not committed to conduct at this time may be later triggered by new study results. This includes the sheephead minnow early life stage test.

Agency acceptance of this Novartis proposal will allow the new herbicide (an isomer of metolachlor) to be registered on a variety of crops. EFED recommends that RD make this registration conditional upon completion of all required studies within the agreed time frame. In the interim the Agency will need to establish toxicity levels based on currently submitted studies in order to complete ecological risk assessments for *s*-metolachlor. These studies include bridging data from metolachlor data as well as acceptable studies submitted for *s*-metolachlor. The proposed risk assessment endpoints from accepted studies are discussed below. Due to the

length of time required for completion and review of new chronic studies with quail, mysid, and fathead minnow using *s*-metolachlor the Agency proposes that start date notification for all studies and interim (midpoint) reports regarding the avian reproduction and fish early life stage studies be provided by Novartis. In addition, any significant adverse effects observed during any of the chronic studies should be reported promptly to the Agency as would normally occur for adverse effects observed in ongoing studies under FIFRA 6a2 regulations.

For purposes of assessing ecological risk for *s*-metolachlor the following endpoints will be used, unless receipt of new information shows increased sensitivity or lower toxicity values for the species groups addressed in the risk assessment process. Unless stated, the values below are based on studies conducted with *s*-metolachlor.

71-1 Avian Oral Toxicity	LD50 > 2194 mg ai/Kg
71-2 Avian Dietary	LC50 > 4912 ppm
71-4 Avian Reproduction (based on mallard-metolachlor)	LOEC > 800 ppm, NOEC=800 ppm
72-1 Fish Acute toxicity	LC50 = 3.2 ppm
72-2 Invertebrate Acute Toxicity	EC50 = 26 ppm
72-4 Chronic Fish Toxicity (based on metolachlor- fathead minnow)	LOEC = 1.6 ppm, NOEC= 0.78 ppm
72-4 Chronic Invertebrate (based on metolachlor daphnid)	LOEC = 6.9 ppm, NOEC=3.2 ppm
72-3 Estuarine Fish acute (based on <i>s</i> -metolachlor(bluegill))	LC50 = 3.2 ppm
72-3 Estuarine shrimp acute	LC50 = 1.4 ppm
72-3 Estuarine shellfish acute (metolachlor-oyster)	EC50 = 1.6 ppm
72-4 Estuarine Fish Chronic (based on metolachlor-fathead minnow)	LOEC = 1.6 ppm, NOEC= 0.78 ppm
72-4 Estuarine Shrimp Chronic(daphnid-metolachlor)	LOEC = 6.9 ppm, NOEC = 3.9 ppm
123-2 Terrestrial plant seed emergence	EC25 ≥ 0.0057 lb ai/A NOEC ≥ 0.0003 lb ai/A
123-2 Terrestrial plant vegetative vigor	EC25 ≥ 0.27 lb ai/A NOEC ≥ 0.01 Lb ai/A
123-2 Aquatic plant (<i>Selenastrum capricornutum</i>)	EC50 = 0.008 ppm
141-1 Honeybee (Non-target Insect) acute contact (pending confirmation of company provided results)	LD50 > 110 ug ai/bee

Though the endpoint scenarios outlined above do not represent the final numbers which may be used in future risk assessments for *s*-metolachlor, they represent a conservative approach for assessing risk to non-target organisms using currently available data on metolachlor and *s*-metolachlor. It is expected that *s*-metolachlor assessments will be conducted with new bobwhite avian reproduction, fathead minnow early life stage, and mysid life cycle study results after the year 2000 when new chronic studies are submitted to the Agency as per this agreement.

Further questions regarding this memorandum of understanding may be addressed to Brian Montague or Arnet Jones of the Environmental Fate and Effects Division, Office of Pesticide Programs (7507C).