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MEMORANDUM **May 28, 2003**

SUBJECT: EFED Risk Assessment for Section 3 Registration of BAS 510 F (Nicobifen)

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Attached please find the Environmental Fate and Effects Division's (EFED) environmental risk assessment for BAS 510 F (nicobifen) registration as a fungicide for use on turf, vegetable, canola, fruit, and nut crops in the U.S. and Canada. Although nicobifen is persistent, it has low mobility in soil; however, nicobifen may move to surface water through spraydrift and runoff of soil and suspended sediments. The degree of surface water contamination is mitigated, though, by the relatively low seasonal application rates (≤ 2.1 lbs. a.i./acre/season) and the chemical's tendency to sorb to soil and sediments.

The fungicide is classified as practically nontoxic to terrestrial animals and is moderately toxic to aquatic animals on an acute exposure basis. Furthermore, the compound does not bioaccumulate appreciably in fish (BCF range: 35X - 105X) and dupurates rapidly. Based on a deterministic assessment, nicobifen acute risk quotients do not exceed acute risk levels of concern and therefore is not likely to pose an acute risk to animals at the maximum proposed application rate

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of 0.350 lbs a.i./A (2.1 lbs a.i./A/season). However, owing to the compound's persistence, estimated residues on terrestrial food items are likely to pose a risk to birds feeding on short grasses following application of nicobifen to turf. All of the proposed uses are likely to represent a risk of chronic toxicity to mammals. Additionally, while nicobifen is not expected to adversely affect aquatic life whose life is primarily spent in open water, bottom-dwelling (benthic) fauna may be more likely to encounter nicobifen based on the chemical's persistence and tendency to sorb to sediments.

Nicobifen is not expected to pose a risk to aquatic plants; however, EFED is uncertain regarding the effects of this fungicide to terrestrial and semi-aquatic plants. Terrestrial plant studies (vegetative vigor and seedling emergence) were classified as supplemental since the studies only tested up to a maximum application rate of 0.55 lbs a.i./A, whereas the maximum proposed seasonal rate, *i.e.*, 2.1 lbs a.i., is considerably higher.

Uncertainties

Although there is a slightly higher potential for nicobifen to reach groundwater when the compound is applied to soils that are low in organic matter, as is often the case with coarse-textured (i.e., sandy) soils which are typically used to grow crops (strawberry, peanut, potato and carrot) included in the proposed uses for nicobifen, EFED is relatively confident that the EEC's determined using SCI-GROW2 are appropriate for the determination of the potential for contamination of groundwater sources, even in such cases. However, this small uncertainty exists with respect to the fate of the compound.

In determining EEC's for surface water, EFED utilized only Tier I models, as there were no exceedences using those values, and a continuation to Tier II modeling was not triggered. However, additional modeling using PRZM/EXAMS was conducted to determine sediment concentrations since that was determined to be a potential issue of concern. It is noted that for persistent compounds, EECs in surface water can be higher using PRZM/EXAMS. Thus, a small uncertainty exists with respect to the EECs determined using Tier I models relative to those determined using PRZM/EXAMS (a Tier II model).

In modeling terrestrial exposure, EFED relied on a default 35-day foliar dissipation half life. The default value was used since no data were available on total foliar residues that could be used to estimate a foliar dissipation half life for nicobifen. Given nicobifen's stability to biotic and abiotic routes of degradation, it is possible that nicobifen residues could be considerably higher than those used as representative of both avian and mammalian food items. EFED has concluded though that even with the 35-day default value, there is a likelihood of chronic risk to birds and mammals. If the foliar residue half-life is longer, then the number of days when chronic levels of concern are exceeded will be extended.

Chronic risk LOCs were exceeded for birds and mammals based on peak estimated foliar residue values. Had estimated environmental concentrations been based on mean residues (roughly 50% of maximum) rather than maximum, the likelihood of chronic LOCs would have been

eliminated for birds. Chronic RQs for mammals would have likely been exceed only by mammals feeding on short grass.

Additionally, the acute risk level of concern for endangered species is exceeded for estuarine/marine invertebrates (RQ range: 0.05 - 0.06). However, there are no currently listed estuarine/marine invertebrate endangered species. Although acute toxicity testing indicates that nicobifen is moderately toxic to aquatic animals, the data suggest that molluscs may be more sensitive. Given the propensity of nicobifen to sorb to sediment and persist, EFED is uncertain regarding the sensitivity of freshwater molluscs.

EFED is uncertain regarding the toxicity of nicobifen to terrestrial and semi-aquatic plants. Under Tier 1 testing standards, the registrant is required to test up to the maximum application rate. In two of the current studies, Vegetative Vigor (MRID 454050-12) and Seedling Emergence (MRID 454050-11), a single application rate of 0.55 lbs a.i./A is used. While the maximum single application rate for nicobifen is 0.547 lbs a.i./A, the maximum proposed seasonal rate is considerably higher. Given the persistence of nicobifen and its potential to accumulate, its effects on terrestrial plants at seasonal application rates as high as 2.1 lbs a.i./A are uncertain.

Data Gap

The environmental fate data base for the parent compound is relatively complete (**Table A1**). Two guideline study areas, aerobic aquatic metabolism (Guideline 162-4) and leaching-adsorption/desorption (Guideline 163-1), have been classified as supplemental; however, EFED is not recommending that the studies be repeated at this time, as the submitted studies did provide sufficient data for the risk assessment.

Although the ecological effect data base is relatively complete (**Table A2**), most of the studies are classified as supplemental. Aquatic toxicity tests using fish and invertebrates were classified as supplemental since water quality parameters did not adhere to standards recommended by the Environmental Fate and Effects Division. If the registrant can demonstrate that pH, water hardness and the use of dechlorinated tap water do not affect the toxicity of nicobifen and if it can be demonstrated that mean measured concentrations accurately reflect the amount of chemical in solution, these studies can be upgraded to core. However, except for the freshwater invertebrate life cycle study, EFED is not requiring that the aquatic toxicity tests classified as supplemental be repeated. In the freshwater invertebrate life cycle study (MRID 454050-05) none of the required data are provided on growth (length and weight) of *Daphnia magna.* If the registrant has these data, they should provide the information for review; otherwise, EFED recommends that the study be repeated.

Additionally, given the persistence of nicobifen and its tendency to partition on to sediments, EFED recommends that toxicity data be provided for a freshwater mollusc such as *Corbicula spp.*

Label Language

The labels for vegetable and turf uses each contain the following warning:

- **Do not apply directly to water, areas where surface water is present, or intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash waters.**

In addition to the environmental hazard warning already on the labels, EFED recommends the following surface water advisory based on nicobifen's low soil-water distribution coefficient (K_d) and its long aerobic soil metabolism half-life (96 - 578 days):

- **This product may contaminate water through drift of spray in wind. This product has a potential for runoff according to the pesticide's "mean" soil partition coefficient (15 mL/g^2) for several months or more after application. Poorly draining soils and soils with shallow watertables are more prone to produce runoff that contains this product. A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.**

Table A1. Status of environmental fate data needs for nicobifen (BAS 510 F).

Guideline #		Data Requirement	Are Data Adequate for Risk Assesment?	MRID #'s	Study Classification
161-1	835.2120	Hydrolysis	yes	45405205	acceptable
161-2	835.2240	Photodegradation in Water	yes	45405206	acceptable
161-3	835.2410	Photodegradation on Soil	yes	45405207	acceptable
161-4	835.2370	Photodegradation in Air	—	—	NA[1]
162-1	835.4100	Aerobic Soil Metabolism	yes	45405208 45405209 45405210 45643802	supplemental supplemental not acceptable[2] acceptable
162-2	835.4200	Anaerobic Soil Metabolism	no[3]	45405211 45405212	supplemental[4] supplemental[4]
162-3	835.4400	Anaerobic Aquatic Metabolism	yes	45405213	acceptable
162-4	835.4300	Aerobic Aquatic Metabolism	yes	45405214	supplemental[5]
163-1	835.1240 835.1230	Leaching-Adsorption/Desorption	yes	45405216 45405217	supplemental[6] supplemental
163-2	835.1410	Laboratory Volatility	—	—	NA
163-3	835.8100	Field Volatility	—	—	NA
164-1	835.6100	Terrestrial Field Dissipation	yes	45405218 45405219 45405220 45405221 45405222	supplemental[7] acceptable acceptable acceptable supplemental[8]
164-2	835.6200	Aquatic Field Dissipation	no	45405215	not acceptable[9]
164-3	835.6300	Forestry Dissipation	—	—	NA
164-4	835.6400	Combination Products and Tank Mixes Dissipation	—	—	NA
165-4	850.1730	Accumulation in Fish	yes	45405007	acceptable
165-5	850.1950	Accumulation – Aquatic Non-target Organisms	—	—	NA
166-1	835.7100	Groundwater – Small Prospective	—	—	NA
201-1	840.1100	Droplet Size Spectrum	yes [10]	NA	NA
202-1	840.1200	Drift Field Evaluation	yes [10]	NA	NA

[1]NA = not applicable. [2]Study data were insufficient and did not extend to the half-life occurrence. Complete data were later reported in MRID 45643802. [3]Not necessary for the risk assessment since an acceptable 162-3 study was submitted. [4]Inadequate experimental method and insufficient data. [5]Inadequate experimental method. [6]May be upgraded to acceptable with additional data. [7]A major degradate was not monitored. [8]Study was not conducted domestically (U.S.) and half-lives were of questionable value due to data variability. [9]Inadequate experimental method.[10] Met through participation in the Spray Drift Task Force.

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Table A2. Status of ecological effect data needs for nicobifen (BAS 510 F).

Guideline #	Data Requirement	Are Data Adequate for Risk Assessment?	MRID #'s	Study Classification
71-1a	Bobwhite Quail Acute Oral	Yes	454049-22	Core
71-2a	Bobwhite Quail Subacute Dietary	No [a]	454049-23	Supplemental [b]
71-2b	Mallard Duck Subacute Dietary	No [a]	454049-24	Supplemental [b]
71-4a	Bobwhite Quail Reproduction	Yes	454049-25	Core
71-4b	Mallard Duck Reproduction	Yes	454049-26	Core
72-1a	Freshwater Fish (Bluegill Sunfish) Acute	No [a]	454049-27	Supplemental [c]
72-1c	Freshwater Fish Rainbow Trout Acute	No [a]	454049-28	Supplemental [c d]
72-1	Freshwater Invertebrate *(Daphnia magna)* Acute	No	454050-01	Supplemental [d]
72-3 a	Estuarine/marine Fish (Sheepshead minnow) Acute	Yes	454050-04	Core
72-3b	Estuarine/marine Invertebrate (Mysid Shrimp) Acute	Yes	454050-02	Core
72-3c	Estuarine/marine Invertebrate (Eastern oyster) Acute	Yes	454050-03	Core
72-4a	Freshwater Fish Early Life Stage (Rainbow Trout)	No [a]	454050-06	Supplemental [c d]
72-4b	Freshwater Invertebrate Life Cycle (*Daphnia magna*)	No [f]	454050-05	Supplemental [d e]
144-1	Honey bee acute contact	Yes	454050-19	Core
Nonguideline	Earthworm Acute	Yes	454050-20	Nonguideline
Nonguideline	Freshwater Sediment Toxicity (*Hyalella azteca*)	Yes	454050-09	Nonguideline
Nonguideline	Freshwater Sediment Toxicity (*Chironomus riparus*)	Yes	454050-08	Nonguideline

Table A2 (cont.). Status of ecological effect data needs for nicobifen (BAS 510 F).

Guideline #	Data Requirement	Are Data Adequate for the RA?	MRID #'s	Study Classification
122-2	Seedling Emergence (Tier 1)	No	454050-11	Supplemental [g]
122-2	Vegetative Vigor (Tier 1)	No	454050-12	Supplemental [g]
123.-2	Vascular Aquatic Plant (*Lemna gibba*)	Yes	454050-13	Core
123-2	Nonvascular Freshwater Diatom (*Navicula pelliculosa*)	Yes	454050-14	Core
123-2	Nonvascular Aquatic Plant (*Anabaena flos-aquae*)	No [a]	454050-15	Supplemental [d]
123-2	Nonvascular Marine Diatom (*Skelotonema costatum*)	Yes	454050-16	Core
123-2	Nonvascular Green Algae (*Pseudokirchneriella subcapitata*)	No [a]	454050-17	Supplemental [c d]

[a] Although study is classified as supplemental and as not having fulfilled guideline testing requirements, EFED is not requiring that the study be repeated at this time.
[b] Poor animal care conditions and too few number of birds used per treatment.
[c] Water hardness and pH exceeded EPA's recommended range.
[d] Test concentrations approached solubility limit of compound; water samples should have been centrifuged and/or filtered prior to analysis for test chemical.
[e] Study failed to provide data on effects of nicobifen on growth (length and weight).
[f] If registrant cannot provide data on animal growth (length and weight), the study must be repeated.
[g] Maximum seasonal application rate not tested.