Petition for Thiabendazole

March 2013
VIA FEDEX

March 18, 2013

Document Processing Desk (AMEND)(E-SUB)(PETN)(REGFEE)
Registration Division (7505P)
Office of Pesticide Programs
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Mr. Tony Kish, PM – Fungicide Team 22

SUBJECT: THIABENDAZOLE
- TOLERANCE PETITION AND LABEL AMENDMENT TO ADD NEW USES – VEGETABLE, ROOT (EXCEPT SUGARBEET); SUBGROUP 1B, ONION, BULB, SUBGROUP 3-07A; BRASSICA, HEAD AND STEM, SUBGROUP 5-A; VEGETABLE, CUCURBIT GROUP 9; ALFALFA; SPINACH (INCLUDING BABY); AND SMALL GRAIN CEREALS (WHEAT, BARLEY, OATS, RYE, AND TRITICALE)
- MERTECT® 340-F FUNGICIDE (EPA Reg. No. 100-889)
- THIABENDAZOLE TECHNICAL MF (EPA Reg. No. 100-963)
- LABEL AMENDMENT TO ADD HIGHER RATE ON SOYBEANS

Dear Mr. Kish:

Syngenta Crop Protection, LLC respectfully submits a label amendment for Mertect 340-F Fungicide (EPA Reg. No. 100-889) and Thiaebendazole Technical MF (EPA Reg. No. 100-963) to add new seed treatment uses on assorted vegetables and small grain cereals. Concurrent with, and in support of this application, Syngenta submits multiple Magnitude of Residue studies on alfalfa, dry bulb onion, cucurbits (cucumbers, muskmelon, summer squash), head and brassica vegetables (broccoli, cabbage), spinach, root vegetables (except sugarbeets) (carrot and radish), wheat and barley. In addition, please find a tolerance petition to establish domestic tolerances for residues of thiabendazole in or on alfalfa, dry bulb onion crop subgroup 3-07A, cucurbit vegetables crop group 9, head and stem vegetables crop subgroup 5A, root vegetables (except sugarbeet) crop subgroup 1B, spinach, barley and wheat (hay and forage).

Please note that although additional residue data for the small grain cereal commodities is not provided, Syngenta received feedback from an EPA ChemSac meeting November 29, 2009 concluding that if the use patterns were similar to existing uses on barley or wheat, then wheat and barley residue data can be used to apply towards additional small grain cereal tolerances. Michael A. Doherty provided the following summation from the ChemSac minutes:
"The SAC concluded that it is acceptable to set a tolerance on oats with wheat and barley residue data provided that the timing of applications to these crops coincides. The SAC will address the establishment of a small grains tolerance using residue data from wheat, barley, and oats in the future."

Further, enclosed please find a request to amend the Mertect 340-F label that contains an approved seed treatment use on soybeans to allow a higher rate. This amended label is based upon new Magnitude of Residue data using a seed treatment application (enclosed) that shows no residues at twice the newly proposed rate. Hence, the existing thiabendazole/soybean tolerance of 0.1 ppm does not need to be amended.

Similarly, there are existing thiabendazole tolerances for wheat, grain and wheat, straw of 1.0 ppm. The enclosed Magnitude of Residues study for thiabendazole on wheat will allow the Agency to grant tolerances for the other 2 wheat commodities: Wheat, hay, and wheat, forage. The residues found in this new Magnitude of Residue study for Wheat, grain and straw, do not exceed the existing tolerances. Hence, I did not petition for these to be amended.

Minor Use Exclusive Use Qualification

Under FIFRA § 3 (c)(1)(F)(vi), Syngenta respectfully requests EPA to allow exclusive use protection of the data submitted in support of the minor use registrations contained in this application for the period of 10 years from the date of submission. The exclusive use period for the pesticide thiabendazole has expired and the data pertaining to the minor use registration is eligible under FIFRA § 3 (c)(1)(F)(vi). Specifically, Syngenta considers the following minor use crops to qualify under this Section: dry bulb onion crop subgroup 3-07A (based upon representative crop dry bulb onion residue data), cucurbit vegetables crop group 9 (based upon representative crops cucumbers, cantaloupe and summer squash residue data), head and stem vegetables crop subgroup 5A (based upon representative crops broccoli and cabbage residue data), root vegetables (except sugarbeet) crop subgroup 1B (based upon representative crops carrot and radish residue data), alfalfa, and spinach.

Under the provisions of this paragraph, Syngenta certifies, to the best of our knowledge, that the exclusive use period for thiabendazole has expired. The original registration of thiabendazole was August 5, 1971, which is more than 10 years ago.

The following representative crop data pertaining solely to the above minor use is eligible for the provisions of this paragraph:

Thiabendazole – Magnitude of the Residues in or on Dry Bulb Onion Following Seed Treatment Application (Report Number: TK0003800)

Thiabendazole (A10466G) - Magnitude of the Residues in or on Carrots and Radish (Representative Commodities of Crop Group 1B) (Report Number: TK0003807)

Thiabendazole (A10466G) - Magnitude of the Residue in or on Cantaloupe, Cucumber, and Summer Squash (Representative Commodities of Crop Group 9) (Report Number: TK0003803)
Thiabendazole 340-F (A10466G) - Magnitude of the Residues in or on Alfalfa (Report Number: TK0050928)

Thiabendazole – Magnitude of the Residues in or on Broccoli and Cabbage as Representative Crops of Head and Stem Brassica, Group 5A Following Seed Treatment Application (Report Number: TK0003802)

Thiabendazole – Magnitude of the Residues in or on Spinach (Report Number: TK0003804)

In addition to the additional uses described above, we have included the following minor revisions to the draft Mertect 340-F label:

- All directions for use (proposed and existing) in the seed treatment section of the label have been revised to a table format as opposed to the textual format previously used. The existing use rates for those uses previously approved have not been changed.

- Revised the Ag Use box to include an exception to allow workers to enter areas where treated seed has been planted provided the seed is covered by soil. This is standard language found on all seed treatment labels.

- Expanded the seed bag label requirements to include good stewardship information such as PPE, disposal instructions treated seed, and replant restrictions similar to what the Agency has requested for other seed treatment products recently.

Please note, all proposed revisions are indicated in the highlighted version of the proposed label included with this submission.

Lastly, enclosed for your information, please find a courtesy copy of the cover letter my regulatory colleague Teresa Cox wrote to accompany the submission of data (and assigned MRID Nos.) provided to EPA to satisfy Conditions of Registration imposed by the Agency in the Notice of Registration for Maxim Quattro (EPA Reg. No. 100-1352).

Fees for Service

In compliance with the Pesticide Registration Improvement Act III, Syngenta will pay the required pesticide registration fee for this action. Syngenta believes that this submission fits the following registration fee category: R190, "Additional food uses; 6 or more...", for a total of $359,856. This fee has been prepaid and documentation attached. Please e-mail the registration fee receipt to bunnie.konat@syngenta.com

Enclosed in support of this submission are the following documents:

- Copy of check indicating PRIA III payment
- Transmittal document
- Tolerance Petition
- Notice of Filing
• Completed EPA Application for Pesticide Registration Form 8570-1 for Mertect 340-F
• The revised Mertect 340-F label, one highlighted to show proposed revisions; one copy of proposed supplemental label
• The revised Thiabendazole Technical MF (100-963) label, one highlighted to show proposed revisions
• Cover letter to EPA dated February 22, 2013 entitled “Thiabendazole Technical (EPA Reg. No. 100-963) Addressing Conditions of Registration” signed by Syngenta Regulatory Manager Teresa Cox
• Two (2) data volumes
• Data Matrices for thiabendazole and Mertect 340-F Insecticide

Please feel free to contact me at 336-632-7317 if you have any questions or concerns.

Sincerely,

Patrick McCain
Senior Regulatory Manager – Seed Care