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E-Submission

July 30, 2018

Document Processing Desk (**REGFEE**)
Office of Pesticide Programs (**7504P**)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Ms. Heather Garvie and Ms. Lindsay Roe; PM Team 22, Registration Division

SUBJECT: PRIA R200 – Reduced Risk Petition Proposing Tolerances for Pydiflumetofen in Multiple Crops
Pydiflumetofen Technical (EPA Reg. No. 100- 1609), Miravis® (EPA Reg. No. 100-1601), Miravis® Top (EPA Reg. No. 100-1602), Miravis® Prime (EPA Reg. No. 100-1603) and Miravis® Neo (EPA Reg. No. 100-1605)
Includes a New Seed Treatment product (Saltro 100-XXXX; PRIA R310) for Rapeseed Subgroup 20A (Canola) & Soybean
Request for Extended Exclusive Use Period
GHS Mixtures Equation Pilot

Dear Ms. Garvie and Ms. Roe:

Syngenta Crop Protection, LLC is submitting a new petition for foliar use of pydiflumetofen on:
Berries, Low Growing Crop Subgroup 13-07G (except cranberry and blueberry)
Brassica Head and Stem Crop Group 5-16
Brassica Leafy Greens Subgroup 4-16B
Bulb Vegetable Crop Group 3-07A
Bulb Vegetable Crop Group 3-07B
Bushberry Crop Subgroup 13-07B
Citrus Crop Subgroup 10-10
Cottonseed Subgroup 20C
Edible-podded Legume Vegetables Subgroup 6A and Succulent Shelled Pea and Bean Subgroup 6B
Pome Fruit Crop Group 11-10
Root Vegetable Crop Group 1A
Sorghum
Stone Fruit Crop Group 12-12 (Subgroups 12A, 12B and 12C)
Sunflower, Oilseed Subgroup 20B
Tree Nuts Crop Group 14-12

Pydiflumetofen is currently unconditionally registered as a reduced risk fungicide for multiple crops, ornamentals and turf. With this petition to expand the foliar crop uses, Syngenta is also submitting a reduced risk document to support reduced risk of the expanded commodities listed above. Additionally, because Pydiflumetofen was granted reduced risk status for use on 13 crops and crop groups from the initial registration (EPA letter enclosed; January 29, 2018), Syngenta believes that pydiflumetofen is registered for at least 9 minor crops to support extending the exclusive use period by 3 years.

In addition to adding the new foliar uses listed above to Miravis® (pydiflumetofen solo; EPA Reg. No. 100-1601) and several mixture products containing pydiflumetofen (Appendix 1 table), Syngenta is also submitting a new seed treatment product, Saltro (100-XXXX) for use on Rapeseed Subgroup 20A and soybean.

To support the seed treatment uses of rapeseed 20A and soybean, Syngenta is submitting a rationale as to why current foliar tolerances of pydiflumetofen on rapeseed 20A (canola) and soybean should cover seed treatment use without the need for any changes in these two established tolerances or any additional residue data. Also in support of the new seed treatment product Saltro® (EPA Reg. No.100-XXXX) is enclosed a product chemistry package, which includes the basic Saltro® CSF 2193/1 and an alternate Saltro® CSF 2194/1. An acute toxicity data set is submitted and a summary is presented in Appendix 2 for the Saltro® formulation (referred to as A21972C in acute toxicity and product chemistry reports). To accompany the acute toxicity data for the Saltro® seed treatment formulation is the Acute Toxicity Estimate (ATE) calculations for A21972C as part of EPA's GHS Mixtures Equation pilot program to evaluate ATE as an alternative to animal testing. The enclosed ATE spreadsheet is in the format and information that the EPA has requested.

In support of the proposed tolerances on the expanded foliar commodities, Syngenta is submitting 18 residue studies (some of which IR-4 conducted and others that Syngenta conducted). The radish residue trial was conducted on the Miravis® Top formulation, which is a mixture of pydiflumetofen and difenoconazole. Concurrent with this submission is a separate tolerance petition for a radish tolerance on difenoconazole, under separate cover, supported by the same residue study report and the same Miravis® Top label. Therefore it is critical to ensure that these two PRIA actions have the same PRIA date.

Enclosed in support of this submission are the following documents:

- (5) Completed EPA Application for Pesticide Registration Forms 8570-1
- Transmittal Document - **MRID# 50587900**
- Courtesy copy of EPA letter granting reduced risk on 13 crops during initial registration of pydiflumetofen (January 29, 2018)
- Residue Data to Support New Pydiflumetofen Foliar Tolerances
 - Residue Data Report for Berries, Low Growing Crop Subgroup 13-07G (IR-4), **MRID# 50587901**
 - Residue Data Report for Brassica Head and Stem Crop Group 5-16, **MRID# 50587902**
 - Residue Data Report for Brassica Leafy Greens Subgroup 4-16B, **MRID# 50587903**
 - Residue Data Report for Bulb Vegetable Crop Group 3-07, **MRID# 50587904**
 - Residue Data Report for Bushberry Crop Subgroup 13-07B (IR-4), **MRID# 50587905**
 - Canadian Residue Study for Blueberry (Crop Group 13-07B) (PMC) **MRID# 50587919**
 - Residue Data Report for Citrus Crop Subgroup 10-10, **MRID# 50587906**
 - Residue Data Report for Cottonseed Subgroup 20C, **MRID# 50587907**
 - Residue Data Reports Edible-podded Legume Vegetables Subgroup 6A and Succulent Shelled Pea and Bean Subgroup 6B, **MRID# 50587908**
 - Residue Data Report for Pome Fruit Crop Group 11-10, **MRID# 50587909**
 - Residue Data Report for Root Vegetable SubGroup 1A, **MRID# 50587910**
 - Residue Data Report for Sorghum, **MRID# 50587911**
 - US Residue Data Report for Peaches and Plums, Stone Fruit Crop Subgroups 12-12B and 12-12C, **MRID# 50587912**
 - Canadian Plum Residue Report (PMC/IR-4), **MRID# 50587917**
 - Canadian Peach Residue Report (PMC/IR-4) **MRID# 50587918**
 - Residue Data Report for Sunflower, Oilseed Subgroup 20B, **MRID# 50587913**
 - Residue Data Report for Tree Nuts Crop Group 14-12, **MRID# 50587914**
 - Residue Data Report for Cherries (IR-4) Stone Fruit Crop Group 12-12A, **MRID# 50587916**
- Reduced Risk Rationale Document for the new foliar uses, **MRID# 50587915**
- Notice of Filing
- Tolerance Petition for the active ingredient Pydiflumetofen
- (10) Clean and highlighted PDF version of the label for Miravis® (100-1601), Miravis® Top (100-1602), Miravis® Prime (100-1603), Miravis® Neo (100-1605) and Technical pydiflumetofen (100-1609) with the proposed new foliar uses

- (11) Certification with Respect to Citation of Data Form 8570-34 for:
 - Five Technical active ingredients (pydiflumetofen, difenoconazole, fludioxonil, azoxystrobin, and propiconazole), and five for the End-Use Products (Miravis®, Miravis® Top, Miravis® Prime, Miravis® Neo)
- (20) Data Matrix Form 8570-35: Private and Public
 - Five Technical active ingredients (pydiflumetofen, difenoconazole, fludioxonil, azoxystrobin, and propiconazole), and five for the End-Use Products (Miravis®, Miravis® Top, Miravis® Prime, Miravis® Neo, and Saltro®).
- Payment Confirmation for Prepayment of PRIA Fee
- Data to Support new seed Treatment Product, Saltro® (EPA Reg. No. 100-XXXX; Formulation A21972C)
 - (1) Completed EPA Application for Pesticide Form 8570-1 for Saltro® (EPA Reg. No. 100-XXXX)
 - Transmittal Document
 - PRIA Payment Receipt
 - Rationale for why current foliar tolerances can cover seed treatment uses without additional residue data; **MRID# 50588015**
 - Product Chemistry
 - Document J: Identity, Manufacturing, Certified Limits; Syngenta Volume No. PC-18-020 – **MRID# 50588001**
 - Physical Chemical Properties; Compilation of Physical-chemical property reports; PC-18-021 – **MRID# 50588002**
 - Document H, MSDS; Compilation of MSDS for active ingredients and inerts; PC-18-022 – **MRID# ADMIN**
 - Analytical Method; Method SF-950/1; Document No. 300089026 – **MRID# 50588003**
 - Validation of Analytical Method SF-950/1; Document No. USGR170464 – **MRID# 50588004**
 - MIII Section I: Identity, A.I certified limits, physical-chemical property summary; Syngenta Volume No. PC-18-018 – **MRID# 50588013**
 - MIII, Section 2: Summary of Analytical Methods; Syngenta Volume No. PC-18-019 – **MRID# 50588014**
 - EPA Form 8570-4 Basic CSF: CSF 2193/1
 - EPA Form 8570-4 Alternate CSF: CSF2194/1
 - Acute Toxicity
 - Acute oral toxicity, Syngenta Report No. A21972C_10010 – **MRID# 50588005**
 - Acute dermal toxicity, Syngenta Report No. A21972C_50016 – **MRID# 50588006**
 - Acute inhalation toxicity, Syngenta Report No. A21972C_50011 – **MRID# 50588007**
 - In Vitro Eye Irritation, Syngenta Report No. A21972C_10002 – **MRID# 50588008**
 - Primary eye irritation, Syngenta Report No. A21972C_10006 – **MRID# 50588009**
 - In Vitro Skin Irritation, Syngenta Report No. A21972C_10004 – **MRID# 50588010**
 - Primary skin irritation, Syngenta Report No. A21972C_10008 – **MRID# 50588011**
 - Dermal sensitization [Local Lymph Node Assay (LLNA)], Syngenta Report No. A21972C_50014 – **MRID# 50588012**
 - Acute Toxicity Estimate (ATE) calculations for A21972C as part of EPA's GHS Mixtures Equation pilot program to evaluate ATE as an alternative to animal testing (XCEL spreadsheet).
- (2) Certification with Respect to Citation of Data Form 8570-34 for:
 - Pydiflumetofen Technical (EPA Reg. No. 100-1609)
 - Saltro (EPA Reg. No. 100-XXXX)

- (4) EPA Data Matrix Forms 8570-35: Private and Public for:
 - Pydiflumetofen Technical (EPA Reg. No. 100-1609)
 - Saltro® (EPA Reg. No. 100-XXXX)
- (1) PDF version of the label for the new seed treatment product, Saltro® (EPA Reg. No. 100-XXXX)

Fees for Services

In compliance with the Pesticide Registration Improvement Act III, Syngenta will pay the required pesticide registration fees for this action. Syngenta believes that this submission fits the following registration fee category: R200 (Additional Food Use; 6 or more submitted in one application; Reduced Risk, \$ 396,742). Syngenta is also paying the required fee, \$5,301, for the new product registration (R310) of the seed treatment formulation (Saltro, EPA Reg. 100-XXXX) that accompanies this submission.

If there are any questions concerning matters contained in this submission, please do not hesitate to contact me at either 336-632-7477 or by email at adora.clark@syngenta.com. Also, you may contact my regulatory assistant Stephanie at 336-632-5970 or by email at Stephanie.cole@syngenta.com

Sincerely,



Federal Team Lead, Fungicides
Syngenta Crop Protection, LLC

Enclosures