SUBJECT: Comments Submitted by Syngenta Crop Protection, LLC. Concerning the Registration of Benzovindiflupyr: EPA Docket ID No.: EPA-HQ-OPP-2013-0141

Benzovindiflupyr (Solatenol™) is a new broad spectrum foliar fungicide developed by Syngenta that belongs to the pyrazole carboxamide chemical group. Solatenol is not cross resistant to strobilurin and triazole chemistry and represents a step change in performance with broad spectrum control of economically important diseases of several key agricultural crops and numerous minor crops. Syngenta appreciates the opportunity to comment on the documents placed into EPA docket ID No. EPA-HQ-OPP-2013-0141.

Syngenta notes that one of the aerobic aquatic studies was considered supplemental, which led to the use of highly conservative default half-life values[1]. Data were previously submitted that will be important to use for refinements in future regulatory reviews that show benzovindiflupyr is unlikely to be persistent in aquatic environments. For example, more environmentally realistic half-lives can be calculated from the extensive data base submitted for benzovindiflupyr in aquatic environments. Syngenta conducted higher tier laboratory studies using light (non-UV)/dark cycles in the presence of algae and macrophytes and in two different model outdoor aquatic sediment systems. These studies indicate more realistic half-lives and are technically robust studies[2]. The half-lives for benzovindiflupyr in aquatic environments range from 19-91 days with algae and 28-81 days with both algae and a macrophyte present. The comprehensive database indicates that benzovindiflupyr is unlikely to persist or accumulate in the aquatic environment.

In reviewing EPA's assessment of soil half-lives from the extensive soils data set for benzovindiflupyr, there are major discrepancies in EPA's calculations of half-lives[3] and differences in Koc/Kd values which result in significantly underestimating the soil degradation rate of benzovindiflupyr. Degradation rates are significantly more rapid than values used in the modelling. Numerous lines of evidence support that benzovindiflupyr is unlikely to leach, including the low aqueous solubility (0.98 mg/L @ 25°C), high mean Koc (5578 mL/g), low mobility results from multiple soil dissipation studies at multiple field locations, and very low groundwater concentrations predicted from highly conservative models (PRZM-GW, SCI-GROW).

---

[1] See for example EPA Document EPA-HQ-OPP-2013-0141-0021, pages 13, 43, 77. Syngenta notes that the duration and the aerobic conditions were adequate and we look forward to discussing this in future registration actions on benzovindiflupyr. PMRA review of the same data resulted in a value 4.3 times more rapid than the EPA half-life value.

[2] These studies achieved high accountability of applied material (>86%) and indicate that the main route of degradation of benzovindoflupyr in the aquatic environment will be microbial (MRID NO. 48604510). These data have also been reviewed and accepted by EU RMS and EFSA who established more realistic aquatic DT50 values for modelling from the benzovindiflupyr higher tier laboratory water-sediment studies, resulting in a geomean DT50 of 154 days for water-sediment systems with algae and 54 days for systems with algae and a macrophyte.

[3] EPA states much longer aerobic soil SFO half-life values compared to what Syngenta calculated using the same data and program (R3.1.3, PestDF 0.8.13), in some cases by a factor of 3.

Syngenta intends to submit a more in-depth summary of discrepancies and differing endpoints used by EPA for future label expansions with our next benzovindiflupyr regulatory action. These discrepancies include endpoints calculated for marine acute studies (sheepshead minnow, mysid and marine diatom) as well as interpretation of the endpoints from the fathead minnow early life stage[4], daphnia lifecycle test, and a freshwater benthic invertebrate test. EPA classified the fish bioconcentration study as "supplemental", although it conforms to OECD guidelines (the use of one dose level). Similarly with the tests on birds, we note discrepancies in EPA's endpoint selection for the mallard reproduction study, and we scientifically disagree with EPA's interpretation of endpoints for the acute zebra finch study.

In the Drinking Water Assessment, use patterns cited for many crops do not reflect current proposed uses on the label[5]. As a result, predicted drinking water exposure concentrations are not representative and over estimate exposure. For future regulatory actions Syngenta requests that the exposure estimates are refined to take into account labeled use rates.

We also would like to point out that there are typographical errors in the proposed crop list in the drinking water assessment document[6] which should indicate "pome fruit" instead of "pomegranate."

Syngenta disagrees with the proposed cancer classification and the methods used by EPA. We will provide information in a later submission and request EPA to utilize this information to reconsider the classification in future regulatory reviews.

Additional methodologies are available for use in future review of additional crops beyond this action to further refine the highly conservative assumptions implicit in various screening level assessments conducted by EPA in the registration of benzovindiflupyr.

Syngenta appreciates the opportunity to comment on the documents related to the registration of the new fungicide Solatenol™.

---

[4] PMRA concluded that the appropriate chronic endpoint was the NOEC from the fathead minnow study (0.95 µg/L); Proposed Registration Decision for Benzovindiflupyr, PRD2015-07, March 19, 2015, Appendix I ,Page 125

[5] Label changes include reduction of single application rates, reduction in the total number of applications, adjusted timing, removal of aerial uses, etc., addition of a vegetative filter strip and addition of A 150' aerial spray drift buffer.

[6] EPA=HQ-OPP-2013-0141-0008, Tier 1 Drinking water Assessment, PC Code 122305, Pages 1-2, 4, 6, 14, 16 and 20. DB Barcode 409374