Cyproconazole

Section 5: Environmental Hazard Assessment

Comments on the ECHA Annex VI Report (Proposal for Harmonised Classification & Labelling) submitted by Ireland 2014

February 2015

Syngenta submits the following position statements in response to the ECHA Annex VI Report (Proposal for Harmonised Classification & Labelling) submitted by Ireland 2014.

Syngenta position regarding the inclusion of 1,2,4-Triazole (CGA71019) studies in the classification and labelling proposal for cyproconazole.

Syngenta considers that the evaluation and classification of cyproconazole should be performed independently of metabolites, including 1,2,4-triazole. As a result, Syngenta proposes that the referenced studies and cited data regarding 1,2,4-triazole in Section 5: Environmental Hazard Assessment, should be disregarded from the classification and labelling proposal.

Those studies to be omitted include:

Annex Point	Reference
5.1., Table 45: Summary degradation studies undertaken for Cyproconazole and 1,2,4-triazole.	Spare, W.C. (1983) Determination of the Hydrolysis rate constants of 1,2,4-H-Triazole, Syngenta file number CGA71019/0033.
5.1.2.1., Table 48: Summary of biodegradation studies undertaken for Cyproconazole and metabolites.	Slangan, P.J. (2000) Degradation of 1,2,4-triazole in Three Soils under Aerobic Conditions, Syngenta file number CGA64250/4345.
5.2.1., Table 49: Summary of relevant information on aquatic toxicity – Toxicity of Cyproconazole Technical to Aquatic Organisms	Hawkins, D.R. (1988) Soil adsorption and desorption of 1,2,4-Triazole, Syngenta file number CGA71019/0014.

Syngenta position regarding omitted route of soil degradation study summaries

Syngenta believes that relevant information pertaining to the route of degradation of cyproconazole in soil, as discussed in Section 5.1.3, is absent from Table 48. Syngenta proposes that the following study summaries should be added to Table 48:

- Glänzel, A. (1994) [U-^{14}C-Triazolyl]-Cyproconazole Laboratory Soil Metabolism Study, AG, Basel, Switzerland. (Syngenta File No. SAN619/5321).
- Glänzel, A. & Wisson, M. (1986) [U-^{14}C-Phenyl]-Cyproconazole, Laboratory Soil Metabolism Study, Sandoz Agro Ltd, Basel, Switzerland. (Syngenta File No. SAN619/5288).
- Wisson, M. (1992) [^{14}C-Benzyl]-Cyproconazole: Aerobic Degradation in Three Types of Soil (Balance Study), Sandoz AG, Basel, Switzerland. (Syngenta File No. SAN619/5362).

Syngenta position regarding re-normalisation of cyproconazole laboratory aerobic degradation DT_{50} values to 12°C with use of the Arrhenious equation.

Syngenta does not seek to rebut the re-normalisation of soil DT_{50} values of existing studies to 12°C as it does not impact the classification of cyproconazole, however Syngenta believes that this re-normalisation, as recommended by the Guidance on Information Requirements and Chemical Safety Assessment: Chapter R.11 (2014), is not a requirement in the absence of new simulation degradation studies at 12°C and that its implementation remains under discussion.

Syngenta position regarding field rates of degradation of cyproconazole.

Syngenta is not familiar with the source of the field degradation rate DT_{50} values for cyproconazole presented in Section 5.1.3., which range from 28.97d (DFOP) to 162d (SFO), and believes those values to be incorrect. Syngenta proposes the use of the un-normalised DT_{50} values that have been evaluated at an EU level and presented in the EFSA conclusions (EFSA Journal 2010;8(11):1987), which range from 26.46d (DFOP) to 141.3 (SFO). In addition, Syngenta believes that the field study summaries pertaining to the field DT_{90} values discussed in Section 5.1.3. and those field DT_{50} values proposed above, are absent from Table 48, and suggests that the following study summaries should be included:

- Bass, P.V. & Hertl, P.* (1994) Cyproconazole Dissipation of Residues from Field Soil after Application of ALTO 100 SL to Bare Soil in United Kingdom. *Report addendum, Hazelton Europe Ltd, Harrogate, North Yorkshire, United Kingdom & Sandoz Hunigue SA, Huningue, France. (Syngenta File No. SAN619/5277).
- Bourry, R. (1991a) Cyproconazole Long Term Soil Dissipation after one application of SAN 709 F 380 EC to bare soil in the FRG, 1988 (Degradation Curve), Sandoz AG, Basel, Switzerland. (Syngenta File No. SAN619/5529).
- Bourry, R. (1991b) Cyproconazole Long Term Soil Dissipation after one application of SAN 709 F 380 EC to bare soil in the FRG, 1988 (Degradation Curve), Sandoz AG, Basel, Switzerland. (Syngenta File No. SAN619/5530).
- Hertl, P. & Vogler, F. (1993) Dissipation of Cyproconazole from Field Soil after Application of ALTO 100 SL to Bare Soil in Germany, 1991-1992 (Field Soil Dissipation), Sandoz AG, Basel, Switzerland. (Syngenta File No. SAN619/5342).