Document Title

Summary of the residues in or on treated products, food and feed
Prothioconazole + Spiroxamine EC 460 (160+300 g/L)

Data Requirement(s)

Regulation (EC) No 1107/2009 & Regulation (EU) No 284/2013

Document MCP

Section 8: Residues in or on treated products, food and feed

According to the Guidance Document SANCO/10181/2013 for applicants on preparing dossiers for the approval of a chemical active substance

Date

2021-03-31

Author(s)

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ERM
On behalf of Bayer AG
Crop Science Division

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Version history

Date [yyyy-mm-dd]	Data points containing amendments or additions[1] and brief description	Document identifier and version number

[1] It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4, 'How to revise an Assessment Report'

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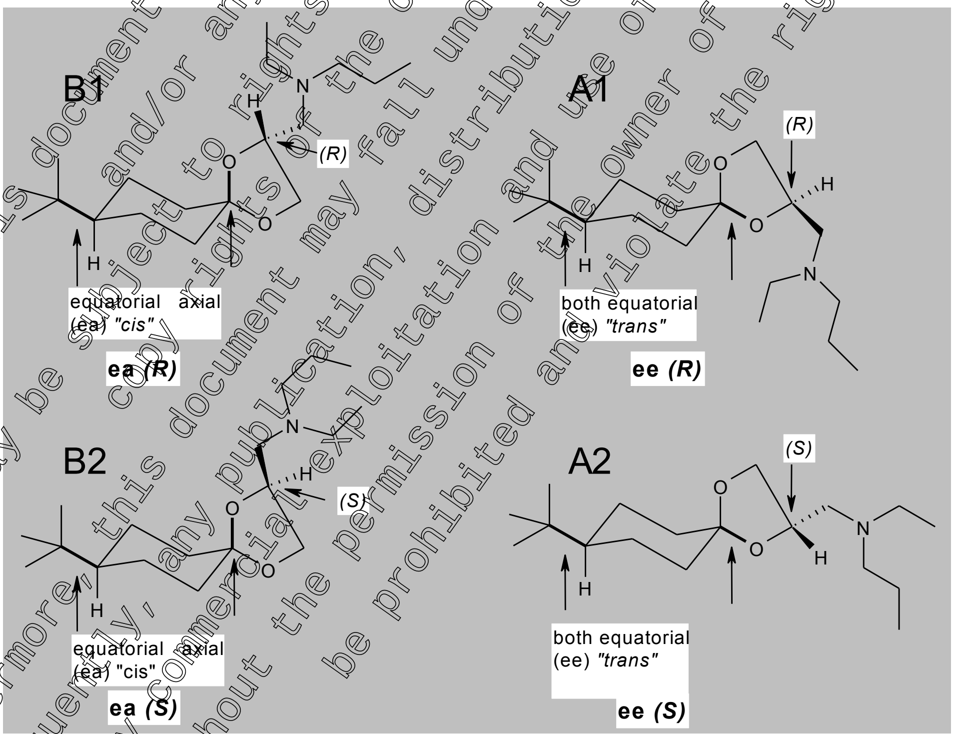
CP 8 RESIDUES IN OR ON TREATED PRODUCTS, FOOD OR FEED

Spiroxamine was included in Annex I to Council Directive 91/414/EEC in 1999 (Directive 1999/73/EC, Entry into Force on 1 September 1999). This Supplementary Dossier contains data which were not submitted at the time of the Annex I inclusion and first renewal of spiroxamine under Council Directive 91/414/EEC and which were therefore not evaluated during the first EU review. However, all studies submitted for the first approval and subsequent first renewal of spiroxamine have also been summarised according to current guidance and included in the dossier. Where studies meet relevant validity criteria, new robust study summaries have been provided in the appropriate dossier section. However, where studies do not meet relevant validity criteria and are not considered acceptable, less detailed summaries may have been provided alongside discussions of study deficiencies. All relied upon study reports are submitted in Document K for this second renewal of approval dossier or in Document K for the previous Annex I inclusion and first renewal submissions.

All data which were already submitted by Bayer AG (former Bayer CropScience) for the Annex I inclusion and first renewal under Council Directive 91/414/EEC are contained in the draft Re-Assessment Report (RAR) 2010 and its revised RAR 2017, and are included in the Baseline Dossier provided by Bayer AG.

Spiroxamine consists of four isomers (two diastereomers each with its corresponding two enantiomers which are in a 1:1 ratio) as shown in the schematic below. The isomer nomenclature presented in some historical documentation may differ with respect to the A/B and corresponding trans/cis notation as a result of a discrepancy in referencing, which is discussed in detail in position paper M-761468-01-1 (see CA 1.7/01). It is recommended that the stereo assignments depicted here, together with the A and B notation should be used exclusively going forward to ensure continuity of information throughout the dossier.



The formulation Prothioconazole + Spiroxamine EC 460 (160+300 g/L), abbreviation PTZ + SPX EC 460, is an emulsifiable concentrate formulation containing 160 g/L of prothioconazole and 300 g/L of spiroxamine. This formulation is registered throughout Europe under trade names such as HELIX, IMPULSE GOLD, INUT 460 EC, INPUT CLASSIC, KROTON, PROLINE MAX 460 EC, Prosaro Plus, ROMBUS POWER, THESORUS, THESORUS 460 EC. PTZ + SPX EC 460 already a

representative formulation of Bayer AG for the Annex I inclusion of spiroxamine under Council Directive 91/414/EEC.

All relevant metabolism and residue data in support of this use are summarized in Document MCA, Section 6.