Document Title

Summary of the residues in or on treated products, food and feed
Fluopyram + Trifloxystrobin SC 500 (250+250 g/L)

Data Requirement(s)

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
2021-03-01

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**Version history**

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\(^1\) It is suggested that applicants adopt a similar approach to showing revision and version history as outlined in SANCO/10180/2013 Chapter 4, ‘How to revise an Assessment Report.’
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CFP 8 RESIDUES IN OR ON TREATED PRODUCTS, FOOD OR FEED

Fluopyram was included in Annex I to Council Directive 91/414/EEC in 2013 (Regulation (EU) 802/2013, Entry into Force on August 22, 2013). This Supplementary Dossier contains only data which were not submitted at the time of the Annex I inclusion of Fluopyram under Council Directive 91/414/EEC and which were therefore not evaluated during the first EU review. All data which were already submitted by Bayer AG (former Bayer CropScience) for the Annex I inclusion under Council Directive 91/414/EEC are contained in the Draft Assessment Report (DAR) and its Addenda and are included in the Baseline Dossier provided by Bayer.

The formulation Fluopyram + Trifloxystrobin SC 500 (250+250 g/L), abbreviation FLU+TFS SC 500, is a SC formulation containing 250 g/L of Fluopyram and 250 g/L of Trifloxystrobin. This formulation is registered throughout Europe under trade names such as Luna Sensation. FLU+TFS SC 500 was not already a representative formulation of Bayer AG for the Annex I inclusion of Fluopyram under Council Directive 91/414/EEC.

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