Document Title

Summary of the Residues in or on treated products, food and feed
Isoflucypram EC 50 (50 g/L)
(Code: BCS-CN88460 EC 50)

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
2018-01-11

Author(s)

Bayer AG
Crop Science Division
OWNERSHIP STATEMENT

This document, the data contained in it and copyright therein are owned by Bayer AG and/or affiliated entities. No part of the document or any information contained therein may be disclosed to any third party without the prior written authorisation of Bayer AG and/or affiliated entities.

The summaries and evaluations contained in this document are based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either:

- from Bayer AG or respective affiliate; or
- from other applicants once the period of data protection has expired.
Version history

<table>
<thead>
<tr>
<th>Date [yyyymm-dd]</th>
<th>Data points containing amendments or additions(^1) and brief description</th>
<th>Document identifier and version number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) 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’.
This document is the property of Bayer AG and/or any of its affiliates. Furthermore, this document may fall under a regulatory data protection regime. Consequently, any publication, distribution, reproduction data protection regime, any commercial exploitation, the owner and third parties. Reproduction and/or publishing and any of its contents may therefore be prohibited and violate the rights of its owner.

It may be subject to rights such as intellectual property and copy rights of the owner and third parties.

Table of Contents

RESIDUES IN OR ON TREATED PRODUCTS, FOOD OR FEED

Page 4 of 5

Document MCP - Section 8: Residues in or on treated products, food and feed
Isoflucypram EC 50 g/L
The purpose of this MCP-Dossier, Section 8, is to support the approval process of the new active substance Isoflucypram in the territory of Europe under Regulation (EC) No 1107/2009.

Isoflucypram EC 50 is the representative formulation being an emulsifiable concentrate (EC) containing 50 g/L Isoflucypram (Bayer-Code: BCS-CN 88460) for use in cereal crops.

According to the “Guidance Document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Commission Regulation (EU) No 283/2013 and (EU) No. 284/2013, SANCO/10181/2013, rev. 3, dated 12 December 2014, and in accordance with Regulation (EC) No 1107/2009, data and information on residues in or on treated products, food and feed shall be submitted in the active substance dossier.

Therefore, the residue data for the intended uses, including the representative uses of Isoflucypram EC 50, is provided in the Summary Document MCP, Section 6.