



Document Title

**Summary of the residues in or on treated products, food and feed for
fosetyl-aluminium WG 80 (800 g/kg)**

Data Requirements

EU Regulation 1107/2009 & EU Regulation 284/2013

Document MCP

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

According to the Guidance Document SANCO/10184/2013 for
preparing dossiers for the approval of a chemical active substance

Date

2015-09-01

Author(s)

[Redacted]

Bayer CropScience

This document is the property of Bayer AG and/or any of its affiliates. It may be subject to rights such as intellectual property and/or patent rights. Furthermore, this document may fall under a regulatory data protection regime. Consequently, any publication, distribution, reproduction and/or publishing and any commercial exploitation and use of this document may therefore be prohibited and violate the rights of its owner.





OWNERSHIP STATEMENT

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

The summaries and evaluations contained in this document are based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority.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authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either: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 CropScience; or
- from other applicants once the period of data protection has expired.

This document is the property of Bayer CropScience and/or any of its affiliates. It may be subject to rights of its owner and third parties. Intellectual property and copy rights of the owner and third parties in this document are protected under a regulatory regime. Furthermore, this document may fall under a regulatory data protection regime. Consequently, any publication, distribution, reproduction or other publishing and any commercial exploitation, distribution, reproduction or other publishing and use of this document may be prohibited and violate the rights of its owner. Without the permission of the owner of this document, reproduction of its contents may be prohibited and violate the rights of its owner.



Version history

Date	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

This document is the property of Bayer AG and/or any of its affiliates. It may be subject to rights such as intellectual property and protection regime. Furthermore, this document may fall under a regulatory data protection and/or publishing and consequently, any publication, distribution, reproduction and/or publishing and without the permission of the owner and third parties. any commercial exploitation, distribution, reproduction and/or publishing and use of this document may therefore be prohibited and violate the rights of its owner.



Table of Contents

CP 8	RESIDUES IN OR ON TREATED PRODUCTS, FOOD OR FEED	Page 5
------	--	--------

This document is the property of Bayer AG and/or any of its affiliates. It may be subject to rights such as intellectual property and copyright. Furthermore, this document may fall under a regulatory data protection regime. Consequently, any publication, distribution, reproduction and/or publishing and any commercial exploitation, distribution, reproduction and/or publishing and without the permission of the owner and third parties may therefore be prohibited and violate the rights of its owner.



Document MCP – Section 8: Residues in or on treated products, food and feed
Fosetyl-aluminium WG 80

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

Fosetyl was included in Annex I to Directive 91/414/EEC in 2006 (Directive 2006/64/CE of 18 July 2006, Entry into Force on 1 May 2007). Fosetyl is the ISO common name for ethyl hydrogen phosphonate (IUPAC) but the aluminium salt fosetyl-aluminium (fosetyl-Al) a variant of fosetyl is used in the formulated product.

The representative formulation fosetyl-Al WG 80 is a water dispersible granules (WG) formulation containing 800 g/kg of fosetyl-Al. The use of fosetyl-Al WG 80 on pome fruit against *Platophthora spp.* and *Erwinia amylovora* has been selected as representative use for the approval renewal of fosetyl. The critical Good Agricultural Practice (GAP) supported at the European level in the approval renewal process of fosetyl consists of 3 foliar spray applications between BBCH 55 and 85 at 3.6 kg/ha of fosetyl-Al with an interval between applications of 7 to 19 days and a PHI of 28 days. All relevant metabolism and residue data in support of this use are summarized in Document MCA, Section 6.

This document is the property of Bayer AG and/or any of its affiliates. It may be subject to rights such as intellectual property and third party rights. Furthermore, this document may fall under a regulatory data protection regime. Consequently, any publication, distribution, reproduction or public sharing and any commercial exploitation, may be prohibited and violate the rights of its owner. Without the permission of the owner of this document or its contents, reproduction of this document or its contents may therefore be prohibited and violate the rights of its owner.