

A14111B

**Chlorothalonil: 400g/L
Azoxystrobin: 80g/L**

**NOTIFICATION OF AN ACTIVE
SUBSTANCE UNDER COMMISSION
REGULATION (EU) 844/2012**

DOCUMENT M-CP, Section 1

**IDENTITY OF THE PLANT PROTECTION
PRODUCT**

Version history

Date	Data points containing amendments or additions ¹	Document identifier or version number

¹ Note how the amendments or additions are represented (italics/colour etc)

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CP 1 IDENTITY OF THE PLANT PROTECTION PRODUCT

This document supports the application for renewal of the regulatory approval of chlorothalonil under Commission Implementing Regulation (EU) 844/2012 of 18 September 2012. This document reviews the identity of the product A14111B containing:

- 400 g/L chlorothalonil
- 80 g/L azoxystrobin

A14111B is a suspension concentrate (SC) containing 400 g/L chlorothalonil and 80 g/L azoxystrobin for use as a fungicide in cereals and other speciality crops. A14111B was not the representative formulation in the EU review of chlorothalonil; for further details refer to the confidential dossier of this submission (Document J).

Chlorothalonil was included in Annex I of Council Directive 91/414/EEC (Commission Directive 2005/53/EC of 15 September 2005). This active substance is an approved active substance under Regulation (EC) 1107/2009 (repealing Commission Directive 91/414/EEC) as specified in Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011.

Azoxystrobin was included into Annex I of Council Directive 91/414/EEC (Commission Directive 1998/47/EC; 7 July 1998) and for which a renewal of this inclusion was voted by SCoFCAH on 9 July 2010 (Commission Directive 2010/55/EU; 20 August 2010). This active substance is an approved active substance under Regulation (EC) 1107/2009 (repealing Commission Directive 91/414/EEC) as specified in Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011.

In accordance with Commission Implementing Regulation (EU) 844/2012, this document summarises new information which are relevant for the renewal of the approval of chlorothalonil under Regulation (EC) 1107/2009.

- Where appropriate this document refers to the Commission Implementing Regulation (EU) No. 540/2011 for chlorothalonil and to the Review Report for chlorothalonil (SANCO/4343/2000 final (revised) 28 September 2006), and in particular the endpoints provided in Appendices I and II thereof.
- Where appropriate this document refers to the Commission Implementing Regulation (EU) No. 540/2011 for azoxystrobin and EFSA report for the renewal of the inclusion of azoxystrobin (**EFSA Journal (2010) 8(4), 1542**), and in particular Appendices I and II thereof.

This document covers data and risk assessments which were not part of the original dossier and which are necessary to reflect changes:

- In requirements under Commission Regulation (EU) No 284/2013, and the associated Annex, which repeals Commission Regulation (EU) No 545/2011 which, under Regulation (EC) 1107/2009, replaced the requirements of Annex III to Directive 91/414/EEC
- In scientific and technical knowledge since the approval or last renewal of the approval
- To representative uses

The proposed representative use pattern is included in Document D1.

Each section of this document provides the agreed EU endpoints and if relevant proposals for amended endpoints.

Where new guidance documents have been introduced since the EU review of chlorothalonil, an updated evaluation of chlorothalonil and A14111B has been included. To adequately assess A14111B to the new guidance documents, it may have been necessary to provide new data, if so these are also included.

Information on the detailed composition of A14111B can be found in the confidential dossier of this submission (Document J).

Details of all relevant data from the scientific peer reviewed open literature on the active substance; metabolites and breakdown or reaction products and plant protection products containing the active substance have been provided in the **Document M-CA Section 9** and are discussed within the relevant data point of the associated dossier for the active substance, chlorothalonil. If the published literature is also relevant to A14111B, it has been discussed within the relevant data point in this document.

CP 1.1 Applicant

Syngenta Crop Protection AG is one of the notifiers for the renewal of the active substance chlorothalonil (R044686).

A Task Force has been formed with the purpose of defending chlorothalonil renewal. Please refer to Document B for details. However it should be noted that each TF-member has presented their own MCP dossier for their separate representative formulation.

The contact point for the Chlorothalonil Task Force and the representative product A14111B is:

Name:	Syngenta Crop Protection AG
Address:	Schwarzwaldallee 215 P.O. Box CH-4002 Basel; Switzerland
Contact:	Dr. Ralph Moray
Telephone number:	+41 (61) 323 0658
Fax number:	+41 (61) 323 6155
E-mail:	ralph.moray@syngenta.com

CP 1.2 Producer of the Plant Protection Product and the Active Substances

Producer of the Plant Protection Product: A14111B

Name:	Syngenta Supply AG
Address:	CH 4002 – Basel Switzerland
Contact:	Simon Baker Syngenta Jealott's Hill, UK
Telephone number:	+44 (0) 1344 414803
Fax number:	+44 (0) 1344 416687
E-mail:	simon.baker@syngenta.com

Location of the manufacturing site

CONFIDENTIAL information - data provided separately (Document J).

Producer of the active substance: chlorothalonil (and azoxystrobin)

Name: Syngenta Crop Protection AG

Address: CH 4002 – Basel
Switzerland

Contact: Simon Baker
Syngenta
Jealott's Hill, UK

Telephone number: +44 (0) 1344 414803

Fax number: +44 (0) 1344 416687

E-mail: simon.baker@syngenta.com

Location of the manufacturing site

CONFIDENTIAL information - data provided separately (Document J).

CP 1.3 Trade Names or proposed Trade Name and Producer's Development Code Number of the Plant Protection Product if appropriate

Trade name: Amistar Opti[®], Olympus[®], Curator[®], Ortiva Opti[®], Vertik Opti[®], Diskobol[®], Arenda 20L[®]

Company code number: A14111B

CP 1.4 Detailed Quantitative and Qualitative Information on the Composition of the Plant Protection Product

CP 1.4.1 Composition of the Plant Protection Product

Chlorothalonil

Table 1.4.1-1: Purity of chlorothalonil (EU Endpoints)

Substance	EU agreed minimum purity (COMMISSION DIRECTIVE 2006/76/EC)
Chlorothalonil	985 g/kg
Relevant impurities	
Hexachlorobenzene	< 0.04 g/kg
Decachlorobiphenyl	< 0.03 g/kg

Pure chlorothalonil in A14111B

content of pure active substance:	400 g/L	32.8 % w/w
limits :	380 - 420 g/L	31.2 - 34.5 %w/w

Technical chlorothalonil in A14111B

at a minimum purity of the technical active substance of 98.5 % w/w.		
content of technical active substance:	406 g/L	33.3 % w/w
limits :	386 - 426 g/L	31.6 - 35.0 %w/w

at a typical purity of the technical active substance of 99 % w/w.		
content of technical active substance:	404 g/L	33.1 % w/w
limits :	384 - 424 g/L	31.5 - 34.8 %w/w

Azoxystrobin

Table 1.4.1-2: Purity of azoxystrobin (EU Endpoints)

Substance	EU agreed minimum purity (COMMISSION DIRECTIVE 703/2011)
Azoxystrobin	930 g/kg
Relevant impurities	
Toluene	< 2 g/kg
Z-isomer (R230310)	< 25 g/kg

Pure azoxystrobin in A14111B

content of pure active substance:	80 g/L	6.56 % w/w
limits :	72.0 - 88.0 g/L	5.91 - 7.22 %w/w

Technical azoxystrobin in A14111B

at a minimum purity of the technical active substance of 93 % w/w.		
content of technical active substance:	86.0 g/L	7.06 % w/w
limits :	77.4 - 94.6 g/L	6.35 - 7.76 %w/w

Technical azoxystrobin in A14111B

at a typical purity of the technical active substance of 98 % w/w.		
content of technical active substance:	81.6 g/L	6.70 % w/w
limits :	73.5 - 89.8 g/L	6.03 - 7.37 %w/w

A14111B Safeners, synergists and co-formulants

CONFIDENTIAL information - data provided separately (Document J).

CP 1.4.2 Information on the Active Substances

Chlorothalonil

Data Point	Type	Name/Code Number
1.4.3.1	ISO common name	Chlorothalonil (R044686)
1.4.3.2	CAS No.	1897-45-6
1.4.3.2	EINECS No.	217-588-1
1.4.3.2	CIPAC No.	288
1.4.3.2	ELINCS	Not available
1.4.3.3	Salt, ester anion or cation present	None

Azoxystrobin

Data Point	Type	Name/Code Number
1.4.3.1	ISO common name	Azoxystrobin (ICI5504)
1.4.3.2	CAS No.	131860-33-8
1.4.3.2	EINECS No.	Not listed
1.4.3.2	CIPAC No.	571
1.4.3.2	ELINCS	Not available
1.4.3.3	Salt, ester anion or cation present	None

CP 1.4.3 Information on Safeners, Synergists and Co-formulants

CONFIDENTIAL information - data provided separately (Document J).

CP 1.5 Type and Code of Plant Protection Product

Type : Suspension Concentrate [Code : SC]

CP 1.6 Function

Fungicide