

# **Chlorothalonil**

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

### **DOCUMENT M-CA, Section 1 Supplement**

#### **IDENTITY OF THE ACTIVE SUBSTANCE**

## Version history

Date	Data points containing amendments or additions <sup>1</sup>	Document identifier or version number

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

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## CA 1 IDENTITY OF THE ACTIVE SUBSTANCE

### Introduction

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, including additional data and risk assessments, for chlorothalonil.

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.

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.

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 283/2013, and the associated Annex, which repeals Commission Regulation (EU) No 544/2011 which, under Regulation (EC) 1107/2009, replaced the requirements of Annex II to Directive 91/414/EEC
- In scientific and technical knowledge since the approval or last renewal of the approval
- To representative uses

Where the conclusions of the EU review had specific areas of concern on chlorothalonil, new data and/or reviews and/or risk assessments have been provided. Where additional and/or new data on chlorothalonil are provided, a justification has been included. Also a justification has been given if new data are required but none were provided.

Details of the literature search undertaken can be found in **M-CA Section 9**. If a relevant scientifically peer-reviewed open literature reference has been identified for chlorothalonil or its major metabolites, it has been discussed within the relevant data point.

## CA 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.

Memberships of the Task Force are **Syngenta Crop Protection AG, Oxon Italia S.p.A. and Arysta Life Science SAS**

The contact point for the Task Force is:

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## CA 1.2 Producer

## Producer of the active substance: chlorothalonil

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### **Location of the manufacturing site**

CONFIDENTIAL information - data provided separately (**Document J**).

### **CA 1.3 Common Name Proposed or ISO-accepted and synonyms**

Chlorothalonil (ISO approved)

### **CA 1.4 Chemical Name (IUPAC and CA nomenclature)**

IUPAC: Tetrachloroisophthalonitrile  
CA: 2,4,5,6-Tetrachloro-1,3-benzenedicarbonitrile

### **CA 1.5 Producer's Development Code Numbers**

R044686

## CA 1.6 CAS, EC and CIPAC Numbers

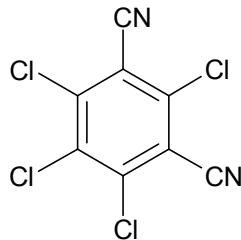
Data Point	Type	Name/Code Number
1.4.3.1	ISO common name	Chlorothalonil (R044686)
1.4.3.2	CAS No.	1897-45-6
1.4.3.2	EINECS No.	217-588-1
1.4.3.2	CIPAC No.	288
1.4.3.2	ELINCS	Not available
1.4.3.3	Salt, ester anion or cation present	None

## CA 1.7 Molecular and Structural Formula, Molar Mass

Molecular Formula : C<sub>8</sub>Cl<sub>4</sub>N<sub>2</sub>

Molecular Mass : 265.9 g mol<sup>-1</sup>

Structural Formula :



## CA 1.8 Method of Manufacture (synthesis pathway) of the active substance

CONFIDENTIAL information - data provided separately (please refer to the confidential Document J, and associated reports, which are provided with the individual company representative product CP dossier as these data have not been shared within the Task Force agreement).

## CA 1.9 Specification of Purity of the Active Substance in g/kg

CONFIDENTIAL information - data provided separately (please refer to the confidential Document J, and associated reports, which are provided with the individual company representative product CP dossier as these data have not been shared within the Task Force agreement).

## CA 1.10 Identity and Content of Additives (such as Stabilisers) and impurities

### CA 1.10.1 Additives

CONFIDENTIAL information - data provided separately (please refer to the individual company confidential Document J, and associated reports, which are provided with the representative product CP dossier).

## **CA 1.10.2 Significant impurities**

**CONFIDENTIAL** information - data provided separately (please refer to the confidential Document J, and associated reports, which are provided with the individual company representative product CP dossier as these data have not been shared within the Task Force agreement).

## **CA 1.10.3 Relevant impurities**

Hexachlorobenzene and decachlorobiphenyl were identified as relevant impurities of chlorothalonil technical material in the original Annex I review (Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011).

## **CA 1.11 Analytical Profile of Batches**

**CONFIDENTIAL** information - data provided separately (please refer to the confidential Document J, and associated reports, which are provided with the individual company representative product CP dossier as these data have not been shared within the Task Force agreement).)