Committee for Risk Assessment

RAC

Opinion

proposing harmonised classification and labelling
at EU level of

5-chloro-2-(4-chlorophenoxy)phenol

EC Number: 429-290-0
CAS Number: 3380-30-1

CLH-O-0000001412-86-69/F

Adopted

09 September 2015

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

09 September 2015

CLH-O-0000001412-86-69/F

OPINION OF THE COMMITTEE FOR RISK ASSESSMENT ON A DOSSIER PROPOSING HARMONISED CLASSIFICATION AND LABELLING AT EU LEVEL

In accordance with Article 37 (4) of Regulation (EC) No 1272/2008, the Classification, Labelling and Packaging (CLP) Regulation, the Committee for Risk Assessment (RAC) has adopted an opinion on the proposal for harmonized classification and labelling (CLH) of:

Chemical name: **5-chloro-2-(4-chlorophenoxy)phenol**

EC Number: **429-290-0**

CAS Number: **3380-30-1**

The proposal was submitted by **Austria** and received by the RAC on **16 January 2015.**

In this opinion, all classifications and labelling are given in accordance with the CLP Regulation.

PROCESS FOR ADOPTION OF THE OPINION

Austria has submitted a CLH dossier containing a proposal together with the justification and background information documented in a CLH report. The CLH report was made publicly available in accordance with the requirements of the CLP Regulation at ***http://echa.europa.eu/harmonised-classification-and-labelling-consultation/*** on **10 March 2015**. Concerned parties and Member State Competent Authorities (MSCA) were invited to submit comments and contributions by **24 April 2015**.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: **Riitta Leinonen**

The opinion takes into account the comments provided by MSCAs and concerned parties in accordance with Article 37(4) of the CLP Regulation and the comments received are compiled in Annex 2.

The RAC opinion on the proposed harmonized classification and labelling was reached on **09 September 2015** by consensus.

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	605-023-00-5	5-chloro-2-(4-chlorophenoxy)phenol	429-290-0	3380-30-1	Eye Dam. Aquatic Acute 1 Aquatic Chronic 1	H318 H400 H410	GHS05 GHS09 Dgr	H318 H410			
Dossier submitters proposal	605-023-00-5	5-chloro-2-(4-chlorophenoxy)phenol	429-290-0	3380-30-1	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09	H410		**Add:** **M = 10** **M = 10**	
RAC opinion	605-023-00-5	5-chloro-2-(4-chlorophenoxy)phenol	429-290-0	3380-30-1	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09	H410		M = 10 M = 10	
Resulting Annex VI entry if agreed by COM	605-023-00-5	5-chloro-2-(4-chlorophenoxy)phenol	429-290-0	3380-30-1	Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H318 H400 H410	GHS05 GHS09 Dgr	H318 H410		M = 10 M = 10	

GROUNDS FOR ADOPTION OF THE OPINION

ENVIRONMENTAL HAZARD ASSESSMENT

RAC evaluation of environmental hazards

Summary of the Dossier submitter's proposal

The Dossier Submitter (DS) proposed to classify 5-chloro-2-(4-chlorophenoxy)-phenol (DCPP) as Aquatic Acute 1; H400, M=10 and Aquatic Chronic 1; H410, M=10. The classification was based on the substance not being rapidly degradable and very toxic to aquatic organisms. The lowest acute toxicity value was a 72-h ErC_{50} of 0.038 mg/L for algae and the lowest chronic toxicity value was a 72-h NOErC of 0.0093 mg/L, also for algae.

Degradation

The hydrolysis of DCPP was investigated in one study at 50 °C in sterile aqueous buffer solutions at pH values of 4, 7 and 9 following the preliminary test of OECD Guideline 111 and GLP. No degradation of test substance was measured after 5 days. Consequently DCPP was considered to be hydrolytically stable.

Phototransformation of DCPP in water was investigated in a study performed according to draft OECD 316 guideline (August 2000) and GLP. The photolysis of DCPP was rapid with its amount decreasing to 53% after 6 hours irradiation. By day 2, it had declined to 1.3% of applied radioactivity (AR) and from day 5 onwards, it was not detectable. The estimated half-life of DCPP in aqueous systems at latitudes between 30°N and 50°N ranged from 0.24 days to 4.86 days. Six major photodegradates accounting more than 10% of the AR were formed namely M1, M4, M7, M8, M16 and M17. It was shown that M1, M16 and M17 are nonhalogenated and highly polar compounds. M2 was identified as 4-chlorocatechol, M7 as monochlordihydroxybiphenylether and M8 as a condensation product. M4 was not identified and regarding the structure of DCPP a dioxine or another hazardous substance could be a potential degradation product. No data is available in the CLH Report to classify the degradates for environmental hazard. Mineralization of the photodegradation products continuously increased with study progress. On day 19 $^{14}CO2$ accounted for 20.3% of the AR.

DCPP was considered to be susceptible to photochemical degradation in the gas phase (Technical Guidance Document, EC 2003). The calculated half-life of DCPP in air due to indirect photodegradation was estimated to be 19.701 hours (0.821 days) with the AOPWIN software program.

There are four ready biodegradability tests and one inherent test available on DCPP. In one of the ready tests the test design was not suitable for determining ready biodegradability but in three other tests the substance was not readily biodegrable. The DS concluded from the inherent test OECD 302B result that DCPP is inherently primary degradable although no DOC was measured and adsorption could not be ruled out. Methyl-DCPP was quantified both in water (maximum on day 7) and two sludge samples (maximum on days 7 and 14, respectively). There is not enough data to classify methyl-DCPP but after Public Consultation the DS gave new data concerning bioaccumulation: "The metabolite methyl-DCPP has a calculated log K_{ow} value of 4.6. An experimental study with *Danio rerio* revealed high Bioconcentration factors: Steady State BCF values of 20800 and 14514 resulting in lipid corrected values of 15273 and 10517.

Table 1 Ready and inherent degrability tests on DCPP

Guideline	Test substance	Test substance concentration	Test period	Degradation
OECD 301B, GLP	Radiolabelled (phenole-U-C14) Diclosan	95 µg/L	28 days 61 days	40-50% 52±9% (both based on ^{14}C CO_2)
OECD 301F, GLP	DCPP	100 mg/L	28 days	0% (no mineralization of the substance provided)
Japan MITI (OECD 301C), GLP	DCPP	100 mg/L	28 days	0% (initial test substance conc. the same as at the end)
OECD 301F, GLP	DCPP	100 µg/L	28 days	100% elimination, no data on ultimate biodegradation
OECD 302B, GLP	DCPP	100 µg/L	28 days	Elimination > 99% after 14 days, no data on ultimate degradation

There is one aerobic aquatic degradation in STP test (OECD 303) on DCPP which according to the CLP Guidance cannot be used for assessing degradation in the aquatic environment. No simulation tests for other environmental compartments are presented in the CLH Report.

Bioaccumulation

The log P_{ow} was measured in an OECD 117 test to be 3.7 at 20°C. The calculated log P_{ow} values are 4.8, 4.6 and 4.5 at temperatures 10, 20 and 30 °C, respectively. The bioconcentration of DCPP in carp (*Cyprinus carpio*) was determined in one test following the OECD guideline 305 and GLP and the Japanese standard method according to the "Testing methods for New Chemical Substances" of the Ministry of International Trade and Industry of Japan of 1974. The mean steady-state BCFs for 0.02 mg/L test concentration and for 0.002 mg/L test concentration were 67.4 and 76.7, respectively. Corrected for a whole body lipid content of 5% the resulting whole body BCFs in fish were 99.1 and 112.8. metabolites were not determined
After Public Consultation the DS provided new data concerning the metabolite methyl-DCPP: "The metabolite methyl-DCPP has a calculated log K_{ow} value of 4.6. An experimental study with *Danio rerio* revealed high bioconcentration factors: Steady State BCF values of 20800 and 14514 resulting in lipid corrected values of 15273 and 10517 were obtained."

Aquatic toxicity

The adsorption of DCPP on soils was tested according to OECD Guideline 121 and GLP. The adsorption coefficient of the substance was calculated as log K_{oc} = 3.1545 (Koc= 1427.25) and the result was substantiated with QSAR data. According to DS DCPP can be assumed to be adsorbed in soils. Adsortion may also be important in the context of aquatic toxicity studies. Since the substance is hydrolytically stable and considerably soluble in lipids, adsorption and subsequent desorption and re-solution may explain the observed fluctuations in the measured concentrations in the static aquatic test media.

In the acute Daphnia test and in the algae test determination of the stability of the test item during the test was measured from the samples incubated with no organisms. In the chronic Daphnia study a part of the test item had adsorbed onto the food particles.

There are altogether 2 acute toxicity tests for fish, one for invertebrates and one for algae. The values are presented in Table 2.

Table 2 Acute aquatic toxicity data available

Species	Test guideline	Test type and duration	Test result
Danio rerio (zebra fish)	92/69/EEC, C.1 OECD 203, GLP	static, 96h	LC_{50} 0.70 mg/L(* total mean measured concentrations (74-112% of nominal)
Danio rerio	OECD 203	semistatic, 96h, screening pre-test, supportive	LC_{50} 0.86 mg/L initial measured concentration levels
Daphnia magna	92/69/EEC, C.2 OECD 202, GLP	static, 48h	EC_{50} 0.32 mg/L(* nominal (mean measured 81-87% of nominal)
***Desmodesmus subspicatus* (green algae)**	**92/69/EEC, C.3 OECD 201, GLP**	**static, 72h**	**EbC_{50} 0.023 mg/L ErC_{50} 0.038 mg/L nominal (measured concentrations 77-124% of the nominal)**

(*The LC_{50} and EC_{50} values were determined as the geometric mean value of the consecutive test concentrations with 0 and 100% mortality.
(* Geometric mean of measured concentrations at the beginning and end of the test.

There are no chronic fish toxicity studies available. There is one study available both for invertebrates and algae. The values are presented in Table 3.

Table 3 Chronic aquatic toxicity data available

Species	Test guideline	Test type and duration	Test result
No fish study			
Daphnia magna	OECD211, GLP	semistatic, 21 days	NOEC 0.094 mg/L(* LOEC 0.27 mg/L(* (** EC_{50} 0.30 mg/L (nominal) mean measured 41-63% of nominal
***Desmodesmus subspicatus* (green algae)**	**92/69/EEC, C.3 OECD 201, GLP**	**static, 72h**	**NOErC 0.0093 mg/L(***

(* averaged measured concentrations from day 14 and 19 for which the used test media per test concentration were poured together after removal of daphnia and which had included food particles
(** 100% mortality at this concentration
(*** Geometric mean of measured concentrations at the beginning and end of the test.

The most sensitive organism in acute and chronic aquatic toxicity tests is algae with an ErC_{50} of 0.038 mg/L and with an NOErC of 0.0093 mg/L.

Comments received during public consultation

Two Member States (MS) supported the DS's proposal for classification. They also commented on the purity. The DS agreed that the original 99.1% (w/w) purity should be corrected with 99.5% (w/w) based on new confidential study submitted.

A comment was also received concerning aquatic bioaccumulation stating that the BCF value for the metabolite methyl-DCPP should be amended to BCF values between 10517 and 17505. The DS agreed with the following: "The metabolite methyl-DCPP has a calculated log K_{ow} value of 4.6. An experimental study with *Danio rerio* revealed high Bioconcentration factors: Kinetic BCF values of 23804 and 16738 were obtained, resulting in lipid corrected values of 17505 and 12129. Steady State BCF values of 20800 and 14514 resulting in lipid corrected values of 15273 and 10517 were obtained. Based on the criteria for PBT/vPvB substances, methyl-DCPP has to be regarded as very bioaccumulative (vB)."

Assessment and comparison with the classification criteria

DCPP is not readily degradable based on 40-50% degradation in a 28 day OECD 301B biodegradation test and 0% degradation in a OECD 301F and in a MITI test (OECD 301C). No relevant degradation simulation tests were presented in the CLH Report. Thus based on the ready degradability test results **DCPP is considered to be 'not rapidly degradable'**.

The metabolite Methyl-DCPP was quantified in the inherent OECD 302B test and in an aerobic aquatic degradation test in STP in small amounts, the maximum concentration mentioned in the CLH Report being 1 µg/L. No data to enable classification of Methyl-DCPP is presented in the CLH Report although it is known to be very bioaccumulative with fish BCFs of 15273 and 10517.

The log K_{ow} values for DCPP are 3.7 (measured) and 4.6 (calculated) at 20 °C. The cut-off value for classification is log $K_{ow} \geq 4$. The measured fish whole body BCFs corrected for a whole body lipid content of 5% are 99.1 and 112.8. The cut-off value being ≥ 500 for the whole fish. Therefore, DCPP does not have a potential to bioconcentrate.

There is acute data available for three trophic levels. The lowest acute fish toxicity result is a 96h LC_{50} of 0.70 mg/L for *Danio rerio*. The lowest acute invertebrate toxity data is a 48h EC_{50} of 0.32 mg/L for *Daphnia magna* and the lowest acute toxicity for algae is a ErC_{50} of 0.038 mg/L for *Desmodesmus subspicatus*.

There is chronic data available for two trophic levels. There is no data on fish. The lowest chronic toxicity result for invertebrates is a 21 day NOEC of 0.094 mg/L for *Daphnia magna* and the lowest chronic toxicity data for the algae was a NOErC of 0.0093 mg/L for *Desmodesmus subspicatus*.

The most sensitive trophic level is algae. The acute classification is based on algae ErC_{50} of 0.038 mg/L which is in the $0.01 < LC_{50} \leq 0.1$ range giving an M-factor of 10. The lowest chronic toxicity value NOErC of 0.0093 mg/L for algae is in the $0.001 <$ NOEC ≤ 0.01 mg/L range giving an M-factor of 10 for non-rapidly degrable substance. Since there is no chronic fish data surrogate system is used for fish. The 96h LC_{50} of 0.70 mg/L and no rapid degradability gives a Chronic 1 classification with an M-factor of 1 which is less stringent than the classification based on chronic data thus having no effect to the classification. **Consequently DCPP is classified as Aquatic Acute 1 (H400), M=10 and Aquatic Chronic 1 (H410), M=10 as proposed by the DS.**

ANNEXES:

Annex 1 Background Document (BD) gives the detailed scientific grounds for the opinion. The BD is based on the CLH report prepared by the Dossier Submitter; the evaluation performed by RAC is contained in RAC boxes.

Annex 2 Comments received on the CLH report, response to comments provided by the Dossier Submitter and RAC (excluding confidential information).