TC NES SUBGROUP ON IDENTIFICATION OF PBT AND VPVP SUBSTANCES

RESULTS OF THE EVALUATION OF THE PBT/VPVB PROPERTIES OF:

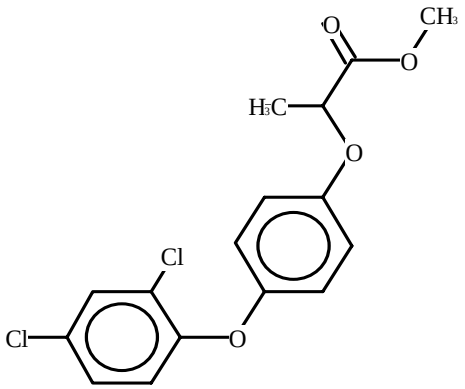
Substance name: Methyl 2-(4-(2,4-dichlorophenoxy)phenoxy)propionate

EC number: 257-141-8

CAS number: 51338-27-3

Molecular formula: C16H14Cl2O4

Structural formula:



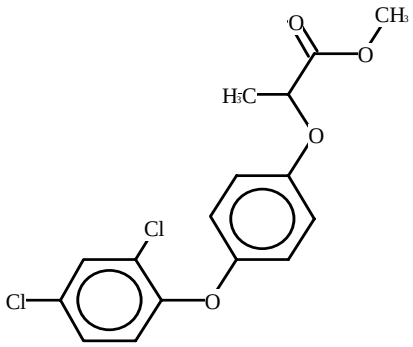
Summary of the evaluation:

Methyl 2-(4-(2,4-dichlorophenoxy)phenoxy)propionate is not considered to be a PBT substance. It does not meet the B criterion. The conclusion covers only the parent substance. The data on persistency and ecotoxicity were not evaluated for this report.

JUSTIFICATION

1 IDENTIFICATION OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

Name: Methyl 2-(4-(2,4-dichlorophenoxy)phenoxy)propionate
EC Number: 257-141-8
CAS Number: 51338-27-3
IUPAC Name:
Molecular Formula: C16H14Cl2O4
Structural Formula:



Molecular Weight:
Synonyms: Diclofop-methyl

1.1 Purity/Impurities/Additives

No data available.

1.2 Physico-Chemical properties

Table 1 Summary of physico-chemical properties.

REACH ref Annex, §	Property	Value	Comments
V, 5.1	Physical state at 20 C and 101.3 Kpa	solid	European Commission (2000)
V, 5.2	Melting / freezing point		
V, 5.3	Boiling point		
V, 5.5	Vapour pressure		
V, 5.7	Water solubility	0.8 mg l^{-1} (at 25 ºC)	WSKOW v1.41
V, 5.8	Partition coefficient n-octanol/water (log value)	4.54 (at 25 ºC) 4.62	KOWWIN v1.67 KOWWIN v1.67 exp. database (Krawchuck and Webster, 1987)(data not evaluated)
VII, 5.19	Dissociation constant		

2 MANUFACTURE AND USES

One company has notified the substance under Regulation 93/793/EEC. The substance is used as an active ingredient in plant protection products and it is hence regulated and assessed under Directive 91/414/EEC.

3 CLASSIFICATION AND LABELLING

Classification according to the Annex I of Directive 67/548/EEC:

Classification

Xn; R22	Harmful if swallowed
Xn; R43	May cause sensitization by skin contact
N; R50-53	Very toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment

4 ENVIRONMENTAL FATE PROPERTIES

4.1 Degradation (P)

4.1.1 Abiotic degradation

Indirect photochemical degradation in the atmosphere is considered to be fast based on the estimated half-life of 20 hours for the reaction with OH-radicals using AOP v1.91 (24 h day^{-1}; $5*10^5$ OH^- cm^{-3}).

Aqueous acid/base –catalysed hydrolysis is predicted by HYDROWIN v1.67 to take place with half-lives of 63 days at pH 8 and 1,7 years at pH 7. No information on the hydrolysis product(s) is available.

The available experimental data was not reviewed for this report.

4.1.2 Biotic degradation

The available experimental data was not reviewed for this report.

4.1.3 Other information [1]

Data not reviewed for this report.

4.1.4 Summary and discussion of persistence

Assessment not completed.

4.2 Environmental distribution

Data not reviewed for this report.

4.2.1 Adsorption

4.2.2 Volatilisation

4.2.3 Long-range environmental transport

4.3 Bioaccumulation (B)

4.3.1 Screening data[2]

A BCF of 720 was calculated by BCFWIN v2.15 using logKow of 4.62.

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1 For example, half life from field studies or monitoring data

2 For example, log K_{ow} values, predicted BCFs

4.3.2 Measured bioaccumulation data[3]

Bioconcentration of diclofop-methyl was tested with bluegill fish (*Lepomis macrochirus*) in a flow through system according to OECD 305. ^{14}C-labelled substance was used. The study consisted of an accumulation phase lasting 28 days followed by an elimination phase over 28 days. A BCF of 220 for a test concentration of 0.0002 mg l^{-1} (nominal, recovery was > 90% on all sampling dates except on day 1 – 65-70%) and a BCF of 240 for a test concentration of 0.002 mg l^{-1} were determined based on total measured radioactivity (Madsen, et al. 2003). The study was conducted under GLP and it is well documented. Despite the variation of the test concentration, which was according to the authors probably caused by rapid hydrolysis of the substances to its acid, the study is considered valid.

Another, non-standard bioaccumulation study was performed using a flow-through system, dichlorophenyl ring^{14}C –labelled diclofop-methyl and bluegill fish (*Lepomis macrochirus*). The test was performed at one concentration (0.0115 mg a.s. l^{-1}, nominal). The study consisted of an accumulation phase lasting 28 days followed by an elimination phase over 14 days. During the uptake phase the mean measured active substance concentration in the aquaria was 0.0111 ± 0.0024 mg a.s. l^{-1} representing a mean recovery of 99.1% (measured as total radioactivity). A BCF of 518 was determined based on total radioactivity measured (Gildemeister et al., 1991). It must be noted, that the test concentration referring to the test substance was highly variable (7.1-90.4 %). In addition, little information is provided with regard to the biological observations and the use of the acid form of dichlofop-methyl as a reference standard. This study is considered for background information, only.

Chronic effects of diclofop-methyl (technical substance, purity 98.5% w/w) were tested by Dionne (1994) in fathead minnow (*Pimephales promelas*) exposed in a flow-through system during one life-cycle (265 days). Test concentrations were 0.0038, 0.0075, 0.015, 0.031, and 0.063 mg a.s. l^{-1} based on mean measured concentrations. Bioconcentration factors were estimated as follows:

Generation and life stage	Tissue type	Measured total diclofop-methyl concentration (mg/kg)	BCF
F0 juveniles (59 days post-hatch) a	Whole body	50.7	770
F0 parental adults at test termination (265 days) b	Whole body	Male average 92.3 Female average 76.5	1500 1200
F1 embryos less than 24 hours old	Whole organism	9.81 c 33.0 d	420
F1 larvae 30 days post-hatch e	Whole body	Average 106	1700

a: composite sample of ca 14 fish exposed to a mean measured concentration of 0.066 mg/L
b: 2 male and 2 female fish exposed to a mean measured concentration of 0.063 mg/L, analyzed separately
c: composite sample of embryos exposed to a mean measured concentration of 0.031 mg/L
d: composite sample of embryos exposed to a mean measured concentration of 0.063 mg/L
e: 2 composite sample of ca 40 to 50 individuals each, exposed to a mean measured concentration of 0.063 mg/L.

Concurrently, a test monitoring effects was conducted. In this test, the NOEC (for reproduction and development minnow) was 0.015 mg a.s. l^{-1} (based on mean measured concentrations, embryo hatching success). Recovery of the active substance in the bioconcentration test ranged from 58 to 63 % of nominal concentrations, which is likely due to the hydrolysis of the substance to its acid form. The acid form was observed in the test medium. The study is well documented and considered as valid.

3 For example, fish bioconcentration factor

4.3.3 Other supporting information[4]

Data not reviewed for this report.

4.3.4 Summary and discussion of bioaccumulation

The predicted BCF of 720 is in the same range as the BCF of 220-240 derived experimentally according to OECD 305 (Madsen et al., 2003). In the full life cycle test of Dionne (1994), where fish were continuously exposed to diclofop-methyl over 265 days, the maximum BCF value of 1500 was reached based on total radioactivity. It can be concluded that the substance has a moderate to high bioaccumulation potential.

5 HUMAN HEALTH HAZARD ASSESSMENT

Data not reviewed for this report.

6 ENVIRONMENTAL HAZARD ASSESSMENT

6.1 Aquatic compartment (including sediment)

Data not reviewed for this report.

[4]For example, measured concentrations in biota

6.1.1 Toxicity test results

6.1.1.1 Fish

Acute toxicity

Long-term toxicity

6.1.1.2 Aquatic invertebrates

Acute toxicity

Long-term toxicity

6.1.1.3 Algae and aquatic plants

6.1.2 Sediment organisms

6.1.3 Other aquatic organisms

6.2 Terrestrial compartment

6.3 Atmospheric compartment

7 PBT AND vPvB

7.1 PBT, vPvB assessment

Persistence: data not reviewed for this report.

Bioaccumulation: dichlofop-methyl does not meet the B criterion. An experimental BCF of 220-240 was obtained according to OECD 305. In a full life cycle test, where fish were continuously exposed to diclofop-methyl over 265 days and the maximum BCF value was determined as 1500 based on total radioactivity. It is noted, that this assessment does not cover possible degradation products of the substance.

Toxicity: data not reviewed for this report.

Summary: dichlofop-methyl does not meet the B criterion. This conclusion covers only the parent substance. The data on persistency and ecotoxicity were not reviewed for this report. It is concluded that dichlofop-methyl is not considered as a PBT substance.

INFORMATION ON USE AND EXPOSURE

Not relevant as the substance is not identified as a PBT.

OTHER INFORMATION

The information and references used in this report were mainly taken from the following sources:

European Commission, 2000. IUCLID Dataset, methyl 2-(4-(2,4-dichlorophenoxy)phenoxy)propionate, CAS 51338-27-3, 19.2.2000.

Other sources:

Dionne, E., 1994. Flow-through chronic toxicity to the fathead minnow in a full life cycle exposure. Study numbers 8.2.1.2/02 and 8.2.2.3/01 in the dossier for the 91/414/EEC evaluation.

Gildemeister H., Rockmann S., Steinau M., Fischer R. and Kelbert K., 1991. Flow-through bioaccumulation and metabolism study of [Hoe 02340814C] in bluegill sunfish. Study number 8.2.3.1/02 in the dossier for the 91/414/EEC evaluation.

Madsen T.J., Leak T. and Meyer B.N., 2003. Bioconcentration and metabolism of [dichlorophenyl-U-^{14}C]-diclofop-methyl in bluegill. Study number 8.2.3.1/01 in the dossier for the 91/414/EEC evaluation.