Committee for Risk Assessment
RAC

Opinion

proposing harmonised classification and labelling
at EU level of

bendiocarb (ISO)

EC Number: 245-216-8
CAS Number: 22781-23-3

CLH-O-0000001412-86-51/F

Adopted

12 March 2015

15 March 2015

CLH-O-0000001412-86-51/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 (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:

Chemicals name: **bendiocarb (ISO)**

EC Number: **245-216-8**

CAS Number: **22781-23-3**

The proposal was submitted by the **United Kingdom** and received by RAC on **02 July 2014**. All classifications are given in the form of CLP hazard classes and/or categories, the majority of which are consistent with the Globally Harmonized System (GHS).

PROCESS FOR ADOPTION OF THE OPINION

United Kingdom 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 **30 July 2014**. Concerned parties and Member State Competent Authorities (MSCA) were invited to submit comments and contributions by **15 September 2014**.

ADOPTION OF THE OPINION OF THE RAC

Rapporteur, appointed by RAC: **Elodie Pasquier**

Co-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.

The RAC opinion on the proposed harmonized classification and labelling was reached on **12 March 2015** and the comments received are compiled in Annex 2.

OPINION OF THE RAC

RAC adopted the opinion on bendiocarb (ISO) that should be classified and labelled as follows:

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 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	006-046-00-8	bendiocarb (ISO); 2,2-dimethyl-1,3-benzodioxol-4-yl N-methylcarbamate	245-216-8	22781-23-3	Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 4 * Aquatic Acute 1 Aquatic Chronic 1	H331 H301 H312 H400 H410	GHS06 GHS09 Dgr	H331 H301 H312 H410			
Dossier submitters proposal	006-046-00-8	bendiocarb (ISO); 2,2-dimethyl-1,3-benzodioxol-4-yl N-methylcarbamate	245-216-8	22781-23-3	**Modify** Acute Tox. 2 Acute Tox. 3 Acute Tox. 2 **Retain** Aquatic Acute 1 Aquatic Chronic 1	**Modify** H300 H311 H330 **Retain** H400 H410	**Retain** GHS06 GHS09 Dgr	**Modify** H300 H311 H330 **Retain** H410		**Add** M=10 M=100	
RAC opinion	006-046-00-8	bendiocarb (ISO); 2,2-dimethyl-1,3-benzodioxol-4-yl N-methylcarbamate	245-216-8	22781-23-3	Acute Tox. 2 Acute Tox. 3 Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1	H300 H311 H331 H400 H410	GHS06 GHS09 Dgr	H300 H311 H331 H410		M=10 M=100	
Resulting Annex VI entry if agreed by COM	006-046-00-8	bendiocarb (ISO); 2,2-dimethyl-1,3-benzodioxol-4-yl N-methylcarbamate	245-216-8	22781-23-3	Acute Tox. 2 Acute Tox. 3 Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1	H300 H311 H331 H400 H410	GHS06 GHS09 Dgr	H300 H311 H331 H410		M=10 M=100	

RAC evaluation of acute toxicity

Summary of the Dossier submitter's proposal

Acute toxicity: oral
Classification as Acute Tox 2; H300 was proposed on the basis of LD_{50} values reported in rats and mice in the range 5 mg/kg bw < ATE ≤ 50 mg/kg bw. In the acute oral studies, LD_{50} values of 25-156 mg/kg bw and 27-40 mg/kg bw were observed in male and female rats, respectively. Values of 28-45 mg/kg bw have been reported in male and female mice.

In one rat study, the LD_{50} values (71.9-155.9 mg/kg bw) were higher than in other rat studies. These higher values were attributed to the use of gum tragacanth as a vehicle as opposed to corn oil or glycerol formal. Comparable values were obtained when glycerol or corn oil were used as the vehicle. The lowest reported LD_{50} was considered relevant for classification.

Acute toxicity: inhalation
In the acute inhalation study, 4 hour LC_{50} values of 0.61 mg/L and 0.47 mg/L were reported in male and female rats, respectively. Bendiocarb was proposed to be classified as Acute Tox 2; H330 (Fatal if inhaled) as the lowest LC_{50} reported (0.47mg/L in female rats) was within the range 0.05 mg/L < ATE ≤ 0.5 mg/L for dusts and mists.

Acute toxicity: dermal
In the acute dermal toxicity studies, LD_{50} values of 566 and 800 mg/kg bw were reported in rats. Bendiocarb was proposed to be classified as Acute Tox 3; H311 (Toxic in contact with the skin) as both LD_{50} values reported (566 mg/kg bw and 800 mg/kg bw) were within the range 200 < ATE ≤ 1000 mg/kg bw.

Comments received during public consultation

Acute toxicity: oral
Three Member State Competent Authorities (MSCAs) supported the proposed classification Acute Tox 2; H300. A manufacturer concluded that a classification as Acute Tox 3; H301 was more appropriate considering that the lowest LD_{50} values in rats were obtained with corn oil that increases the bioavailability of the substance. When results obtained with glycerol formal as a vehicle were averaged, an LD_{50} of 52 mg/kg bw was obtained which would meet the criteria for Acute Tox 3; H301.

Acute toxicity: inhalation
Two MSCA supported the proposed classification as Acute Tox 2; H330. A third MSCA supported classification as Acute Tox 3; H331 on the basis of a lethality of only 2/5 females (the most sensitive sex) at 0.512 mg/L. A manufacturer commented that the study by inhalation was performed using whole-body exposure that resulted in exposure of the animals also via the oral and dermal routes and at a dose exceeding that calculated in the study. On this basis a classification as Acute Tox 3; H331 was considered appropriate.

Acute toxicity: dermal
Three MSCAs supported the proposed classification as Acute Tox 3; H311.

Assessment and comparison with the classification criteria

Acute toxicity: oral

Acute oral toxicity of bendiocarb has been investigated in rats, mice, Guinea pigs, rabbits, hamsters, hens and cats, as summarised in Table 1 below.

Table 1. Summary of acute oral toxicity studies for bendiocarb

Strain/ species	Observation period	Design	Vehicle	Purity	LD_{50}	CAR Reference
RATS						
SD rat (M)	7 days	n=6/group 13 doses tested	0.5% w/w aq. gum tragacanth	4 batches tested with purity 91% to 98.9%	71.9-155.9 mg/kg bw	6.1.1/01
SD rat (M/F)	14 days	n=6/group/sex 4 doses tested	Corn oil	98.8%	**M: 25 mg/kg bw** **F: 27.3 mg/kg bw**	6.1.1/02
Wistar rat (M/F)	24 hr	n=2-10 /group/sex 5-6 doses tested	Glycerol formal	Not stated	**M: 45-48 mg/kg bw** **F: 34-40 mg/kg bw**	6.1.1/03
Rat (M)	Not specified (≥ 24 hr)	n=4/group 6 doses tested	Glycerol formal	Not stated	**M: 40-64 mg/kg bw**	6.1.1/04
MOUSE						
CFW mouse (F)	24 hr	n=2-4/group 3 doses tested	Glycerol formal	Not stated	**F: 45 mg/kg bw**	6.1.1/03
CD-1 mouse (M/F)	14 days	n=6/group/sex 9 doses tested	0.5% w/w aq. gum tragacanth	91.8%	**M: 28.3 mg/kg bw** **F: 28.2 mg/kg bw**	6.1.1/05
GUINEA PIG						
Guinea pig (F)	24 hr	n=2 /group 2 doses tested	Glycerol formal	Not stated	**F: 35 mg/kg bw**	6.1.1/03
RABBIT						
Rabbit (M/F)	24 hr	n=2 /group/sex 2-3 doses tested	Glycerol formal	Not stated	**M: 40 mg/kg bw** **F: 35 mg/kg* bw**	6.1.1/03
HAMSTER						
Syrian hamster (F)	7 days	n=4 /group 5 doses tested	Water	Not stated	F: 141 mg/kg bw	6.1.1/06
HEN						
Domestic hen (F)	21 days	n=5/group 5 doses	Corn oil	Not stated	F: 137 mg/kg bw	6.9/01
CAT						
Cat (F)	14 days	n=1-2/group 4 doses	Gelatin	79.4%	**F: 11 mg/kg bw**	6.13.2/01

Bold values indicate LD_{50} below the cut-off of 50 mg/kg bw between category 2 and category 3 classifications.

* 35 mg/kg bw according to CLH report. Two doses were tested and 0/2 animals died at 20 mg/kg bw and 2/2 died at 40 mg/kg bw supporting an LD_{50} of 30 mg/kg bw.

F=females, M=males; n=number

All studies were considered by the dossier submitter (DS) of sufficient reliability. RAC notes that some studies (on Guinea pig, rabbit, cat) were performed using a limited number of doses and with a small number of animals and their respective reliability is considered lower. It is also noted that the observation period in many studies was less than 14 days as recommended in the test guideline (minimum 24 hr). However, in all studies and all species, deaths were observed within two hours after administration of the test substance and a short observation period is not considered to affect the estimation of the LD_{50}.

In all species tested, clinical signs typical to direct cholinesterase inhibition were observed and generally included muscular fibrillation, urinary incontinence and salivation. Available results showed a similar magnitude of sensitivity in rats, mice, Guinea pigs, rabbits and cats while hamsters and hens appeared slightly less sensitive to acute toxicity of bendiocarb.

According to the Guidance on the Application of the CLP Criteria (Version 4; CLP guidance), the lowest value available in the most sensitive appropriate species should be used for

classification. Considering the relative reliability of the available data, results in rats and mice are considered the most relevant for the classification purpose.

Available studies were performed using different vehicles that may have impacted the bioavailability of the test compound. In particular in SD rats, toxicity was more pronounced using corn oil than 0.5% w/v aqueous gum tragacanth. There is however no reason to exclude studies performed with corn oil that resulted in the lowest LD_{50} of 25 mg/kg bw in rats. This LD_{50} is within the range of 5 mg/kg bw < LD_{50} ≤ 50 mg/kg bw and justifies classification as Acute Tox 2; H300.

The classification is further supported by similar LD_{50} values obtained in rats with glycerol formal as a vehicle, in mice with glycerol formal or gum tragacanth as a vehicle as well as in Guinea pigs, rabbits and cats although these latter studies are given less weight.

On this basis, RAC supports classification Acute Tox 2; H300 for acute oral toxicity of bendiocarb.

Acute toxicity: inhalation

One OECD TG 403 study investigated acute inhalation toxicity of bendiocarb in rats as summarised in Table 2 below.

Table 2. Summary of acute inhalation toxicity studies for bendiocarb

<table>
<tr><th>Strain/ species</th><th>Observation period</th><th>Design</th><th>Exposure</th><th>Purity</th><th>LD_{50} / lethality</th><th>CAR Reference</th></tr>
<tr><td colspan="7">RATS</td></tr>
<tr><td>SD rat (M/F)</td><td>14 days</td><td>n=5/group/sex
4 doses tested</td><td>4hr to dust in air
51-65.5% of particles < 5.5 µm in diameter</td><td>97.9%</td><td>M: 0.61 mg/L
F: 0.47 mg/L
M&F: 0.55 mg/L
<table><tr><th>Conc. (mg/l)</th><th>M</th><th>F</th></tr><tr><td>0.248</td><td>0</td><td>0</td></tr><tr><td>0.377</td><td>0</td><td>1/5</td></tr><tr><td>0.512</td><td>2/5</td><td>2/5</td></tr><tr><td>0.701</td><td>3/5</td><td>5/5</td></tr></table></td><td>6.1.3/01</td></tr>
</table>

Females appeared slightly more sensitive than males in this study and the LC_{50} of 0.47 mg/L observed in females is within the range 0.05 mg/L < LC_{50} ≤ 0.5 mg/L for dusts and mists and justifies a classification as Acute Tox 2; H330.

It is noted that most of the deaths (1/1 death at 0.377 mg/L, 3/4 at 0.512 mg/L and 5/8 at 0.701 mg/L) occurred already during the 4-hour exposure time. Because of this short latency, although a contribution of exposure through grooming cannot be fully excluded, the deaths are considered to be caused by respiratory exposure. Besides, at the macroscopic examination, congestion of the lungs was the principal finding in those animals that died before the end of the observation period, which provides some indication that mortality was linked to inhalation exposure.

It is also noted that a 50% rate of mortality was not attained in females at the dose of 0.512 mg/L. However, the LC_{50} is a calculated value that also takes into account the steepness of the dose-response curve over all doses tested. An LC_{50} value of 0.47 mg/L was given for female rats in this study.

The determination of the LC_{50} can be accomplished relatively simply by the use of different statistical packages. Small variations in the numerical results for the LC_{50} can be expected depending on how the statistical analysis of the dose-response data is performed. A re-calculation of the study data for female rats using PROAST software was performed by RAP to determine an LC_{50} value according to the dose-response model that better fits the data (Table 3).

Table 3. Re-calculation of LC_{50} values using PROAST software

Model	Likelihood (loglik)	Accept	LC_{50}	Lower CI	Upper CI
null	-15,67	--	NA	NA	NA
full	**-5,87**	--	NA	NA	NA
two-stage	-10,52	no	0.556	NA	NA
log-logist	-6,67	yes	0.497	0.421	0.591
Weibull	**-6,26**	yes	**0.511**	0.438	0.592
log-prob	-6,6	yes	0.492	0.419	0.586
gamma	-6,51	yes	0.496	0.424	0.588
logistic	-6,48	yes	0.508	0.435	0.596
LVM: E2-	-6,38	yes	0.504	0.433	0.591
LVM: H3-	-6,57	yes	0.497	0.42	0.59

Parameters: no covariate; BMR: 0 ED50; constraint: yes; P-value: 0.05; CI=confidence interval

Using the Weibull model that fitted the data with the highest likelihood, an LC_{50} of 0.511 mg/L was determined with a 95% confidence interval of 0.438-0.592 mg/L. RAC concludes that the reported LC_{50} of 0.47 mg/L for female rats is not robust enough to establish that the female LC_{50} value is below the classification limit of 0.5 mg/L between category 2 and 3.

Overall, RAC concludes that a classification as Acute Tox 3; H331 is appropriate for bendiocarb on the basis of the recalculated female LC_{50} of 0.51 mg/L. This is supported by the combined LC_{50} of 0.55 mg/L for male and female rats.

Acute toxicity: dermal

Acute dermal toxicity of bendiocarb had been investigated in rats as summarised in Table 4 below.

Table 4. Summary of acute dermal toxicity studies for bendiocarb

Strain/ species	Obs. period	Design	Vehicle	Purity	LD_{50}	CAR Reference
RATS						
Wistar rat (M/F)	7 days	n=4/group/sex 2 doses tested	Glycerol	Not stated	M & F: 566 mg/kg bw	6.1.2/01
Wistar rat (F)	7 days	n=2 1 dose tested	Glycerol formal	Not stated	F: 800 mg/kg bw	6.1.2/02

None of the studies completely fulfilled the guideline requirements. Due to a very limited number of animals tested at a single dose in the second study, its reliability to establish the LD_{50} is limited. The first study appears to be of higher reliability. The LD_{50} calculated in both studies are within the range of $200 < LD_{50} \leq 1000$ mg/kg bw and justify a classification as Acute Tox 3; H311 for acute dermal toxicity of bendiocarb.

RAC evaluation of environmental hazards

Summary of the Dossier submitter's proposal

Bendiocarb is an insecticide used to control crawling and flying insects. The DS proposed to classify the substance as Aquatic Acute 1 (H400) with an M-factor of 10 and Aquatic Chronic 1 (H410) with an M-factor of 100. The classification was based on the substance being not rapidly degradable, non-bioaccumulative and very toxic to aquatic organisms. The lowest acute toxicity

value was a 48-hour EC_{50} of 0.038 mg/L for *Daphnia magna* and the lowest chronic toxicity value was a 21-day NOEC of 0.000882 mg/L, also for *Daphnia magna.*

Degradation

Bendiocarb hydrolysed at 25°C with a half-life of 46.5 days at pH 5, 48.1 hours at pH 7 and 43.8 minutes at pH 9 using radiolabelled [^{14}C]-bendiocarb in a test performed according to US EPA Subdivision N guidelines (161-1,1982) and largely according to OECD TG 111. At pH 7 and at 12°C the half-life was predicted to be 5.7 days. The major metabolite at pH 7, NC 7312 (2,2-dimethyl-1,3-benzodioxol-4-ol), was identified. This reached 87.9% of the applied parent compound.

Photolysis studies were carried out on [^{14}C]-bendiocarb according to US EPA guidelines. Photolysis was shown to be only a minor route of removal of bendiocarb with a DT_{50} of 187 days predicted from the available data.

No ready biodegradability studies are available. The study on aerobic degradation in sewage treatment process was carried out to determine the effects of bendiocarb on an activated sludge process using 48-hour shake flask assays. Only limited uptake into the biomass and only minimal metabolisms to CO_2 took place. Analysis of the effluent indicated that [^{14}C]-radiolabel was present as a metabolite. It was suggested that this metabolite was most likely NC 7312 as supported by the hydrolysis study. Based upon the results in this study, it can be concluded that bendiocarb is neither readily or inherently biodegradable.

Degradation of [^{14}C]-bendiocarb was studied in two simulated aerobic sediment-water systems. The later study was carried out according to US EPA guidelines. Under aerobic conditions in a sediment/water system, bendiocarb was shown to degrade to a single major metabolite NC 7312 with a half-life of 17.1 days at 12°C. NC 7312 further degraded to CO_2. NC 7312 reached a maximum mean level of 28-32% applied radioactivity (AR) in water phase after 7 days and 17-18% AR in the sediment after 2-3 days. The rate of degradation of the metabolite was enhanced in the presence of sediment, with DT_{50} values between 22.6 days in sediment-water system and 132.8 days in filtered water at 12°C. The available data suggests that NC7312 binds to sediment before undergoing further degradation to CO_2. There is evidence of greater degradation in the presence of sediment and NC 7312 does have a log Kow of 3.15 indicating that adsorption to sediment is likely. According to these data NC 7312 would also be considered not rapidly degradable. The former study was not carried out according to a recognised test guideline, but supported the findings of the later study.

Bioaccumulation

In the bioaccumulation study on radiolabelled [^{14}C]-bendiocarb in bluegill sunfish (*L. macrochirus*) performed according to US EPA 72-6 guideline, a BCF of 6.0 was found for the whole fish. The $logP_{ow}$ was 1.7 (25°C, pH 6.9) in the shake flask test according to EEC-Method A8 (1992). Thus bendiocarb has a low potential to bioconcentrate and hence bioaccumulate in fish.

Aquatic toxicity

Table 5. Summary of relevant aquatic toxicity data for bendiocarb

Substance and purity	**Species**	**Test Guideline**	**Endpoint**	**Toxicity value**	**Conditions**
Bendiocarb 98%	*Cyprinodon variegatus*	US EPA 72-3	96h LC50	0.86 mg a.s./L	Flow-through, mean measured, pH 7.8 to 8.0
Bendiocarb 100%	*Salmo gairdneri*	In house (broadly OECD 210)	78d NOEC	0.07 mg/l	Flow-through, mean measured, pH 6.8 to 7.5
Bendiocarb 97.62%	***Daphnia magna***	**OECD 202**	**48h EC50**	**0.038 mg a.s./L**	**Flow-through, mean**

					measured, pH 7.56 to 7.84
Bendiocarb 95.15%	***Daphnia magna***	**US EPA 72-4**	**21d NOEC**	**0.000882 mg a.s./L**	**Flow-through, mean measured, pH 7.6 to 8.2**
Bendiocarb 97.62%	*Pseudokirchneriella subcapitata*	OECD 201	72h E_rC50 72h NOE_rC	0.408 mg a.s./L 0.087 mg a.s./L	Static, mean measured, pH 7.76 to 9.96

Table 6. Summary of relevant aquatic toxicity data for degradant NC 7312

a.s. = active substance

Substance and purity	Species	Test Guideline	Endpoint	Toxicity value	Conditions
NC 7312 > 99%	*Salmo gairdneri*	US EPA 660	96h LC50	10 mg/L	Semi-static, nominal
NC 7312 > 99%	*Daphnia magna*	OECD 202	48h EC50	25.4 mg/L	Static, nominal
NC 7312 99.2%	*Desmodesmus subspicatus*	OECD 201	72h E_rC50 72h NOE_rC	88.3 mg a.s./L 0.95 mg a.s./L	Static, nominal

The aquatic toxicity test results for bendiocarb are presented in Table 5. There are both acute and chronic toxicity data available for each trophic level namely fish, invertebrates and algae. The most sensitive trophic level is invertebrates. The two key studies for deriving acute and chronic M-factors are presented in more detail in the CLH Report. The acute toxicity to *Daphnia magna* was assessed following OECD TG 202 and GLP and using flow-through conditions. Exposure concentrations were 0.0125, 0.025, 0.05, 0.1 and 0.2 mg active substance (a.s)./L. Actual mean measured concentrations were 0.015, 0.029, 0.05, 0.11 and 0.16 mg a.s./L. Observations were undertaken at 0, 24 and 48 hours noting immobilisation and sublethal effects. Based on the mean measured concentrations the 48h EC_{50} was 0.038 and the 48h NOEC was 0.015 mg a.s./L.

The chronic toxicity to *Daphnia magna* was assessed following US EPA guideline 72-4 and GLP. The study used [^{14}C]-radiolabelled bendiocarb and was performed in flow-through conditions for 21 days and is considered broadly in line with OECD TG 211 and the respective validity criteria are met. The exposure concentrations were 0.625, 1.25, 2.5, 5.0 and 10.0 µg a.s./L. Measured concentrations were 100.5 to 118.1% of nominal which is considered to reflect both bendiocarb and the hydrolysis degradant NC 7312. If it is assumed that all radioactivity represented bendiocarb, the mean measured concentrations were 0.74, 1.47, 2.71. 5.2 and 10.05 µg a.s./L. Bendiocarb was qualitatively analysed by Thin Layer Chromatography (TLC) in the highest exposure concentration on days 0, 1, 2, 6, 9, 13, 16, and 21, and accounted for between 63.7 and 98.4% of the radioactivity. The hydrolysis degradant NC 7312 was considered to account for between 1.7 and 36.3% of radioactivity. Bendioacarb was also quantitatively determined by High Performance Liquid Chromatography (HPLC) in two samples (day 6 and 16) of the highest exposure concentration. The percentage bendiocarb was 99 and 62.1% radioactivity with NC 7312 as 0.2 and 27.1% of radioactivity, respectively. The pH of exposure solutions was determined on days 0, 7, 14, and 21. The study pH range was 7.8 to 8.2. The pH range for the exposure concentration 1.47 µg a.s./L was 7.8 to 8.2. In summary, analysis by both TLC and HPLC showed bendiocarb to be the principle component. However, as the substance hydrolyses fairly quickly, the exact concentrations of bendiocarb over the test period are unclear. The evaluating Member State for the biocide assessment adjusted the study NOEC of 1.47 µg/L by 60% to account for the lowest value of 62.1% bendiocarb recorded. Hence the originally reported NOEC and LOEC values of 1.47 and 2.71 µg/L were reduced to

0.882 and 1.626 µg/L respectively. Whilst the available data is not ideal, this adjusted NOEC of 0.000882 mg/L is considered a reasonable worst case approach.

Table 6 summarises the available toxicity data for the hydrolysis degradation product NC 7312 which is more toxic to fish than to invertebrates, but it is less toxic to fish than its parent bendiocarb. It is also much less toxic to invertebrates than bendiocarb.

Comments received during public consultation

Four Member States (MS) supported the proposed environmental classification. One MS commented that some information should be added to the table summarising the relevant aquatic toxicity information for bendiocarb: namely that the *Salmo gairdneri* NOEC is based on larval growth and that the *Daphnia magna* NOEC is based on reproduction. Another MS pointed out that the ErC_{50} of 0.408 mg/L for the green algae *Pseudokirchneriella subcapitata* can not be consired reliable. The DS agreed with these comments. One MS had noticed that although the CLH report mentions two hydrolysis studies being performed, only one study is described. The DS confirms that only one study was relied upon and described in the CLH report. A short summary on the environmental distribution was requested by one MS. The DS presented the following: The geometric mean Koc value of 33.35 l kg^{-1} (ref. 4.1.2.1 in CAR) indicates that bendiocarb would not adsorb strongly to soil/sediments and suggests a high mobility in soil. Other studies at 4.1.1.2 also indicate that bendiocarb would primarily be associated with the water phase in effluent or other water/sediment systems. Section 4.1.1.2.4 indicates that volatilization is not expected to constitute a majos dissipation pathway for bendiocarb.

Assessment and comparison with the classification criteria

The substance is not rapidly degradable. There is no biodegradability test available. Although the hydrolysis is moderate under environmental temperatures and pH (DT_{50} of 5.7 d at pH 7 and predicted at 12°C), the major hydrolysis NC 7312 product fulfills the criteria for classification as hazardous to the environment being not rapidly degradable with the chronic algae NOE_rC of 0.95 mg/L. No rapid degradability was shown in an aerobic sediment-water test either.

Comparision with the classification criteria BCF ≥ 500 and $logK_{ow}$ ≥ 4 shows that the substance is not bioaccumulative based on a fish BCF of 6 and $logK_{ow}$ of 1.7

The lowest acute toxicity value is 0.038 mg/L for *Daphnia magna* which is in the range 0.01 < L(E)C50 ≤ 0.1 leading to Aquatic Acute 1 classification with an M-factor of 10. However, because it was pointed out in the public consultation that the only given acute toxicity value for algae is not reliable, there is currently no reliable information on the acute algae toxicity.

There is adequate chronic toxicity data available for all three trophic levels. The lowest chronic toxicity value is 0.000882 mg/L for *Daphnia magna* which is in the range 0.0001 < NOEC ≤ 0.001. Because bendiocarb is not rapidly degradable, classification as Aquatic Chronic 1 with an M-factor of 100 is justified.

In conclusion, RAC agrees with the DS's proposal to classify bendiocarb for environmental hazards as Aquatic Acute 1 (H400) with an M-factor of 10 and Aquatic Chronic 1 (H410) with an M-factor of 100.

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 rapporteurs' comments (excl. confidential information).