Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

to the Opinion proposing harmonised classification and labelling at EU level of

MCPA-thioethyl (ISO); S-ethyl (4-chloro-2-methylphenoxy)ethanethioate; S-ethyl 4-chloro-o-tolyloxythioacetate

EC Number: 246-831-4
CAS Number: 25319-90-8

CLH-O-0000001412-86-194/F

Adopted

9 March 2018

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON MCPA-THIOETHYL (ISO); S-ETHYL (4-CHLORO-2-METHYLPHENOXY)ETHANETHIOATE; S-ETHYL 4-CHLORO-O-TOLYLOXYTHIOACETATE

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the public consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the public consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties.

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Substance name: MCPA-thioethyl (ISO); S-ethyl (4-chloro-2-methylphenoxy)ethanethioate; S-ethyl 4-chloro-o-tolyloxythioacetate
EC number: 246-831-4
CAS number: 25319-90-8
Dossier submitter: Poland

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
24.03.2017	Germany		MemberState	1
Comment received				
The used reference substance "MCPA-thioethyl" in sections 1.1 and 1.2 in the IUCLID Dossier does not include the inventory information e.g. EC-No. 246-831-4. As this is a main identifier for this substance please add this information. The German CA proposes that additional classification as STOT RE (Cat.2, H373) is needed. The issue of eye irritation should be clarified since presentation of the data, as it is now, appears not conclusive (See specific comment regarding eye damage/irritation). The German CA agrees with the proposed classification for environmental hazards as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) and the acute/chronic M-factor of 10.				
Dossier Submitter's Response				
IUCLID – the inventory information will be included. STOT RE – see response to comment number 9. Eye Irritation – see response to comment number 7. Thank you for your support for environmental classification.				
RAC's response				
We note the support for the proposed environmental classification.				

CARCINOGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
31.03.2017	France		MemberState	2
Comment received				
No comment				

Dossier Submitter's Response
Noted
RAC's response
Noted

MUTAGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
31.03.2017	France		MemberState	3
Comment received				
No comment				
Dossier Submitter's Response				
Noted				
RAC's response				
Noted				

TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
31.03.2017	France		MemberState	4
Comment received				
No comment				
Dossier Submitter's Response				
Noted				
RAC's response				
Noted				

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
10.03.2017	Spain		MemberState	5
Comment received				
In the oral toxicity studies, the lowest LD50 was 450 mg/kg bw in rats, meeting the criteria for classification under CLP as Acute Tox 4, H302 [Acute Toxicity Estimate (ATE) > 300 but ≤ 2000 mg/kg bw]. Therefore, the Spanish CA considers that the proposed classification as Acute Tox 4, H302: Harmful if swallowed is warranted for MCPA-thioethyl.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
31.03.2017	France		MemberState	6
Comment received				
Comparison with criteria relevant for acute toxicity classification (page:27) The proposal for classification Acute Tox. 4: H302 is supported				

Dossier Submitter's Response
Thank you for your support.
RAC's response
Noted.

OTHER HAZARDS AND ENDPOINTS – Eye Hazard

Date	Country	Organisation	Type of Organisation	Comment number
24.03.2017	Germany		MemberState	7

Comment received

The German CA notes that Table 13 "Summary table of relevant eye irritation studies" on page 30 is not fully comprehensible and does not facilitate comparison with criteria. In both studies, 6 animals (males and females combined) were employed but for comparison criteria were used that are applicable for a study with three rabbits (4.4.2.4). For calculation of mean scores corneal, iris and conjunctival effects should be taken into account. Here, a rather unusual approach was taken in Table 13 to present the data. According to the text, the dossier submitters' proposal of no classification might be appropriate but the arguments should be presented in a more convincing way. This is particularly important since MCPA was already classified as Eye Dam. 1 and for this closely related compound there are several studies available which have shown serious eye damage in rabbits.

Dossier Submitter's Response

There are 2 studies with MCPA-thioethyl. In both cases 6 rabbits were used instead of the 3 required in OECD 405. It is agreed that the data presentation for these studies is not helpful. The Dickhaus (1991e) study showed no findings in any animal after 24, 48 or 72 hours. Using the standard presentation the data is as follows:

	Mean score 24, 48 and 72 hours after instillation					
Ocular structure/finding	**1**	**2**	**3**	**4**	**5**	**6**
Cornea	0	0	0	0	0	0
Iris	0	0	0	0	0	0
Conjunctiva - redness	0	0	0	0	0	0
Conjunctiva - chemosis	0	0	0	0	0	0

In the Kobayashi (1982) study there are no findings in the iris or cornea of any animal. The findings the individual data are summarised below:

	Mean score 24, 48 and 72 hours after instillation					
Ocular structure/finding	**1M**	**2M**	**3M**	**4F**	**5F**	**6F**
Cornea	0	0	0	0	0	0
Iris	0	0	0	0	0	0
Conjunctiva - redness	0.3	0.3	0.3	1.3	0.3	0.3
Conjunctiva - chemosis	0	0	0	0	0	0.3

NONE of the 6 animals tested presented with a mean conjunctival score ≥ 2 for either redness or chemosis. All findings had fully reversed by 4 days after instillation of MCPA-thioethyl.
The results of 2 independent studies with MCPA-thioethyl in a total of 12 rabbits support a classification of "not classified" for eye irritation.

RAC's response

Agreed that the table in the CLH report is not clear. The reported response from the DS is

much more clear.

OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Repeated Exposure

Date	Country	Organisation	Type of Organisation	Comment number
31.03.2017	France		MemberState	8

Comment received

Comparison with criteria of repeated dose toxicity findings relevant for classification as STOT RE page 46-48
FR is of the opinion that classification as STOT RE category 2 could be triggered. Indeed, based on the most reliable studies, kidney effects (effect on organ weight supported by clinical chemistry) were observed in the range of guidance value both in rats and dogs. As regard severity, in the absence of numerical data and/or of results in tabular format, it is difficult to assess the magnitude of the effects reported.
Regarding the 90-day dog study, it cannot be excluded that the severe clinical symptoms observed in 7/8 high dose dogs were consecutive of renal failure.

Dossier Submitter's Response

Judgements are based primarily on data from MCPA-thioethyl i.e. the 90 day Morrow 1974 study in rats and supported by longer term GLP studies in the rat, dog and mouse. Of course, results from more recent studies with the main metabolite, MCPA, have also been considered. It is accepted that as several of these studies are not GLP compliant full data are not always available.

Based on the metabolism data MCPA-thioethyl is extensively converted to MCPA and excreted in the urine. Some effect on the kidney is not unexpected but the findings in all repeat dose studies are considered not to indicate significant target organ toxicity. In the Morrow 1974 study effects on the kidney at 35 and or 150 mg/kg bw/day were limited to discolouration and increased relative kidney weight in both sexes, and increased BUN concentration in females. The only effect at dose levels below the relevant guidance values (10 or 30 mg/kg bw/day) was some evidence of increased absolute and/or relative kidney weight. Changes in organ weights with no evidence of organ dysfunction are considered NOT to support classification for specific target organ toxicity

Kidney weights and kidney to body weight ratios (from Morrow, 1974)

	Dose level (mg/kg bw/day)				
Parameter	**0**	**1.4**	**7.0**	**35.0**	**150.0**
MALE kidney weight (g)	3.519	3.504	3.845*	4.309**	2.990**
MALE kidney /100 g body weight	0.6938	0.7083	0.7642**	0.8559**	0.8192**
FEMALE kidney weight (g)	2.017	2.253**	2.090	2.131	1.982
FEMALE kidney /100 g body weight	0.6728	0.6944	0.6916	0.7206	0.7722**

In the rat study with MCPA (Mellert et al, 1994b) although relative kidney weight was significantly increased for males at 500 ppm (34 mg/kg bw/day) and there was an associated increase urea and creatinine levels, there was no adverse pathology correlate.

In the 2 year dog study with MCPA-thioethyl the only kidney effects reported were pigmentation in the proximal tubules of the kidney at dose levels of 5 and 25 mg/kg bw/day. It is considered that these findings do not represent significant target organ toxicity i.e. there are no reports of cell death/necrosis. These dose levels are equivalent to guidance values of 40 and 200 mg/kg/day.

Incidence and severity of pigment in cortical tubules of the kidney (from Mastalski, 1976)

	Dose level (mg/kg/day, approximate)							
Severity	**Males**				**Females**			
Pigment in cortical tubules	**0**	**1**	**5**	**25**	**0**	**1**	**5**	**25**
Examined	**4**	**4**	**4**	**4**	**4**	**4**	**4**	**4**
not detected	4	2	1	1	4	4		
trace								
minimal		2	3					1
mild				1			3	1
moderate				2			1	2

The Member State comment refers to a 90 day study in dogs with MCPA (Reuzel et al, 1980). The highest dose level of 48 mg/kg bw was in a lethal range and led to severe clinical symptoms and to a spontaneous death of one dog while the others were killed in a moribund state. Feed consumption was markedly reduced and weight loss occurred at this dose level. The changes consisted of pustules, papules, necrotic skin lesions, focal stomatitis, conjunctivitis, diarrhoea, anorexia, dehydratation, lethargy and signs of icterus and effects on liver function. The findings affected several body systems and degenerative and/or regenerative changes were found in the liver and gastro-intestinal tract as well as kidneys. There is not sufficient information to attribute the adverse effects in this study to kidney toxicity. Is was reported that kidney function was adversely affected in dogs fed 3 and 12 mg/kg bw/day. As we do not have access to the report, information limited to that reported in the DAR and the severity of the changes and correlation with STOT-RE guidance levels cannot be determined. However based on findings in other studies with MCPA-thioethyl and MCPA it is expected that these are small changes which are of doubtful or minimal toxicological importance in the absence of supporting pathology findings.

The weight of evidence shows that although the kidney is a target organ for the effects of MCPA-thioethyl and MCPA, the effects seen (typically increases in organ weight and pigmentation in the absence of evidence of organ dysfunction) is not sufficient to trigger STOT-RE.

RAC's response

The effects observed in the 90 day study in dogs with MCPA (Reuzel et al. 1980) and the 2 year study in dogs with MCPA-thioethyl (Mastalski 1976) should be interpreted with care the latter being a international Bio-Test study and thus not used by RAC. It is well known that, for the group of phenoxyacetic acid, toxicokinetic and metabolism data in dogs were distinct from other species. Dogs were found to have a reduced capacity for urinary excretion of phenoxyacetic acid such as MCPA and MCPA-thioethyl, that lead to a higher plasma half-live and higher sensitivity of dogs to the toxic effects of MCPA and MCPA-thioethyl in comparison with other species including human (European Commission, 2001), (Timchalk C, 2004). Effects like organ weight changes and pigmentation in the absence of evidence of clear organ dysfunction is not considered adverse in relation to trigger STOT-RE..

Date	Country	Organisation	Type of Organisation	Comment number
24.03.2017	Germany		MemberState	9

Comment received

The German CA proposes a STOT RE classification, mainly based on effects on the nervous system in a 90-day feeding study with Wistar albino rats (Shirakawa, 1973) that was performed with MCPA-thioethyl. The critical effects consisted of atrophy of nerve cells in the

spine and brain stem, more pronounced in females, and reduced spermatogenesis, even at doses below the guidance value of 10 mg/kg bw per day. This would even justify category 1 (H372). An impact on spermatogenesis is in line with lower testis weights in the more recent subacute neurotoxicity study of Mellert et al. (1994) with MCPA which were observed at 500 ppm (34 mg/kg bw/day) and above. Effects on spermatogenesis were seen in this study only above the classification limit but, on the other hand, MCPA thioethyl might be more toxic as suggested, e.g., by a higher acute oral toxicity (LD50 450 mg/kg bw as compared to 962 mg/kg bw for MCPA) or lower NOAELs in the short-term studies.

Even though a particular vulnerability of dogs to this class of herbicides is under discussion, the rather severe effects on a multitude of organs (blood, liver, kidneys, eyes) observed in this species generally support the need for a STOT RE classification.

These issues have been discussed extensively in the CLH dossier but, on balance, STOT RE 2 (H373) is suggested.

Dossier Submitter's Response

There are concerns about the study management and health of the animals in the 90 day study in rats and mice reported by Shirakawa 1973. Six of 10 rats in an intermediate dose group were lost due to cannibalisation. There was a background of infection (pneumonia and bronchitis) in test and, to a lesser extent, control rats and an unusually high incidence of adenoma for a study of this duration. In addition the results for this study are inconsistent with all other repeat dose studies with MCPA-thioethyl and MCPA. No evidence of nervous system damage was seen in the more modern GLP compliant specific neurotoxicity study at dose levels up to 177 mg/kg bw/day.

Although the single dose LD50 for MCPA-thioethyl is lower than that for MCPA, the more relevant repeat dose data does not support the conclusion that MCPA-thioethyl is more toxic than MCPA. Although previous information did indicate a lower short term NOAEL for MCPA-thioethyl than MCPA, this is based on a mis-reading of the data for the 90 day rat study (Morrow et al, 1974). The dose levels in the report issued and signed by Morrow et al are clearly stated as mg/kg/day. In addition the report describes that the diets were prepared weekly and levels of test substance incorporated based on the body weight and food consumption of the animals the previous week. The EC Commission working document (SANCO/4062/2001-final, 11 July 2008 Review report for the active substance MCPA for MCPA-thioethyl) uses the no observed-effect level from the Morrow study "is 35 ppm for males and females which corresponds to 2.23 mg/kg/day" but reports the level as ppm instead of the correct mg/kg bw/day. Although the Morrow report is not GLP compliant the findings (effects on body weight and haematology parameters) at the high dose of 150 mg/kg/day are consistent with those seen in the 2 year study with MCPA-thioethyl at a similar dose i.e. 177 mg/kg bw/day.

Based on this information it would seem that MCPA-thioethyl is either of similar toxicity or less toxic than MCPA. This is not surprising as MCPA-thioethyl is rapidly converted to MCPA and 80% is excreted as MCPA in the rat at 5 and 100 mg/kg (Ohyama, 1977). The comments on the CLH proposal suggest that an impact on spermatogenesis is in line with lower testis weights in the more recent subacute neurotoxicity study of Mellert et al. (1994) with MCPA which were observed at 500 ppm (34 mg/kg bw/day) and above. Effects on spermatogenesis were seen in this study only above the classification limit and therefore MCPA-thioethyl does not require classification.

RAC's response

It is hard to evaluate the histopathological slides from the study report from Shirakawa 1973. The pictures from the histopathological slides are of very bad black/white quality. As

no similar effects were seen in newer GLP studies both for MCPA and MCPA-thioethyl, the effects will not be suggested to lead to a STOT-RE classification for other organs than liver.

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
06.04.2017	Belgium		MemberState	10
Comment received				
BE CA supports the environmental classification of MCPA thioethyl with Aquatic Acute 1, H400; M=10 Aquatic Chronic 1, H410; M=10 Some minor comment : In the decision scheme on potential bioconcentration (III.5) of the guidance on application of CLP criteria, decision is, in first instance, based on a valid experimental BCF. If such BCF is not available than preference is given to a valid log Kow. In absence of such experimental data, an estimated (QSAR) log Kow can be used. For MCPA-thioethyl, however, a valid experimental log Kow is available (4.35 at pH 7) whereby the substance meets the bioconcentration criterion.				
Dossier Submitter's Response				
Simulation tests show rapid primary biodegradation of MCPA-thioethyl in the environment with the main degradation product being MCPA (Section 5.1.3). For MCPA the log Pow is <<3 (MCPA Review Report, SANCO/4062/2001-final, 11 July 2008) and therefore the potential for bioconcentration of MCPA is of no concern. All the evidence from mammalian studies also points to rapid metabolism of MCPA-TE to MCPA. Thus the conclusion in Section 5.3.1 that 'exposure leading to MCPA-TE bioconcentration is deemed not likely to occur' is reasonable. Whist the CLP decision criteria does not explicitly say how such information should be used, the guidance is clear that 'other information might be considered on a case by case basis' (Section 4.1.3.1.1, p490). For MCPA-TE the weight of evidence suggests that bioaccumulation is not likely to occur, therefore it would be misleading to suggest otherwise purely on the basis of the measured Log Kow.				
RAC's response				
We note the support for the proposed environmental classification. RAC agrees with the Dossier Submitter that the substance is unlikely to be bioaccumulative in aquatic organisms due to rapid primary transformation to a more hydrophilic substance.				

Date	Country	Organisation	Type of Organisation	Comment number
31.03.2017	France		MemberState	11
Comment received				
We agree with the classification proposal regarding environmental hazard. For the acute and chronic M factors, we also agree with the proposed values.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
We note the support for the proposed environmental classification.				

Date	Country	Organisation	Type of Organisation	Comment number
24.03.2017	Germany		MemberState	12
Comment received				
Regarding Table 22: summary of relevant information on aquatic toxicity and page 90 point 5.4.3 Algae and aquatic plants: The study of Bell, G. (1995) resp. Study 1 for assessing toxicity of a 20 % EC formulation of MCPA-thioethyl to algae species Selenastrum capricornutum is not relevant for classification and labelling of MCPA-thioethyl as a pure substance. From our point of view it is only supplementary information. Study 2 (Grunert, B. 1991c) and Study 3 (Mantilacci, S. 2014) are on their own sufficient and reliable for assessing the toxicity to algae and aquatic plants and for classification and labelling of MCPA-thioethyl as a substance according to CLP regulation.				
Dossier Submitter's Response				
It is agreed that the Bell study can be considered as supporting information only, since this study is on the formulation.				
RAC's response				
Studies with simple formulations of an active substance in water may be useful for classification purposes. However, in this case no information has been provided on any co-formulants. In addition, it is a static test and the results are expressed in terms of nominal concentrations; given the rapid abiotic transformation of MCPA-thioethyl, this may under-estimate toxicity. Since valid studies are available for algae and *Lemna*, we do not think this study needs to be taken into account.				

Date	Country	Organisation	Type of Organisation	Comment number
16.03.2017	United Kingdom		MemberState	13
Comment received				
The OECD 204 test guideline is not considered to derive a valid chronic endpoint for classification. On this basis, the surrogate approach should be considered for chronic classification using the acute fish endpoint. We think further details should be presented to validate the Grunert, 1991 chronic toxicity to invertebrates endpoint. These include - Were test guideline validation criteria met? - Was analytical verification of exposure concentrations undertaken over the study period to support the use of nominal concentration endpoints? - Given the reproduction NOEC is greater than the mortality NOEC, it would be useful to present study data and discuss if a dose-response was observed. We think further details should be presented to validate the Grunert, 1991 algal study endpoints for Scenedesmus subspicatus. These include - Were test guideline validation criteria met? - Was analytical verification of exposure concentrations undertaken over the study period to support the use of nominal concentration endpoints? - Is a valid ErC10 value available for growth inhibition? - We note the quoted NOEC is based on stimulated growth rather than inhibition of growth. It would be useful to present growth rate stimulation / inhibition data to understand the dose-response and potential hormesis to consider which endpoint is most relevant for				

chronic classification.
2

Dossier Submitter's Response

We accept that the OECD 204 has limited utility for predicting chronic toxicity to fish and that the fish acute test may be used instead. OECD 204 is no longer a recommended OECD Test Guideline. However, the study does indicate that longer term exposure of mature fish does not lead to increased toxicity and also provides further anecdotal evidence that bioaccumulation is unlikely. We therefore consider that it should be included in the CLH report, but agree that the fish acute endpoint (especially as it is more sensitive than the OECD 204 test result) should be used for classification purposes.

With respect to the chronic invertebrate study (Grunert, 1991) the following details could be added from the report;
In the first renewal period the 0.036, 0.144 and 0.575 mg/L test concentrations were confirmed by specific analysis at 0h, 48h and 72h. Measured concentrations ranged from 91 to 97%, 88 to 97% and 83 to 89% of nominal at 0h, 48h and 72h, respectively. Since these concentrations were >80% of nominal the results were all based on nominal test concentrations. The 0.009 mg/L test concentration was lower than the limit of detection and the 2.3 mg/L test concentration was not measured as there was 100% mortality by 48 hours.
Throughout the test the temperature was maintained at 21-22 °C, dissolved oxygen at 5.9-9.5 mg/L and pH at 7.2-8.5.
For reproduction, a non-linear dose response was observed and it was not possible to calculate EC50 values. The reproduction rates were reported as follows;

Nominal concentration (mg/L)	Average* number of young alive per surviving female					
	After 7 days	SD	After 14 days	SD	After 21 days	SD
Control	5.6	± 3.95	47.0	± 7.18	74.3	± 12.79
0.009	8.8	± 3.91	42.1	± 9.47	67.1	± 15.08
0.036	11.6	± 2.27	59.5	± 3.57	78.6	± 11.32
0.144	10.0	± 1.35	69.0	± 19.42	102.4	± 25.19
0.575	0	± 0.0	40.0	± 22.49	40.3	± 22.49
2.3	-	-	-	-	-	-

*Average of 8 vessels per test concentration
The Guideline performance criteria in the control(s) were met, namely: the mortality of the parent animals does not exceed 20% at the end of the test and the mean number of live offspring produced per parent animal surviving at the end of the test is > 60 (actual mean was 74.3).

With respect to the algae study (Grunert, 1991) the following details could be added from the report;
No specific chemical analysis was undertaken – All results are based on nominal test concentrations.
We have noted that the temperature and light intensity given in the study summary is incorrect in the CLH – it should read; *'The flasks were incubated at 22-23 °C in an orbital shaker under continuous light at approximately 8000 lux...'*
The pH was measured at 0h and 72h and was within the range 8.31 – 9.27 in all test and

control vessels (within 1.5 units as per Guideline criterion).
Coefficients of variation in the controls were not reported, however only two control replicates were used vs OECD 201 guideline recommendation of 6 so comparison with guideline criteria for coefficient of variation is not really meaningful.
The guideline validity criteria for control growth rate was met (>16 times).
The reported NOEC of 0.009 mg/L represents the test concentration where neither a significant inhibition nor a significant stimulation of cell growth was obtained. Normally the relevant endpoint for classification purposes is growth inhibition but it is questionable if growth stimulation should be ignored. As stated in the CLH study summary; the reported ErC10 for growth rate inhibition was 0.8 mg/L.

RAC's response

We agree that the OECD TG 204 should not be used for acute classification and so the surrogate method should be used for fish in this case. We note that this study appears to be much less sensitive than the OECD TG 203 test too.
RAC agrees that the validity criteria were met for the long-term *Daphnia* study, but considers that the failure to confirm test concentrations beyond 72 hours may have introduced some uncertainty over the actual exposure levels (which might explain some of the variation seen in the reproduction end point, along with the significant mortality seen at the higher test concentrations). Since the critical data point is the NOEC, which occurred at the lowest concentration, the Dossier Submitter should have provided the limit of detection.
Regarding the algal study, RAC considers that a significant change compared to the controls may be detrimental to the organism, and agrees that stimulation might have adverse consquences for algae (e.g. in terms of energy and nutrient depletion, etc.). It is therefore a relevant end point for classification. Given the rapid abiotic primary transformation of MCPA-thioethyl to MCPA observed in environmental fate tests, RAC notes that data expressed in terms of nominal concentrations may under-estimate toxicity. The alkaline pH of the static algal test as well as light irradiation would suggest that the parent substance did not remain in the solutions for long. RAC therefore considers the algal NOEC to be below 0.009 mg/L, but we do not know by how much. The Dossier Submitter does not provide any additional details about the aquatic toxicity of MCPA so the significance of this cannot be assessed.

OTHER HAZARDS AND ENDPOINTS – Physical Hazards

Date	Country	Organisation	Type of Organisation	Comment number
31.03.2017	France		MemberState	14

Comment received

There is a typo error in the last column of the table for flammability properties.
The test A10 is performed to demonstrate the flammability of the substance not oxidizing properties.

Dossier Submitter's Response

Thank you for your comments. The typo error will be corrected.

RAC's response

Noted.