# Committee for Risk Assessment

# RAC

## Opinion

proposing harmonised classification and labelling at EU level of

## Ethephon

**EC number: 240-718-3**

**CAS number: 16672-87-0**

ECHA/RAC/CLH-O-0000001734-74-03/F

**Adopted**

**19 November 2012**

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**CLH-O-0000001734-74-03/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 the Regulation (EC) No 1272/2008 (CLP Regulation), the Committee for Risk Assessment (RAC) has adopted an opinion on the proposal for harmonised classification and labelling of

**Substance Name:** **Ethephon**

**EC Number:** **240-718-3**

**CAS Number:** **16672-87-0**

The proposal was submitted by **The Netherlands** and received by RAC on **14 June 2011.**

**The proposed harmonised classification***

| | **Regulation (EC) No 1272/2008 (CLP Regulation)** | **Directive 67/548/EEC (DSD)** |
|---|---|---|
| **Current entry in Annex VI of CLP Regulation (EC) No 1272/2008** | Acute Tox 4* - H332<br>Acute Tox 4* - H312<br>Skin Corr. 1B - H314<br>Aquatic Chronic 3 - H412<br><br>STOT SE 3 – H335: C ≥ 5 %: | Xn; R20/21<br>C; R34<br>R52-53<br><br>C ≥ 10 %: C; R34<br>5 %< C < 10 %:Xi; R36/37/38 |
| **Proposal by dossier submitter for consideration by RAC** | Acute Tox 3 - H311<br>Acute Tox 4 - H332<br>Acute Tox 4 - H302<br>STOT SE 3 - H335<br>EUH071<br>~~Aquatic Chronic 3 - H412~~ | Xn; R22<br><br>~~R52-53~~ |
| **Resulting harmonised classification (future entry in Annex VI of CLP Regulation) as proposed by dossier submitter** | Acute Tox 3 - H311<br>Acute Tox 4 - H332<br>Acute Tox 4 - H302<br>Skin Corr. 1B - H314<br>STOT SE 3 - H335<br>EUH071<br><br>STOT SE 3 – H335: C ≥ 5 % | Xn; R20/21/22<br>C; R34<br><br>S: (1/2)-26/28-36/37/38-45<br><br>C ≥ 10 %: C; R34<br>5 %< C < 10 %:Xi; R36/37/38 |

* The table reflects the original classification proposal by the dossier submitter. Following the public consultation, the dossier submitter has altered their view on corrosivity, specific target organ toxicity and environmental classification. These altered views are addressed in the appropriate sections below

## PROCESS FOR ADOPTION OF THE OPINION

**The Netherlands** have submitted a Harmonised Classification & Labelling (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 **14 June 2011.** Parties concerned and MSCAs were invited to submit comments and contributions by **29 July 2011**.

## ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: **Thomasina Barron**

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

The RAC opinion on the proposed harmonised classification and labelling has been reached on **19 November 2012** in accordance with Article 37 (4) of the CLP Regulation, giving parties concerned the opportunity to comment. Comments received are compiled in Annex 2.

The RAC Opinion was adopted by **consensus**.

## OPINION OF RAC

The RAC adopted the opinion that **ethephon** should be classified and labelled as follows:

**Classification and labelling in accordance with the Regulation (EC) 1272/2008 (CLP Regulation)**

| Index No | International Chemical Identification | EC No | CAS No | Classification | | Labelling | | | Specific Conc. Limits, M-factors | Notes |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Hazard Class and Category Code(s) | Hazard state-ment Code(s) | Pictogram, Signal Word Code(s) | Hazard state ment Code(s) | Suppl. Hazard statement Code(s) | | |
| 015-154-00-4 | Ethephon; 2-chloroethylphosphonic acid | 240-718-3 | 16672-87-0 | Acute Tox 3<br>Acute Tox 4<br>Acute Tox 4<br>Skin Corr. 1C<br>Aquatic Chronic 2 | H311<br>H332<br>H302<br>H314<br>H411 | GHS05<br>GHS06<br>GHS09<br>Dgr | H311<br>H332<br>H302<br>H314<br>H411 | EUH071 | | |

**Classification and labelling in accordance with the criteria of Directive 67/548/EEC (DSD)**

| Index No | International Chemical Identification | EC No | CAS No | Classification | Labelling | Concentration Limits | Notes |
|---|---|---|---|---|---|---|---|
| 015-154-00-4 | Ethephon; 2-chloroethylphosphonic acid | 240-718-3 | 16672-87-0 | Xn; R20/21/22<br>C; R34<br>N; R51-53 | C<br>R: 20/21/22-34-51/53<br>S: (1/2)-26-36/37/38-45-61 | Xi; R37: 5 %< C < 10 % | |

# SCIENTIFIC GROUNDS FOR THE OPINION

The opinion relates only to those hazard classes that have been reviewed in the proposal for harmonised classification and labelling, as submitted by Netherlands.

## HEALTH HAZARDS

## Carcinogenicity

### Summary of the dossier submitter's assessment

Two studies assessing carcinogenicity were reported in the CLH report. A combined toxicity/carcinogenicity study was performed in Sprague Dawley CD® rats in accordance with OECD 453. For the evaluation of the carcinogenic potential of the test substance 90-100 animals/sex/dose were used. Doses of 0, 300, 3000, 10000 and 30000 mg/kg food were used (equal to 0, 13, 131, 446 and 1416 mg ethephon/kg bw/day in males and 0, 16, 161, 543 and 1794 mg/kg bw/day in females). Final sacrifices were in week 97 for males and in week 104 for females. In the liver, the incidence of biliary hyperplasia was significantly higher in males at 30000 mg/kg food at terminal sacrifice. The dossier submitter concludes that there was no evidence of carcinogenicity.

In addition, a 78-week carcinogenicity study in mice was performed in accordance with OECD 451. For the evaluation of the carcinogenic potential of the test substance 70 animals/sex/dose were given 0, 100, 1000, 10000 and 50000 mg/kg food (equal to mean intake of 14, 139 and 1477 mg/kg bw/day for males and 17, 173 and 1782 mg ethephon/kg bw/day for females). Two tumour types in males (hepatocellular adenoma and lung adenoma) and two types in females (thymic region lymphosarcoma and lung adenoma) were observed in frequencies above 5%, but only the increased incidence of lung adenomas in males at 1000 mg/kg food reached the level of statistical significance. The dossier submitter stated that lung adenomas commonly occur in the strain of mouse used and no dose-response was observed, this finding was not considered to be related to treatment. The particular mouse strain used was not documented in the CLH report or the available EFSA Draft Assessment Report (DAR). There were no carcinogenicity studies carried out *via* other routes. The dossier submitter concluded that classification for carcinogenicity is not warranted for ethephon.

### Human data

No data on human exposure were reported.

### Information received during the public consultation

All comments made during the public consultation supported of the proposal for no classification with respect to carcinogenicity. There was a request for information on the historical control data for lung adenoma in mice. Subsequently, industry provided this historical control data for lung adenomas in the mouse strain used in the laboratory conducting the testing. The data indicate that the occurrence of lung adenomas in the 78-week study was within the historical control range.

### Comparison with the criteria

There was no evidence of treatment-related carcinogenicity in the long-term oral mouse and rat studies. No carcinogenic effects were observed up to 1477 mg/kg bw/day in mice and 1416 mg/kg bw/day in rats, the highest doses tested. No data were available regarding carcinogenic effects after dermal or inhalation exposure. In addition, no human carcinogenicity data were available. The dossier submitter concluded there was no evidence of carcinogenicity based on these oral studies.

### RAC Opinion

RAC agrees with the dossier submitter's opinion and with the comments received during the public consultation that classification for carcinogenicity is not warranted.

## Mutagenicity

### Summary of the dossier submitter's assessment

The CLH report described four *in vitro* assays on genotoxicity and one *in vivo* study. An Ames test was conducted according to OECD 471 of 1983. Although ethephon base 250 induced point mutations in *S. typhimurium* in the absence and presence of metabolic activation in tester strain TA 1535, in four other strains, ethephon was negative. Ethephon Base 250 was also negative in a gene mutation test (OECD 476 of 1984) with CHO Chinese hamster ovary cells. An *in vitro* UDS test with rat hepatocytes (although the study was considered not acceptable) and a chromosome aberration test (OECD 473 of 1984) with CHO Chinese hamster ovary cells. Furthermore, ethephon base 250 was negative in an *in vivo* unscheduled DNA synthesis test (OECD 486) in rats. The Dossier Submitter considers ethephon base 250 to be non-genotoxic and classification not necessary.

### Information received during the public consultation

All comments made during the public consultation supported the proposal for no classification with respect to mutagenicity.

### Comparison with the criteria

Based on the results of all studies provided, (according to both CLP and DSD) ethephon does not demonstrate genotoxic potential.

### RAC Opinion

RAC agrees with the dossier submitter's opinion and with the comments received during the public consultation that classification for mutagenicity is not warranted.

## Reproductive Toxicity

### Effects on sexual function and fertility

### Summary of the dossier submitter's assessment

One oral two-generation reproduction study in rats (OECD 416) was reported in the CLH report. The NOAEL for reproductive effects was ≥ 2444 mg/kg bw/day, since no effects on mating performance or fertility were noted. At 2444 mg/kg bw/day, parental effects included decreased body weight (gain) and decreased food consumption of F0 and F1 males and females. No treatment-related adverse effects were observed in adult animals at lower dose levels. The dossier submitter proposes no classification for effects on sexual function and fertility.

### Information submitted during public consultation

All comments made during the public consultation were in support of the proposal for no classification with respect to sexual function and fertility.

### Comparison with the criteria

There were no adverse effects on fertility in a 2 generation study conducted to 2444 mg/kg day and therefore classification for effects on sexual function and fertility is not necessary according to either CLP or DSD regulation.

### RAC Opinion

RAC agrees with the dossier submitter and with the comments made during the public consultation that classification for fertility is not required. It is noted that the tabular presentation of results without actual data is not sufficient for decision making. However, this endpoint was previously finalised by the Technical Committee on

Classification and labelling (Annex I and II of the BD) and does not require further discussion.

**Effects on development**

**Summary of the dossier submitter's assessment**

Two developmental toxicity studies were made available in the CLH report, one in rats and one in rabbits. In the study in rats (OECD 414), no treatment-related clinical signs or adverse observations at parental necropsy were reported. In addition, no adverse developmental effects were observed at doses up to 500 mg/kg bw. In a developmental study in rabbits (OECD 414), treatment related mortality was observed at 250 mg/kg bw/day as well as clinical signs of toxicity and weight loss in the does. Macroscopic examination of does revealed erosions, reddened area and black foci in the stomach at a greater incidence at 250 mg/kg bw/day than in controls. The percent of early resorptions and post-implantation losses were considerably higher and the percent of live foetuses was lower in the remaining dams at 250 mg/kg bw, reflected in a lowered number of foetuses per litter (i.e. only at doses that caused severe maternal toxicity). These effects were considered likely to be related to the maternal toxicity.

In addition, some developmental effects were observed at the high maternally toxic dose of 2444 mg/kg bw/day in the oral 2-generation reproduction study in rats (OECD 416) described above. These included reduced litter weight in F1 and F2 pups, increased still births and deaths during early lactation in F1B and F2B litters. At the same dose, also maternal toxicity was observed, including reduced body weight, body weight gain and increased clinical signs of toxicity. Therefore, the effects observed in the pups may be related to maternal toxicity. This is difficult to assess fully without more detailed presentation of the study data. No treatment-related lesions were observed at necropsy.

Both in the two-generation study and the developmental toxicity studies, no ChE measurements in plasma, erythrocytes or brain were performed. Therefore, the NOAEL for parental toxicity in these studies is tentative. Nevertheless, based on the observed effects, the Dossier Submitter considers classification for developmental effects not necessary according to the criteria of CLP and DSD, since developmental effects were only observed at a very high dose that also induced maternal toxicity.

**Information submitted during public consultation**

All comments made during the public consultation supported the proposal for no classification with respect to developmental toxicity.

**Comparison to the criteria**

Based on the observed effects, classification for developmental effects is considered not necessary according to the criteria of CLP and DSD, since developmental effects were only observed at a very high dose that also induced maternal toxicity in the rat 2 generation study (2444 mg/kg bw) and severe maternal toxicity in the rabbit developmental toxicity study (250 mg/kg/day).

**RAC opinion**

RAC supports the conclusion of the dossier submitter that no classification for developmental toxicity is warranted.

## Respiratory Sensitisation

**Dossier submitter's assessment**

No data available

## Other Hazard Classes

## Acute Toxicity

### Summary of the dossier submitter's assessment

One acute oral rat study (OECD 401) was reported with an $LD_{50}$ value of 1564 mg/kg bw. In an additional acute oral neurotoxicity study (OECD 424) 2/12 females died after administration of a dose of 2000 mg/kg bw (without correction) but these data were considered less relevant than the acute toxicity study. One rat inhalation study (OECD 403) with an $LC_{50}$ of 3.26 mg/l and one rabbit dermal study (OECD 402) with an $LD_{50}$ of 983 mg/kg bw were reported. The dossier submitter proposed to confirm a minimum classification of Acute Tox. 4 for inhalation – H332 and amend the minimum classification to Acute Tox. 3 for dermal – H311. They furthermore proposed adding classification as Acute Tox. 4 for oral – H302. The dossier submitter also proposed to add Xn; R22 to the existing DSD classification.

The dossier submitter considered that it could be argued that the classification of ethephon for acute dermal toxicity and corrosivity is a double classification based on the same effect and therefore not warranted. Although the mechanism of toxicity in the dermal study possibly is corrosivity, it cannot be excluded that at least part of the effects are unrelated to the corrosive properties. Therefore, the substance should be classified for acute dermal toxicity as proposed, based on the $LD_{50}$ in females. Also, no classification for acute dermal toxicity for corrosive substances would be inconsistent with existing harmonized classifications of many corrosive substances in Annex VI which are also classified for acute dermal toxicity (some even in a more severe category such as R24). In such cases, the classification for acute dermal toxicity provides additional information to the user. Therefore, classification for both skin corrosivity and acute dermal toxicity is required.

The classification of ethephon was discussed by the Technical Committee on Classification and labelling (TC C&L) in November 2006. The TC C&L agreed with the proposed classification for Xn; R20/21/22 and with the specific concentration limit for respiratory tract irritation according to the DSD criteria.

### Information submitted during the public consultation

The classification proposal for acute toxicity was supported by those member states who commented. The comments received from industry did not support classification for the dermal route on the basis that dermal studies should not be conducted with corrosive substances. It was considered that mortality was secondary to corrosion and distress associated with pain. It was stated that as ethephon was classified as corrosive to the skin and that no additional classification for acute effects following dermal exposure should apply. The dossier submitter concluded that although the study should not have been conducted, the data were now available and supported classification for toxicity *via* the dermal route which is considered a different endpoint, *albeit* associated in this case with severe local effects.

### Comparison with the criteria

According to CLP, ethephon should be classified as Cat 4; H302 (limits 300 – 2000 mg/kg bw, oral), Cat 3; H311 (limits 200 – 1000 mg/kg bw, dermal) and Cat 4; H332 (limits aerosol 1 – 5 mg/l).

According to DSD ethephon should be classified as Xn; R20/R21/R22 because the $LC_{50}$ is within the limits of 1 - 5 mg/l, the oral $LD_{50}$ is within the limits of 200 - 2000 mg/kg bw and the dermal $LD_{50}$ is within the limits of 400 – 2000 mg/kg bw.

In addition, in the acute inhalation study, rats exposed to 2.11 and 6.12 mg/l ethephon base 250 (~ 1.49 and 4.32 mg/l ethephon) showed audible respiration. This indicates respiratory tract irritation. Based on this study and following the current classification, a

specific concentration limit is advised according to DSD: Xi; R37: 5% ≤ C < 10% (and C; R34:C≥10%, see 5.4).

**RAC opinion**

The classification proposal of the dossier submitter for acute toxicity is supported by RAC.

## Irritation/Corrosion

**Summary of the dossier submitter's assessment**

A skin irritation/corrosion study was performed which was not in full conformity with OECD 404. Ethephon has a pH of 1.6, therefore, a skin irritation study should not be performed, or should have been initiated with one animal. Despite some methodological shortcomings and considering the results of the test the study was considered acceptable for classification. A classification of corrosive to skin was proposed on the basis of necrosis in 5/6 animals following a 4 hour application. Reversibility was not demonstrated as the study was terminated at 48 hours. The Dossier Submitter proposed to classify ethephon as Skin Corr. 1B – H314.

Furthermore, the dossier submitter proposed to classify additionally for STOT SE 3 – H335 to be consistent with the specific concentration limits already included in the Annex VI entry (C≥5%; STOT SE 3 – H335) and to add the supplemental hazard statement EUH071 – Corrosive to the respiratory tract.

**Information submitted during public consultation**

Comments received during public consultation questioned whether Skin Corr. 1B was appropriate and suggested classification as Skin Corr. 1C. A number of comments also raised the question of whether STOT SE H335 (May cause respiratory tract irritation) or EUH071 (Corrosive to the respiratory tract) should be applied to account for the potential to cause respiratory tract damage (as implied by the acute inhalation study, the pH of 1.6 and the demonstration of dermal corrosion (dermal irritation study and acute dermal study)).

Based on comments received during public consultation, the dossier submitter altered their view on the classification of irritation/corrosion. As expressed in the RCOM and the revised CLH report submitted after public consultation, they considered that ethephon should be classified as Skin Corr. 1C – H314. Furthermore, the dossier submitter expressed the view that classification for STOT SE 3 – H335 and the associated SCL (Specific Concentration Limit) of C≥5%; STOT SE 3 – H335 is superfluous. The reasons given are that classification for corrosivity and inclusion of EUH071 is sufficient to communicate the hazard of respiratory irritation.

**Comparison with the criteria**

Based on the low pH of ethephon (1.6) and the results of the skin irritation study, it can be concluded that ethephon is corrosive. Therefore, ethephon should be classified with R34 according to the criteria of DSD. Since necrosis was only observed after a 4 hour exposure period and not after a 1 hour period, ethephon should be classified as Skin Corr1C; H314 according to the criteria of CLP.

In addition, a Specific concentration limit (SCL) for R37 should be applied for a concentration between 5 and 10%.

No SCL for Skin Corr 1C is needed as the current SCL of 10% for R34 is a generic concentration limit which is included because all concentration limits were included at that time in the entry in Annex I of DSD.

No eye irritation study was performed with ethephon, due to the pH of 1.6. The substance should not be labelled with R41 as R34 is already assigned.

According to the CLP criteria, additional labelling with EUH071 (Corrosive to the respiratory tract) is proposed by the dossier submitter. The criteria state that in addition to inhalation toxicity, if the data indicate that the mechanism is *via* corrosivity the mixture or substance shall be labelled as 'corrosive to the respiratory tract'. Additional information such as animal data and pH shall be used based on expert judgement (see Annex I 3.1.2.3.3 and footnote 1 to table 3.1.3, Annex II 1.2.6 and CLP Guidance 3.1.4.2). This additional labelling is supported as there were effects on the lungs in the inhalation study, also due to the corrosivity to the skin and to the acidic nature (pH=1.6) of the substance.

The classification of ethephon was discussed by the TC C&L in November 2006. The TC C&L did not propose changes in classification (C; R34, with an SCL of 5-10% for R36/37/38).

**RAC opinion**

RAC supports the view of the dossier submitter as expressed in the RCOM and revised CLH report submitted after public consultation. Ethephon should be classified as Skin Corr. 1C – H314 and EUH 071 under CLP. It should be classified as C; R34 under the DSD criteria. The generic concentration limits for C, R34 are: C; R34: C ≥ 10 % and Xi; R36/38: 5 %< C < 10 %. RAC is therefore of the opinion that the concentration limits of C; R34: C ≥ 10 % and Xi; R36/38: 5 %< C < 10 % should not be listed as specific concentration limits in Annex VI. The SCL of Xi; R37: 5 %< C < 10 % is required, however.

Furthermore, RAC agrees with the view of the dossier submitter as expressed in the revised report after public consultation that classification and SCLs for STOT SE 3 –H335 are not appropriate.

## Sensitisation

**Summary of the dossier submitter's assessment**

Ethephon did not show sensitising properties in a Buehler test or in an LLNA test. However, both tests were of limited value since the Buehler test was performed with too few animals, and the influence of adjusting the pH of ethephon is not properly addressed in the LLNA test. Eight out of twenty experimental animals (40%) in the maximisation study reacted positively to the challenge phase. It is however not clear whether these findings can be interpreted as a sensitisation reaction or whether they are the result of the low pH of the test substance. The dossier submitter concludes that the data for ethephon do not support classification for sensitisation. The classification of ethephon was discussed by the TC C&L in November 2006. The TC C&L did not propose changes in classification and agreed not to classify ethephon for sensitisation.

**Comparison with the criteria**

No reliable findings were obtained in a Buehler test, LLNA assay or a GPMT study. No comparison with criteria can therefore be made.

**RAC opinion**

RAC supports the dossier submitter proposal and the conclusion of the TC C&L.

## ENVIRONMENTAL HAZARDS

**Summary of the dossier submitter's assessment**

The initial proposal of the dossier submitter was a revision of the harmonised classification for environmental hazards in Annex VI to the CLP Regulation (included with the 29$^{th}$ ATP to Directive 67/548/EEC, 2004). The dossier submitter proposed to delete

the existing classification of Aquatic Chronic 3 – H412 and R52-53 based on discussions in the TC C&L in January 2007. The conclusion of this discussion was that ethephon needed not be classified for the environment. However, after public consultation the dossier submitter revised their proposal and took into account the revised criteria for classification for the aquatic environment which were introduced with the 2nd ATP to the CLP Regulation (published in March 2011). Taking into consideration the revised criteria for environmental hazards the dossier submitter eventually concluding that the data for ethephon do support classification for chronic aquatic hazards according to the CLP Regulation.

**Information submitted during public consultation**

One comment received during public consultation questioned whether the proposed deletion of Aquatic Chronic 3 – H412 was appropriate and suggested to consider keeping the chronic classification as Aquatic Chronic 3 – H412 based on a study mentioned in the CLH report (i.e. Section 7.1.1.3 in the Background document: Study 5 - on the fresh water plant *Lemna gibba*) which was not previously considered for classification. Other comments received supported the deletion of the existing classification.

Based on the comment received during public consultation, the dossier submitter altered their view on the proposed deletion of the environmental classification. As expressed in the RCOM and the revised CLH report submitted after public consultation, they consider that ethephon should be classified as Aquatic Chronic 3 – H412 taking into consideration the revised criteria for classification as hazardous to the aquatic environment which were implemented with the 2nd ATP to the CLP Regulation.

**Comparison with criteria**

Based on the available information on acute and chronic aquatic toxicity aquatic plants are the most sensitive to ethephon. The lowest $ErC_{50}$ and $ErC_{10}$ values observed for *Lemna gibba* after 14 days is 1.6 mg ethephon/l (which is in the toxicity range of 1 mg/l ≤ 10 mg/l according to Annex VI to DSD) and 0.21 mg ethephon/l (which is > 0.1 to ≤ 1 mg/l according to Table 4.1.0(b)(i) of Annex I to CLP), respectively, based on growth rate and mean measured concentrations.

The log Kow of ethephon (-1.89 at neutral pH) is lower than the criterion for bioaccumulation according to CLP (log Kow >4) and DSD (log Kow > 3). Ethephon is therefore considered as substance with limited potential for bioaccumulation.

Four studies relevant for the assessment of degradation of ethephon are available. In a standard ready biodegradability test ethephon is considered not to be readily biodegradable.

The hydrolysis of ethephon was tested at different pH values (see also Section 4.1.1, Table 4.1.1.-1 of the Background document) showing half-lives at 20°C of 2.5 and 1.4 days for pH 7 and 9, respectively. The half-life for acidic conditions (pH 5) was much longer, i.e. 99.1 days (measured). The longest half-life determined, 99.1 days at pH 5, exceeds the cut-off value of 16 days. A pH value of 5 is at the lower end of environmentally realistic pH values; no information is available at pH values between 5 and 7. Based on the available information, ethephon cannot be considered to undergo fast primary degradation in hydrolysis studies (cf. CLP guidance Annex II, Section II.2.3.8).

The available simulation studies in water/sediment do not demonstrate ultimate degradation of the substance in surface water with > 70% degradation in 28 days (cf. CLP guidance Annex II, Section 2.3). The studies confirmed the rapid primary degradation rate of the substance with a DT50 for the whole system of 2.2 and 2.6 days at pH ≥ 7 with formation of the degradation products ethylene and phosphoric acid. These degradation half-lives obtained in the water/sediment studies are comparable to those obtained in the hydrolysis studies, suggesting that the mechanism of degradation

is abiotic. As the water/sediment studies do no provide information on the degradation of ethephon at pH values below 7, it cannot be excluded that the primary degradation half-life of ethephon at pH values below 7 in water/sediment studies is longer than 16 days. Therefore, it can not be concluded that ethephon undergoes rapid primary degradation.

Thus, based on the results from the ready biodegradation study, the hydrolysis study and the two simulation studies RAC concludes that it has not been demonstrated that ethephon undergoes fast primary degradation. Furthermore, mineralisation of more than 70% has not been demonstrated. Ethephon cannot, therefore, be regarded as rapidly or readily degradable. Taking into consideration the results of the acute aquatic toxicity studies (14d-$EC_{50}$ = 1.6 mg a.s./l) it can be concluded that ethephon should be classified as dangerous to the aquatic environment with N; R51-53 according to the criteria of DSD.

Furthermore, based on the lack of rapid degradation and the lowest $ErC_{10}$ for chronic aquatic toxicity for the aquatic plant *L. gibba* (0.21 mg ethephon/l), ethephon should be classified with Aquatic Chronic 2 – H411 according to the revised criteria of the CLP Regulation included in the 2nd ATP to the CLP Regulation (published in March 2011).

**RAC opinion**

RAC supports the view of the dossier submitter as expressed in the revised CLH report submitted after public consultation to classify ethephon as hazardous to the aquatic environment. However, as regards the hazard category RAC suggests to classify ethephon with Aquatic Chronic 2 – H411 under CLP. In this respect RAC also proposes an environmental classification with N; R51-53according to the DSD criteria.

## ANNEXES

Annex 1 Background Document (BD)[1]

Annex 2 Comments received on the CLH report, response to comments provided by the dossier submitter and RAC's comments (excl. confidential information)

[1] The Background Document (BD) supporting the opinion contains scientific justifications for the CLH proposal. The BD is based on the CLH report prepared by a dossier submitter.