# Committee for Risk Assessment
# RAC

Annex 2

## Response to comments document (RCOM)

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

## fenoxaprop-P-ethyl

**EC number: -**
**CAS number: 71283-80-2**

CLH-O-0000002445-76-03/A2

**Adopted**
**7 March 2013**

**COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION**

*ECHA has compiled the comments received via the internet that refer to several hazard classes and entered them under each of the relevant categories/headings as comprehensively as possible. Please note that some of the comments might occur under several headings, when splitting the information provided is not reasonable.*

## Substance name: fenoxaprop-P-ethyl

## EC number: -
## CAS number: 71283-80-2
## Dossier submitter: Austria

### GENERAL COMMENTS

| Date | Country | Organisation | Type of Organisation | Comment number |
|---|---|---|---|---|
| **23/05/2012** | **Germany** | | **MSCA** | **1** |
| **Comment received** | | | | |
| The German CA supports the proposed classification.<br>However, we have some comments on the proposed labelling:<br><br>Concerning labelling based on Regulation (EC) No 1272/2008 we like to remark the following:<br>- The applicable pictograms (GHS07, GHS08 and GHS 09) are missing and should therefore be added.<br>- The Hazard statement H400 is part of the classification but not of the labelling and should therefore be omitted here.<br>- The Precautionary statement "(P102)" should be added in case the substance may be available for the consumer/ general public.<br>- The Precautionary statement "P261" should be replaced by "P260" which is also possible (H373) as this statement is from our point of view more stringent.<br>- Finally the Precautionary statement "P321" seems to us not really necessary.<br><br>Concerning labelling based on Directive 67/548/EEC we like to remark the following:<br>- The indication of danger for a sensitizing substance is "Xi, Irritant" and not "Xn, Harmful".<br>- The S-phrase 2 should be as usual in brackets "(S2-)".<br>- The number of S-phrases is relatively large; some of them (S29, S56, S57) are quite unusual compared to similar labels (R-phrases).<br>- Furthermore some S-phrases (S13, S29, S46, S56) are not applicable if the substance is not likely to be used by the consumer/ general public. | | | | |
| **Dossier Submitter's Response** | | | | |

Fenoxaprop-P is used as an herbicide on cereal fields and grass. In Austria no uses are intended or authorised in home and garden. As far as we are aware of the situation is similar in other Member States. Therefore use by general public is unlikely.

Revision of labelling according to the CLP Regulation and DSD:

Proposed labelling according to the CLP Regulation(EC) 1272/2008
Hazard pictogram: GHS07, GHS08, GHS09
Signal word: Warning
Hazard statements: H317, H373, H400, H410
Precautionary statements: P260, P272, P273, P280, P314, P302+P352, P333+P313, P363, P391, P501

Proposed labelling according to DSD Proposed classification according to DSD
Indication of danger: Xi, Irritant, Dangerous for the environment
R-phrases: R43, R50/53
S-phrases: (S2), S24, S37, S60, S61

**RAC opinion**

As Precautionary statements are not part of the Annex VI entry, RAC does not conclude on them. RAC concluded on the S-phrases as indicated in the tables in the opinion document

| Date | Country | Organisation | Type of Organisation | Comment number |
|---|---|---|---|---|
| 28/05/2012 | Spain | | MSCA | 2 |

**Comment received**

We are in agreement with the classification proposal for the environment submitted by Austria

**Dossier Submitter's Response**

Noted

**RAC opinion**

Noted.

| Date | Country | Organisation | Type of Organisation | Comment number |
|---|---|---|---|---|
| 30/05/2012 | Denmark | | MSCA | 3 |

**Comment received**

Denmark agrees with the classification proposal for Fenoxaprop-P-ethyl

**Dossier Submitter's Response**

Noted

**RAC opinion**

Noted

**CARCINOGENICITY**

| Date | Country | Organisation | Type of Organisation | Comment number |
|---|---|---|---|---|
| 30/05/2012 | Spain | MSCA | MSCA | 4 |

**Comment received**

p 169. Summary and discussion of carcinogenicity
The Spanish CA agrees with the dossier submitter that classification for carcinogenicity is not necessary for fenoxaprop-p-ethyl under de DSD and CLP classification criteria.
Fenoxaprop-p-ethyl is the biologically active enantiomer in the racemic form fenoxaprop-ethyl (which is formed by 50% of the fenoxaprop-p-ethyl (D+)-enantiomer active and 50% of fenoxaprop-p-ethyl (D-)-enantiomer inactive). No long term toxicity or carcinogenicity studies have been performed with fenoxaprop-p-ethyl. To assess the toxicity of fenoxaprop-p-ethyl were used the studies performed with fenoxaprop-ethyl.
The Spanish CA would like to draw attention to the fact that, when the racemic form (fenoxaprop-ethy) is used, toxicity could be underestimated as the active substance (fenoxaprop-p-ethyl (D+)-

enantiomer) is half lower.
It is worth to highlight the different range of renal involvement between both active substances in the short-term toxicity studies. At 13-week study in mouse (Suter P, 1987a) with fenoxaprop-p-ethyl, treatment-related tubular injury was noted from the dose of 16,5 mg/kg p.c /day in the kidneys of females (necrosis and degeneration of the tubular lining cells), whereas at 13-week study in mouse with fenoxaprop-ethyl (Ehling G, 1993a) renal tubular injury was observed in females from higher doses of 113,8 mg/kg p.c /day (tubular atrophy combined with single cell necrosis). The short-term toxicological profile of fenoxaprop-p-ethyl and fenoxaprop-ethyl were not comparable at the same dose levels.

It is worth to highlight the different range of renal involvement between both active substances in the short-term toxicity studies. At 13-week study in mouse (Suter P, 1987a) with fenoxaprop-p-ethyl, treatment-related tubular injury was noted from the dose of 16,5 mg/kg p.c /day in the kidneys of females (necrosis and degeneration of the tubular lining cells), whereas at 13-week study in mouse with fenoxaprop-ethyl (Ehling G, 1993a) renal tubular injury was observed in females from higher doses of 113,8 mg/kg p.c /day (tubular atrophy combined with single cell necrosis).

**Dossier Submitter's Response**

We do not agree that short term toxicological profile of fenoxaprop-p-ethyl and fenoxaprop-ethyl is not comparable at the same dose levels in the 13 week study in mice. In the study with fenoxaprop-ethyl the lowest dose tested was 320 ppm, where already some effects on kidneys were found. However the impact of these effects compared to the control group is questionable. For fenoxaprop-p-ethyl no marked kidney effects were seen in the control group, therefore a dose response relationship is much clearer seen in the Suter (1987a) study. However at 80 ppm only minimal renal unilateral tubular injury was noted in one female and the dose of 320 ppm was not tested in the Suter (1987a) study. Therefore it seems likely that the comparability of the two studies is masked by the kidney effects seen in the control group with fenoxaprop-ethyl. At 640 ppm the kidney effects seem comparable.

In the 13 week study in mice with fenoxaprop-P-ethyl (Suter 1987a) minimal renal unilateral tubular injury was noted in one female receiving 80 ppm, and moderate (7 females: grade 3) to marked (3 females: grade 4) tubular injury was noted in all females receiving 640 ppm. In five males receiving 640 ppm minimal (4 males: grade 1) to slight (1 male: grade 2) tubular injury was observed, no tubular injury was observed in males receiving 640 ppm. No dose level between 80 and 640 ppm was tested.

Kidney effects in the 13 week study in mice with fenoxaprop-P-ethyl (Suter 1987a), total No of animals per group: 10

| Effect | Males No of animals (grade) | | | | Females No of animals (grade) | | | |
|---|---|---|---|---|---|---|---|---|
| | Control | 10 ppm | 80 ppm | 640 ppm | Control | 10 ppm | 80 ppm | 640 ppm |
| Round cell infiltr. | 2 (1) | 1 (1) | 3 (1) | 2 (1-2) | 5(1-2) | 3 (1) | 2 (1-2) | 5 (1-2) |
| Tubular injury | | | | 5 (1-2) | | | 1 (1) | 10 (3-4) |
| Corticomedul. Calcif. | | | | | | | | 10 (1-2) |
| Tubular casts | | | | | | | | 4 (1-2) |
| Cortical cysts | | | | | | | | 2 (1) |
| Hydronephrosis | | 1 (1) | | | | | | |
| Tubular dilatation | | | | | | | | 1 (1) |

In the 13 week study in mice with fenoxaprop-ethyl (Ehling 1993a) according to the study author compound related alterations in the kidney were only observed in female animals. Tubular atrophy in band-like arrangement in the inner cortex, combined with single cell necrosis of tubular epithelial cells was observed at doses of 640 ppm (3 females) and higher (6 females). Additional single cell necrosis without tubular atrophy was noted at 1280 ppm. Minimal grade vacuolation of tubular cells

was seen at 320 ppm (2 females) and above (2 females at 640 ppm; 6 females at 1280 ppm). No dose level below 320 ppm was tested.

Kidney effects in the 13 week study in mice with fenoxaprop-ethyl (Ehling 1993a), total No of animals per group: 20

| Effect | Males No of animals (grade) | | | | Females No of animals (grade) | | | |
|---|---|---|---|---|---|---|---|---|
| | Control | 320 ppm | 640 ppm | 1280 ppm | Control | 320 ppm | 640 ppm | 1280 ppm |
| Cortical cyst | | | 1 | | | | | |
| Tubular atrophy | 6 (1) | 9 (1-2) | 9 (1-2) | 17 (1-2) | 6 (1) | 6 (1-2) | 12 (1-3) | 11 (2-4) |
| Tubular cast | | 2 (1) | 7 (1-2) | 12 (1-3) | 5 (1) | 6 (1-2) | 4 (1) | 6 (1-3) |
| Insterst. Lymph. C. inf. | 4 (1-2) | 7 (1-3) | 11 (1-3) | 7 (1-3) | 8 (1-2) | 6 (1-3) | 6 (1-2) | 6 (1-3) |
| Vacuol. Epithel. Cells | | | | | | 2 (1) | 2 (1) | 6 (1) |
| Tub. single cell necr. | | | | | | | 10 (1-3) | 17 (1-2) |
| Tubular hyperplasia | 1 (1) | | | | 2 (1-2) | | 1 (1) | 1 (1-2) |

**RAC opinion**

For classification purposes preference was given to the 13-week study on fenoxaprop-P-ethyl. Mild effects in a single female at 80 ppm were noted as dose-response related effect and were considered for NOAEL derivation, but the nature/severity of the effects were not considered significant enough to be relevant for the classification. No clear indication was given that fenoxaprop-P-ethyl exerts its renal toxicity at lower doses than fenoxaprop-ethyl.

**MUTAGENICITY: no comments received**

**TOXICITY TO REPRODUCTION**

| Date | Country | Organisation / Person | Type of Organisation | Comment number |
|---|---|---|---|---|
| 30/05/2012 | Spain | MSCA | MSCA | 5 |

**Comment received**

p 201. Summary and discussion of reproductive toxicity

The CLH dossier specifies that no multigenerational toxicity studies have been performed with fenoxaprop-p-ethyl. Developmental toxicity studies with fenoxaprop-p-ethyl have only been carried out.

As the developmental toxicological profiles of fenoxaprop-p-ethyl and fenoxaprop-ethyl were similar with comparable effect levels, the Spanish CA agrees to use the multigenerational studies with fenoxaprop-ethyl for the evaluation of the reproductive toxicity of fenoxaprop-p-ethyl.

Based on the results of teratogenicity and development studies performed with both active substances, we agree that not to classify of fenoxaprop-p-ethyl for fertility and development effects under de DSD and CLP classification criteria.

**Dossier Submitter's Response**

Noted

**RAC opinion**

Noted

**RESPIRATORY SENSITISATION: no comments received**

**OTHER HAZARDS AND ENDPOINTS**

**SKIN SENSITISATION**

| Date | Country | Organisation / | Type of Organisation | Comment number |
|---|---|---|---|---|
| 22/05/2012 | Denmark | Cheminova A/S | Company-Importer | 6 |

**Comment received**

According to a study we have made on the substance, it is not a skin sensitizer. The study is attached. This is contrary to the proposal, which is based on a study with a positive result.
The substance, an active ingredient in herbicides, has been used by hundreds of thousands of farmers worldwide, if not millions. No cases of allergy caused by the substance have been reported. We are not aware of any indication of a possible allergenic effect of the substance.
In our opinion, the positive result found in the study on which the proposal is based may be due to the exact composition of the substance in this study.

ECHA comment: The document: Fenoxaprop-P-ethyl Technical: LOCAL LYMPH NODE ASSAY IN THE MOUSE[ fpe-123-rep.pdf ] was submitted as a separate attachment.

**Dossier Submitter's Response**

No impurity profile of fenoxaprop-P-ethyl from the new LLNA study is available (batch 660-PSH-45, purity 95.6%). An impurity profile of fenoxaprop-P-ethyl from the positive maximisation test (Diehl et al. 1986a) batch No.: Hoe 046360-OH ZC960002 purity 95.6%) can be provided on request by Austria (confidential document).

In our opinion the positive result of the maximisation test should not be disregarded unless the sensitisation potential can clearly be linked to an impurity present in the respective batch in the maximisation test.
An evaluation of the LLNA can be found below.

Evaluation of Fenoxaprop-P-ethyl Technical: LOCAL LYMPH NODE ASSAY IN THE MOUSE[ fpe-123-rep.pdf ]:

| | |
|---|---|
| Report: | Sanders A., 2005 |
| Title: | Fenoxaprop-P-ethyl technical Local Lymph Node Assay in the Mouse |
| Document No: | SPL Project Number: 545/339 |
| Guidelines: | OECD 429, 2002, Method B42 of Commission Directive 2004/73/EC |
| GLP | Yes |

Material and Methods:
Fenoxaprop-P-ethyl Technical CHA 480 (Batch 660-PSH-45, purity 95.6%) is a white solid, which was freshly prepared in acetone/olive oil 4:1 for the LLNA in mice. Female CBA/Ca (CBA/CaBkl) strain mice were supplied by B&K Universal Ltd, Hull, UK and CBA/CA (CBA/Ca CruBR) strain mice were supplied by Charles River UK Limited, Margate, Kent; UK. One mouse was treated by daily application of 25 µl of the test material at a concentration of 50% w/w, in acetone/olive oil 4:1, to the dorsal surface of each ear for 3 consecutive days, for a preliminary screening test regarding the systemic toxicity/ irritancy potential. For the main test groups of 4 mice were treated with the test material at concentrations of 10%, 25% or 50% w/w in acetone/olive oil 4:1 by daily application of 25 µl of the appropriate concentration to the dorsal surface of each ear for 3 consecutive days. Five days following the first topical application (day 6) the mice received an intravenous injection of 20 µCi of 3H-methyl thymidine in 250 µL of phosphate buffered saline into the tail vein. 5 hours after the 3H-

thymidine injection, the mice were sacrificed and the draining auricular lymph nodes were excised and pooled for each experimental group. 3H-methyl thymidine incorporation was measured via the number of radioactive disintegrations per minute using the Beckman LS6500 scintillation system. The respective test was completed in Nov. 2005. In April 2005 α-Hexylcinnamaldehyde, Tech., 85% was tested as a positive control.

Findings:
The preliminary screening test suggests that the test material would not produce systemic toxicity or excessive local irritation at 50% w/w.
When applied as 10, 25 and 50% concentrations in acetone/olive oil 4:1, fenoxaprop-P ethyl did not induce a biologically relevant response in the 3H-thymidine incorporation (no increase above the cut off stimulation index of 3).
No signs of systemic toxicity were noticed in the animals during the study period and no deaths occurred during the course of the study.
Bodyweight changes of the test animals between day 1 and 6 were comparable to those observed in the corresponding control group animals over the same period.
α-Hexylcinnamaldehyde was considered to be a sensitizer under the conditions of the test.

Results of mouse LLNA - Group mean values and stimulation indices

| Test Material | Treatment | $^3$H-thymidine incorporation [DPM/lymph node pair] | Stimulation index1 |
|---|---|---|---|
| Fenoxaprop-P-ethyl | vehicle (acetone/olive oil 4:1) | 1221.15 | 1.00 |
| | 10% in acetone/olive oil 4:1 | 1569.70 | 1.29 |
| | 25% in acetone/olive oil 4:1 | 2081.85 | 1.70 |
| | 50% acetone/olive oil 4:1 | 1304.94 | 1.07 |
| α-Hexylcinnamaldehyde | 5% in 70% ethanol in distilled water | | 2.6 |
| | 10% in 70% ethanol in distilled water | | 8.4 |
| | 25% in 70% ethanol in distilled water | | 12.9 |

1 test group x / test group 1 (vehicle control)

Conclusion:
Under the conditions of this test fenoxaprop-P-ethyl is not a skin sensitizer.

**RAC opinion**

The information is included in the opinion document; RAC agrees with the dossier submitter's argumentation that the positive test could not be disregarded.

| **Date** | **Country** | **Organisation** | **Type of Organisation** | **Comment number** |
|---|---|---|---|---|
| 23/05/2012 | Germany | | MSCA | 7 |

**Comment received**

The German CA supports the proposed classification Skin Sens. 1B, H317 for Fenoxaprop-P-ethyl.

**Dossier Submitter's Response**

Noted

**RAC opinion**

Noted

| Date | Country | Organisation | Type of Organisation | Comment number |
|---|---|---|---|---|
| 30/05/2012 | Spain | MSCA | MSCA | 8 |
| **Comment received** | | | | |
| p 43. Conclusions on classification and labelling of skin sensitisation<br>The Spanish CA supports the proposed classification of fenoxaprop-p-ethyl as Xi; R43 May cause sensitization by skin contact according to DSD (when an adjuvant type guinea pig test method for skin sensitisation is used, a response of at least 30 % of the animals is considered as positive) and as Skin Sens 1B, H317: May cause an allergic skin reaction according to the 2nd ATP of CLP Regulation (in a guinea pig maximisation test with >1% intradermal induction dose a response ≥ 30% of the animals is considered as positive).<br>This classification is based on the results of the dermal maximisation study in guinea pigs (Diehl, 1986a) where positive response was obtained in all test animals (100%) using 5% of test article for intradermal induction dose. | | | | |
| **Dossier Submitter's Response** | | | | |
| Noted | | | | |
| **RAC opinion** | | | | |
| Noted | | | | |

| Date | Country | Organisation | Type of Organisation | Comment number |
|---|---|---|---|---|
| 01/06/2012 | Sweden | | MSCA | 9 |
| **Comment received** | | | | |
| SE supports classification of fenoxaprop-P-ethyl (Cas No 71283-80-2) as Skin Sens. Cat. 1B as proposed in the CLH report. | | | | |
| **Dossier Submitter's Response** | | | | |
| Noted | | | | |
| **RAC opinion** | | | | |
| Noted | | | | |

**SPECIFIC TARGET ORGAN TOXICYTY - REPEATED EXPOSURE**

| Date | Country | Organisation | Type of Organisation | Comment number |
|---|---|---|---|---|
| 23/05/2012 | Germany | | MSCA | 10 |
| **Comment received** | | | | |
| The German CA supports the proposed classification STOT RE2, H373 for Fenoxaprop-P-ethyl.<br>In mouse studies sex-specific nephrotoxicity was found. The severity of the described effects (moderate to marked tubular injury in females) at the dose level of 122 mg/kg bw/day (90 day study) and 280 mg/kg bw/day (28 day study) supports the classification for STOT RE2. | | | | |
| **Dossier Submitter's Response** | | | | |
| Noted | | | | |
| **RAC opinion** | | | | |
| Noted | | | | |

| Date | Country | Organisation | Type of Organisation | Comment number |
|---|---|---|---|---|
| 30/05/2012 | Spain | MSCA | MSCA | 11 |
| **Comment received** | | | | |
| p 106. Summary and discussion of repeated dose toxicity<br>The Spanish CA supports the proposed classification of fenoxaprop-p-ethyl as STOT RE cat. 2 H373 according to 1272/2008/EEC Regulation, based on renal injury observed 28 days and 13-week in mice studies (necrosis and degeneration of tubular lining cells, mainly affecting the proximal tubule) which occured below the cut-off value for STOT RE cat. 2 H373, according to 1272/2008/EEC | | | | |

Regulation (300 and 100 mg/kg p.c /day for studies of 28 days and 13-week, respectivelly). However, we would like to highlight for the RAC´s consideration some findings observed at studies in rats, on the basis of which a classification as R 48/22 could be discussed:
- On the one hand in the 28 days study in rats (Suter P, 1987a) all animals at the highest dose, 126/144 mg/kg bw/d, were sacrificed in extremis on treatment day 9, this dose is below the DSD classification criteria (< 150 mg/kg p.c /day).
- On the other hand, this increase on mortality was not repeated at the 13-week study in rats (Tennekes H, 1987). However, it should be noted that the doses used in the 13-week were half lower (49/51,8 mg/kg p.c /day).

**Dossier Submitter's Response**

The dose level of 5120 ppm is equivalent to 126 (M)-144 mg/kg bw/d because of the low food intake and stagnation of growth (cf. 1280 ppm is equivalent to 95 (M)- 94 (F) mg/kg bw/d). Therefore for us it is likely that preliminar termination of this group might be related to starvation whereby palatability effects cannot be excluded. According to the Directive on Dangerous Substances changes in body weight gain as well as food consumption and water intake are not indicating classification and labeling with R48.
For further details please see CLH report page 115.

**RAC opinion**

It is to be noted that palatability problems were not indicated in any of the diet studies.
In addition to STOT RE as proposed by DS, RAC agrees that fenoxaprop-p-ethyl should be classified as R48 according to DSD, based on the kidney toxicity observed at 56/61 mg/kg bw/d in mice (28-day study, Suter et al., 1987b).
With regard to the severe non-specific toxicity reported in the range-finding 28-day study in rats (Suter, 1987a) as mentioned by the commenter, more weight is given to the 13-week study in rats. The observation in the 28-day rat study was used as supportive argument for R48.

**AQUATIC ENVIRONMENT**

| Date | Country | Organisation | Type of Organisation | Comment number |
|---|---|---|---|---|
| 31/05/2012 | Belgium | | MSCA | 12 |

**Comment received**

Based on the results of the aquatic toxicity test for the most sensitive species (fish : 96hLC50=0.19mg/l; 91dNOEC=0.036 mg/l) the fact that the substance is not rapidly biodegradable, it is justified to classify, following the classification criteria of the 2nd ATP, as Aquatic acute 1, H400 and Aquatic chronic 1, H410. However, the CLP criteria for bioaccumulation are not met (BCF between 280 and 338 <500). The major metabolite Fenoxaprop-P also fulfils the criteria for classification as hazardous for the aquatic environment, but is less toxic that the parent compound.

In view of the proposed classification and the L(E)C50 for acute toxicity, an M-factor for acute toxicity of 1 could be assigned, and an M-factor for chronic toxicity of 1(not rapidly degradable substance and toxicity band between 0.01mg/l and 0.1 mg/l).

Based on the classification and labelling criteria in accordance with dir. 67/548/EEC, Fenoxacaprop-P-ethyl should be classified as N, R50/53.

In conclusion: we agree with the proposed the environmental classification by the Austrian MSCA.

Some editorial or/and minor comments:
p. 254 Summary and discussion : acute (short-term) aquatic toxicity
It is stated that the green algae Pseudokirchn. Subcapitata is the most sensitive species when considering the acute toxicity of the degradation product fenoxaprop-P. Although this does not

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|---|
| influence the labelling of the parent compound : why is the aquatic plant Lemna gibba not considered as most sensitive species for Fenoxaprop-P?<br><br>p.233, 5.2.1 Adsorption/desorption<br>Paragraph above table 187 : Please add "soils" at the end of the sentence : "Following evaluation in the EU review process …" |
| **Dossier Submitter's Response** |
| p. 254 Summary and discussion : acute (short-term) aquatic toxicity<br>The acute toxicity study with the green algae Pseudokirchn. subcapitata and the degradation product fenoxaprop-P has been used to show that Fenoxacaprop-P has to be classified and a rapid degradation of the parent can be excluded.<br>For Lemna gibba only a study with the parent is available, no study is available with degradation product Fenoxaprop-P.<br><br>p.233, 5.2.1 Adsorption/desorption<br>Noted |
| **RAC opinion** |
| Noted. RAC agrees with comments from BE and with DS conclusion. |

**PHYSICAL HAZARD**

| Date | Country | Organisation | Type of Organisation | Comment number |
|---|---|---|---|---|
| 30/05/2012 | Spain | MSCA | MSCA | 13 |
| **Comment received** | | | | |
| p 12. Summary of physico-chemical properties. (Table 9)<br>The Spanish CA supports the proposal of the dossier submitter not to classify fenoxaprop-p-ethyl about his physic-chemical properties. In this section we want to highlight the fact that CLH report provides two studies with very different values of log Kow; the study of Tognucci A, (1999a) with a log Kow = 1.9 and the study of Wolf R, Le Gren I, (2004) with a log Kow = 4.58 next to 5. We think that is necessary to clarify this difference and to specify the correct value. | | | | |
| **Dossier Submitter's Response** | | | | |
| The study Tognucci, A., (1999a) was performed using a metabolite of Fenoxaprop-P-ethyl, namely AE F054014 (6-chloro-2,3-dihydro-benzoxazol-2-one) showing a log Kow of 1.9. The other study mentioned [Wolf, R., Le Gren, I. (2004)] was conducted using the active itself (purified product; Fenoxaprop-P-ethyl) showing a log Kow of 4.58. Therefore, the correct value is 4.58 for Fenoxaprop-P-ethyl. | | | | |
| **RAC opinion** | | | | |
| Noted | | | | |

**ATTACHMENTS RECEIVED: 1**

1. **fpe-123-rep.pdf** - **Fenoxaprop-P-ethyl Technical: LOCAL LYMPH NODE ASSAY IN THE MOUSE***.* Commment no. 1, submitted by Denmark/ Gerard H. van Brakel / Company-Importer on 22/05/2012.