Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

acequinocyl

ECHA/RAC/CLH-O-0000001401-89-01/A2

Adopted

28 October 2010

ANNEX 2 – COMMENTS AND RESONSE TO COMMENTS ON THE CLH PROPOSAL ON ACEQUINOCYL

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

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

Substance name:Acequinocyl

CAS number: 57960-19-7

EC number: -611-595-7

General comments

Date	Country/Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
26/03/2010	Germany / Jan Averbeck / MSCA	Page 42 The German CA supports to establish a harmonised classification & labelling for acequinocyl, which is an active ingredient in plant protection products (Dir. 91/414/EEC).	Thank you for the support	We acknowledge the German MSCA support to all CLH endpoints proposed by NL.
02/04/2010	Belgium / Frederic Denauw / MSCA	Please find the Belgian comments: - Acute inhalation study in rats: pulmonary lesions starting at a dose of 0.62 mg/l. These effects are considered to be the result of respiratory tract irritation. è Xi; R37 according to Dir 67/548/EEC STOT SE Cat.1 H370 according to Reg	Thank you for the support of the proposal.	We acknowledge the Belgium MSCA support to all CLH human endpoints proposed by NL, including the conclusions that .repeated dose toxicity and carcinogenicity classifications are not needed. Please note that the "respiratory tract irritation" was rather considered by RAC as sufficiently severe and irreversible to drive a R39/23

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Date	Country/Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
		EC 1272/2008 - Skin sensitizer in guinea pig maximisation test (M&K) è R43 or Skin Sens. Cat.1 H317 - 13-week oral rat study: mortality, haemorrhages, atrophic or necrotic organs at ≈ 253/286 mg/kg bw/d haematological effects and single case of haemorrhage in the eye at about 120 mg/kg bw/d - 13-week oral mouse study: mortality at ≥81/100 mg/kg bw/d haemorrhages and haematological effects at ≥81/100 mg/kg bw/d - 2-year toxicity/carcinogenicity study in rats: effects on coagulation system and the eye from 9 mg/kg bw/d è STOT RE Cat.2 H373 No classification according to Dir. 67/548/CEE		classification in place of the R37 initially proposed.
06/04/2010	France / AntonyFastier / AFSSA	We agree with the classifiaction proposal.	Thank you for the support of the proposal.	We acknowledge the French food safety agency support to all CLH endpoints proposed by NL.
08/04/2010	Portugal / Maria do Carmo Palma / MSCA	Considering the present proposal, we agree to establish a harmonised classification & labelling for Acequinocyl. The proposed Classification and	Thank you for the support of the proposal.	We acknowledge the Portugal MSCA support to all CLH endpoints proposed by NL.

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		Labelling fulfils the criteria established both in CLP Regulation and 67/548/EEC Directive (health and environment).Therefore, we support the proposal.		
				In conclusion, we acknowledge 5 general supports to NL proposal and no comments against the proposed CLH.

Carcinogenicity

Date	Country/Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
26/03/2010	Germany / Jan Averbeck / MSCA	Page 28f The German CA supports not to classify acequinocyl for carcinogenic hazard.	Thank you for the support	We acknowledge the German MSCA support to NL's conclusion that carcinogenicity classification is not needed.

Mutagenicity

Date	Country/Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
26/03/2010	Jan Averbeck / German MSCA	Page 25ff The German CA supports not to classify acequinocyl for mutagenic	Thank you for the support	We acknowledge the German MSCA support to NL's conclusion that mutagenicity classification is not

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		hazard.		needed.

Toxicity to reproduction

Date	Country/Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
26/03/2010	Jan Averbeck / German MSCA	Page 29ff Considering the presented data and information The German CA supports not to classify acequinocyl for reproductive or developmental hazard. Regarding the intended discussion on classification of acequinocyl for developmental effects using read-across from warfarin, the potency of acequinocyl concerning effects on blood clotting should be evaluated more extensively.	Thank you for the support. We agree that the potency of acequinocyl concerning effects on blood clotting should be evaluated more extensively. We are currently drafting the CLH dossier for the coumarinflocoumafen. The proposal for the classification of flocoumafen for developmental toxicity will be used to make a comparable proposal for acequinocyl. It is proposed that the classification of acequinocyl for developmental toxicity is discussed together with the coumarins.	We acknowledge the support of German MSCA to the conclusion that observed toxicity during development is probably secondary to the maternal toxicity and thus no reprotox classification needed. German MSCA express here the need to further clarify the blood clotting potential, notably by read-across with other vitamin K competitive inhibitors. As some elements hadn't be brought in this dossier, would it be only to conclude that read-across can be made or not RAC will only consider the available studies that show no effects. This will not prevent the committee from considering possibly this substance when a working group will discuss read-across between the coumarines.
02/04/2010	Belgium / Frederic Denauw / MSCA	Please find the Belgian comments: - Reproductive toxicity	As we also state in the Annex VI dossier (5.9.4 Other relevant information), we agree with the argumentation. Based on the available	Belgium MSCA has some concern about not to include a read-across with warfarin teratogenicity. This is based on two arguments: on one

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		Based on the results of the conventional rat and rabbit developmental toxicity studies, no classification is necessary. However, as acequinocyl is a structural analogue of vitamin K, its mechanism of toxicity is expected to be competitive inhibition of the vitamin K dependent prothrombin synthesis. A reduction of prothrombin synthesis will result in a prolonged blood clotting time and an increase in haemorrhages and related haematological effects as observed in the repeated dose toxicity studies. Warfarin, another structural analogue of vitamin K is an established human teratogen classified Repr. Cat.1; R61 (Repr. Cat. 1A H360D). It is uncertain whether teratogenicity of warfarin can be detected in pre-natal developmental toxicity studies (including OECD TG414). The teratogenic mechanism of warfarin is likely to involve maternal vitamin K depletion and/or direct effects on embryo/fetus via transplacental exposure. Given the vitamin K inhibition, there is a concern that other anti-vitamin K compounds could cause similar teratogenic effects as warfarin in	information for acequinocyl, there is no need to classify for reproduction toxicity, however, eventual classification for developmental effects using read-across from warfarin should be discussed together with the other coumarines.	hand that's really possible that other anti-vitamin K compounds cause similar teratogenic effects as warfarin, on the other hand the standard pre-natal developmental toxicity study may be unable to detect warfarin teratogenicity. Again the comparison with other vitamin K competitive inhibitors may be useful to decide if read-across should drive a developmental or teratogenicity classification. As responded for the German MSCA comment, without data in the dossier and with clear negative results in studies made according to the rules, RAC conclude no-classification at this point. However, this issue may be a working group will appear as necessary to deepen the comparison between vit. K competitive inhibitors.

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		humans. Given the uncertainties surrounding the ability of the standard pre-natal developmental toxicity studies to detect warfarin teratogenicity, the predictive value to humans of these studies is uncertain. Therefore, eventual classification of acequinocyl for developmental effects using read-across from warfarin should be discussed.		
				In conclusion about the toxicity to reproduction endpoint, rapporteurs acknowledge the request of two MSCAs and previously expressed by NL in its proposal to assess this hazard also by a read-across with other coumarines. Indeed, RAC decided to conclude that no-classification is needed regarding the negative results of the fertility and developmental studies. This conclusion don't exclude a possible inclusion of this substance in the future discussion on read-across between the different coumarines..

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Respiratory sensitisation

Date	Country/Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
26/03/2010	Jan Averbeck / German MSCA	Page 20 The German CA supports not to classify acequinocyl for respiratory sensitising hazard.	Thank you for the support	We acknowledge the German MSCA support to NL's conclusion thatrespiratory sensitising classification is not needed.

Other hazard classes

Date	Country/Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
26/03/2010	Jan Averbeck / German MSCA	Page 10ff The German CA agrees with the proposal for environmental classification and labelling of Acequinocyl. We do not completely agree with the proposal for environmental classification and labelling according regulation EC/1272/2008 .We would suggest the addition of: Aquatic chronic 1 - H410 Explanatory remarks ref. chapter 4 environmental fate properties, point 4.3 Bioaccumulation:	We agree with the opinion that BCF value should be corrected for lipid content. However, we do not agree to add H410. The fact that the current BCF values were based on total radioactivity and the fish homogenate did not contain any parent compound suggests that the parent compound might not be bioaccumulated in fish and the BCF value is likely lower than the cut-off value for classification. H410 was therefore not included.	German MSCA asks for a correction of BCF in order to correct the non-standard lipid content. Rapporteur supports this request as normalising data to a fat content of 5% is mentioned in Echa guidance R11. Even NL also agrees the need to normalise BCFs, on its opinion H410 still not pertinent because data are based on total radioactivity and thus cannot be totally attributed to acequinocyl. As the guidance recommendation "Clean-up procedures may be employed in radiolabelled studiesin order to determine BCF based on the parent compound, and the major metabolites may becharacterised if deemed

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		Measured bioaccumulation data (1 reference) are summarized which indicates a potential for bioconcentration of Acequinocyl in fish. The results of the BCF study with common carp (McEwen, 1997) at 0.17 µg/L exposure concentration BCF 366 L.kg-1 (related to total measured radioactivity) should be corrected for lipid content of test fish (2.35%) to BCF 779 L.kg-1 (lipid normalized to 5% lipid content) and at 1.7 µg/L exposure concentration BCF 288 L.kg-1 (related to total measured radioactivity) should be corrected for lipid content of test fish (2.15%) to BCF 670 L.kg-1 (lipid normalized to 5% lipid content). Both lipid normalized BCF values are above the decision trigger (BCF > 500) for the classification into category: Aquatic chronic 1 - H410 according regulation EC/1272/2008. Minor remark: It is not usual to make overall average BCFs for two or more exposure levels for risk assessment. The maximum BCF (lipid normalized to 5% lipid content) is used for risk assessment and also for classification and	Overall average BCF value has been deleted in the text.	necessary" wasn't followed, the fish acequinocyl degradation rate cannot be estimated; indeed it's not possible to refine BCF in order to use it for H410 classification. It should however be recalled that a Log Kow equal to 6.2 announces rather a potential to be bioaccumulated (CLP threshold value is Log Kow ≥ 4). An average BCF value was calculated from the two tested concentrations. According to German MSCA this is unusual and NL agrees. However, Rapporteur recalls that this two tested concentrations should in a well designed experiment converge as much as possible and that it's said in Echa guidance R7c that ".When more reliable BCF values are available for the same species and life stage etc., the geometric mean (of the lipid normalised values, where appropriate) may be used as the representative BCF value"; Rapporteur thus recommends keeping the method that was first used by NL.

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		labelling. Page 19 STOT SE: The German CA does not support the classification of the substance acequinocyl based on regulation (EC) No 1272/2008 in STOT SE category 1 as a substance which causes damage to organs (lung) after inhalatory exposure with the hazard statement H370. The classification of acequinocyl as irritating to the respiratory tract: Xi; R37 according to 67/548/EEC is supported. Classification of acequinocyl in STOT SE category 3 as a substance which may cause respiratory irritation with the hazard statement H335 seems more appropriate and would be in accordance with the translation table in Annex VII of regulation (EC) No 1272/2008. Reasons for the classification in STOT SE category 3 are on the one hand the reversibility of the observed effects, on the other the lack of "severe toxic effects of relevance to human health … at generally low exposure concentrations" (regulation (EC) No	*Page 19, STOT SE:* We agree that classification with R37 under 67/548/EEC and STOT-SE Cat 1 under CLP is not in line with the translation table in Annex VII. However, we think applying the criteria is more important than having comparable classifications for the same effect in both legislations. As 67/548/EEC will be revoked within a few years, the CLP classification is considered the most important It is true that most of the observed effects are reversible. However, reversibility is not the main determinant for STOT-SE as it is for R68 and R39. Further, we do not agree that 'there is a lack of severe toxic effects … at generally low concentration'. Two animals died, one at a dose of 0.69 mg/L and one at a dose of 0.84 mg/L. We therefore conclude that classification as STOT SE cat 3 is not correct as more severe organ effects than requiring Cat 3 in the respiratory system were observed (3.8.2.2.1(e)) and that, according to the CLP criteria, acequinocyl should be classified as STOT SE cat 1. The equivalent classification under	German MSCA supports Xi/R37 (DSD) proposal but rather STOT SE category 3 / H335 then cat. 1 / H370 (lung) (CLP) proposal. This modification is because effects are reversible, because effects can be considered as not severe for human and because effects are rather unspecific caused by the soap-like property. All in agreeing that arguments are not totally in line with the criteria set in annex VII, NL is confirming that cat.1 is more appropriate as irreversibility is not required under CLP and as some animals died at low and medium doses through respiratory system injury. According to NL in Acequinocyl case conclusion cannot be the same under DSD and CLP. According to Rapporteur CLP criteria should be discussed separately and by taking account of the new criteria; in addition several RAC members underlined that the observed effects appear rather as severe and cannot really be considered as reversible.

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		1272/2008 Table 3.8.1). As mentioned in the Annex VI report the pulmonary lesions are probably caused due to the soap like properties of acequinocyl (p. 18) and not by a specific mechanism of action. Hence, no specific target organ toxicity is observed but rather an unspecific effect caused by the physico-chemical properties of the compound. Furthermore all treated animals had recovered from the effects of acequinocyl in the acute inhalation toxicity study by day 3 of observation. Because of the mentioned points and the fact that the animals in the acute inhalation toxicity study were exposed to the maximum attainable concentration of acequinocyl we propose to discuss the classification of the substance in STOT SE category 3 instead of category 1. Page 20ff STOT RE: The German CA supports the classification of the substance acequinocyl based on regulation (EC) No 1272/2008 in category 2 as a substance which may cause damage to organs (blood coagulation) with the	67/548/EEC would be R39/23. However, this would require irreversible effects. The only irreversible effect would have been the mortality. However, mortality is normally not used for classification with R69/X and R39/X because then every substance with a classification for acute toxicity would also require a classification with R68/X or R39/X. Therefore, R39/23 is not justified. *Page 20, STOT RE:* We believe we have provided a description of the critical effects as detailed as possible considering the available study descriptions. The critical effect is observed at the	We acknowledge the support of German MSCA to STO RE cat. 2 / H373 proposal. The request of quantitative data and description of the effects in the critical studies may be pertinent especially if well focused on classification issues. According to guidance R8, the default assessment factor equal to 3 should be applied to extrapolatefrom a 28-day study towards a 90 days study; we thus don't see why this factor should be reduced to 2.

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		hazard statement H373. To follow the differences in the LOAELs in table 5.6 (p. 20) and the effective doses in table 5.7 (p. 24) of the Annex VI report the quantitative data and a detailed description of the effects in the critical studies are needed. It is proposed that RAC gives advice how to do duration-extrapolation to apply R48 (according to DSD): According to Table R.8-5 Assessment factors for duration extrapolation of the guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health the default assessment factor 2 is appropriate for duration extrapolation between sub-chronic and chronic toxicity studies. An effective dose of 18 mg/kg bw is derived from the chronic (104 weeks) toxicity study in rats, if this default assessment factor is applied. Due to the effective dose of 18 mg/kg bw the classification Xn; R48/22 according to Directive 67/548 EEC would be appropriate. Page 19f	end of the exposure period (only time point of analysis for critical effects). Therefore, we consider an assessment factor of 2 too small. According to 67/548/EEC, a factor of 3 has already to be used for extrapolating from a 90 day study to a 28 day study. When dose/exposure time extrapolation is used in the same way as for CLP (as is done in table 5.7), no classification is warranted. This conclusion is strengthened by the fact that the effects observed at the lowest effect level are only minimal of nature. In conclusion, we do not agree with the classification Xn; R48/22 according to Directive 67/548 EEC as proposed by Germany.	We acknowledge the support of German MSCA for the skin sensitizer cat. 1 / H317classification proposal.

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		Skin Sensitisation: The German CA supports the classification of the substance acequinocyl based on regulation (EC) No 1272/2008 in category 1 as a substance which may cause an allergic skin reaction with the hazard statement H317.	*Page 19f:* Thank you for the support	
08/04/2010	UK / Daniel Merckel / MSCA	- Classification for the Environment: we agree with the proposal to classify the substance N: R50/53 (according to Directive 67/548/EEC) and Aquatic Acute I (H400) (according to regulation EC 1272/2008) based on the data in the dossier. -M-factor (page 5 and page 41): The M factor of 1000 is based on the result with the marine crustacean Mysidopsis bahia. We agree with this as the basis for the factor (based on the freshwater invertebrate data (Daphnia magna EC50 3.9 ug/l) it would be 100). -page 5: please consider adding the specific concentration limits (from the preparations directive) for the purpose of classification of mixtures containing	Thank you for the support of the proposal. Thank you for the support. The concept of M-factors has been established to give an increased weight to substances that are very toxic for the aquatic environment, which includes marine environment. Concentration limits have been added	We acknowledge the UK MSCA support to H400 proposal and the M-factor of 1000 based on the marine crustacean M. b. We agree all comments made by UK MSCA and would like in particular to support the request on page 39 about additional information on ecotoxicity tests conditions and validity. So we thank on one side UK MSCA for these recommendations and on the other hand NL to have followed these recommendations. The duration of the Mysidtest should be clarified, since it is indicated as

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		this substance. -Page 4, summary, Impurities: should be stated here that the impurities are claimed as confidential (as is done in section 1.2) -Page 8, phys-chem, table 1.3.1: please correct the title of the entry referring to solubility in solvents other than water. It is currently listed as "stability in organic solvents and identity of relevant degradation products" -Page 12, biodegradation in soil, aerobic degradation: in fourth line change "biodegradation" to "apparent mineralisation". - page 13, 4.1.3, biodegradation in water: Please add to the summary that acequinocyl is considered not readily biodegradable according to the result of the OECD 301B test. - Page 13, 4.1.3 last para, please	according to the suggestion. *-Page 4, summary, Impurities:* We have added the statement that the identity of the impurities is confidential on page 4. *-Page 8, phys-chem, table 1.3.1:* We have changed the title in 'solubility in organic solvents' *Changed according to the suggestion.* *Added according to the suggestion.*	96h-EC50 in Table 7.1. but 48h-EC50 in Section 7.6 (Conclusions on environmental…). It can be noted that Mysid acute toxicity OPPTS 850.1035 guidelineestablishes under flow-through conditions both the 48– and the 96–h LC50 values. Confirmation was made later on that duration is 96h.

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		consider rephrasing: "Overall, even though acequinocyl is not readily biodegradable, it rapidly disappears in the most relevant compartments (for its properties and environmental behaviour) and…"	*Changed according to the suggestion.*	
		- page 13, 4.1.3 last para: the main mechanism of degradation is stated to be biodegradation. We do not entirely agree with this statement. Presumably this is concluded because of the low rate of degradation seen in the sterile aerobic soil study as opposed to the more rapid removal under non-sterile conditions in the same test. But hydrolysis seems to be a very important degradation process at environmentally relevant pHs (t1/2 at pH 7 and 9 is 77 hours and 99 mins, respectively). So it would be worth stating that hydrolysis is an important mechanism of degradation in some conditions.	*Hydrolysis was added as a possible mechanism.*	Even hydrolysis test indicates that acequinocyl may by this way degrade quickly in the water column, we are in favour to also balance this fact with other arguments in favour of some persistency (hydrolysis maybe slower in acidic conditions, some metabolites may be classifiable, an important part can bound to sediment…).
		-page 13, 4.2.2: even though the substance has a low water solubility, the Henry's law constant could be referred to here as indicating that volatilisation from surface waters	*Information has been added.*	

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		would be fairly limited. -page 14, section 4.3.1: The 24 – 32% radioactivity – please add that this was for the water – "This accounted for 24 – 32% of the radioactivity in the water". -page 14, section 4.3.1: no parent compound (or primary hydrolysis product) was found in the fish tissue. Please add a comment that the BCF reported according to total radioactivity is unlikely to be representative of the parent compound, and most likely represents concentrations of metabolites present in the fish tissue. Was any work conducted to identify the metabolites in fish tissue responsible for the observed radioactivity? -page 13, 4.3.3: add here also that the measured BCFs are likely to be representative of metabolites and not the parent compound, which was shown to metabolise in vivo.	Added according to the suggestion. *This comment has been added according to the suggestion. No report could be found in the original document on the effort for identifying the metabolites in fish tissue.* Changed according to the suggestion.	We agree that total radioactivity cannot be considered as representative of only the parent compound, this notably seems confirmed by HPLC chromatograms in fish tissue. However, as responded by NL, the original report is insufficient to calculate the real BCF. Overall it cannot be conclude with sufficient certainty if BCF is under or below the threshold values of 100 or 500.Nevertheless, the not readily degradability conclusion – combined to the ecotox - seems sufficient to classify the substance for aquatic chronic toxicity.

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		-Page 39, ecotoxicity results: there is no information on the conditions (e.g. exposure regime, test concentrations and maintenance, dose-response, etc.) and validity of the tests listed in Table 7.1. It is important to include such information on the key studies (i.e. the Daphnia and mysid shrimp studies) in the report, to avoid having to look for it in the background information. Minor Comments - Typos etc -Page 10, first para section 4, fifth line missing "of" before "biocidal" -Page 10, 4.1.1 first para, missing "as" before "R1" -Page 11 first para, "applied to a sandy loam"; "Table 4.2 presents the calculated DT50 and DT90 values that were calculated…"; last line, "which indicates that photolysis is not a major contributor to the degradation of acequinocyl in soil." -Page 12, table 4.4 title, delete "with" -page 12, anaerobic degradation, first line "applied to a flooded sandy loam soil" -page 12, field dissipation test, third	Information on two key studies of Daphnia and Mysid has been added according to the suggestion. *Minor Comments:* Thank you for the comments. We have corrected the typos etc in the annex VI dossier.	

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		line from bottom, "The residue at time 0 was taken as the sum of…" -Page 14, 4.3.1; "The major observed degradant…"; "this accounted for 24 – 32%..." -Page 38, 7, first line: change "fate properties" here to "hazard" -Page 39 second line – delete "been"		
08/04/2010	UK / Andrea Caitens / MSCA	Pages 18 and 19 Classification for STOT-SE 1 and R37 In section 5.2.5 of the dossier it states that classification with R39/25 is not applicable as the effects in the acute inhalation study (which included deaths, bronchiolar epithelial erosion or necrosis etc.) are expected to be reversible (with the exception of lethality). In addition, in section 5.3.3 it states that these effects are probably related to an effect on the surface tension in the alveoli and could be considered as irritation to the respiratory tract. It has therefore been concluded that classification with Xi; R37 under DSD is appropriate. However, it states in section 5.2.5 that due to the severity of these effects, classification with STOT-SE 1 under CLP is appropriate. The proposed	We agree that the CLP classification and the classification according to 67/548/EEC, and the underlying argumentation in paragraphs 5.2.5 and 5.3.3 seem inconsistent. However, the criteria for classification under CLP and 67/548/EECare somewhat different. Under CLP, severe specific non lethal target organ toxicity at concentrations ≤ 1 mg/L (4h) require classification in STOT SE Cat 1. For this classification it does not matter whether the effects are reversible when effects at a low dose are considered severe. Since pulmonary lesions are observed starting at a dose of 0.62 mg/L, STOT SE Cat 1 is required. We do not agree that there is no specific organ toxicity due to the fact that the effects are probably	Similarly to German MSCA, UK MSCA disagree the CLP classification STOT-SE-1 which appears inconsistent with the DSD classification R37. The NL argument (severe specific non lethal target organ toxicity at concentrations ≤ 1 mg/L (4h) require classification in STOT SE Cat 1) seems robust to rapporteurs, however this point could be discussed by RAC in plenary meeting.

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		CLP classification therefore appears to be inconsistent with the proposed DSD classification.	caused by the physico-chemical properties of the substance. For classification according to 67/548/EEC, reversibility of effects can make the difference between R37 and R39. Since the effects are considered reversible, classification for R37 seems appropriate.	
				In conclusion about environmental hazard classification proposal, rapporteurs think that normalisation of BCFs to lipid content (as suggested by German MSCA) is necessary. After weighting the BCFs (which become higher) with other environmental fate information rapporteurs wish to read the original fish BCF study and to propose to RAC a discussion about the addition of an Aquatic chronic toxicity category 1 classification based on ecotox and not readily degradability plus some uncertainties about real BCF value.