



Committee for Risk Assessment
RAC

Annex 2
Response to comments document (RCOM)
to the Opinion proposing harmonised classification and
labelling at EU level of
nonanoic acid

EC number: 203-931-2
CAS number: 112-05-0

CLH-O-0000002588-64-03/A2

Adopted
6 June 2013

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON NONANOIC ACID**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: nonanoic acid**EC number: 203-931-2****CAS number: 112-05-0****Dossier submitter: Austria****GENERAL COMMENTS**

Date	Country	Organisation	Type of Organisation	Comment number
19/07/2012	Spain		MSCA	1
Comment received				
<p>p. 6 Proposal for harmonised classification and labelling The Spanish CA does not agree with the Austrian proposal to classify nonanoic acid as: – Skin Irrit. 2, H315: Causes skin irritation according to Regulation EC 1272/2008 and as Xi; R38: Irritating to skin according to Directive 67/548/EC. – Eye Irrit. 1, H318: Causes serious eye damage according to Regulation EC 1272/2008 and as Xi; R41: Risk of serious damage to eyes according to Directive 67/548/EC The following classification is proposed by the Spanish CA instead of the Austrian proposal: – Skin Corr. 1C, H314: Causes severe skin burns and eye damage according to Regulation EC 1272/2008 and as C; R34: Causes burns according to Directive 67/548/EC.</p>				
Dossier Submitter's Response				
Thank you for your review. It is on the RAC to decide on this borderline case.				
RAC's response				
<p>When tested in rabbits and guinea pigs nonanoic acid induced mild to severe skin irritation. When determined, there was reversibility within 15 days. Irritation was also seen after repeated application of 0.1 ml neat nonanoic acid to the forearm of 1 volunteer. Based on a weight of evidence approach and in agreement with the dossier submitter, RAC concludes that nonanoic acid should be considered as irritating to the skin and classified as Skin Irrit. 2 - H315 according to CLP (Xi; R38 according to DSD). For nonanoic acid, no eye damage or eye irritation data are available. However, based on the information on octanoic acid and decanoic acid, RAC concludes that classification as Eye Irrit. 2 H313 according to CLP (Xi; R36 according to DSD) for nonanoic acid is justified.</p>				
Date	Country	Organisation	Type of Organisation	Comment number
26/07/2012	France		MSCA	2
Comment received				
FR agrees with the classification proposal.				
Dossier Submitter's Response				
Thank you for your agreement!				
RAC's response				
Noted. Please see response to comment 1.				
Date	Country	Organisation	Type of Organisation	Comment number
27/07/2012	Germany	OXEA GmbH	Company-Importer	3
Comment received				

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ECHA comment: The text below is copied from the first paragraph and the conclusion part of the attachment name OXEA GmbH comments.pdf. Attachment no. 1.

Oxea GmbH was acting as Lead Registrant for the substance and we would like to provide some comments to the "Proposal for Harmonized Classification and Labelling" of Nonanoic acid posted on June 21 on the ECHA homepage. Our comments are based on the evaluation of the studies we did together with other registrants for the registration dossier, but are only given on behalf of Oxea GmbH:

4. Conclusion

In light of the above (*ECHA comment: comment text from the attachment name OXEA GmbH comments.pdf*), the classification proposal should be amended to:

Skin Corr. 1C
Eye Damage 1

with corresponding changes to the DSD classification proposal. We will communicate this to the other registrants and intend to update the registration dossier accordingly.

End of attachment no. 1 - first paragraph and conclusion part.

Dossier Submitter's Response

We think that the available data are clearly described (in the CLH report and in the IUCLID study summaries of OXEA GmbH) and remain of the opinion that nonanoic acid is a borderline case for classification as skin corrosive and we support classification for skin irritation. It is on RAC to decide this case.

RAC's response

Noted. Please see response to comment 1.

Date	Country	Organisation	Type of Organisation	Comment number
03/08/2012	Germany		MSCA	4

Comment received

The German CA supports the proposed C&L.

Nevertheless we have some comments concerning SID:

Main constituent: The given concentration range for the main constituent is not in line with the information obtained within the biocidal active ingredient evaluation (please refer to Doc. IIA confidential).

Impurities: In chapter 13, Doc IIA confidential more impurities are stated compared to the IUCLID file, chapter 1.2. It would be beneficial to harmonise the information provided in both chapters/documents.

Impurities: Within the reference substance file of the Decanoic acid the molecular and structural information is missing and should therefore be added.

Dossier Submitter's Response

The missing information has been added to the IUCLID file

RAC's response

Noted. Please see response to comment 1.

Date	Country	Organisation	Type of Organisation	Comment number
03/08/2012	Sweden		MSCA	5

Comment received

SE supports classification of nonanoic acid (Cas No 112-05-0) as specified in the proposal. In general, SE agrees with the rationale for classification into the proposed hazard classes and differentiations.

The proposals for harmonized classification and labelling should refer to the criteria of Dir. 67/548/EEC and of Reg. (EC) No 1272/2008. Please replace references to the GHS criteria throughout the report with the latter.

Dossier Submitter's Response

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Thank you for your support and your comment.
The submitter was asked not to update the CLH-report at this stage.

RAC's response

Noted. Please see response to comment 1.

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Germany	Fatty Acid Consortium	Company-Manufacturer	6

Comment received

ECHA comment: The document 20120806_FATTY ACIDS CONSORTIUM_COMMENTS_NONANOIC_C9_final_final.pdf was submitted as a separate attachment. Attachment no. 2.Summary/conclusion and Overall conclusions were copied below.

Currently nonanoic acid, CAS# 112-05-0 is listed in Annex VI to the CLP Regulation EC1272/2008 with classification of corrosive Cat. 1B, H314 without specific concentration limits. Based on the evaluation of available data of nonanoic acid, the following table illustrates the proposed classifications as were listed in the CLH dossier and as is suggested by FAC:

Table 1 Summary/conclusion of C&L for nonanoic acid proposed by RAC (CLH) and FAC

Endpoint	FAC according 1272/2008/EC	FAC according 67/548/EEC	CLH according EC1272/2008	CLH according 67/548/EEC	Comments by FAC
Skin corrosion/irritation	<u>Current C&L according to Annex VI:</u> GHS 05 "Danger" Cat 1B H314 <u>Proposed C&L:</u> GHS07 "Warning" Cat 2 H315	<u>Current C&L according to Annex VI:</u> C, R34 <u>Proposed C&L:</u> Xi, R38	Cat 2, H315	Xi, R38	Agree with CLH/RAC's CLP proposal: Cat 2, H315
Serious eye damage/eye irritation	<u>Current C&L according to Annex VI:</u> Covered by Cat 1B, H314 No reliable data available for self-classification	<u>Current C&L according to Annex VI:</u> Covered by C, R34 No reliable data available for self-classification	Cat 1, H318	Xi, R41	Disagree with CLH/RAC's CLP proposal. New test will be commissioned for C9.
Aquatic chronic toxicity	No classification needed	No classification needed	Cat 3	No classification	Disagree with CLH/RAC CLP proposal: Refer to Section Environmental Hazards

Overall conclusions

1. Companies of FAC ask Competent Authorities/RAC to include C&L proposals as listed in Table 2.

Table 2 C&L proposal by FAC

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Endpoint	FAC according 1272/2008/EC	FAC according 67/548/EEC
Skin corrosion/irritation	GHS07 "Warning" Cat 2 H315	Xi, R38
Serious eye damage/eye irritation	No reliable data available for self-classification. Test will be commissioned.	No reliable data available for self-classification. Test will be commissioned.
Aquatic chronic toxicity	No classification	No classification

2. Companies of FAC ask Competent Authorities/RAC to postpone the decision as new results on serious eye damage / eye irritation will be available end of 2012.

3. Companies of FAC ask Competent Authorities/RAC to be further involved in the process of decisions on C&L for nonanoic acid.

REFERENCES

ALL REFERENCES CAN BE MADE AVAILABLE TO THE AUTHORITIES ON REQUEST.

[1] Arcelin G (2001). Primary Skin Irritation Study in Rabbits (4-Hour Semi-Occlusive Application). Testing laboratory: RCC Ltd., Füllinsdorf, Switzerland. Report no.: 833231. Owner company: OXEA Group. Study number: T01664. Report date: 2001-11-15.

[2] Weterings PJJM (1984). Assessment of primary skin irritation by Prifrac 2914 in the rabbit. Testing laboratory: Notox, 's-Hertogenbosch, Netherlands. Report no.: 0038/90. Owner company: (sponsored by UNICHEMA Chemie B. V. /NL). Study number: T01157. Report date: 1984-10-18.

[3] Neudorff B6.2.s/01 (1997) – ACUTE DERMAL IRRITATION/CORROSION NEU 1170 H 21%IG, BioChem GmbH, Daimlerstr. 5b, D-76185 Karlsruhe, Germany, Report No 97 10 42 803 A, GLP, Unpublished

[4] Neudorff B6.2.e/01 (1997) – ACUTE EYE IRRITATION/CORROSION NEU 1170 H 21%IG, BioChem GmbH, Daimlerstr. 5b, D-76185 Karlsruhe, Germany, Report No 97 10 42 803 B, GLP, Unpublished

[5] Celanese (1999). Pelargonic acid - Assessment of ready biodegradability - Modified Sturm test. unpublished study report. Testing laboratory: Huntingdon Life Sciences Ltd. Report no.: CSD 025/992285. Owner company: OXEA Group. Study number: T00856. Report date: 1999-03-24.

[6] Brooke LT, Call DJ, Geiger DL and Northcott CE (1984). Acute toxicities of organic chemicals to fathead minnows (*Pimephales promelas*), Vol. 1. Center for Lake Superior Environmental Studies, University of Wisconsin-Superior, Superior, WI, USA: 414. Testing laboratory: Center for Lake Superior Environmental Studies, University of Wisconsin-Superior, Superior, WI, USA. Study number: T04901. Report date: 1984-01-01.

[7] Office of Pesticide Programs (OPP) (2000). Pesticide Ecotoxicity Database (Formerly: Environmental Effects Database (EEDB)). Environmental Fate and Effects Division, US EPA, Washington, DC. Testing laboratory: Wildlife International Inc., MD. Report no.: EPA Identification: 43065303. Study number: T05055. Report date: 2000-01-01.

[8] NITE (2009). Chemical Risk Information Platform: Heptanoic acid (CAS 111-14-8). National Institute of Technology and Evaluation (NITE) /Japan; National Institute of Technology and Evaluation (NITE); database available online, URL: <http://www.safe.nite.go>.

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jp/english/sougou/view/TotalSrchInput_en.faces; Search performed: 02 Nov 2009. Report no.: Class reference No. 2-608. Study number: T10069. Report date: 2009-11-02.

[9] Neudorff GmbH KG (2002) Ready biodegradability of pelargonic acid in a manometric respirometry test, including 1st amendment from July 2006, IBACON GmbH, Rossdorf, Germany, Project 14737160, Report No.: 11841087, GLP, Unpublished

[10] Neudorff (1998) NEU 1170 H – ACUTE TOXICITY TESTING OF NEU 1170 H IN GOLDEN ITE (*LEUCISCUS IDUS*) (TELEOSTEI, SALMONIDAE) ArGe GAB

Biotech/IFU, D-75223 Niefern Öschelbronn, Report No. 99024/01-AALi, GLP, Unpublished

[11] ACUTE IMMOBILISATION TEST DAPHNIA – DAPHNIA MAGNA ACCORDING TO OECD GUIDELINE 202-I (1984) NEU 1170 H (22 %) BioChem Agrar, Labor für biologische und chemische Analytik, D-04451 Cunnersdorf, Report No. 981048039, GLP, Unpublished

[12] Neudorff GmbH KG (1999) ALGAE GROWTH INHIBITION TEST *SCENEDESMUS SUBSPICATUS* OECD GUIDELINE 201 (1984) NEU 1170 H (22%) BioChem Agrar, Labor für biologische und chemische Analytik D-04451 Cunnersdorf Report No. 981048040, GLP, Unpublished

[13] Neudorff (1998) 28 – DAY PROLONGED TOXICITY TEST OF NEU 1170 H IN RAINBOW TROUT (*ONCORHYNCHUS MYKISS*) (TELEOSTEI, SALMONIDAE) ArGe GAB Biotech/IFU, D-75223 Niefern Öschelbronn, Report No. 99024/01-ACOm, GLP, Unpublished

[14] Neudorff GmbH KG (1999) ASSESSMENT OF TOXIC EFFECTS OF NEU 1170 H ON DAPHNIA MAGNA USING THE 21 DAY REPRODUCTION TEST ArGe GAB Biotech/IFU, D-75223 Niefern Öschelbronn, Report No. 99024/01-ARDm, GLP, Unpublished

End of Summary/conclusion and Overall conclusion of attachment no. 2.

Dossier Submitter's Response

Based on the evaluation of available data for nonanoic acid the dossier submitter is of the opinion that the proposed C&L for the environment should stay as presented in the CLH report (reference is made to comments number 14, 15 and 16).

So far no new data are available for the classification of eye irritation / corrosion. We cannot comment on the time lines and potential outcomes.

RAC's response

Environment: Aquatic Chronic 3 classification is justified as proposed by the DS. However, under DSD, there is not a measured ErC50 value for the test performed with *Scenedesmus subspicatus* which is the most sensitive species in the chronic test. For decanoic acid, which is a similar substance, the ErC50 value for this species is 2 mg/L; if a read-across is carried out as a worst case scenario (decanoic acid is suspected to be more toxic because it is more hydrophobic), ErC50 for nonanoic acid is 1.84 mg/L, which would lead to a classification with R51 and in combination a BCF >100 L/kg classification as N; R51/53 is justified.

Regarding skin and eye irritation please see response to comment 1.

OTHER HAZARDS AND ENDPOINTS

Skin hazard

Date	Country	Organisation	Type of Organisation	Comment number
19/07/2012	Spain		MSCA	7

Comment received

p. 27 Summary and discussion of corrosion/irritation
Nonanoic acid is currently listed in Annex VI of CLP Regulation as Skin Corr. 1B, H314 according to CLP Regulation and as C; R34 according to Directive 67/548/EC.
The Spanish CA considers a classification for nonanoic acid as Skin Corr. 1C, H314: Causes severe

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skin burns and eye damage according to Regulation EC 1272/2008 and as C; R34: Causes burns according to Directive 67/548/EC.

This classification is mainly based on the signs of corrosion observed in the skin 4-hour irritation study in rabbit (Otterdijk, 2001c) with brown discolouration (necrosis) between days 1 and 8 in all animals, scab and/or fissuring among the animals and areas of alopecia at the end of the observation period in all animals. There was visible necrosis through the epidermis into the dermis and the cornified layer was destroyed.

In the submitted studies in the Chemical Safety Report (under REACH) of nonanoic acid corrosion signs were observed. In one study (Unichema, Notox, 1984), visible necrosis was observed 48 hours after exposition and variable hair growth at the end of the observation period. In the other one (Hoechst, 1990), carried out with the potassium salt of nonanoic acid, there were scars at the end of the study.

It was mentioned in the Draft Assessment Report of July 2007, and in other papers (HERA, Fatty Acid Salts; Human Health Assessment, June 2002), that the length of the hydrophobic chain is a main factor which determines the corrosion of the free fatty acids. Shorter hydrophobic chains increase corrosive effects. In the DAR (2007), was established a cut off value of 9-carbon length to distinguish between corrosivity and irritation in free fatty acids (free fatty acids with $C \leq 9$ are corrosive). These effects warrant a classification as corrosive.

Dossier Submitter's Response

Thank you for your review. As mentioned in the CLH report "giving more weight to the later animal studies (Celandese/RCC 2001 from OXEA GmbH and Otterdijk 2001) that include in contrast to the earlier studies also a 14 day post exposure period (where recovery is seen – and it may be discussed if this is considered as full recovery) and giving also more weight to the human data (Jirova et al. 2008 and Wahlberg 1983 and Robinson 1999) presented in this CLH Dossier the overall weight of evidence supports a classification as skin irritant rather than skin corrosion." It is on RAC to decide this borderline case.

RAC's response

Noted. Please see response to comment 1.

Date	Country	Organisation	Type of Organisation	Comment number
27/07/2012	Germany	OXEA GmbH	Company-Importer	8

Comment received

The CLH reports reports the substance to be "borderline" with respect to corrosivity and refers to octanoic and decanoic acid as structurally similar substances with respect to eye irritation. It also lists more recent animal studies (RCC 2001, Notox 2001), that had not been taken into account for the current entry in Annex VI, CLP (Skin Corr. 1B).

For both octanoic and decanoic acid there are proposals for harmonized classification and labeling currently open for public comment. For decanoic acid Skin Irritation 2 is being proposed, for octanoic acid Skin Corrosion 1C. It is also well known that corrosivity of aliphatic carboxylic acids is less pronounced with higher homologues, indicating the "classification range" that might be expected for nonanoic acid.

The CLH report explicitly describes the Notox-Study from 2001, it is concluded that severe earlier erythema seen in the study as well as the areas of alopecia observable 14d after application would support classification as corrosive category 1 under GHS. The study used an exposure time of 4h, leading to Cat. 1C.

The other fairly recent study was reported by Oxea (RCC, 2001). This study tested for corrosivity at exposure times of 3 min, 1h and 4h. The study shows no corrosivity after 3 min and 1h exposure. After 4h exposure, the mean values of erythema score gradings after 24, 48 and 72h after patch removal for each of the three test animals are 3 / 3,3 / 2,3. This meets CLP classification criteria for corrosivity in category 1C and is fully in line with the Notox study.

Other reported studies showing no skin corrosion and human data were using diluted concentrations. While the pure acid has been demonstrated to be corrosive in valid animal studies, one might

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consider setting specific concentration limits for mixtures.

In summary, we support the observation given in the CLH report, that the classification of Annex VI, CLP as Skin. Corr. 1B is too severe. However, two valid recent animal studies show corrosivity of the pure substance as Skin Corr. 1C and should be used for classification. This is also fully in line with structurally similar substances quoted in the CLH report.

ECHA comment: The text above is identical with Skin Corrosivity part in attachment document no.1.

Dossier Submitter's Response

The Celandese/RCC 2001 study is only available to us in the IUCLID study summary; from this it appears the effects are reversible till 14 days. For the NOTOX 2001 study it may be discussed (see our CLH report, first 2 paragraphs in 4.4.1.1.) if the effects can be considered as reversible. The human data include also exposure to undiluted nonanoic acid (see our CLH report), therefore we think that they are useful for this evaluation. We remain of the opinion that nonanoic acid is a borderline case for classification as skin corrosive/irritant and so far we support classification for irritation. It is on RAC to decide this case.

RAC's response

Noted. Please see response to comment 1.

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Germany	Fatty Acid Consortium	Company-Manufacturer	9

Comment received

ECHA comment: The document 20120806_FATTY ACIDS CONSORTIUM_COMMENTS_NONANOIC_C9_final_final.pdf was submitted as a separate attachment. Attachment no. 2.Skin corrosion/irritation from page 3 was copied below.

Skin corrosion/irritation

The companies of FAC agree with the reduced classification for the undiluted nonanoic acid on skin irritation to be Cat 2; H315 according to EC1272/2008 and Xi, R38 according to 67/548/EEC.

FAC reasons for the reduced classification:

The substance is currently listed in Annex VI with classification as Skin Cat. 1B. There are two reliable GLP guideline studies [1, 2] with nonanoic acid available, which support the classification as skin irritant as proposed by CLH/RAC.

Nonanoic acid was tested in a reliable primary skin irritation study by Arcelin (2001) [1]. Three New Zealand white rabbits were dermally exposed to 0.5 mL of the undiluted test substance according to OECD Guideline 404. After 4 h of semi occlusive exposure the test substance caused well-defined to severe erythema (mean score: 2.89) and very slight to moderate oedema (mean score: 2.11). All effects disappeared 14 days after treatment. Scaling was observed in one animal after 72 h, in all animals after 7 and 10 days and in 2 of 3 animals after 14 days. No corrosive effects were noted. Thus, nonanoic acid is considered as skin irritant under the conditions of the test.

In a another GLP study performed according to OECD Guideline 404 by Weterings (1984) the potential of nonanoic acid for irritation and corrosion to the skin was examined in three New Zealand white rabbits [2]. The animals were dermally exposed to 0.5 mL of the undiluted test substance. After 4 h of semiocclusive exposure, the test substance caused severe erythema and eschar formation (mean score 24 - 48 -72 h: 3.2) and moderate oedema (mean score 24 - 48 -72 h: 1.6). One hour after exposure, the exposed area was light-brown stained. After 48 h, the skin became necrotic with eschar formation in all animals. During the first days of the 14-day observation period, the hairs in the exposed area continued to grow. This means that the hair roots, residing in the deeper layers of the dermis, were not directly affected by the test substance. However, seven days after exposure, the hairs had ceased to grow. After the formation and loosening of the crust, the skin had almost returned to normal 14 days after exposure, though with variable hair growth.

Since delayed abnormality of hair growth is not a criterion of corrosiveness, nonanoic acid can be considered as skin irritant under the conditions of this test.

FAC conclusion for skin irritation/corrosion

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- Nonanoic acid is considered a skin irritant (CLP: Cat 2, H315; DSD: Xi, R38)
- No data is available to set specific concentration limits. The acute dermal irritation/corrosion test [3] performed with the nonanoic acid formulation product NEU 1170 H (Neudorff B6.2.s/01, 1997) cannot be considered, since it contains the ammonium salt of nonanoic acid. Therefore, a proposal for setting specific concentration limits is not possible.

End of Skin corrosion/irritation of attachment no. 2.

Dossier Submitter's Response

The FAC obviously agree with our proposal to classify nonanoic acid for skin irritation. The data that they report seem in agreement with our conclusion. However the data are not available to us, neither the study reports nor as IUCLID study summary. It is upon the RAC to decide this case.

RAC's response

Noted. Please see response to comment 1.

Eye hazard

Date	Country	Organisation	Type of Organisation	Comment number
27/07/2012	Germany	OXEA GmbH	Company-Importer	10

Comment received

We agree with the classification proposal of the CLH report.

Dossier Submitter's Response

Thank you for your review.

RAC's response

Noted. Please see response to comment no. 1.

Date	Country	Organisation	Type of Organisation	Comment number
03/08/2012	Sweden		MSCA	11

Comment received

Page 35-36: We agree that it is a borderline case between skin corrosion and skin irritation based on animal data. In addition, human data indicate no skin corrosion, but irritating to skin. However, we would like to question the rationale to alleviate classification of skin corrosion to skin irritation but still classify for Eye Damage 1 (and not Eye Irritation 2)? Please consider to present clearer motivation and discussion behind this classification (i.e. expand section 4.4.2.4 Comparison with criteria). There is no eye damage/eye irritation data available for nonanoic acid and hence according to CLP regulation nonanoic acid should be classified as Eye Irritation 2 in line with the classification Skin Irritation 2 when data is lacking. The dossier submitter uses read across from octanoic and decanoic acid, but no data is presented in the current dossier. Only two pre-GLP studies with limited data available are mentioned to be used as basis for classification of octanoic acid and decanoic acid in Eye Damage category 1 (octanoic acid is classified in Skin Corr 1C, and Eye damage 1 is included in this classification; decanoic acid is classified in Skin Irritation category 2 and Eye Damage category 1). Nevertheless, in the CLH proposals for octanoic acid and decanoic acid some information on the two studies for eye damage classification is presented. In one study (Smyth et al., 1962) there are indications of serious damage to eye: score 9 of 10 for corneal necrosis. In the second study (Briggs et al., 1976) corneal opacity and moderate conjunctivitis up to 72 h are reported, but no information on number of animals affected or scores (or reversibility within 21 days) for the corneal opacity is presented. Since these studies cannot be fully evaluated this data is not entirely convincing for classification purpose in Eye damage category 1 for nonanoic acid. Further discussion on the justification of the proposed classification for eye damage/irritation would be helpful.

Replace 'Eye Irritant Category 1' with 'Eye Damage Category 1' throughout the report.

Dossier Submitter's Response

Thank you for your review. We agree with your summary of the available data. However in the presence of some evidence for severe eye damage of the structurally related decanoic acid and

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octanoic acid (Smyth et al. 1962) and the absence of fully valid eye irritation data for nonanoic acid we suggest to classify for eye damage category 1. It is also our understanding of the OECD TG 405, that mentions that severe skin irritation should exclude further eye irritation testing with animals and result in classification as severely eye damaging.
We were instructed by ECHA not to update the report at this moment.

RAC's response

Noted. Please see response to comment 1.

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Germany	Fatty Acid Consortium	Company-Manufacturer	12

Comment received

ECHA comment: The document 20120806_FATTY ACIDS CONSORTIUM_COMMENTS_NONANOIC_C9_final_final.pdf was submitted as a separate attachment. Attachment no. 2. Serious eye damage/eye irritation from page 4 was copied below.

Serious eye damage/eye irritation

FAC conclusion for serious eye damage/eye irritation

- The substance is currently listed in Annex VI with classification as Skin Cat. 1B and thus covers a classification for serious eye damage.
- The read across proposed in the CLH dossier indicates the potential of serious eye damage (Xi, R41/Cat. 1, H318). Nevertheless, there is currently no reliable data available by FAC for a self-classification of nonanoic acid. In order to improve data for C&L an in vitro study for identifying ocular corrosives and severe irritants will be commissioned. Results will be available by end of 2012.
- No data is available to set specific concentration limits. The acute eye irritation/corrosion test [4] performed with the nonanoic acid formulation product NEU 1170 H (Neudorff B6.2.e/01, 1997) cannot be considered, since it contains the ammonium salt of nonanoic acid. Therefore, a proposal for setting specific concentration limits is not possible.

End of Serious eye damage/eye irritation of attachment no. 2.

Dossier Submitter's Response

We appreciate that new data are being generated. We strongly recommend following the testing strategy recommended in OECD TG 405 that is starting with the available validated in vitro tests. In case an animal test is absolutely unavoidable, the test should be carried out according to the very last update of the TG 405 (October 3, 2012) that includes the use of analgesics.

RAC's response

Noted. Please see response to comment 1.

Hazardous to the aquatic environment

Date	Country	Organisation	Type of Organisation	Comment number
27/07/2012	Germany	OXEA GmbH	Company-Importer	13

Comment received

ECHA comment: The document: Comments on the Proposal for Harmonized Classification and Labelling [OXEA GmbH comments.pdf] was submitted as a separate attachment. Attachment no. 1. Comment about Aquatic Toxicity is copied below.

A classification in the chronic aquatic toxicity categories can be based on chronic toxicity data (e.g. NOEC) or, in the absence of such data, on biodegradability and bioaccumulation.

The substance is readily biodegradable and logKow and BCF are below regulatory thresholds. All acute toxicity data are above regulatory thresholds.

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There were long-term toxicity data reported for all three trophic levels. The NOEC for fish was 19.2 mg/l, for daphnia 9,93 mg/l. There are 3 studies on algae/aquatic plants showing NOEC values of 3.48 and 9.6 and 0,568 mg/l.

The classification proposal therefore is based solely on one chronic NOEC value¹. In this study, the highest initial concentration not inhibiting cell growth was 20.0 mg/l. Because of poor measurements of the test item, the EC values could only be given in nominal values. Seeing that the value of 0,568 mg/l is not supported by any other chronic NOEC value for the substance and that the study had poor measurements, at least some doubt of the validity of the result may be appropriate.

- The calculated NOEC of 0,568 mg/l and the observed threshold value of 20 mg/l are separated by a factor of >40 in a study, in which measurements were difficult or poor.
- 2 other algae/aquatic plant studies show NOEC values clearly above 1, so did chronic studies on fish and daphnia.
- The substance is readily biodegradable and has low bioaccumulation potential.

Looking at the available data as a whole, there is in our view not sufficient evidence to justify classification in Aquatic Chronic 3.

¹ derived from an OECD 201 study on *Scenedesmus subspicatus* (Kleiner, R. (1999), OECD 201, Algae growth inhibition test, *Scenedesmus subspicatus*).

End of Aquatic Toxicity comment from attachment no. 1

Dossier Submitter's Response

It is not surprising that the algae **NOE_rC (72 h) value of 0.57 mg/L** (CLH report on nonanoic acid, mean measured, *Scenedesmus subspicatus*) is not supported by NOE_rC values <1 from other trophic levels. **Nonanoic acid (C 9)** is used as algicide and as herbicide, since it exhibits non selective herbicidal activity, which is only due to contact action. The mechanism of action is a physical effect on plant cell walls which affects cell wall integrity. Due to its lipophilic characteristics the active substance quickly penetrates into the plant tissue and disrupts normal cell membrane permeability. The result is the destruction of the photosynthesis mechanisms and other membrane bound physiological processes. Finally, an uncontrolled leakage of cell contents occurs. Plant tissue is destroyed within 24 hours after treatment and severe necrosis of treated plant parts can be observed.

The low NOE_rC value is further confirmed by the algae NOE_rC (72 h) value of 0.57 mg/L for decanoic acid (CLH-report for decanoic acid, mean measured at the beginning and at the end of the test, *Scenedesmus subspicatus*). This value has meanwhile been recalculated as **geometric mean from the measured concentration at the beginning of the test and from half of the limit of quantification at all other measuring points**. This way the total test duration (72 h) can be used for effect investigation including estimation of chronic effects.

According to this new approach, the **NOE_rC (72 h)** of this algae study with **decanoic acid (C 10)** was recalculated with **0.25 mg/L**.

Furthermore in the CSR on **octanoic acid (C 8) a NOE_rC (72 h) value of 0.07 mg/L** (meas. TWA, *Pseudokirchnerella subcapitata*) is presented.

In contrast to our argumentation in the CLH-report we are meanwhile of the opinion, that this value is valid, since recalculation as geometric mean from the measured concentration at the beginning of the test and from half of the limit of quantification at all other measuring points, gives approximately the same value. The low LOQ also explains the low effect value compared to chronic algae results for the other fatty acids.

NOE_rC (72 h) values which are >1 mg/L:

nonanoic acid (C 9): 3.48 mg/L (mean measured, *Anabaena flos-aquae*) and 9.6 mg/L (nominal, *Lemna gibba*) both presented in the CLH report on nonanoic acid);

heptanoic acid (C 7): 29 mg/L (CSR on nonanoic acid; *Pseudomkirchnerella subcapitata*)

Therefore based on the available chronic toxicity data on algae classification of nonanoic acid with

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON NONANOIC ACID

Aquatic Chronic 3 is still considered appropriate by the submitter.				
RAC's response				
<p>Aquatic Chronic 3 classification is justified as proposed by the DS.</p> <p>Regarding chronic toxicity, there are two tests, one in Daphnia with a NOEC of 9.93 mg/L, and one in algae (<i>Desmodesmus subspicatus</i>), which is the most sensitive species with a NOEC of 0.568mg/L. Taking into account this value and its rapid degradation, nonanoic acid classifies as aquatic chronic Category 3 (H412) according to CLP. Although there are no chronic tests in fish, because the available prolonged toxicity study following the OECD TG 204 cannot be considered a chronic test, the surrogate approach is not relevant, since nonanoic acid is readily biodegradable and has a fish BCF <500 L/kg and therefore it leads to no classification, and it is not going to affect the proposal.</p>				
Date	Country	Organisation	Type of Organisation	Comment number
02/08/2012	United Kingdom		MSCA	14
Comment received				
<p>Under REACH, nonanoic acid (C₉H₁₈O₂) is considered as part of a category approach with analogues such as heptanoic acid (C₇H₁₄O₂), octanoic acid (C₈H₁₆O₂) and decanoic acid (C₁₀H₂₀O₂). A consolidated set of all available ecotoxicity data would be useful for the classification dossier. Although some analogue data appears to be potentially conflicting e.g. the chronic toxicity to Daphnia, these still need to be considered in the dossier.</p>				
Dossier Submitter's Response				
<p>The intention of the submitter of the CLH-report on nonanoic acid is to initiate a harmonised C&L for nonanoic acid, which is important under the biocides regime.</p> <p>In order to enable read across with other medium chain fatty acids we now provide a summary of all available acute and chronic eco-toxicity data for all three trophic levels from CARs on octanoic, nonanoic and decanoic acid and CSRs on nonanoic and octanoic acid.</p> <p>For available acute eco-toxicity data on all three trophic levels and for all analogues reference is made to comment number 16.</p> <p>For available chronic eco-toxicity data on algae for all analogues reference is made to comment number 14.</p> <p>Summary of chronic toxicity data for fish and crustacean available from CARs on octanoic, nonanoic and decanoic acid and CSR for nonanoic and octanoic acid:</p> <p>fish NOEC (28d): sodium laurate (C 12): based on growth rate: 6.4 mg/L, based on mortality 2 mg/L (CSR on octanoic acid, nominal, flow through, <i>Danio rerio</i>) nonanoic acid (C 9): ≥19.2 mg/L (CLH report on nonanoic acid, no effects at the highest conc. tested, nominal confirmed, flow through, based on mortality and non-lethal effects, <i>Oncorhynchus mykiss</i>)</p> <p>crustacean NOEC (21d): decanoic acid (C 10): 0.2 mg/L (CSR on octanoic acid, nominal, semi static, based on reproduction, <i>Daphnia magna</i>) nonanoic acid (C 9): 9.93 mg/L (CLH report on nonanoic acid, mean measured, based on reproduction and mortality, <i>Daphnia magna</i>); heptanoic acid (C 7): 18 mg/L (CSR on nonanoic acid, based on reproduction, static, <i>Daphnia magna</i>);</p> <p>Conclusion: Based on all available data for nonanoic acid we are of the opinion that the proposed C&L in the CLH report (no classification, according to DSD and classification with Aquatic Chronic 3, according to CLP is appropriate.</p>				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON NONANOIC ACID

RAC's response

Environment: Aquatic Chronic 3 classification is justified, as proposed by the DS. However, under DSD, there is not a measured ErC50 value for the test performed with *Desmodesmus subspicatus* which is the most sensitive species in chronic tests. For decanoic acid, which is a similar substance, the ErC50 value for this species is 2 mg/L; if a read-across is carried out as a worst case scenario (decanoic acid is suspected to be more toxic because it is more hydrophobic), ErC50 for nonanoic acid is 1.84 mg/L which would lead to a classification with R51 and in combination a BCF >100 L/kg classification as N; R51/53 is justified.

Regarding the toxicity to algae, which is clearly the most sensitive taxonomic group, there are some data (algae test performed with octanoic acid from REACH registration) which are too inconsistent to enable a classification to be established.

However, the result from the REACH registration dossier is not consistent with the results obtained in daphnia and fish or with the trend observed in the algae tests carried out on the other substances of the group. When this test is not considered, it appears that toxicity increases with hydrophobicity.

Furthermore, there are some deficiencies in the test from REACH registration documents, such as the inconsistency in dose-responsiveness at the lowest concentrations, the rapid loss of the test concentration and the highest effect at 24 hours. Therefore, taking into account that the reliability of this test cannot fully be confirmed and that this test is not consistent with the results of the other taxonomic groups, it should not be used for classification purposes.

For nonanoic acid there is an algae test available with *Desmodesmus subspicatus*, the same species used for decanoic acid test, which can be used to classify as Aquatic Chronic 3.

Date	Country	Organisation	Type of Organisation	Comment number
03/08/2012	Belgium		MSCA	15

Comment received

Based on the results of the aquatic toxicity test (all EC50>1mg/l, 72hNOEC *Scenedesmus subspicatus* =0.568 mg/l), the fact that the substance is rapidly degradable (76 % degradation within 28d), it is justified to classify, following the classification criteria of the 2nd ATP, as Aquatic Chronic 3, H412.

In conclusion: we support the CLP classification for the environment as proposed by the Austrian MSCA.

p.64 Reasoning DSD classification :

Based on the data given in the CLH report it can't be concluded that fish is the most sensitive species as for both fish and algae no effects were seen at the highest test concentration (nominal 100mg/l). The mean measured concentrations (fish *Leuciscus idus*: 96h LC50>7.2 mg/l, algae *Anabaena flos-aquae*: 96hEC50>3.5 mg/l) indicate that the test procedure chosen (fish : semi-static; algae : static) wasn't appropriate and that constant concentration of the test substance wasn't guaranteed during test period (degradation, adsorption). Therefore it isn't possible to conclude on the toxicity of fish and algae.

However on the dissemination site of registered substances, for nonanoic acid the key study for fish *Pimephales promelas* (OECD 203, flow through, reliability 2) results in a 96hLC50 = 104 mg/l(meas). The 96hEC50 for algae was determined by calculated using ECOSAR vers? (96hEC50=96 mg/l, reliability 3) and by read across with heptanoic acid 72hEC50=29 mg/l (reliability 2).

Calculation of the toxicity of nonanoic acid via ECOSAR vers. 1.00, supports the findings that the LC50-values will be above 10 mg/l.

ECOSAR v1.00 Class(es) Found

Neutral Organics-acid

Predicted

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ECOSAR Class Organism Duration End Pt mg/L (ppm)

=====
--> Acid moiety found: Predicted values multiplied by 10

Neutral Organics-acid : Fish 96-hr LC50 55.567
Neutral Organics-acid : Fish 14-day LC50 57.582
Neutral Organics-acid : Daphnid 48-hr LC50 39.254
Neutral Organics-acid : Green Algae 96-hr EC50 36.125
Neutral Organics-acid : Fish 30-day ChV 6.412
Neutral Organics-acid : Daphnid ChV 5.794
Neutral Organics-acid : Green Algae ChV 17.799
Neutral Organics-acid : Fish (SW) 96-hr LC50 68.803
Neutral Organics-acid : Mysid Shrimp 96-hr LC50 18.678
Neutral Organics-acid : Fish (SW) ChV 19.437
Neutral Organics-acid : Mysid Shrimp (SW) ChV 1.028
Neutral Organics-acid : Earthworm 14-day LC50 1911.759 *

Note: * = asterisk designates: Chemical may not be soluble enough to measure this predicted effect.

The acute toxicity of Octanoic acid was only tested in a fish study, the toxicity on the other trophic levels was based on read across with Decanoic acid, with algae as most sensitive species (72hErC50 *Scenedesmus subspicatus* = 2 mg/l, 72hNOErC50=0.57mg/l).

Dossier Submitter's Response

Thank you for supporting the CLP classification proposal!

In the CLH report we stated that the lowest LC₅₀ value (fish) is >7.2 mg/L. Further on we argued that 7.2 mg/L was the highest concentration tested in the respective study. No effects were observed at that concentration. In contrast to this value the long term NOEC (fish) for Nonanoic acid was found to be 19.2 mg/L. There is also a LC₅₀ (fish) available from Octanoic acid (C8 fatty acid) with 68 mg/L (Draft Competent Authority Report, Document I, Octanoic acid, Product Type 4 and 18, 2011). Therefore as a weight of evidence decision it is proposed not to classify Nonanoic acid according to Dir. 67/548/EEC.

→ No classification

Summary of acute toxicity data for all three trophic levels available from CARs on octanoic, nonanoic and decanoic acid and CSR for nonanoic and octanoic acid:

fish LC₅₀ (96h):

nonanoic acid (C 9): > 7.2 mg/L (CLH report on nonanoic acid, no effects at the highest conc. tested, mean measured, *Leuciscus idus*); **104 mg/L** (CSR on nonanoic acid, mean measured, *Pimephales promelas*)

octanoic acid (C 8): 68 mg/L (CLH report on octanoic acid, nominal confirmed, *Brachydanio rerio*); **22 mg/L and 39.9 mg/L** (CSR on octanoic acid, both nominal and *Lepomis macrochirus*)

crustacean EC₅₀ (48h):

decanoic acid (C 10): 16 mg/L (CLH report on decanoic acid, nominal confirmed, *Daphnia magna*); **21 mg/L** (CSR on octanoic acid, mean measured, *Daphnia magna*)

nonanoic acid (C 9): 23.63 mg/L (CLH report on nonanoic acid, mean measured, *Daphnia magna*); **96 mg/L** (CSR on nonanoic acid, nominal, *Daphnia magna*)

heptanoic acid (C 7): 859.6 mg/L (CSR on nonanoic acid, arithmetic mean, *Daphnia magna*)

algae E_rC₅₀ (72h):

decanoic acid (C 10): 2 mg/L (CLH report on decanoic acid, mean measured, *Scenedesmus subspicatus*)

nonanoic acid (C 9): 103.4 mg/L (CLH report on nonanoic acid, nominal, *Scenedesmus subspicatus*);

octanoic acid (C 8): 31 mg/L (CSR on octanoic acid, measured TWA, *Pseudokirchnerella subcapitata*)

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heptanoic acid (C 7): 60 mg/L (CSR on nonanoic acid, *Pseudokirchnerella subcapitata*)

Therefore we completely agree with you that most of the L(E)C₅₀ values available for all three trophic levels are >10 mg/L. The only exception is an algae E_rC₅₀ (72 h) value of 2 mg/L for decanoic acid.

Based on the available acute toxicity data no classification of nonanoic acid according to Dir. 67/548/EEC is still considered appropriate by the submitter.

Based on the available chronic toxicity data on algae classification of nonanoic acid according to CLP with Aquatic Chronic 3 is still considered appropriate by the submitter.

RAC's response

Environment: Aquatic Chronic 3 classification is justified as proposed by the DS. However, under DSD, there is no measured ErC50 value for the test performed with *Desmodesmus subspicatus* which is the most sensitive species in chronic tests. For decanoic acid, which is a similar substance, the ErC50 value for this species is 2 mg/L; if a read-across is carried out as a worst case scenario (decanoic acid is suspected to be more toxic because it is more hydrophobic), ErC50 for nonanoic acid is 1.84 mg/L which would lead to a classification with R51 and in combination a BCF >100 L/kg classification as N; R51/53 is justified.

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Germany	Fatty Acid Consortium	Company-Manufacturer	16

Comment received

ECHA comment: The document 20120806_FATTY ACIDS CONSORTIUM_COMMENTS_NONANOIC_C9_final_final.pdf was submitted as a separate attachment. Attachment no. 2. Environmental hazards was copied below.

ENVIRONMENTAL HAZARDS

Data relevant for the classification of nonanoic acid, CAS 112-05-0:

Endpoint	Fatty Acid Consortium	CLH
Biodegradation	Readily [5]	Readily [9]
Bioaccumulation	log Kow 3.42 (BCFBAF v3.00); low potential for bioaccumulation	BCF: 195.88 (calc.); statement: no bioaccumulation
Acute aquatic toxicity:		
fish (LC50)	104 mg/L [6]	> 7.2 mg/L [10]
daphnia (EC50)	96 mg/L [7]	23.63 mg/L [11]
algae (EC50)	RA from heptanoic acid 60 mg/L [8]	RA from n-nonanoic acid, ammonium soap 22% 103.4 mg/L [12]
Chronic aquatic toxicity:		
fish (NOEC)	no data	19.2 mg/L [13]
daphnia (NOEC)	RA from heptanoic acid 18 mg/L [8]	9.93 mg/L [14]
algae (NOEC)	RA from heptanoic acid 29 mg/L [8]	RA from n-nonanoic acid, ammonium soap 22% 0.568 mg/L [12]

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Regulations	Fatty Acid Consortium		CLH
	Classification	Reasoning	
DSD	no classification	The lowest L(E)C50 is between 10 and 100 mg/L; readily biodegradable	No classification
CLP 1st ATP	no classification	The lowest L(E)C50 is > 1 mg/L; readily biodegradable; low potential of bioaccumulation	No classification
CLP 2nd ATP	no classification	The lowest L(E)C50 is > 1 mg/L; ready biodegradability; the lowest NOECx > 1 mg/L is expected.	Chronic 3

DSD classification

FAC conclusion

The Fatty Acid Consortium agrees with **"no classification"** according to Directive 67/548/EEC.

FAC reasons against the proposed CLP classification: Chronic aquatic toxicity, category 3

The CLH dossier proposes a classification as Category Chronic 3, based on the reported algal NOEC of 0.568 mg/L [12]. The Fatty Acid Consortium considers this NOEC value to be unreliable for the following reasons:

- The test substance used in this OECD 201 test is a technical product of n-nonanoic acid (ammoniated soap of fatty acids) 22%
- No analytical concentration control was conducted during the test. The reported analytics refer to a study performed one year earlier. The test results were reported based on the nominal concentration of the test item, because the test concentration could not be recovered and no concentration-effect relationship revealed between the measured concentration and inhibition of the algae growth rate. The reported "measured" concentrations of test item were converted based on the old analytical report values.
- The value given in the CLH dossier (0.568 mg/L) is not mentioned in the study report, and it is neither clear nor documented on how this value was derived. In the original study report only the nominal value of NOEC = 20 mg/L of test item is given, but the NOEC used for classification assessment in the CLH dossier is based on the "measured" value, as cited in the Table 27 of the CLH dossier.
- Based on the above, only the nominal values can be considered reliable. The nominal NOEC is 20 mg/L of the technical product corresponding to 4.4 mg/L of active ingredient, n-nonanoic acids (ammoniated soap of fatty acids).

FAC conclusion for aquatic toxicity

The Fatty Acid Consortium proposes to use the nominal value of 4.4 mg/L [12], supported by a read-across from heptanoic or decanoic acid, that represent the fatty acids with a shorter (C7) and a longer carbon chain, respectively. Based on the available data as was reported within the REACH registration dossier one can expect an increase in aquatic toxicity as the chain length increases from C7 to C10. C10 therefore, represents the worst case of these three structure analogue substances and clearly supports the nominal values of the n-nonanoic study, since all reliable long-term NOECs for these two read across substances are clearly above 1 mg/L.

It is concluded that nonanoic acid does not need to be classified for long term hazards for the aquatic environment.

End of Environmental hazards attachment no. 2.

Dossier Submitter's Response

Reasons why the results of the chronic algae study are reliable:

- Yes, the tested substance is n-nonanoic acid, but the given results are calculated for nonanoic acid (technical grade, 18.67%). (Reference is made to Doc. III-A 7.4.1.3 and to Doc. II-A confidential, which have been attached to the CLH report.)

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- An analytical concentration control was conducted during the test. The analytical report has the same project ID number as the algae growth inhibition test. The final report for the growth inhibition test was finished on the 5th of January 1999. The analytical report was completed on 21st December 1998.
- The value in the CLH report (0.568 mg/L) is not mentioned in the study report, since the study report refers to the tested product (NEU 1170 H), which contains 22% of n-nonanoic acid. In the original study report the nominal values at the beginning of the study and the measured concentrations after 72 h are given for the tested product. Based on these values the geometric mean of NEU 1170 H was calculated with 2.86 mg, which corresponds to 0.568 mg nonanoic acid/L technical grade (Kleiner R., 1999). This information is given in Doc. III-A 7.4.1.3 and in Doc. II-A confidential.
- Contrary to the conclusion drawn in the original study report as well as by FAC the nominal values cannot be considered as reliable, since the concentration dropped to values < 80% of nominal.

Conclusion for aquatic toxicity:

We cannot follow the conclusion drawn by FAC. There are algae NOE_C (72 h) values available for heptanoic (C 7), octanoic (C 8), nonanoic (C 9) and decanoic acid (C 10) with 29 mg/L, 0.07 mg/L, 0.57 mg/L and 0.25 mg/L, respectively (reference is made to answer to comment number 14).

Therefore we are of the opinion that classification of nonanoic acid with Aquatic Chronic 3 is appropriate.

RAC's response

Environment: Aquatic Chronic 3 classification is justified as proposed by the DS. However, under DSD, there is not a measured ErC50 value for the test performed with *Scenedesmus subspicatus* which is the most sensitive species in the chronic test. For decanoic acid, which is a similar substance, the ErC50 value for this species is 2 mg/L; if a read-across is carried out as a worst case scenario (decanoic acid is suspected to be more toxic because it is more hydrophobic), ErC50 for nonanoic acid is 1.84 mg/L, which would lead to a classification with R51 and in combination a BCF >100 L/kg classification as N; R51/53 is justified.

Regarding nonanoic acid, all tests (except testing of the effects on microbial aquatic activity) were conducted with the ammonium salt of nonanoic acid in the form of the "intermediate formulation" NEU 1170 H.

In these studies, the formulation NEU 1170 H, containing approximately 20% nonanoic acid (nominal), was tested. As in this formulation nonanoic acid is, apart from water, the main component and the bioavailability of the active substance in the formulation is higher than for the technical active substance, these tests are considered to be appropriate for the evaluation of the active substance. The end-points of the tests were corrected to take into account the exact concentration of nonanoic acid.

The Biocide TM agreed on the use of the formulation NEU1170 H to study the toxicity.

Furthermore, based on the concentration and DSD classification of the other components of the formulation, they are unlikely to contribute to its toxicity and if the toxicity obtained for nonanoic acid with this formulation is compared with other similar acids, it follows a logical trend which is an increase of toxicity as the hydrophobicity increases. Therefore, the use of the formulation NEU 1170H for the purpose of classification and labelling is considered appropriate.

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON NONANOIC ACID

REFERENCES: none

ATTACHMENTS RECEIVED: 2

1. **OXEA GmbH comments.pdf** (Comments on the Proposal for Harmonized Classification and Labelling). Submitted by Germany/ OXEA GmbH / Company-Importer. *Part 3 of comment is copied in the table and part 1 and 2 are identical with the text in the table.*
2. **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_NONANOIC_C9_final_final.pdf** (Comments of FAC Companies on CLH for nonanoic acid, EC # 203-931-2, CAS# 112-05-0 4 Aug 2012). Submitted by Germany/ Fatty Acid Consortium/ Company-Manufacturer. *Part of document is copied in the table.*