Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

decanoic acid

EC number: 206-376-4
CAS number: 334-48-5

CLH-O-0000002590-79-03/A2

Adopted

6 June 2013

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON DECANOIC 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: Decanoic acid
EC number: 206-376-4
CAS number: 334-48-5
Dossier submitter: Austria

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
19/07/2012	Spain		MSCA	1
Comment received				
p.6 Proposal for harmonised classification and labelling The Spanish CA agrees with the Austrian proposal to classify decanoic 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. Besides, RAC should consider the following additional classification: – STOT SE 3, H335: May cause respiratory irritation according to Regulation 1272/2008 and as Xi; R37: Irritating to respiratory system. Additionally we consider RAC should asses the respiratory tract irritation potential of decanoic acid.				
Dossier Submitter's Response				
Thank you for your review. In our understanding respiratory tract irritation should be mainly derived from specific human data, which are not available.				
RAC's response				
In the human patch test neat decanoic acid was irritant after 4 hrs, induced irritation in rabbits at 24 hrs as well as in the acute dermal toxicity test in rats with reversibility within 15 days. Taking into account the information from octa- and nonanoic acids the RAC in agreement with the dossier submitter concludes that decanoic acid should be considered as irritating to the skin and classified as Skin Irrit. 2 - H315 according to CLP (Xi; R38 according to DSD). The available information on the effects of decanoic acid on the eyes is contradictive and does not allow a clear differentiation between irreversible and reversible effects on the eyes. The poorly described Smyth et al(1962) study indicates irreversible effects for octanoic and decanoic acid, which is not supported by the study of Briggs et al (1976) and the more recent study by Leoni and Riedel (2011) on octanoic acid. During public consultation, industry referred to a Bovine Corneal Opacity and Permeability (BCOP) test for decanoic acid. The RAC has evaluated this OECD 437 study and supports the conclusion of the report that based on the criteria of the guideline a 20% dilution of decanoic acid is not corrosive or a severe irritant to the eye. Based on this and the information from octa- and nonanoic acids the RAC concludes that classification as Eye Irrit. 2 H313 according to CLP (Xi; R36 according to DSD) is justified.				
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 review.				

RAC's response				
Noted. Please see response to comment 1.				
Date	**Country**	**Organisation**	**Type of Organisation**	**Comment number**
03/08/2012	Germany		MSCA	3
Comment received				
It should be clearly pointed out on which data the proposal is based. If data obtained with decanoic acid are not sufficient for classification, a proper read across to other medium chain carboxylic acids should be provided. Specific concentration limits should be added if sufficiently supported by the data.				
Dossier Submitter's Response				
The summary tables in the CLH report are clear on which substance was tested in the summarized tests. The read across with octanoic acide was done with the available data under the biocides regime in order to complete the CAR. In order to enable read across with other 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 for nonanoic and octanoic acid (reference is made to comment number 20). We do not have sufficient data to support specific concentration limits for skin or eye irritation. No specific concentration limits are needed for environmental C&L, since there are no data which would support a classification with R50 or R50/53. The same holds true for M-factors, since there are no data which would support a classification with Acute1 or Chronic1.				
RAC's response				
Noted. Please see response to comment 1.				
Date	**Country**	**Organisation**	**Type of Organisation**	**Comment number**
06/08/2012	Denmark	Individual		4
Comment received				
*ECHA comment: The document **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_NONANOIC_C10_final for submission.pdf** was submitted as a separate attachment and claimed confidential. Attachment no. 5*				
Dossier Submitter's Response				
We suppose the Fatty Acids Consortium comments on decanoic acid were meant. Therefore please refer to our answer to comment number 5.				
RAC's response				
Noted. Please see response to comment 1.				
Date	**Country**	**Organisation**	**Type of Organisation**	**Comment number**
06/08/2012	Belgium	Oleon NV	Company-Manufacturer	5
Comment received				
ECHA comment: The document **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_DECANOIC_C10_final_final.pdf** was submitted as a separate attachment. *Attachment no. 1.Summary/conclusion and Overall conclusions were copied below.* **Summary/conclusion of C&L for decanoic acid proposed by RAC (CLH) and FAC** Currently there is no entry in Annex VI to the CLP Regulation for this substance. Based on the evaluation of available data on decanoic acid, CAS# 334-48-5, the following table illustrates the classification as is suggested by the Fatty Acids Consortium and indicated in the CLH dossier. Table 1 Summary/conclusion of C&L for decanoic acid proposed by RAC (CLH) and FAC				

Endpoint	FAC according CLP 1272/2008/EC	FAC according 67/548/EEC	CLH according CLP EC1272/2008	CLH according 67/548/EEC	Comments by FAC
Skin corrosion /irritation	Cat 2, H315	Xi, R38	Cat 2, H315	Xi, R38	**Agree with CLH/RAC's CLP proposal**
Serious eye damage/eye irritation	No reliable data available for self-classification	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 C10.
Aquatic chronic toxicity	No classification needed	No classification needed	Cat 3,H412	N, R51/53	**Disagree with CLH/RAC's CLP proposal:** Refer to Section Environmental Hazards **Disagree with CLH/RAC's CLP proposal 67/548/EEC:** Refer to Section Environmental Hazards

OVERALL CONCLUSIONS

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

Table 2: C&L proposal by FAC

Endpoint	FAC according CLP 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 will be available in Oct 2012 for toxicity to algae and for the endpoint serious eye damage/eye irritation at the end of the year 2012.

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

REFERENCES

ALL REFERENCES CAN BE MADE AVAILABLE TO THE AUTHORITIES ON REQUEST.
[1] Smyth, H. F. et al. (1962b). Range-finding toxicity data: List VI. Am Ind Hyg Assoc J. 23:95-107

[2] Briggs, G. B. et al. (1976). Safety studies on a series of fatty acids. Am Ind Hyg Assoc J. 37(4):251-253

[3] Richterich, K. and Mühlberg (1999), B. 1-Undecanecarboxylic acid (Laurinsäure) - Ultimate biodegradability in the closed bottle test, Henkel KGaA, Düsseldorf, Germany,R 0100793,

COGNIS Deutschland GmbH, Düsseldorf, Germany

[4] van Egmond (1999) Bioconcentration, biotransformation, and chronic toxicity of sodium laurate to zebrafish (Danio rerio), Envir. Tox. Chem. 18 (3), 466–473, 1999

[5] NITE (1999) Fish (Oryzias latipes) acute toxicity test for decanoic acid, Sumika Technoservice Corporation, Takarazuka, Japan, EFA98008, Ministry of the Environment, Government of Japan

[6] NITE (1999) Daphnia magna, acute toxicity test for decanoic acid, Sumika Technoservice Corporation, Takarazuka, Japan, EDI98008, Ministry of the Environment, Government of Japan

[7] NITE (1999) Alga (Selenastrum capricornutum), growth inhibition test for decanoic acid, Sumika Technoservice Corporation, Takarazuka, Japan, EAI98008, Ministry of the Environment, Government of Japan

[8] NITE (1999) Daphnia magna, reproduction toxicity test for decanoic acid, Sumika Technoservice Corporation, Takarazuka, Japan, EDR98008, Ministry of the Environment, Government of Japan

[9] Schlechtriem, C. (2012), Daphnia magna, Reproduction test (OECD 211) Semi-static exposure, Fraunhofer Institute for Molecular Biology and Applied Ecology (IME) Schmallenberg, Germany, EME-001/4-21/G, Emery Oleochemicals GmbH, Germany

[10] SOPURA N.V. (2006) DECANOIC ACID: READY BIODEGRADABILITY IN A MANOMETRIC RESPIROMETRY TEST; RCC LTD, Itingen, Switzerland; RCC Study Number: A86567, Unpublished

[11] SOPURA (2006) Octanoic Acid: Acute Toxicity to Zebra Fish (Brachydanio rerio) in a 96-hour semi-static Test, RCC Ltd; Itingen, Switzerland RCC Study Number A86501

[12] SOPURA (2006) First Amendment to Study Plan Octanoic Acid: Acute Toxicity to Zebra Fish (Brachydanio rerio) in a 96-hour semi-static Test RCC Ltd; Itingen, Switzerland RCC Study Number A86501

[13] SOPURA (2006) DECANOIC ACID: ACUTE TOXICITY TO DAPHNIA MAGNA IN A 48-HOUR IMMOBILIZATION TEST; RCC Ltd, Itingen, Switzerland; RCC Study Number: A86488, Unpublished

[14] SOPURA (2008) DECANOIC ACID: TOXICITY TO SCENEDESMUS SUBSPICATUS IN A 72-HOUR ALGAL GROWTH INHIBITION TEST; RCC Ltd, Itingen, Switzerland, RCC Study Number: A86523 (inclusive A86534), Unpublished

[15] OECD Guideline 211 for Testing of Chemicals: Daphnia magna Reproduction Test, adopted 03 October 2008

End of Summary/conclusion and Overall conclusion of attachment no. 1.

Dossier Submitter's Response

Neither new data on eye irritation nor on algae are available to the RMS. We cannot comment on this.
Based on the evaluation of available data for decanoic acid and read across to other medium chain fatty acids for endpoint for which no data for decanoic acid are available we are of the opinion that the proposed C&L for the environment should stay as presented in the CLH report.

RAC's response

Environment: RAC agrees with the DS proposal, taking into account the deficiencies of the test submitted under REACH registration and the new test submitted by the industry and the justified use of measured concentrations in the algae tests conducted on nonanoic and decanoic acids.
Regarding skin and eye irritation, please see response to comment 1.

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

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

Comment received
*ECHA comment: The document **20120806_FAC_COMMENTS_on_CLH_DECANOIC_C10_final.pdf** was submitted as a separate attachment and claimed confidential. Attachment no.6*
Dossier Submitter's Response
You are kindly asked to refer to our answer to comment number 5.
RAC's response
Noted.

Date	**Country**	**Organisation**	**Type of Organisation**	**Comment number**
06/08/2012	United Kingdom	Fatty Acid Consortium	Company-Manufacturer	7

Comment received
*ECHA comment: The document **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_DECANOIC_C10_final_final.pdf** was submitted as a separate attachment. Attachment no. 2. The document text is identical with attachment 1,3,4,5,6,7.*
Dossier Submitter's Response
You are kindly asked to refer to our answer to comment number 5. Without further information this document cannot be considered as confidential. It does not contain any information that is subject to data protection.
RAC's response
Noted.

Date	**Country**	**Organisation**	**Type of Organisation**	**Comment number**
06/08/2012	Netherlands	Wilmar Europe Trading BV	Company-Importer	8

Comment received
*ECHA comment: The document **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_DECANOIC_C10_final_final.pdf** was submitted as a separate attachment. Attachment no. 3. The document text is identical with attachment 1,2,4,5,6,7.*
Dossier Submitter's Response
You are kindly asked to refer to our answer to comment number 5. Without further information this document cannot be considered as confidential. It does not contain any information that is subject to data protection.
RAC's response
Noted.

Date	**Country**	**Organisation**	**Type of Organisation**	**Comment number**
06/08/2012	Switzerland		Company-Downstream user	9

Comment received
Please refer to the attachment. *ECHA comment: The document **FAC Comments on CLH of decanoic acid - 04.08.12.pdf** was submitted as a separate attachment. Attachment no. 4. The document text is identical with attachment 1,2,3,5,6,7.*
Dossier Submitter's Response
You are kindly asked to refer to our answer to comment number 5. Without further information this document cannot be considered as confidential. It does not contain any information that is subject to data protection.
RAC's response
Noted.

OTHER HAZARDS AND ENDPOINTS

Skin hazard

Date	Country	Organisation	Type of Organisation	Comment number
19/07/2012	Spain		MSCA	10

Comment received

p.25 Summary and discussion of skin corrosion/irritation
The Spanish CA supports a classification for decanoic 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.
This classification is mainly based on the resulted of the TER corrosivity test (York, 1996) with a resulting value of 29.9 ± 5.4 kΩ/disc, above the trigger value to classify a substance as skin corrosive.
It was mentioned in the Draft Assesment Report of July 2007, and in other papers (HERA, Fatty Acid Salts; Human Health Assesment, 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 ≤ 9 are corrosive). Decanoic acid is out of the range of corrosive free fatty acids.
This data support a classification as irritant to skin.

Dossier Submitter's Response

Thank you for your review.

RAC's response

Noted. Please see response to comment 1.

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

Comment received

4.4.1.1 Human information:
It should be clarified how many positve reactions ocurred in volunteers 19/29 for nonanoic acid and 28/29 for decanoic acid (as mentioned in the text) or 18/29 for decanoic acid (as mentioned in the table).

4.4 1.3 Summary of Skin Irritation:
The presented in vitro data giving negative results for corrosion (TER) or positive results for irritation (EpiDerm Test) do not allow for exclusion of corrosive properties. According to "Guidance on the Application of the CLP Criteria" (2012, p.229) TER only allows a classification into Skin Corrosion Cat. 1A, whereas negative in vitro corrosivity responses must be subject to further evaluation.
Moreover, animal data obtained with nonanoic acid were used to support irritant properties of decanoic acid. Likewise, corrosive properties of octanoic acid as shown in animal studies with rabbits and in vitro (TER) should also be considered. Reduction of irritant properties with increasing chain length (as mentioned) was not shown in the dossier. On the contrary, higher or similar reactivity of decanoic acid was reported from human patch tests compared to nonanoic acid in the dossier (Jirova et al. 2008).

Dossier Submitter's Response

Human information: thank you the typing error in the table needs to be corrected: 28/29 positive reaction in humans is correct
For these carbonic acids irritation is at the borderline of classification to corrosion and many data are available. Therefore this evaluation is difficult and needs a WoE approach. We are convinced to have transparently summarized the available data and made a scientifically supported proposal. It is on RAC to take a decision.

RAC's response

Noted. Please see response to comment 1.

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Belgium	Oleon NV	Company-Manufacturer	12
Comment received				
*ECHA comment: The document **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_DECANOIC_C10_final_final.pdf** was submitted as a separate attachment. Attachment no. 1.Skin corrosion/irritation was copied below.* Skin corrosion/irritation **FAC conclusion** The companies of FAC agree with the classification and labelling for the undiluted decanoic acid on skin irritation that is proposed in the CLH dossier, Page 6. *End of Skin corrosion/irritation of attachment no. 1*				
Dossier Submitter's Response				
Thank you for your review.				
RAC's response				
Noted. Please see response to comment 1.				

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Germany		Company-Manufacturer	13
Comment received				
see confidential attachment *ECHA comment: The document **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_DECANOIC_C10_final_final.pdf** was submitted as a separate attachment and claimed confidential. Attachment no. 7.*				
Dossier Submitter's Response				
Without further information this document cannot be considered as confidential. It does not contain any information that is subject to data protection.				
RAC's response				
Noted.				

Eye hazard

Date	Country	Organisation	Type of Organisation	Comment number
19/07/2012	Spain		MSCA	15
Comment received				
p.33 Summary and discussion of eye irritation The Spanish CA supports the Austrian proposal for a classification for decanoic acid as 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. In the only available publications (Briggs, 1976 and Smith, 1962) severe eye irritation lesions were observed in ocular irritation studies with octanoic acid. The Spanish CA considers that decanoic acid should be classified for severe risk damage to the eye.				
Dossier Submitter's Response				
Thank you for your review.				
RAC's response				
Please see response to comment 1.				

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Belgium	Oleon NV	Company-Manufacturer	16

Comment received

*ECHA comment: The document **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_DECANOIC_C10_final_final.pdf** was submitted as a separate attachment. Attachment no. 1.Serious eye damage/eye irritation was copied below.*

Serious eye damage/eye irritation

Discussion of available data on serious eye damage/eye irritation

Two publications [1, 2] are available regarding the eye irritation for decanoic acid, indicating the potential of severe eye effects. Decanoic acid reached a score 9 from 10 for corneal necrosis according to the applied scoring system by Smyth et al. (1962) [1]. However, the applied scoring system is not applicable for classification purposes in the EU as it cannot be transferred into the Draize Scoring system as required for assessment according to OECD guideline 405. Furthermore, there is no information on the reversibility, nor on the reading time points and no other details were reported. In the publication from Briggs et al. (1976), the only information given is, that decanoic acid caused corneal opacity and moderate conjunctivitis in rabbits, which did not subside within 72 hours [2]. The results of both studies are considered not be sufficient for a classification assessment.

FAC conclusion
Currently no **reliable** data for self-classification is available. 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.

End of Serious eye damage/eye irritation of attachment no. 1

Dossier Submitter's Response

No new data on eye irritation are available to the RMS. We cannot comment on this.

RAC's response

Please see response to comment 1.

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Germany		Company-Manufacturer	17

Comment received

see confidential attachment

*ECHA comment: The document **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_DECANOIC_C10_final_final.pdf** was submitted as a separate attachment and claimed confidential. Attachment no. 7.*

Dossier Submitter's Response

Without further information this document cannot be considered as confidential. It does not contain any information that is subject to data protection.

RAC's response

Noted.

Specific target organ toxicity – single exposure

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

Comment received

p.34 Summary and discussion of respiratory tract irritation
There are not enough data in the acute inhalation toxicity studies (no clinical signs available) to confirm respiratory tract irritation. In the DAR (2007) respiratory tract irritation was observed in an acute inhalation study made with the formulate NEU 1128 I (mixture of potassium salts of fatty acids). Moreover in the DAR (2007) was proposed a classification for free fatty acids wit C ≥ 9 of Xi;

R36/37/38.
A more in depth and detailed evaluation on the respiratory tract irritation potential of decanoic acid could be conducted by RAC.

Dossier Submitter's Response

Thank you for your review. In case human data are necessary for STOT RE 3 classification we would not expect that further relevant information can be summarized here.

RAC's response

The available information does not allow evaluation of respiratory tract irritation. Since the melting points and boiling points of the three organic acids are relatively high (octanoic acid: MP 16.7 °C, BP 239.7 °C; nonanoic acid: MP 12.5 °C, BP 254 °C; decanoic acid: MP 31.6 °C, BP 269 °C) a significant inhalation exposure, which may lead to respiratory irritation, seems to be unlikely.
Based on the information on the three organic acids and considering their close structural and physical similarities, RAC does not propose classification of decanoic acid as a respiratory irritant.

Hazardous to the aquatic environment

Date	Country	Organisation	Type of Organisation	Comment number
02/08/2012	United Kingdom		MSCA	20

Comment received

Under REACH, decanoic acid (C10H20O2) is considered as part of a category approach with analogues such as heptanoic acid (C7H14O2) octanoic acid (C8H16O2) and nonanoic acid (C9H18O2). A consolidated set of all available ecotoxicity data would be useful to understand the read-across, its validation and classification. At present not all relevant data is included in the dossier and it appears some analogue data is potentially conflicting.

We think the decanoic acid data (algal and chronic Daphnia) that was read-across to the octanoic acid classification proposal should be assessed for the decanoic acid classification proposal. [The same points we have raised in our comments for the octanoic acid dossier for these data should be addressed here.]

Dossier Submitter's Response

The intention of the submitter of the CLH-report on decanoic acid was to initiate a harmonised C&L for decanoic acid, which is important under the biocides regime. We realise that in fact some data relevant for read across were not included in the CLH report. We apologize for that and hope we have done a better job this time.

In order to enable read across with other medium chain fatty acids the submitter now provides 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.

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

fish LC_{50} (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 EC_{50} (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_rC_{50} (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)*
heptanoic acid (C 7): 60 mg/L (CSR on nonanoic acid, *Pseudokirchnerella subcapitata)*

2) **Summary of chronic toxicity data for all three trophic levels available from CARs on octanoic, nonanoic and decanoic acid and CSRs on nonanoic and octanoic acid:**

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, *Danio rerio)*
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 ant non-lethal effects, *Oncorhynchus mykiss*)

crustacean NOEC (21d):
decanoic acid (C 10): 0.2 mg/L (CSR on octanoic acid, nominal, semi static, based on reproduction, *Daphnia magna)*
nonanoic acid (C 9): 9.93 mg/L (CLH report on nonanoic acid, mean measured, based on reproduction and mortality, *Daphnia magna);*
heptanoic acid (C 7): 18 mg/L (CSR on nonanoic acid, based on reproduction, static, *Daphnia magna);*

algae NOE_rC (72 h):
decanoic acid (C 10): 0.57 mg/L was recalculated with **0.25 mg/L** (CLH report on decanoic acid, mean measured, *Scenedesmus subspicatus*); (reference is made to comment number 22)
nonanoic acid: (C 9) 0.57 mg/L (CLH report on nonanoic acid, mean measured, *Scenedesmus subspicatus*); **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);
octanoic acid (C 8): 0.07 mg/L (CSR on octanoic acid, meas. TWA, *Pseudokirchnerella subcapitata*). 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 (LOQ =0.008 mg/L) 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.
heptanoic acid (C 7): 29 mg/L *(*CSR on nonanoic acid; static, *Pseudomkirchnerella subcapitata)*

According to the comments from FAC a new chronic daphnia study with decanoic acid is in progress and should be completed in October 2012 (ref. to comment number 22).

Conclusion:
Based on (hopefully) all available data for decanoic acid and read across to other medium chain fatty acids for those endpoint for which no data for decanoic acid are available the dossier submitter is of the opinion that the proposed C&L for the environment should stay as presented in the CLH report (N; R51/53, according to DSD and Aquatic Chronic 3, according to CLP).

RAC's response

RAC agrees with the DS proposal, taking into account the deficiencies of the test submitted under REACH registration and the new test submitted by the industry and the justified use of measured concentrations in the algae tests conducted on nonanoic and decanoic acids
New Daphnia test:
The NOEC ≥1.3 mg/L (TWA) supports the conclusion that Daphnia is not the most sensitive species.

This new test does not affect the classification. This conclusion is also applicable to octanoic acid if a read-across from decanoic acid is used as a worst case scenario, providing NOEC values higher than 1 (NOEC (octanoic acid) >1.09 mg/L).

Date	Country	Organisation	Type of Organisation	Comment number
03/08/2012	Belgium		MSCA	21

Comment received

Based on the results of the aquatic toxicity test (most sensitive species : algae with 72hEC50=2mg/l, 72hNOEC=0.57mg/l) the fact that the substance is rapidly degradable (92% degradation within 28d), it is justified to classify, following the classification criteria of the 2nd ATP, as Aquatic Chronic 3, H412.

Based on the classification and labelling criteria in accordance with dir. 67/548/EEC, LC50 between 1 en 10 mg/l, log Kow>3, decanoic acid should be classified as N, R51/53.

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

Dossier Submitter's Response

Thank you for your support.

RAC's response

RAC agrees with the DS proposal, however, the log kow may be an unreliable predictor of bioconcentration potential for this substance (surface active substance) and it is not appropriate to compare it with the classification criteria. No measured BCF data are available for decanoic acid itself. The C_{12} analogue lauric acid is more hydrophobic than octanoic acid, so a direct read across of its measured fish BCF is likely to be a worst case scenario approach. The implication in the absence of any further evidence is that the BCF of octanoic acid is below 500 L/kg, but it cannot be ruled out that the BCF is above 100 L/kg.

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Belgium	Oleon NV	Company-Manufacturer	22

Comment received

*ECHA comment: The document **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_DECANOIC_C10_final_final.pdf** was submitted as a separate attachment. Attachment no. 1. Environmental hazards was copied below.*

CLH proposal:
Aquatic chronic toxicity category 3; H412 = Harmful to aquatic life with long lasting Effects

According to the CLH dossier decanoic acid CAS 334-48-5, is proposed to be classified as Aquatic Chronic toxicity, category 3 (N, R51/53).

FAC proposal:
No classification due to new data

Data relevant for the classification of decanoic acid, CAS No. 334-48-52:

Endpoint	Fatty Acid Consortium	CLH
Biodegradation	RA from lauric acid readily [3]	Readily [10]
Bioaccumulation	BCF 225 L/kg [4]; statement: no bioaccumulation	log Kow 4.09; BCF 597.72 (calc. EPI Suite); statement: no bioaccumulation
Acute aquatic toxicity:		
fish (LC50)	> 16 mg/L [5]	RA from octanoic acid 81.2 mg/L [11,12]
daphnia (EC50)	> 21 mg/L [6]	16 mg/L [13]
Algae (EC50)	15 mg/L [7]	2 mg/L [14]
Chronic aquatic toxicity:		
fish (NOEC)	no data	no data
daphnia (NOEC)	Current data in CSR 2012: 0.2 mg/L [8] New data in the update CSR (in progress): No effect on reproduction observed up to the highest test concentration (2 mg/L nominal, 0.6 mg/L measured) (RA from decanoic acid) [9]	no data
algae (NOEC)	3.2 mg/L [7]	0.57 mg/L [14]

DSD classification

General rule for R51/53

Acute toxicity (Algae or fish or daphia) 1 - 10 mg/L
AND
not readily biodegradable OR log Pow ≥ 3 (experimental BCF ≤ 100)

CLH Proposal: N, R51/53

The CLH dossier proposes a DSD classification in accordance with directive 67/548/EEC as N,R51/53, based on the lowest short-term value of 2 mg/L in combination with bioaccumulation potential, derived from a log Kow of 4.09 (EPI Suite).

The Fatty Acids Consortium (FAC) considers the assessment of bioaccumulation potential based solely on the log Kow inappropriate for fatty acids, which occur naturally in all aquatic organisms and are ubiquitous in the aquatic environment, where they are readily biodegraded by microorganisms. The log Kow is a physico-chemical parameter, describing the partitioning of a substance between water and an organic phase. It is a good parameter for estimation of bioaccumulation where uptake and distribution are passive, that means driven by physico-chemical processes of dissolution in different media. In case where specific up-take and distribution mechanisms and a regulated metabolism are in place in the respective organism, it is not applicable for such an estimation. Short- and medium chain fatty acids (C1 - C12) are absorbed via intestine capillaries into the blood stream. In the body, fatty acids are rapidly metabolised by various routes to provide energy, stored as lipids in adipose tissue and used as precursors for signalling molecules and for the phospholipids of the cell membranes. Relevant literature is discussed in detail in the REACh registration dossier for octanoic acid.

FAC conclusion for C&L according DSD 67/548/EEC: "no classification"

In conclusion, fatty acids are considered very low risk to aquatic organisms from their bioaccumulation properties. The bioconcentration factors of fatty acids are generally of low concern.

Consequently, since all short-term values are above 1 mg/L and the substance is readily biodegradable and is not expected to bioaccumulate, it does not need to be classified according to Directive 67/548/EEC.

CLP classification

Inconsistencies of algae data reported in CLH

The CLH dossier proposes a CLP classification in accordance to Regulation (EC) No. 1272/2008 as Chronic 3, based on the NOEC of 0.57 mg/L from an algae study [14]. The Fatty Acids Consortium does not have access to this report. However, since our valid data shows a NOEC of 3.2 mg/L [7], we have good reasons to assume that the value in the CLH dossier is not reliable.

FAC Conclusion for environmental hazard (algae)

The discrepancy between the two studies (NITE, 1999 [8] and SOPURA, 2008 [14]) needs to be cleared. The Fatty Acids Consortium thus proposes to re-evaluate the available data and consequently the classification of decanoic acid.

New daphnia data provided by FAC

A long-term study conducted with Daphnia magna resulted to a NOEC of 0.2 mg/L for decanoic acid [8]. In this study, however, a solvent was used as a vehicle. Additionally, the test shows methodological deficiencies, due to which the outcome is considered ambiguous**.** Since the NITE test results [8] could not be used for pesticide registration in the USA (FIFRA, EPA) the test had to be repeated aiming at a better control of test conditions. A new longterm test (OECD 211) with decanoic acid without solvent was therefore conducted, in order to comply with global regulations for chemicals. Based on a preliminary test, a 2 mg/L concentration could be held stable under the test conditions, and 2.0 mg/L was thus used as highest test concentration. However, in the definite test, only 0.592 mg/L (TWA) was

measured of the nominal 2.0 mg/L [9]. Since no mortality and no effect on reproduction were observed at the highest test concentration, it was concluded to repeat the test for the NOEC determination under stable concentration conditions.

FAC conclusion for environmental hazard (daphnia)

Daphnia limit test is in process because the present data give no reason to expect effects to occur, and the NOEC is therefore expected to be above 1 mg/L. Test results are expected by Oct 2012 [15].

In conclusion, since the discrepancy between the two algal studies still needs to be cleared and new relevant data is expected on long-term toxicity to aquatic invertebrates, the Fatty Acids Consortium asks to postpone the decision of the harmonisation of classification of decanoic acid until both action points have been completed.

End of Environmental hazards of attachment no. 1

Dossier Submitter's Response

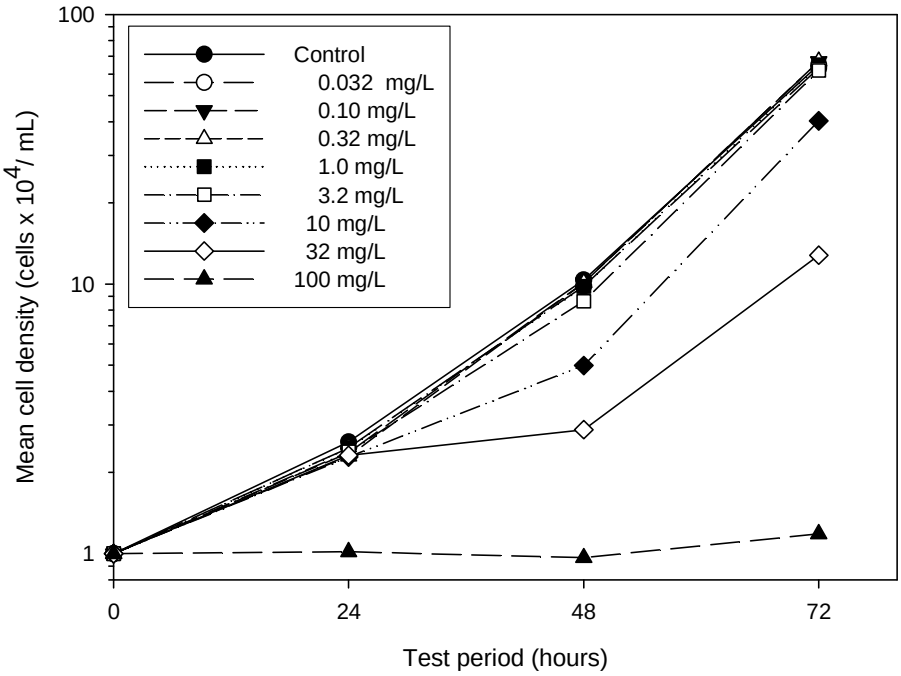
No new data on eco-toxicity and fate and behaviour are available to the RMS, therefore we cannot comment on this.

Information on algae study: (reference is also made to Doc III-A 7.4.1.3 attached to the CLH

report)

If fatty acids are used for nutrition of green algae, the growth curves should show an increase compared to the control in the time interval when the test substance is present in the test medium (in the first 24 hours). This fact cannot be observed in the 72-hour algal growth inhibition test with Decanoic acid (Bätscher, R., 2008). On the contrary, at 100 mg/L, when the test substance is present in notable concentrations during the test, a significant decrease of algal growth could be observed. (ple ase see the figure and the tables below).

Growth curves in the 72- hour algal growth inhibition test with Decanoic acid (Bätscher, R., 2008)



The table below gives the corresponding actual measured concentrations.

The measured concentrations of the test item (Decanoic acid) during the test period can be summarized as follows: Nominal test item concentration in mg/L	Measured concentration (mg/L)			
	0 h	24 h	48 h	72 h
3.2	2.9	< LOQ *	< LOQ *	< LOQ *
10	9.4	5.5	< LOQ *	< LOQ *
32	30	28	< LOQ *	< LOQ *
100	96	93	90	7.4

*below the limit of quantification (LOQ) of 0.22 mg/L

Therefore the argument that fatty acids are used for nutrition of green algae in relevant amounts cannot be confirmed. The observed effects are not caused by a metabolic adaption phase with little growth but by disruption of the cell membrane with subsequent destruction of photosynthesis mechanisms and other membrane bound physiological processes. Finally, an uncontrolled leakage of cell content occurs. The plant tissue is destroyed visibly within 24 hours after treatment. Severe necrosis of treated plant parts can be observed (Review report for the active substance Fatty acids C_7 to C_{20} in view of the inclusion in Annex I of Directive 91/414/EEC, 2008). For this reason, fatty acids are also used as herbicides. The delayed appearance of effects can be explained by the fact that the

plant tissue is destroyed within 24 hours after treatment and not as a lag-phase for re-adaptation to the autotrophic mode. The supposition that a lack of nutrition causes the effects seen in the test cannot be confirmed. Therefore the nominal values are not relevant for C&L purpose.

As the test substance was not detectable at the end of the test, a duration of 48 h might be regarded as relevant time interval. However, in the 72- hour algal growth inhibition test with Decanoic acid (Bätscher, R., 2008), the following validity criterion given in OECD guideline 201 (2006, 2011) is not fulfilled: "The test period may be shortened to at least 48 hours to maintain unlimited, exponential growth during the test as long as the minimum multiplication factor of 16 is reached". In case of the algae test with Decanoic acid it is only a factor of approximately 10 (see table below, cell concentration data). So the total test duration of 72 h has to be used for effect investigation and to estimate chronic effects.

The cell concentration data of the test with Decanoic acid are given in the table below.

Test-Substance nominal/[mg/l]	**Cell concentrations (mean values) [x 10^4cells/ml]**							
	Measured				**Percent of control**			
	0 h	**24 h**	**48 h**	**72 h**	**0 h**	**24 h**	**48 h**	**72 h**
Control	1.0	2.6	10.3	65.0	-	-	-	-
0.032	1.0	2.5	9.8	63.3	100	96	95	97
0.10	1.0	2.4	10.1	66.9	100	92	98	103
0.32	1.0	2.3	10.1	67.0	100	88	98	103
1.0	1.0	2.5	9.8	65.0	100	96	95	100
3.2	1.0	2.4	8.6*	62.0	100	92	83*	95
10	1.0	2.3	5.0*	40.3*	100	88	49*	62*
32	1.0	2.3	2.9*	12.8*	100	88	28*	20*
100	1.0	1.0*	1.0*	1.2*	100	-*	-*	-*

*significantly lower than control

The test in algae shows a dose response inhibition of growth rate with a NOEC significantly different from control at nominal 3.2 mg/L.

For the growth inhibition rates of the test with Decanoic acid please see the table below.

Growth rates μ and percentage inhibition of μ (I_μ) during the test period Nominal test item concentration	Growth rate μ and % inhibition of μ					
	0-24 h		0-48 h	0-72 h		
(mg/L)	μ (1/day)	I_μ (%)	μ (1/day)	I_μ (%)	μ (1/day)	I_μ (%)
Control	0.95	0.0	1.17	0.0	1.39	0.0
0.032	0.90	6.0	1.14	2.3	1.38	0.7
0.10	1.09	-14.5	1.27	-8.9	1.48	-6.2
0.32	0.83	12.9	1.16	1.0	1.40	-0.7
1.0	0.90	5.5	1.14	2.3	1.39	0.0

3.2	0.87	9.0	1.08	7.7	1.38	1.1
10	0.82	13.8	0.80 *	31.3	1.23 *	11.6
32	0.84	12.0	0.53 *	54.7	0.82 *	41.0
100	0.02 *	98.3	-0.02 *	101.6	0.05 *	96.2

*significant different to control

At the relevant concentration for the NOEC (3.2 mg/L), analytical results showed that the measured concentrations were below the limit of quantification after 24, 48 and 72 h test duration. Therefore the NOEC of this study was 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 $NOEC_{72h}$ of this algae study was recalculated with 0.249 mg/L.

Conclusion on environmental hazards (algae):

No new data are available to the submitter, therefore we cannot comment on this.

We cannot follow the conclusion drawn by FAC. There are algae NOE_rC (72 h) values available for heptanoic (C 7), octanoic (C 8), nonanoic (C 9) and decanoid acid (C 10) with 29 mg/L, 0.07 mg/L, 0.57 mg/L and 0.25 mg/L, respectively (reference is also made to the information on mode of action of medium chain fatty acids on plant cells, and their use as algicides and herbicides, see **Information on algae study** above).

For decanoic acid this justifies a classification with Aquatic Chronic 3.

Information on chronic daphnia toxicity study:

The chronic Daphnia magna test resulted in a NOEC of 0.2 mg/L (nominal). A solvent was used in the study, but this was done in accordance with OECD guideline 211.

Nominal concentrations used in the test were 0.2, 0.64 2.0, 6.4 and 20 mg/L. For the 3 lowest concentrations no TWA could be established, since the measured concentrations were below the limit of detection (LOD =0.01 mg/L). Already at a concentration of 0.64 mg/L (nominal) a significant inhibition was detected. Therefore The NOEC was set to 0.2 mg/L (nominal).

Having also in mind the chronic daphnia values for nonanoic and heptanoic acid with 9.93 mg/L and 18 mg/L, respectively it may be reasonable to await the outcome of the new study from FAC.

Nevertheless a chronic daphnia NOEC >1 mg/L won't change the classification of decanoic acid seen the NOE_rC values for algae for all fatty acid analogues.

Overall conclusion:

The dossier submitter is of the opinion, that the C&L proposal for decanoic acid for environmental hazards in the CLH-report with N; R51/53, according to DSD and Aquatic Chronic 3, according to CLH, is appropriate.

RAC's response

RAC agrees with the DS proposal and with the interpretation that the observed effects are not caused by a metabolic adaption phase with little growth. Therefore the use of measured concentrations is justified.

New Daphnia test:
The NOEC ≥1.3 mg/L (TWA), supports the conclusion that Daphnia is not the most sensitive species, This new test is not going to change the classification.

Date	Country	Organisation	Type of Organisation	Comment number
06/08/2012	Germany		Company-Manufacturer	23

Comment received

see confidential attachment

*ECHA comment: The document **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_DECANOIC_C10_final_final.pdf** was submitted as a separate attachment and claimed confidential. Attachment no. 7.*

Dossier Submitter's Response

You are kindly asked to refer to our answer to comment number 22.

RAC's response

RAC agrees with the DS proposal taking into account the deficiencies of the test submitted under REACH registration for octanoic acid and the justified use of measured concentrations in the algae tests conducted with decanoic acid.

REFERENCES: None

ATTACHMENTS RECEIVED: 7

1. **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_DECANOIC_C10_final_final.pdf,** submitted by Belgium/ Company-Manufacturer
2. **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_DECANOIC_C10_final_final.pdf,** submitted by United Kingdom / Fatty Acid Consortium/Company-Manufacturer.
3. **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_DECANOIC_C10_final_final.pdf,** submitted by Netherlands / Wilmar Europe Trading BV / Company-Importer.
4. **FAC Comments on CLH of decanoic acid - 04.08.12.pdf,** submitted by Switzerland / Company-Downstream user

Confidential attachments : 3

5. **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_NONANOIC_C10_final for submission.pdf,** submitted by Denmark/ Individual. Confidential attachment.
6. **20120806_FAC_COMMENTS_on_CLH_DECANOIC_C10_final.pdf.** Submitted by Germany / Company-Manufacturer. Confidential attachment.
7. **20120806_FATTY ACIDS CONSORTIUM_COMMENTS_DECANOIC_C10_final_final.pdf,** Submitted by Germany/Company-Manufacturer. Confidential attachment.

ECHA note: The attachment no.1-7 are identical in contents.