Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

Opinion

proposing harmonised classification and labelling at EU level of

bis(α,α-dimethylbenzyl) peroxide

EC Number: 201-279-3
CAS Number: 80-43-3

CLH-O-0000001412-86-217/F

Adopted

8 June 2018

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON BIS(α,α -DIMETHYLBENZYL) PEROXIDE

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the public consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the public consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties.

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Substance name: bis(α,α-dimethylbenzyl) peroxide
EC number: 201-279-3
CAS number: 80-43-3
Dossier submitter: Norway

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
03.08.2017	Belgium		MemberState	1
Comment received				
BE CA would like to thank the Norwegian Environment Agency for this proposal for harmonized classification and labelling. As a general comment, we regret the absence of evaluation of adverse effects on sexual function and fertility, probably due to a lack of data and which might have support the classification for bis(α,α-dimethylbenzyl) peroxide.				
Dossier Submitter's Response				
The NO CA thanks the BE CA for the comment. We agree that evaluation of adverse effects on sexual function and fertility would have been useful, but as you rightly point out the reason for the lack of evaluation is because there was no such data. We can however add in this respect that the 90-day study did not show any effects on reproductive organs or parameters, i.e. estrous cycle, sperm examination, organ weights etc.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
03.08.2017	Germany		MemberState	2
Comment received				
We agree that the current classifications of bis(a,a-dimethylbenzyl)peroxide as Skin Irrit. 2 and Eye Irrit. 2 are not justified and could be removed. Regarding reproductive toxicity, there are developmental effects and these are not correlated with maternal toxicity when analysed on an individual basis. Therefore in our opinion classification of bis(a,a-dimethylbenzyl)peroxide as Repr. 2 (H361d) is justified and in accordance with the CLP guidance. However, the effects may be a borderline case to category 1B.				
Dossier Submitter's Response				
The NO CA would like to thank the DE CA for their comment and support. Concerning that				

the effects could be borderline 1B, please see our response to the NL CA comment below (comment number 6) with additional data.
RAC's response
RAC concluded that classification as Repr. 1B for developmental toxicity is warranted. The reasons are given in the opinion.

TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
31.07.2017	France		MemberState	3
Comment received				
FR agrees with the classification proposal of the dossier submitter. P14: it seems that there is a mistake concerning the reference to the figure 2 of the annex. This figure refers to the correlation between dam's body weight and malformations, and not between dam's body weight and clinical signs. Consequently, is the statement that the reduction in both food intake and body weight gain alone could not explain the observed clinical signs and necropsy findings still correct?				
Dossier Submitter's Response				
The NO CA would like to thank the French CA for their comment and support. Concerning the reference to figure 2 on page 14 in the report, this reference is to figure 2 in the confidential annex, not the annex that is open to the public. We see that this could be a bit confusing and we should probably have underlined the word confidential, or named the figure otherwise, in order for it to be clearer.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
03.08.2017	Belgium		MemberState	4
Comment received				
BE CA supports the Repr. 2 (H361d) classification proposal for bis(α,α-dimethylbenzyl) peroxide as a suspected human reproductive toxicant. The fetal toxicity after a 450 mg/kg bw/d bis(α,α-dimethylbenzyl) peroxide (LOAEL) exposure resulted in major alterations, including a statistically significant increase in post-implantation loss and total intrauterine mortality, but also an increase in percentage of fetuses with decreased body weight and major skeletal variation and/or malformations in up to 12/17 litters (mainly through incomplete ossification). Regarding those observations, clinical signs of maternal toxicity were quite lower, concerning only 4/17 dams (including a deceased dam, salivation being rejected as an adverse effect) for the same concentration exposure. Necropsy findings on dams showed especially enlarged adrenals, blood in uterus and more general effects (enlarged spleen, stomach distended, pale liver and kidneys) in up to 4/17 dams. Thereby, when comparing fetal and maternal toxicity, we can reasonably presume that the developmental toxicity is not secondary to maternal toxicity. Moreover, the weight of evidence provided by the re-evaluation of the prenatal developmental toxicity study (BSL Bioservices) and a non-guideline embryotoxicity study on white leghorn chicken embryos (Korhonen et al., 1984) let us conclude that bis(α,α-				

dimethylbenzyl) peroxide should be classified as a human reproductive toxicant. Although, the classification proposal being based on a single guideline developmental toxicity study (reliability 1), the category Repr. 2 (H361d) seems to be the most appropriate.
Dossier Submitter's Response
The NO CA would like to thank the BE CA for their comment and support.
RAC's response
Noted. Thanks for the comment regarding repr.dev.tox. We agree that there is a concern related to the dev.tox. RAC concluded that classification in Cat. 1B for developmental toxicity is warranted. Whether the intrauterine mortality incl. post implantation loss, is a direct consequence of the dosing or second to maternal toxicity has been considered by RAC.

Date	Country	Organisation	Type of Organisation	Comment number
04.08.2017	Germany	PERGAN GmbH	Company-Manufacturer	5
Comment received				
The Norwegian Environment Agency proposed to classify Bis(α,α-dimethylbenzyl) peroxide for reproductive toxicity (Repr 2; H361d). The proposal is based on one prenatal developmental toxicity study in rats (OECD 414). The findings of developmental toxicity are limited to the high dose group and no clear dose-response is observed over the range of the three dose groups. In addition, marked maternal toxicity is apparent at the high dose group and may account for the foetal toxicity. Bis(α,α-dimethylbenzyl) peroxide was administered to 24 pregnant female Hsd. Brl. Han: WISTAR rats per dose by oral gavage at dose levels of 0, 50, 150 and 450 mg/kg bw/day from day 5 through 19 of gestation. The highest administered dose elicited pronounced maternal toxicity, including death, piloerection, reduced activity, coldness, paleness, vaginal bleeding and hypotonicity, enlarged adrenals and spleen and blood in the uterus, markedly reduced food consumption, lower body weight, markedly reduced body weight gain and weight loss as well as markedly reduced corrected body weight and body weight gain. Effects of the highest dose on fetuses included increased post implantation loss (and lower number of viable foetuses), a decreased foetal weight, an increased percentage of foetuses with body weight retardation, malrotated fore- and hindlimbs as well as skeletal malformations of the pectoral girdle and extremities, increase of skeletal variations and placentas with dark brownish discoloration or fibrinoid degeneration. The foetal effects have been considered secondary to the marked maternal toxicity and would not support classification as Repro 2. In addition, ECHA currently undergoes a testing proposal examination related to a PND study in the rabbit as second species. We would recommend to discuss any potential effect on teratogenicity when the results of this study are available in the course of next year.				
Dossier Submitter's Response				
Thank you for your comments. As described in the CLH report and annex, we do not agree that the foetal effects may be regarded as secondary to maternal toxicity. In our view, the findings fulfill the criteria for classification as at least Repr. 2 with regard to the developmental effects. We think the data is already sufficient for a harmonized classification and that testing in a second species is unnecessary.				
RAC's response				
RAC noted that the DS has analysed the individual data for dam toxicity and correlated them with the foetal effects. However, RAC considered whether the observed data on maternal toxicity are sufficient to describe maternal toxicity or not. Only clinical observations and necropsy data are available. Nethertheless, the skeletal malformations observed are considered as specific malformations, which cannot be explained only by				

weight loss and the other effects seen in mothers.

Date	Country	Organisation	Type of Organisation	Comment number
31.07.2017	Netherlands		MemberState	6

Comment received

The provided developmental study in rats shows a clear increase in intrauterine mortality and skeletal malformations in the presence of maternal toxicity at the highest dose level. The comparison of the individual dam/litter data between maternal toxicity and fetal toxicity does not show a correlation. The absence of a correlation suggests that the observed developmental toxicity is not secondary to the maternal toxicity. The severity and incidence of the observed effects especially the high level of intrauterine death is considered severe enough to justify Cat 1B. Could you also add the individual data of the intrauterine mortality and absolute maternal body weight in the confidential Annex? In addition, there is some indication of effects in the mid dose with a non-significant increase in bent or short scapula in line with the high dose level. Is there information from historical controls that this is outside the normal range? This would support classification in Cat 1B seen the very limited maternal toxicity at this dose level. The necropsy finding in the dams included some effects on the uterus which could be considered secondary to the increase in intrauterine mortality. Was there a correlation between these two parameters showing that uterine effects were only observed in dams with an increase in intrauterine mortality? Further, the observed maternal clinical and necropsy findings could be compared to the results of the repeated dose studies to determine whether the effects are consistent or may be related to the exposure of pregnant animals. Overall, the requested additional information is needed to assess the correct classification as either Cat 2 or 1B.

Dossier Submitter's Response

The NO CA would like to thank the NL CA for their support and comments.

- The NL CA has asked for the individual data for:
  - Intrauterine mortality: see confidential annex to the RCOM
  - Absolute maternal body weight: see confidential annex to the RCOM

- Scapula, bent and/or short, malformation, compared to historical control data:

The NL CA asks whether the increase in bent and/or short scapula in the foetuses of the mid-dose are within historical control.

There are historical control data available and they seem robust as they are from the same laboratory, same strain of rats and the data are approximately from the same period of time (2009-2012) as the study (2013). For your information we have included the relevant historical control data in the confidential annex.

The incidence of bent and/or short scapula (malformation) in the foetuses in the study were the following:

Pectoral girdle					
- Scapula bent and/or short	N %	0 0	0 0	3 3	12 ** 16

In the historical control data the closest endpoint that covers "bent and/or short scapula" as a malformation is "pectoral girdle, forelimbs: scapula and/or humerus and/or radius, ulna malformations". This endpoint has a mean percentage of 0.55 % and range of group means

of 0-5.1 %. It is difficult to compare these figures as they do not completely cover the same effects, and the figures in the historical control data cover more effects than only "bent and/or short scapula". It is also worth noting that there is quite a difference between the mean (0.55%) and the range high (5.1%), which could be an indication that the 5.1% result is an outlier, however this is not possible to verify without asking the performing laboratory for more information.
From the facts we have available to us we can say that the incidence of "bent and/or short scapula" in the mid-dose is above the historical control data when compared to the mean percentage, but may be within when compared to the ranges, depending on whether the percentage of 5.1% refers to the incidence of bent and/or short scapula, or some other malformation. The incidence in the mid-dose does seem to indicate a degree of dose-response over the range of doses as the incidence in the control and low-dose group is 0.

- Effects on uterus, secondary to increase in intrauterine mortality:

The NL CA asks whether there is a correlation between the two parameters showing that uterine effects were only observed in dams with an increase in intrauterine mortality.

We have included in the confidential annex to the RCOM a table of the macroscopic findings in the individual dams in the high-dose group. Comparing these data to the data for intrauterine mortality (also included in the annex) there seems to be no correlation between effects in the uterus and intrauterine mortality.

Effects in the uterus were seen in 5/18 high-dose dams and are described as: blood in the uterus (2/18), blood in uterine horn (1/18), uterus filled with blood (1/18) and blood in vaginal orifice (1/18).

Six of the dams has total intrauterine mortality above 45 %. Of these only one had effects in the uterus (blood in uterus), however most of the intrauterine mortality seen in this dam was due to pre-implantation loss. Five dams had post-implantation loss above 20%. None of these had effects in the uterus.

One of the dams with effects in the uterus was the dam that died (of unknown reasons and on the day of scheduled necropsy), but she had 11 viable foetuses at the time of death and only one pre-implantation loss.

The three other dams with effects in the uterus had intrauterine mortality lower than 25 %.

- Comparison of maternal clinical and necropsy findings with results in the repeated dose study.

The NL CA asks whether there are consistent findings between clinical and necropsy findings in this PNDT study and the recent 90-day repeat dose study or whether the effects may be related to the exposure of pregnant animals.

The 90-day study had the following dose levels: 20, 80 and 320 mg/kg bw/day. There were no mortalities in the study. The only clinical signs were salivation and scar/scabs. This is similar to the PNDT study however, in addition some of the dams in the PNDT study displayed other effects such as piloerection (4/18) and reduced activity/hypotonicity (3/18). In the 90-day study all effects disappeared in the recovery period.

Body weight development in the 90-day study was reduced in the male and female animals of 320 mg/kg bw/day group during the entire treatment period. The changes in body weight were only reversible in male animals. In the PNDT study there was a clear effect in body

weight development in the high- and mid-dose groups.

No macroscopic alterations were found in the 90-day study. However, some effects in kidney and liver were seen in clinical chemistry and organ weight results in the high dose group of the 90-day study. The elevated enzyme activities (ALT, GGT and TBIL) and slightly higher concentration of urea, blood urea nitrogen in males and females, and higher concentration of bile acid and inorganic phosphorous in male animals, together with the slight changes in liver and kidney weights indicates altered liver and/or kidney functions. In the PNDT some effects in liver and kidney were seen, such as pale liver and kidneys in some animals. In addition enlarged spleen and enlarged adrenals were seen in the PNDT study. This was not seen in the 90-day study.

RAC's response

Overall RAC agrees that the dose of 450 mg/kg bw/d generally induces toxicity in the dams. Not all parameters are given in the PNDT study. However, these are described in the RDT study and seem not to be marked at the highest dose group. In the RDT study the higest dose of 320 mg/kg bw/d was set according to the guideline, so it must be expected that the dose of 450 mg/kg bw/d might induce maternal toxicity.

Date	Country	Organisation	Type of Organisation	Comment number
03.08.2017	Germany		MemberState	7

Comment received

We would like to provide following observations on the information provided in the background document:
Table1 should be interpreted differently: For example information on dams with no clinical signs but with necropsy findings should be interpreted as dams with no adverse clinical signs but with necropsy findings since several dams in the relevant group show salivation and/or alopecia.

Annex I: page 14, Necropsy findings: Numbers of dams with necropsy findings relate sometimes to all dams including the one which died at GD 20. For example, counting of cases of "blood in vaginal orifice" (1), "enlarged adrenals" (5), and "enlarged spleens" (2) include the dam which died. So it should be interpreted as 1/18, 5/18, and 2/18, respectively.

Dossier Submitter's Response

The NO CA would like to thank the DE CA for their comments.

First comment: we agree that we should have included the word "adverse" in the description of the mentioned dams.

Second comment: you are right about the number of dams in the counting of necropsy findings on page 13 (not 14) of the annex to the CLH report. Thank you for noticing this mistake. The dam who died was also included in the count and the total number should therefore be 18. We see that the same mistake was made in the paragraph on clinical signs on the same page. We also noticed two other numbers that were wrong and that have now been corrected. In addition we can add that the first sentence under results and discussion, also page 13, should have been supplemented with information on the litter of the dam that died. The relevant paragraphs on page 13 should have been as follows (new text highlighted in yellow):

Results and discussion
In total, there were 23, 20, 21 and 17 evaluated live pregnant females with live foetuses at termination on gestation day 20 in the 0, 50, 150 and 450 mg/kg bw/day groups, respectively (Table 1). The one dam who died in the high dose group died on the day of scheduled necropsy and had a litter of 11 live foetuses. The dam was subject to the same examinations as the other dams, however the 11 live foetuses were not examined.

Clinical signs: No clinical observations were noted for the dams in the 50 mg/kg bw/day dose group.
The only clinical sign in the 150 mg/kg bw/day dose group was salivation, seen in four (4/21) dams. Salivation was seen in eight dams (8/18 dams) in the 450 mg/kg bw/day dose group. In both dose groups this observation was made mainly immediately after treatment and in one case before treatment. Salivation was judged to be treatment-related however, it was not considered an adverse effect.
In the 450 mg/kg bw/day dose group, piloerection, reduced activity, paleness, vaginal bleeding, hypotonicity and coldness were noted which was attributed to an effect of the test item. Other symptoms like red discoloration around the eye of one dam and alopecia (3/18 dams) were recorded, however; these symptoms were not considered adverse effects.

Necropsy findings: There were no macroscopic findings observed in the dams in the 50 and 150 mg/kg bw/day dose groups.
In the 450 mg/kg bw/day dose group, 11/18 dams had no macroscopic findings. In the remaining dams findings included enlarged adrenals (5/18), enlarged spleen (2/18), blood in the uterus (2/18), blood in uterine horn (1/18), uterus filled with blood (1/18) and blood in vaginal orifice (1/18). These findings were considered adverse and treatment related.

Only 5/18 dams (27 %) had both clinical signs and necropsy findings, while 5/18 dams (29 %) had no clinical signs and no necropsy findings.

RAC's response
Noted.

OTHER HAZARDS AND ENDPOINTS – Skin Hazard

Date	Country	Organisation	Type of Organisation	Comment number
03.08.2017	Belgium		MemberState	8

Comment received
BE CA agrees with the proposition to remove the actual skin irritation classification. We acknowledge that the criteria for classifying bis(α,α-dimethylbenzyl) peroxide as a skin irritant are actually not fulfilled. Nonetheless, the major deviation of the only study presented, as the absence of vehicle used with the test substance (a granular solid), suggests a reasonable possibility of an increased skin reaction if the substance was applied with a vehicle. Indeed, the purpose of the vehicle is to optimize the contact between the substance and the skin. Accordingly, we might reasonably assume that the dose level exposition was lower than reported. On this point, BE CA disagrees with the conclusions of the Norwegian Environment Agency saying that "with this uncertainty it seems plausible that the substance does not have enough irritant effect to fulfill the CLP criteria for skin irritation".
Dossier Submitter's Response
The NO CA would like to thank the BE CA for their support and comment. When testing solids (e.g. pulvers) the test substance should be moistened sufficiently to ensure good skin contact, so we agree with BE that the contact with the substance/exposure probaby was lower than it would have been in the right vehicle, and

that this may have masked some of the irritation potential of the substance. However, seeing the very low irritation scores in this study, in addition to very low irritation scores in the eye irritation study (which was applied with a vehicle), we believe that the substance would not have fulfilled the CLP criteria for irritation even if it had been applied with a vehicle.

The scores in the skin irritation study were as follows: at 24-72 hours for erythema (0/0,7/0,3) and oedema (0/0,3/0) which is well below the classification criteria of ≥ 2,3 - ≤ 4,0 for both erythema and oedema.

As supporting information on the irritation potential of this substance we also add the scores from the eye irritation study: at 24-72 hours for corneal opacity (0/0/0,7), iritis (0/0/0), conjunctival redness (0/0,3/0,3) and conjunctival chemosis (0/0/0), which also is well below the classification criteria (≥ 1, ≥ 1, ≥ 2, ≥ 2 for the four effects respectively).

In sum we therefore still propose to remove the classification for skin irritation.

RAC's response

RAC considers the lack of vehicle as a significant limitation of the study in this case.
In addition RAC notes that the substance is a peroxide; according to ECHA guidance on the Application of the CLP Criteria which cross refers to ECHA Guidance on IR & CSA, Chapter R7, section R.7.2.6.2 testing and assessment strategy for skin corrosion/irritation, if the substance is an organic peroxide it is considered to be a skin irritant Cat. 2.

Date	Country	Organisation	Type of Organisation	Comment number
19.07.2017	Finland		MemberState	9

Comment received

Skin irritation study in rabbits conducted with bis(α,α-dimethylbenzyl) peroxide shows that the substance has slight and reversible skin irritating effect. However, the classification criteria for Skin Irrit. 2; H315 is not met. Mean scores per rabbit at 24-72 hours for erythema (0/0,7/0,3) and oedema (0/0,3/0) are below the classification criteria (≥ 2,3 - ≤ 4,0).

FI CA supports the proposal to delete the classification of Skin Irrit. 2; H315 for bis(α,α-dimethylbenzyl) peroxide.

Dossier Submitter's Response

The NO CA would like to thank the FI CA for their comment and support.

RAC's response

Noted, see comment 8.

Date	Country	Organisation	Type of Organisation	Comment number
31.07.2017	Netherlands		MemberState	10

Comment received

The DSD legislation contained criteria for the classification of organic (hydro) peroxides for skin and eye irritation/corrosion if no data on the contrary were available. As now such data are available showing no classification is required, we agree with the proposal to remove the classification as skin and eye corrosive.

Dossier Submitter's Response

The NO CA would like to thank the NL CA for their comment and support.
RAC's response
Noted, see comment 8.

Date	Country	Organisation	Type of Organisation	Comment number
31.07.2017	France		MemberState	11
Comment received				
According to the decision logic of the CLP guidance, if the substance is an organic peroxide, it should be classified in category 2. The argumentation of the dossier submitter to declassify the substance is that the study available do not provide evidence that bis(α,α-dimethylbenzyl) peroxide induce irritation. FR disagrees with this position: we consider that the study suffers from a serious deficiency since the substance was applied in its dry form, and was not moistened. This study is not considered sufficiently robust to declassify the substance.				
Dossier Submitter's Response				
The NO CA would like to thank the FR CA for their comment. When testing solids (e.g. pulvers) the test substance should be moistened sufficiently to ensure good skin contact, so we agree with FR that in this case the contact with the substance/exposure probaby was lower than it would have been in the right vehicle, and that this may have masked some of the irritation potential of the substance. However, seeing the very low irritation scores in this study, in addition to very low irritation scores in the eye irritation study (which was applied with a vehicle), we believe that the substance would not have fulfilled the CLP criteria for irritation even if it had been applied with a vehicle. The scores in the skin irritation study were as follows: at 24-72 hours for erythema (0/0,7/0,3) and oedema (0/0,3/0) which is well below the classification criteria of ≥ 2,3 - ≤ 4,0 for both erythema and oedema. As supporting information on the irritation potential of this substance we also add the scores from the eye irritation study: at 24-72 hours for corneal opacity (0/0/0,7), iritis (0/0/0), conjunctival redness (0/0,3/0,3) and conjunctival chemosis (0/0/0), which also is well below the classification criteria (≥ 1, ≥ 1, ≥ 2, ≥ 2 for the four effects respectively). In sum we therefore still propose to remove the classification for skin irritation.				
RAC's response				
See comment 8.				

OTHER HAZARDS AND ENDPOINTS – Eye Hazard

Date	Country	Organisation	Type of Organisation	Comment number
03.08.2017	Belgium		MemberState	12
Comment received				
BE CA agrees with the proposal to remove the actual eye damage/eye irritation classification for bis(α,α-dimethylbenzyl) peroxide. We acknowledge the absence of sufficient data to validate the classification, as in the one study presented, the test substance only had a slight eye irritant effect. Furthermore, this study presented a deviation in the choice of species which has not been justified and the purity was not stated, although the results				

have been considered reliable.
Dossier Submitter's Response
The NO CA would like to thank the BE CA for their comment and support.
RAC's response
RAC consideres that stronger irritation could have occurred had the substance been applied in a lipophilic vehicle and therefore considers retaining the current classification more appropriate.

Date	Country	Organisation	Type of Organisation	Comment number
19.07.2017	Finland		MemberState	13
Comment received				
Eye irritation study in rabbits conducted with bis(α,α-dimethylbenzyl) peroxide shows that the substance has slight and reversible eye irritating effect. However, the classification criteria for Eye Irrit. 2; H319 is not met. Mean scores per rabbit at 24-72 hours for corneal opacity (0/0/0,7), iritis (0/0/0), conjunctival redness (0/0,3/0,3) and conjunctival chemosis (0/0/0) are below the classification criteria (≥ 1, ≥ 1, ≥ 2, ≥ 2). FI CA supports the proposal to delete the classification of Eye Irrit. 2; H319 for bis(α,α-dimethylbenzyl) peroxide.				
Dossier Submitter's Response				
The NO CA would like to thank the FI CA for their comment and support.				
RAC's response				
Noted, see comment 12.				

Date	Country	Organisation	Type of Organisation	Comment number
31.07.2017	Netherlands		MemberState	14
Comment received				
The DSD legislation contained criteria for the classification of organic (hydro) peroxides for skin and eye irritation/corrosion if no data on the contrary were available. As now such data are available showing no classification is required, we agree with the proposal to remove the classification as skin and eye corrosive.				
Dossier Submitter's Response				
The NO CA would like to thank the NL CA for their comment and support.				
RAC's response				
Noted, see comments 8 and 12.				

Date	Country	Organisation	Type of Organisation	Comment number
31.07.2017	France		MemberState	15
Comment received				
FR agrees with the proposal of the dossier submitter.				
Dossier Submitter's Response				
The NO CA would like to thank the FR CA for their comment and support.				
RAC's response				
Noted, see comments 4, 8 and 12.				