Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

4,5-dichloro-2-octyl-2H-isothiazol-3-one; [DCOIT]

EC Number: 264-843-8
CAS Number: 64359-81-5

CLH-O-0000001412-86-258/F

Adopted

30 November 2018

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 4,5-DICHLORO-2-OCTYL-2H-ISOTHIAZOL-3-ONE; [DCOIT]

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: 4,5-dichloro-2-octyl-2H-isothiazol-3-one; [DCOIT]
EC number: 264-843-8
CAS number: 64359-81-5
Dossier submitter: Norway

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Belgium		MemberState	1
Comment received				
BE CA has no fundamental comment on the HH part of the CLH and supports the proposed human health classification. Although the Skin Corr. 1 classification proposal is based on three different formulations, it is further supported by structural read-across. BE CA would also appreciate the findings in spleen, thymus and adrenals to be discussed for a possible STOT RE classification, including the supportive observations in the 2-generation study.				
Dossier Submitter's Response				
Thank you for your support regarding the proposed classification for health hazard. A broader discussion of findings in spleen, thymus and adrenal with regard to a potential STOT-RE classification is requested. The Dossier Submitter has the following argumentation for why we believe that no classification for STOT-RE is supported by the available data. The LOAELs for several of the RDT studies are below the limit qualifying for STOT-RE 2 classification. However, the Dossier Submitter has not proposed any STOT-RE classification mainly because local toxicity in the form of local irritation of the GI tract and reduced feed consumption appear to be the major drivers of the toxicities observed in the RDT studies. Thus, most of the observations can reasonable be regarded as secondary effects. Furthermore, the effects of DCOIT are in general dependent on concentration and not on the duration of exposure. Consequently, we have proposed to consider the local toxicity as acute toxicity, and thus classification for STOR-RE is not warranted. Some more specific considerations are given below.				

Reduced feed consumption is a likely cause of the changes observed in thymus, and this interpretation is supported by rodent[1] and dog[2] restricted feeding studies.

Increase in granulocytes in the spleen was observed at the high dose (500 mg/kg bw/day) in a rat subacute study (A6.3.1/01) and is considered likely to be related to significant GI irritation at this dose level. Similar effects on the spleen was not reported in the other RDT studies, and this effects is thus suggested to be associated with high dose administration.

Reduced pup thymus and spleen weights were reported in the two available fertility studies. These effects were supported by histopathological findings at the higher dose level in the study by Dow, and the higher dose levels were also associated with reduced body weights in both studies. Decreases in thymus and/or spleen weights were reported also at the mid doses in F1 and/or F2 pups. These findings suggests that pups might be more sensitive to the cytotoxic effects of DCOIT than adult animals and dams. The findings appear (at least partly) to be related to reduced body weight compared to control.

Lipid accumulation in the adrenal cortex was reported from 100 mg/kg bw/day, and increased absolute and relative adrenal weights were reported at the high dose (500 mg/kg bw/day) in a rat subacute study (A6.3.1/01). The effect was not reversible in the high dose group (500 mg/kg bw/day). Increase in relative adrenal weight in males was reported from 70 mg/kg bw/day in one of the two rat subchronic studies (A 6.4.1-01; 7.5.1-01), but not in the other at doses up to approximately 250 mg/kg bw/day. The effect on relative adrenal weight in the first study was not associated with histopathological findings and appears to be related to the reductions in body weight at the same doses. In the fertility study by Dow, adrenal cortex pathology (hypertrophy/vacuolization) was reported at the high dose (3200 ppm/ 235-259 mg/kg bw/day), a dose for which also reduced body weight gain and pathology of the stomach (hyperplasia and hyperkeratosis of non-glandular mucosa) were observed. In the fertility study by Thor, an increased relative adrenal weight was observed at the high dose (1050 ppm/57- 71 mg/kg bw/day) in females associated with reduced body weight. Taken together, the Dossier Submitter does not find sufficient support for direct adrenal toxicity at dose levels below 300 mg/kg bw/day in the subacute studies and at doses below 100 mg/kg/bw in the subchronic studies or in the parental generation in the fertility studies.

1. *Moriyama, T. et al. 2008. Effects of reduced food intake on toxicity study parameters in rats, The Journal of Toxicological Sciences, 33(5):537-47.*
2. *Takamatsu, K. et al., 2015. Effects of four-week feed restriction on toxicological parameters in beagle dogs. Exp. Anim. 64(3), 269–280.*

RAC's response

Thank you very much for the comment. RAC fully agrees with the DS's arguments that do not support a classification for STOT-RE on the basis of the reported effects in these organs.

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 4,5-DICHLORO-2-OCTYL-2H-ISOTHIAZOL-3-ONE; [DCOIT]

Date	Country	Organisation	Type of Organisation	Comment number
05.03.2018	Belgium	CEPE	Industry or trade association	2
Comment received				
We are submitting a document that raises the attention on the importance of that biocide active substance for dry-film preservation due to fact that the Biocide Product Regulation forbids consumer products containing a biocide substance classified as skin sensitizer above the induction threshold. ECHA note – An attachment was submitted with the comment above. Refer to public attachment CEPE input public consultation DCOIT 201803.pdf				
Dossier Submitter's Response				
We acknowledge the importance of having a variety of substances with a broad spectrum of activity for preservation of paints and wood coatings. However, considerations on the acceptance of DCOIT as a film preservation substance, are not relevant for a hazard based classification process. Classification of chemicals should be based on the intrinsic properties of the substance, not taking into consideration neither risk nor downstream consequences of the classification. The goal should be to classify the chemical based on the available data using agreed criteria, thus enable consumers to make informed choices and take individual precautions in handling of products. DCOIT has been authorised for used as a wood preservatives (PT8) and an antifouling agent (PT21) and will, in the coming years, be assessed for additional four product types (film preservative (PT7), Fibre, leather, rubber and polymerised materials preservatives (PT9), Construction materials preservatives (PT10) and Preservatives for liquid-cooling and processing systems (PT11). The discussion of DCOIT used at at film preservative in paints etc. will be taken in the appropriate fora when the evaluation of the substance for this specific use is finalised by the eCA (time limit: 12.2020). At that time, also other PT7 active substances will be discussed, and proper actions can be taken to ensure that enough effective substances are left on the market.				
RAC's response				
Thank you very much for the comment. RAC fully supports the DS's answer.				

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany		MemberState	3
Comment received				
The proposal for classification of DCOIT are generally supported. Nevertheless, we have some general remarks: The ATE values used for classification as Acute Tox. 1, H330 and Acute Tox. 4, H302 should be harmonized and included in the column "specific Conc. Limits, M-factors, ATE". Only with harmonized ATE value is it possible to classify a mixture containing DCOIT correctly for the hazard class acute toxicity. It is proposed to classify DCOIT as Skin Corr. 1, H314. The substance is also suggested to have a specific skin irritancy concentration threshold				

of ≥ 0.01 %: Skin Irrit. 2; H315: C ≥ 0.01 %.

Thus, mixtures containing DCOIT can be classified from a concentration of
- 0.01 % as Skin Irrit. 2, H315,
- 1 % as Eye Irrit. 2, H319 and Skin Irrit. 2, H315,
- 3 % as Eye Dam. 1, H318 and Skin Irrit. 2, H315,
- 5 % as Skin Corr. 1, H314 and Eye Dam. 1, H318

DCOIT is regarded as corrosive to skin. As a consequence, and in accordance with the Technical Notes for Guidance on Data Requirements (chapter 2 section 6.1.4), DCOIT was not tested in the eyes of rabbits. DCOIT is classified as corrosive to skin and serious damage to eyes is thus implicit.

The CLP Criteria Application Guide, Version 5.0 - July 2017, 3.3.2.4 "Decision on Classification" states:
"A skin corrosive substance is also classified for serious eye damage which is indicated in the hazard statement for skin corrosion (H314: Causes severe skin burns and eye damage). However, although classification for both endpoints (Skin Corr. 1 and Eye Dam. 1) is required, the hazard statement H318 'Causes serious eye damage' is not indicated on the label because of redundancy (CLP Article 27)."
Thus, DCOIT should also be classified as Eye Dam. 1, H318.

For DCOIT, a specific concentration limit is proposed for skin irritation: Skin Irrit. 2; H315: C ≥ 0.01 %.
Since a low SCL is suggested for "skin irritation", also an SCL for "eye irritation" should be considered. Otherwise mixtures are classified with regard to eye irritation only from 1 %, while mixtures with regard to skin irritation are already classified from 0.01 %.

Dossier Submitter's Response

Thank you for the useful comments.

We agree that harmonized ATE values should be established for DCOIT (and be included in the column "specific Conc. Limits, M-factors, ATE") to facilitate the classification of mixtures containing DCOIT for acute toxicity.

One acute toxicity study in mice and two in rats with oral exposure to DCOIT technical resulted in LD_{50}-values between 500 and 2000 mg/kg bw; 567 mg/kg bw in mice, 1636 mg/kg bw and between 500 and 2000 mg/kg bw in two rat studies. As severe toxicity was observed at the 500 mg/kg bw dose in Wistar rats and lethality at the 750 mg/kg bw in Crl:CD® BR (Sprague-Dawley) rats, the Dossier Submitter proposes an ATE for oral acute toxicity of 567 mg/kg bw, the mouse LD_{50}.

Acute dermal toxicity was low, above 2000 mg/kg bw.

Acute inhalation toxicity (4h exposures to mixture of aerosol and vapour) was high, and the study provided by Dow that resulted in a LC_{50} of 0.26 mg/L was considered the most reliable of the two inhalation studies available. Consequently an ATE value of 0.26 mg/L is proposed.

We agree that serious damage to eyes is indicated due to the skin corrosion. According to the CLP Criteria (3.3.2.4, July 2017), DCOIT should additionally be classified with Eye Dam. 1, H318. Furthermore, we agree that a SCL should be considered for eye irritation as the GCL for this effect (1%) for substances classified for irreversible eye effects

(Category 1) or Skin Corrosion is not considered sufficiently protective. We propose to include a SCL of 0.01% for eye irritation (Eye Irrit. 2; H319) as this is the highest non-irritating concentration identified for skin, and there are no data to suggest a lower sensitivity of the eye.

Mixtures containing DCOIT should be classified as follows:
≥ 0.01 %; Skin Irrit. 2, H315 and Eye Irrit 2; H319
≥ 3 %; Eye Dam. 1, H318 and Skin Irrit. 2, H315
≥ 5 %; Skin Corr. 1, H314 and Eye Dam. 1, H318 (H318 not to be included on the label).

RAC's response

Thank you very much. RAC disagrees with the comments above on the selection of the most appropriate acute inhalation toxicity study, the choice of the ATE by inhalation and the SCLs regarding eye and skin effects. The arguments are presented in the RAC opinion.

Date	Country	Organisation	Type of Organisation	Comment number
03.04.2018	France		MemberState	4

Comment received

According to the LOEP of the assessment report (March 2014), the temperature of auto-flammability is 264°C (not 260°C).

Dossier Submitter's Response

The value given in the CLH report is the average self-ignition temperature from the two applicants (Dow Europe GmbH & Thor GmbH), whereas the auto-ignition temperature referred in the LOEP in the Assessment Report for DCOIT in PT21 is from Dow only (Dow being the only applicant for that specific product type).

RAC's response

Thank you very much. Noted.

Date	Country	Organisation	Type of Organisation	Comment number
12.04.2018	Germany	German Paint and Printing Ink Association (VdL)	Industry or trade association	5

Comment received

DCOIT is a biocidal active substance under the BPR (Regulation (EU) No 528/2012), which is currently evaluated for several product types. DCOIT is a potent fungicide and is mainly used in paints and coatings as film-preservative (PT 7), but also as wood preservative (PT 8).

CLP classification is hazard-based and hence the actual risk of a specific application is not considered. However, the classification (e.g. setting specific concentration limits for skin sensitization) has direct consequences for the approval of active substances under the BPR, which we would like to point out. The use of DCOIT as biocidal active substance in PT 7 and PT 8 is considered as safe. However, we fear that the proposed specific concentration limit of 10 ppm would lead to a de facto ban of DCOIT in many Do-It-Yourself (DIY) applications, since typically higher concentrations are needed to achieve the desired effects (see also specific comments).

Dry-film preservation is most important for organic resin-based coatings and prevents the growth of microorganisms like algae and fungi on coated surfaces, such as the facades of buildings. Currently there are only very few substances left, which can be used as film preservatives and act as fungicides and those are also under pressure due to the CLH and BPR processes, such as Zinc pyrithion. Thus, if the number of actives available on the market is further decreasing, the film-preservation as a whole is at risk. To be effective usually a dosage of at least 100 ppm of DCOIT is needed, which is significantly above the proposed specific concentration limit of 10 ppm. Therefore, we fear that the proposed classification will have the consequence that façade paints with a functioning film-preservation might in future no longer be available for DIY applications. Hence, they can only be applied by professional painters, thus burdening homeowners with higher costs.

Functioning dry film preservation of façade paints and plasters is essential in view of sustainability of buildings thanks to enlarging renovation cycles and thermal insulation. Preventing algae and fungi growth on façades leads to retaining of water repellence, thus, maintaining long lasting effective thermal insulation of houses. For more details on the importance of dry-film preservation, we refer to the contribution of CEPE.

We remain available to provide further information.

The German paint and printing ink association (VdL) represents over 180 – mostly mid-sized – manufacturers of paints, coatings and printing inks. The VdL stands for nearly 90 percent of this industry in Germany. In 2016 the German manufacturers of paints, coatings and printing inks realized sales of ca. 8 billion euros and employed ca. 25,000 staff.

Dossier Submitter's Response

Please refer to our response to CEPE above (comment number 2).

RAC's response

Thank you very much for the comment. Noted.

Date	Country	Organisation	Type of Organisation	Comment number
12.04.2018	Switzerland	Dow Europe GmbH & Thor GmbH	Company-Manufacturer	6

Comment received

On the whole we welcome the conclusions of the Dossier Submitter with respect to classification of DCOIT for acute oral and dermal toxicity, skin and eye corrosivity and skin sensitization category 1A. However we provide in attachment further evidence and comments for consideration regarding;
1) the applicability of inhalation classification to solid substances of low volatility
2) the proposed Specific Concentration Limit for Dermal Irritation
3) the proposed Specific Concentration Limit for Dermal Sensitisation
In support of arguments made concerning point 3 above, additional confidential attachments have been provided to assist the Rapporteur and RAC in their deliberations.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Manufacturers Comments Regarding DCOIT CLH dossier.docx
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Confidential attachments for DCOIT CLH consultation.zip

Dossier Submitter's Response
See response to comments number 12 (acute toxicity), 16 (irritation) and 21 (sensitisation).
RAC's response
Thank you very much for the comment. Noted.

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany	Thor GmbH	Company-Manufacturer	7
Comment received				
On the whole we welcome the conclusions of the Dossier Submitter with respect to classification of DCOIT for acute oral and dermal toxicity, skin and eye corrosivity and skin sensitisation category 1A. However we provide comments for consideration regarding: 1) the applicability of inhalation classification to solid substances of low volatility. 2) the proposed Specific Concentration Limit for Dermal Irritation. 3) the proposed Specific Concentration Limit for Dermal Sensitisation.				
Dossier Submitter's Response				
See response to comments number 12 (acute toxicity), 16 (irritation) and 21 (sensitisation).				
RAC's response				
Thank you very much for the comment. Noted.				

CARCINOGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany		MemberState	8
Comment received				
Proposal for non-classification supported.				
Dossier Submitter's Response				
Thank you for the support.				
RAC's response				
Thank you very much for the comment. Noted.				

MUTAGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany		MemberState	9
Comment received				
Proposal for non-classification supported.				
Dossier Submitter's Response				
Thank you for the support.				
RAC's response				
Thank you very much for the comment. Noted.				

TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany		MemberState	10
Comment received				
Proposal for non-classification supported.				
Dossier Submitter's Response				
Thank you for the support.				
RAC's response				
Thank you very much for the comment. Noted.				

RESPIRATORY SENSITISATION

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany		MemberState	11
Comment received				
Indications from human case studies for the chemically similar substances MIT. But no test system available. Proposal for non-classification supported.				
Dossier Submitter's Response				
Thank you for the support.				
RAC's response				
Thank you very much for the comment. Noted.				

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany	Thor GmbH	Company-Manufacturer	12
Comment received				
Acute inhalation toxicity As manufacturer supporting the active substance DCOIT we question the relevance to the end user of labelling DCOIT for inhalation hazards based on its physicochemical properties, form placed on the market and potential inhalation exposure during normal use. The potential of inhalation exposure to DCOIT during intended, known or reasonably expected use is not foreseen. Hence, classification for acute inhalation toxicity for the technical material is not warranted. For the same reason supplementary labelling with both EUH 071 (corrosive to the respiratory tract) and STOT SE 3 (transient respiratory tract irritation and narcotic effects) is not justified and should be disregarded. Please note that Thor GmbH fully supports the detailed comments jointly prepared by the manufacturers Dow and Thor GmbH in the document "Manufacturers Comments on DCOIT CLH dossier" submitted as public attachment by Dow.				
Dossier Submitter's Response				
The classification of a substances is based on intrinsic properties of the substance and should not take into account exposure considerations (including possible use of RMM), ref. Guidance on the Application of the CLP Criteria, July 2017, 1.2.2. The classification of the active substance is not only important for the classification and labelling of the active substance (technical material), but also for classification and				

labelling of products of the active substances for which actual test results are usually not available.

We disagree with the statement that the potential of inhalation exposure to DCOIT during intended, known or reasonably expected use is not foreseen. Inhalation exposure to aersols of formulations containing DCOIT is foreseen for certain use areas (e.g. spray painting of ships hulls with antifouling paint with high pressure airless spraying). Hence, the substance should be classified for inhalation toxicity, enabling the users of the products to take individual precautions in handling of the products.

The acute inhalation studies were performed according to the OECD 403 guidelines with exposure to generated respirable aerosols and vapour. The active substance should be classified for acute inhalational toxicity based on these studies.

The effects observed in the acute inhalation toxicity tests and the 13 week repeated dose study provided by Dow are consistent with the clinical signs of respiratory irritation. According to the CLP guidance, a classification for corrosivity is generally considered to cover the potential to cause respiratory tract irritation, and the additional STOT SE 3 is thus superfluous. However, the substance shall in addition to classification for inhalation toxicity, also be labelled as EUH071: 'corrosive to the respiratory tract'.

RAC's response
Thank you very much for the comment. Noted.

Date	Country	Organisation	Type of Organisation	Comment number
12.04.2018	Switzerland	Dow Europe GmbH & Thor GmbH	Company-Manufacturer	13

Comment received
See attached comments ECHA note – An attachment was submitted with the comment above. Refer to public attachment Manufacturers Comments Regarding DCOIT CLH dossier.docx ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Confidential attachments for DCOIT CLH consultation.zip
Dossier Submitter's Response
See response to comment number 12.
RAC's response
Thank you very much for the comment. Noted.

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany		MemberState	14

Comment received
Proposal for classification supported.
Dossier Submitter's Response
Thank you for the support.
RAC's response
Thank you very much for the comment. Noted.

OTHER HAZARDS AND ENDPOINTS – Skin Hazard

Date	Country	Organisation	Type of Organisation	Comment number
12.04.2018	Switzerland	Dow Europe GmbH & Thor GmbH	Company-Manufacturer	15
Comment received				
See attached comments ECHA note – An attachment was submitted with the comment above. Refer to public attachment Manufacturers Comments Regarding DCOIT CLH dossier.docx ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Confidential attachments for DCOIT CLH consultation.zip				
Dossier Submitter's Response				
See response to comment number 16.				
RAC's response				
Thank you very much for the comment. Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany	Thor GmbH	Company-Manufacturer	16
Comment received				
Thor GmbH agrees with the proposed classification for DCOIT as Skin Corrosive category 1 based upon our study (1989). However, when following a weight of evidence approach based on all available animal and human data, we trust a more appropriate specific concentration limit (SCL) of 250 ppm can be derived for dermal irritation. Please find the detailed argumentation on the proposed SCL of 250 ppm for dermal irritation in the joint comments made by the manufacturers Dow and Thor GmbH in the document "Manufacturers Comments on DCOIT CLH dossier" submitted as public attachment by Dow.				
Dossier Submitter's Response				
The manufacturer argue that 250ppm to 350 ppm is at or near the threshold for dermal irritation in the human studies and propose a SCL of 0.025% (250ppm). The Dossier Submitter agrees that in the human patch tests studies available, slight skin irritation has been observed at concentrations of 0.025%-0.035%, and that the response to DCOIT appears to depend on solvent formulation. However, we would argue that the findings are in accordance with the observations in animal studies in which the highest non-irritating concentrations reported are in the range of 0.01% - 0.03%. Consequently, we are in favour of a SCL of 0.01%.				
RAC's response				
Thank you very much for the comment. For skin sensitisation, RAC disagrees with the DS's proposals for an SCL of 0.01% (100 ppm). Arguments are presented in the RAC opinion.				

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Belgium		MemberState	17
Comment received				
See general comments.				

Dossier Submitter's Response
See response to general comments.
RAC's response
Thank you very much for the comment. Noted.

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany		MemberState	18
Comment received				
Specific time points for the classification into subcategories 1A, B, C of the endpoint Skin corrosion were not addressed by the studies Therefore, Skin Corr. 1, H314 is supported.				
Dossier Submitter's Response				
Thank you for the support.				
RAC's response				
Thank you very much for the comment. Noted.				

OTHER HAZARDS AND ENDPOINTS – Eye Hazard

Date	Country	Organisation	Type of Organisation	Comment number
12.04.2018	Switzerland	Dow Europe GmbH & Thor GmbH	Company-Manufacturer	19
Comment received				
See attached comments ECHA note – An attachment was submitted with the comment above. Refer to public attachment Manufacturers Comments Regarding DCOIT CLH dossier.docx ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Confidential attachments for DCOIT CLH consultation.zip				
Dossier Submitter's Response				
See response to comment number 16.				
RAC's response				
Thank you very much for the comment. Noted.				

OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard

Date	Country	Organisation	Type of Organisation	Comment number
12.04.2018	Switzerland	Dow Europe GmbH & Thor GmbH	Company-Manufacturer	20
Comment received				
See atached comments ECHA note – An attachment was submitted with the comment above. Refer to public attachment Manufacturers Comments Regarding DCOIT CLH dossier.docx ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Confidential attachments for DCOIT CLH consultation.zip				
Dossier Submitter's Response				
See response to comment number 21.				
RAC's response				
Thank you very much for the comment. Noted.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 4,5-DICHLORO-2-OCTYL-2H-ISOTHIAZOL-3-ONE; [DCOIT]

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany	Thor GmbH	Company-Manufacturer	21

Comment received

We agree with the Dossier Submitter that on the basis of the animal data and principally the result of the local lymph node assay (LLNA; Thor, 2003), the appropriate classification for DCOIT is as a Dermal Sensitiser Subcategory 1A, with extreme potency (in accordance with the Guidance on the application of the CLP Criteria (version 5.0), section 3.4.2.2.5). However, when taking into account the available animal and human data (weight of evidence approach), we trust that 350 ppm is a more appropriate threshold for induction of dermal sensitisation (specific concentration limit (SCL)), compared to the default SCL of 10 ppm.

Please find the detailed argumentation on the proposed SCL of 350 ppm for skin sensitisation in the joint comments made by the manufacturers Dow and Thor GmbH in the document "Manufacturers Comments on DCOIT CLH dossier" submitted as public attachment by Dow.

Dossier Submitter's Response

The manufacturers argue that an SCL of 0.035% (350 ppm) would be most appropriate as defined in relevant human studies in which exposure to DCOIT was strictly controlled.

The Dossier Submitter has reassessed the human sensitisation data due to the manufacturers comments. In ref. A6_12_6_ref_06, 12 of 34 participants induced by 350 ppm and challenged with 250 ppm showed a moderate to strong reaction 72 hours after challenge. In ref. A6_12_6_ref_07, 14 of the 34 participants in the previous study were invited for a re-challenge study. However, only 8 participated. Of these, all the participants had a reaction in the first study ranging from mild (score 1) to marked (score 3) reactions. After re-challenge, 3 of 8 had a positive response. The manufacturers claim that of the 3 volunteers, 2 were noted also to react to the vehicle alone calling into question whether the dermal reactions in these individuals were due to the presence of DCOIT or were in fact due to the irritant nature of the vehicles used. Furthermore, the manufacturers claim that based on these finding, only 1 of 34 showed a clear and confirmed response.

The Dossier Submitter agrees that one of the participants had a positive reaction to the vehicle (ethanol), making the positive re-challenge to DCOIT questionable. Thus, 2 of 8 participant, i.e. 25%, had a positive and confirmed allergic response. Translating this figure to the 34 participants, one have to take into consideration that not all of the participants in the first study were re-challenged. In the first study, 12 of 34 (35%) participants had positive response (score≥1). Thus, it can be expected that 25% of these would show an allergic response after re-challenge, corresponding to 3 of 34 persons (9%). Thus, the manufacturers' claim of 1 of 34 reacting is not correct.

The Dossier Submitter considers that a sensitisation rate of 9% after testing DCOIT in humans at 350 ppm at induction and 250 ppm at challenge is of concern. Therefore, the Dossier Submitter does not agree that the human studies give scientific evidence to support changing the SCL from 0.001% to 0.035%.

RAC's response

Thank you very much for the comment. For skin sensitisation, RAC agrees with the manufacturers and the DS on the classification of DCOIT in category 1A for skin

sensitisation. RAC however disagrees with the DS's proposal for an SCL of 0.001% (10 ppm) and with the manufacturers for an SCL of 0.035 % (350 ppm). RAC concludes that an SCL of 0.0015% (15 ppm) is more appropriate. The arguments are presented in the RAC opinion.

Date	Country	Organisation	Type of Organisation	Comment number
12.04.2018	Germany	German Paint and Printing Ink Association (VdL)	Industry or trade association	22
Comment received				
Concerning the isothiazolinones it is expected that the implementing regulation approving the respective active substance under the BPR will contain a statement that treated articles placed on the market for use by the general public shall not contain the active at a concentration triggering classification as skin sensitizer. If the specific concentration limit for skin sensitization is lower than the threshold of efficacy of the active, the substance is de facto banned from the DIY sector. For consumer protection it is of course necessary to communicate the presence of skin sensitizing above a certain threshold. Our industry is committed to ensure a high level of consumer protection and a transparent substance declaration. This is reflected by the self-commitment of CEPE members to communicate the presence of MIT above 15 ppm and the provisions set out in the VdL directive 01. However, we want to point out that the ban of actives in DIY paints has severe socioeconomic consequences, which need to be considered.				
Dossier Submitter's Response				
Please refer to our resonse above to CEPE (comment number 2).				
RAC's response				
Thank you very much for the comment. Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany		MemberState	23
Comment received				
Based on animal (LLNA: extreme, GPMT: > 60 positive and human) data, the dossier submitter proposed classification as Skin sensitizer 1A, H317 (May cause an allergic skin reaction) and proposed a specific concentration limit of 0.001 %. Classification and SCL proposal for DCOIT are supported.				
Dossier Submitter's Response				
Thank you for the support.				
RAC's response				
Thank you very much for the comment. For skin sensitisation, RAC agrees with the German CA and the DS on the classification of DCOIT in category 1A for skin sensitisation. RAC however disagrees with the German CA and the DS's proposal for an SCL of 0.001% (10 ppm). RAC concludes that an SCL of 0.0015% (15 ppm) is more appropriate. The arguments are presented in the RAC opinion.				

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Finland		MemberState	24
Comment received				
DCOIT has been shown to be a skin sensitiser in a Local lymph node assay (LLNA) and in two Guinea Pig Maximisation Tests (GPMT). Data from human studies support that				

exposure to DCOIT can lead to sensitisation. In the LLNA study (Anon., 2003 Doc III/7.4.1), the derived EC3-level (estimated concentration value based on stimulation index of 3) was calculated from the presented LLNA data to be 0.03% (15 µg/cm2). The EC value meets the criteria for cat. 1A, according to which EC3 value should be ≤2%. In the first GPMT test (Anon., 2003 A6.1.5/01) the animals were exposed in the induction phase to three different doses (0.01%, 0.02% and 0.03%). At the lowest exposure dose 0.01% (4.4 µg/cm2), 75 % were positive at 24 hours and 55 % at 48 hours after the challenge. At both time points, 95 % were positive at 0.02% (8.8µg/cm2), and 100 % were positive at 0.03% (12.12 µg/cm2). Due to the lack of lower doses without allergic response, the GPMT is not fully con-ducted according to OECD 406. However, the response rate fulfils the criteria for Skin Sens. 1A, according to which ≥ 30% should respond positively after induction with concentration ≤ 0.1%. In the second GPMT test (Anon., 2001 Doc III/7.4.1) 60% of the animals in the treatment group were positive at 24 hours and 45% at 48 hours at an induction concentration of 5 %. Due to the use of only one exposure level, the sensitisation potency cannot be derived from this study. Based on the results from the LLNA and GMPT study, the skin sensitisation potency category for DCOIT can be determined to be "extreme". Setting the specific concentration limit (SCL) of 0.001 % for skin sensitization seems justified based on available data, which is lower than the generic concentration limit (GCL) for a skin sensitiser in category 1A. The proposed SCL would be 25-fold below the lowest tested exposure level (0.025%) inducing sensitization in human studies and might be adequately protective for DCOIT. Overall, the Finnish CA supports the proposed classification as Skin Sens. 1A, H317 (May cause an allergic skin reaction) with the SCL 0.001% (C ≥ 0.001 %) for DCOIT.
Dossier Submitter's Response
Thank you for the support.
RAC's response
Thank you very much for the comment. For skin sensitisation, RAC agrees with the Finnish CA and the DS on the classification of DCOIT in category 1A for skin sensitisation. RAC however disagrees with the Finnish CA and the DS's proposal for an SCL of 0.001% (10 ppm). RAC concludes that an SCL of 0.0015% (15 ppm) is more appropriate. The arguments are presented in the RAC opinion.

OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Single Exposure

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany		MemberState	25
Comment received				
Proposal for non-classification supported.				
Dossier Submitter's Response				
Thank you for the support.				
RAC's response				
Thank you very much for the comment. Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany	Thor GmbH	Company-Manufacturer	26
Comment received				
Please refer to above comments made for acute inhalation toxicity.				
Dossier Submitter's Response				
Please refer to our response on the comments (comment number 12).				
RAC's response				
Thank you very much for the comment. RAC fully supports the DS's answer.				

OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Repeated Exposure

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Belgium		MemberState	27
Comment received				
See general comments.				
Dossier Submitter's Response				
See response to general comments (comment number 1).				
RAC's response				
Thank you very much for the comment. RAC fully supports the DS's answer.				

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany		MemberState	28
Comment received				
Proposal for non-classification supported.				
Dossier Submitter's Response				
Thank you for the support.				
RAC's response				
Thank you very much for the comment. Noted.				

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Belgium		MemberState	29
Comment received				
BE CA supports the proposed environmental classification for DCOIT : aquatic acute 1, H400 and Aquatic Chronic 1, H410. The acute M factor of 100 is determined based on the 24hErC50 = 1.6µg/L with the algae Navicula pelliculosa. However Er C50 for Skeletonema costatum is much lower (24h ErC50= 0.48 µg/L (init. meas)). Due to the several deficiencies (lack of analytical monitoring, high variations in cell density at 24h resulting in low statistical power, very steep dose-response curve: +/- no difference between NOEC and EC50, …) described for this study in the CLH report, BE CA is of the opinion that this 24hErC50 should indeed not be used for classification purposes but reliability should be downgraded from 2 to 3, otherwise this study should be used in the weight of evidence approach and thus be used for setting the most conservative M-factor. Furthermore CLP guidance (I.4.1 unstable substances) recommends to calculate				

L(E)C50, where measured data are available for the start and end of the test, on the geometric mean of the start and the end of test. If concentrations at the end of the study are below the analytical detection limit, half the detection limit should be considered. Therefore BE CA is of the opinion that 24hErC50 for Navicula pelliculosa should be recalculated using the geom mean and using half the detection limit as end concentration of the test.

Some editorial or/and minor comments :
-Long term toxicity for fish : In Table 31 the reported NOEC in the 35d study with Zebra fish (Brachydanio rerio) (Applicant Thor) is 0.43µg/L while in the description on p100 a NOEC of 0.47µg/L is mentioned.
- Acute toxicity invertebrates : In table 31 it is mentioned that the study with Daphnia magna (Aplicant Thor) is conducted under static conditions while in the description on p101 it is mentioned as semi-static.

Dossier Submitter's Response

Thank you for your comments.

Skeletonema costatum: There are clear methodological problems with algae studies on DCOIT (and other isothiazolinones). The study is, however, only considered as additional information and is not used as the basis for the classification.

Navicula pelliculosa: Using the suggested approach to calculate the 24h ErC50 could be an option. Calculated new geomeans are shown in the table below. For the two lowest test concentrations, half the LOQ (0.8/2=0.4) is used as measured conc after 24 hours. Just looking at the data without using any EC50 calculating tool, we can see that the new ErC50 would likely be in the same order of magnitude, and would not have any impact on the proposed classification.

Measured initial conc (µg a.s./L)	Measured conc after 24h (µg a.s./L)	Geomean (µg a.s./L)	Response (% inhibition)
1.39	<LOQ	0.75	27
2.20	<LOQ	0.94	44
3.32	0.63	1.45	100
5.84	2.60	3.89	97
9.60	6.05	7.62	80

The editorial/minor comments will be amended.

RAC's response

In the *Skeletonema costatum* study the 24h cell density variability precludes the use of this endpoint for classification purposes. It is unknown for RAC, however, if the test fulfils the criterion: mean coefficient of variation for section-by-section specific growth rates < 35% which would be a reason to invalidate the test. In addition, at 24 hours the algae growth rate is lower than the established criterion 0.92 per day both for the control and solvent control.

As mentioned in the comment below, at 48h exponential growth criterion is not met. The only valid endpoint seems to be 72h, beyond 72h growth is not exponential. Considering the mode of action of DCOIT which produces the highest effect early in the test and the

points mentioned above, RAC agrees with the DS in considering the *Skelotonema costatum* study as additional information non forming the basis for classification purposes.

In relation to the use of geomean, RAC considers that the use of initial measured concentrations is a better approach due to the mode of action of isothiazolones.

Date	Country	Organisation	Type of Organisation	Comment number
09.04.2018	Finland		MemberState	30

Comment received

FI CA supports the conclusion that DCOIT is not rapidly degradable but it is potentially bioaccumulative.

In the aquatic toxicity tests of DCOIT there were difficulties in maintaining exposure concentrations during the tests due the rapid removal of DCOIT from the test systems. According to CLP Guidance page 494 "For larger data sets, preference should be given to information with Klimish score 1 (reliable without restrictions) while information with Klimisch score 2 can be used as supportive information". Thus the preference for classification purposes should be given to studies, which are reliable without restictions.

In the CLH proposal the classification is based on the lowest acute toxicity value of 24 h ErC50 1.6 µg/L and the chronic toxicity value of 24 h NOErC 0.34 µg/L for algae (Navicula pellicusa). It is unclear why this N. pelliculosa study (A7.4.1.3.a/03) is not given Klimisch score 2 as the other aquatic algae tests in the CLH proposal where difficulties to measure exposure concentrations during the tests were recorded? In the CLP Guidance, page 560, it is said that "Where instability is a factor in determining the level of exposure during the test, an essential prerequisite for data interpretation is the existence of measured exposure concentrations at suitable time points throughout the test". It is stated in the Annex 1 dossier for the active substance that establishing geometric mean concentrations is not possible due to lack of proper monitoring at the lower test substance concentrations for this study. Thus this N. pelliculosa study (A7.4.1.3.a/03) should not be considered as Klimisch score 1 (reliable without restrictions).

The classification of DCOIT should be based on key studies that are reliable without restrictions. The lowest acute toxicity with Klimisch score 1 was LC50 value of 2.7 µg/L for rainbow trout and the lowest chronic toxicity were NOEC 0.4 and 0.43 µg/L for Daphnia magna and zebra fish, respectively. These key studies result in the classification of Aquatic Acute 1, H400 with M-factor of 100 and Aquatic Chronic 1, H410 with M-factor of 100 for DCOIT as originally proposed in the CLH dossier.

Based on classification criteria FI CA supports the proposed environmental classification Aquatic Acute 1, H400 with M-factor of 100 and Aquatic Chronic 1, H410 with M-factor of 100 for DCOIT.

Dossier Submitter's Response

Thank you for your comments.

Regarding the use of RI 1 vs. RI 2 studies, we generally agree that studies with an RI of 1 should be preferred. However, the CLP guidance also opens for the use of RI 2 studies for classification purposes.

In our opinion, the N. pelliculosa study is well performed. The exponential growth criteria are fulfilled and the results are reliable, even though there are general problems with maintaining the test concentrations of DCOIT and other isothiazolinones over time. Algae seems to be the most sensitive test organisms, and we think they should be used as long as the study reports are of acceptable quality. In this case, the classification conclusions would have been the same as if we had used invertebrates or fish.
RAC's response
RAC agrees that reliability 2 studies can be also used for classification purposes. CLP Guidance indicates that "in general, only reliable information (i.e. with a Klimisch reliability score of 1 (reliable without restrictions) or 2 (reliable with restrictions)) should be used for classification purposes". The most sensitive organism is therefore used for classification. Only for larger data sets, preference should be given to information with Klimisch score 1, while information with Klimisch score 2 can be used as supporting information. RAC considers that a reliability 1 for the *Navicula Pelliculosa* test is appropriate. The test fulfils validity criteria including a growth rate higher of 0.92 per day. Losses of test substance are general for isothiazolones due to their mode of action.

Date	Country	Organisation	Type of Organisation	Comment number
05.04.2018	Netherlands		MemberState	31
Comment received				
It is agreed that DCOIT is classified as Aquatic Acute 1 and Aquatic Chronic 1, both with a M factor of 100.				
Dossier Submitter's Response				
Thank you for your support regarding the proposed classification for environmental hazard.				
RAC's response				
Thank you.				

Date	Country	Organisation	Type of Organisation	Comment number
19.03.2018	United Kingdom		MemberState	32
Comment received				
We agree that that DCOIT should be considered not rapidly degradable. Algal ecotoxicity endpoints: We agree that ecotoxicity endpoints based on initial measured concentrations should be presented. Based on the mode of action for isothiazolinones, we consider this is the most appropriate endpoint basis to most accurately consider the concentration which induces the observed algal growth inhibition. Overall, we do not consider the CLH presents sufficient detail to consider the most appropriate classification endpoints. Please can you consider the following points? Sindermann A.B., Kendall T.Z. and Krueger H.O., 2007 (Navicula pelliculosa)				

- The 24-h endpoints (ErC50 1.6 µg/l and NOErC 0.34 µg/l) are presented in the CLH as based on 'initial measured concentrations'. Please can you confirm if these are based on initial or mean measured concentrations as the NOEC value does not appear to match the 0h measured concentrations presented in the DocIIIA (Directive 98/8/EC on the placing of Biocidal products on the market).
- Please can you confirm the study NOErC values? From the DocIIIA, it looks like growth rate effects were seen in all treatments at 24 and 48 hours.
- We note that chronic endpoints should cover multiple generations. As such the quoted 24 hour NOEC does not meet this criteria and should not form the basis of the chronic classification. Please can you consider if exponential growth criteria were met at 48 and 72 hours and present NOErCs for these periods based on initial measured concentrations.

Boeri R.L., Wyskiel D.C., Ward T.J. (2002b) (Skeletonema costatum)
- Given the noted issues with the 24 hour cell counts, it appears the presented 24 hour ErC50 is not reliable. Please can you present a 48-hour ErC50 (based on initial measured concentrations) for comparison as a valid acute endpoint?
- We note that chronic endpoints should cover multiple generations. As such the quoted 24 hour NOEC does not meet this criteria and should not form the basis of the chronic classification. Please can you consider if exponential growth criteria were met at 48 and 72 hours and present NOErCs for these periods based on initial measured concentrations.

Dossier Submitter's Response

Thank you for your comments.

Navicula pelliculosa, 2007: The 24h ErC50 is calculated based on the initial measured concentrations (time 0), where the lowest concentration tested was 1.4 µg/L (1.3 µg/L nominal). Since the NOErC at 24 and 48h were below the lowest concentration tested (1.4 µg/L), the calculated EC10 values were used instead (0.34 and 0.77 µg/L, respectively).

In general, we agree that chronic endpoints should cover multiple generations. This is also in line with OECD 201, where it is stated: "the test which runs over a period of normally 72 hours, in spite of being a relatively brief test duration, effects over several generations can be assessed…..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." We can confirm that the biomass in the control cultures increased exponentially by a factor of at least 16 within 48-hours (initial: 10,000 cells/mL, 24h: 63,458 cells/mL, 48h: 222,568 cells/mL, 72h: 723,445, 96h: 1,126,361).

The endpoints from the study were as follows:

Time (hours)	ErC50 (µg a.s./L)	NOErC (µg a.s./L)
24	1.6	0.34 (EC10)
48	2.6	0.77 (EC10)
72	3.1	1.4
96	3.4	2.2

There were statistically significant effects on the growth rates in all treatments at 0-24 hours and 0-48 hours. In general, we would prefer the 48h NOErC over the 24h NOErC to include multiple generations. In this case, the 48h value is higher than the 24h value, and is also higher than the chronic NOECs for Daphnia magna and for zebra fish (NOEC: 0.4 and 0.43 µg a.s./L, respectively), which would then be the lowest chronic values. The resulting classification would be the same. Since all the algae studies have problems with

maintaining the test concentrations over time, using chronic data from other trophic levels could be a preferable option.

Skeletonema costatum: Looking at the study report, the 24h and 48h ErC50 values are 0.394 and 1.58 µg a.s./L, respectively. The 96h NOErC is 1.44 µg a.s./L. The biomass in the control cultures increased exponentially by a factor of at least 16 within 72-hours and thus the exponential growth criteria were met at 72 hours but not at 48 hours (initial: 10,000 cells/mL, 48h: 102,000 cells/mL, 72 hours: 647,000 cells/mL).

The ErC50s (calculated based on the initial measured concentrations) in the study were as follows:

Time (hours)	ErC50 (µg a.s./L)	NOErC (µg a.s./L)
24	0.394	-
48	1.58	-
72	2.27	-
96	>3.58	1.44
120	>3.58	0.193

Only the 96 hour (1.44 µg a.i./L) and 120 hour (0.193 µg a.i./L) NOErCs from the study were presented in the study report. Since the exponential growth criteria were not met at 48 hours, this would not be a reliable value. The 72 hours value could be used, but the value are higher than the N. pelliculosa study.

RAC's response

RAC agrees on the use of intial measured concentrations and considers that longer time-periods than 24h are more relevant to assess chronic toxicity for algae so multiple generations can be covered. Classification should be based on the lowest relevant chronic endpoint.

In the *Skeletonema costatum* study the 24h cell density variability precludes the use of this endpoint for classification purposes. It is unknown for RAC, however, if the test fulfils the criterion: mean coefficient of variation for section-by-section specific growth rates < 35% which would be a reason to invalidate the test. In addition, at 24 hours the algae growth rate is lower than the established criterion 0.92 per day both for the control and solvent control.

At 48h exponential growth criterion is not met. The only valid endpoint seems to be 72h, beyond 72h growth is not exponential. Considering the mode of action of DCOIT which produces the highest effect early in the test and the points mentioned above, RAC agrees with the DS in considering the *Skelotonema costatum* study as additional information non forming the basis for classification purposes.

Date	Country	Organisation	Type of Organisation	Comment number
03.04.2018	France		MemberState	33
Comment received				
We agree with the environmental assessment of the CLH report.				
Dossier Submitter's Response				
Thank you for your support regarding the proposed classification for environmental hazard.				

RAC's response
Thank you.

Date	Country	Organisation	Type of Organisation	Comment number
13.04.2018	Germany	Thor GmbH	Company-Manufacturer	34

Comment received

Regarding the Annex 1/ 4.1.2.9 "Rapid degradability of organic substances" of the CLP regulation, there is a strong indication that the results of our study according to OECD 308 demonstrate rapid degradation of DCOIT.
After 28 days there is less than 30% of the relevant radioactivity associated with parent substance and its metabolites left in the system.
In our opinion it cannot be scientifically justified to consider exclusively the classification of the metabolites and ignore their concentrations in the temporal course. For an evaluation of the metabolites in the context of rapid degradability the same rules have to be applied as for the parent substance.

Consequently, Thor proposes an M-Factor (chronic) of 10.

In support of the argumentation made above, an additional attachment is provided for consideration by the Rapporteur and RAC.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment rapid degradation_OECD 308.pdf

Dossier Submitter's Response

Thank you for your comments.

In the note ("Evidence for rapid biodegradability of DCOIT") you argue that DCOIT degrades rapidly in the environment with reference to the water/sediment study performed in accordance with OECD guideline 308 (Adam, 2008). However, the other applicant, Dow, has also performed several water/sediment studies, including one in accordance with OECD 308 (Millais A.J., 2005). The classification must take all available studies into account.

In CLP Annex I: 4.1.2.9.5 (c) a decision scheme for determination of rapid degradability is presented: "A substance is considered to be not rapidly degradable unless at least one of the following is fulfilled:
a. The substance is demonstrated to be readily biodegradable in a 28-day test for ready biodegradability…..; or
b. The substance is demonstrated to be ultimately degraded in a surface water simulation test with a half-life of <16 days (corresponding to a degradation of >70 % within 28 days); or
c. The substance is demonstrated to be primarily degraded biotically or abiotically e.g. via hydrolysis, in the aquatic environment with a half-life <16 days (corresponding to a degradation of >70 % within 28 days), and it can be demonstrated that the degradation products do not fulfill the criteria for classification as hazardous to the aquatic environment".

It is clear that point a. is not fulfilled. DCOIT could not be classified as readily biodegradable, due to inhibition of the inoculum by DCOIT in ready biodegradation studies.

Water/sediment studies from both applicants are used to conclude on whether DCOIT fulfills the criteria in points b. and c. There are variations in the submitted studies, but in general, there is a tendency for accumulation of metabolites as bound residues and limited formation of CO_2. In addition, one of the degradation products, which in some studies are found in significant amounts, fulfils the criteria for classification as hazardous to the environment. Therefore, according to the decision scheme, DCOIT cannot be regarded as rapidly degradable.
RAC's response
RAC agrees with the DS and considers DCOIT non rapidly degradable.

PUBLIC ATTACHMENTS
1. rapid degradation_OECD 308.pdf [Please refer to comment No. 34]
2. Manufacturers Comments Regarding DCOIT CLH dossier.docx [Please refer to comment No. 6, 13, 15, 19, 20]
3. CEPE input public consultation DCOIT 201803.pdf [Please refer to comment No. 2]

CONFIDENTIAL ATTACHMENTS
1. Confidential attachments for DCOIT CLH consultation.zip [Please refer to comment No. 6, 13, 15, 19, 20]