

Committee for Risk Assessment
RAC

Annex 2

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

**cymoxanil (ISO); 2-cyano-N-[(ethylamino)carbonyl]-2-
(methoxyimino)acetamide**

EC Number: 261-043-0
CAS Number: 57966-95-7

CLH-O-0000007044-81-01/F

Adopted
16 September 2021

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON CYMOXANIL (ISO); 2-CYANO-N-[(ETHYLAMINO)CARBONYL]-2-(METHOXYIMINO)ACETAMIDE

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during 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 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 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. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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Substance name: cymoxanil (ISO); 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide
EC number: 261-043-0
CAS number: 57966-95-7
Dossier submitter: Lithuania

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
23.10.2020	France		MemberState	1
Comment received				
FR: Physical hazards: - p11: Based on ECHA SID Team conclusion, 93195-85-8 is a deleted CAS no. associated to CAS 57966-95-7 (see RAR). - P27 (2.2.1.1.7.1): typo mistake, self-reatng substance should be read self-reacting substances. - In the Summary of physicochemical properties of the active substance (p 390), method used and purity of the test substance should be reported for the better traceability.				
Dossier Submitter's Response				
Noted. The comments will be taken into account in the revised RAR.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
16.10.2020	Germany		MemberState	2
Comment received				
The substance is classified as Acute Tox. 4, H302. The decisive factor for this classification is the LD50 value (oral) = 356 mg / kg bw. In the line "Resulting Annex VI entry if agreed by RAC and COM"/column "Specific Conc. Limits, M-factors and ATE" is not indicated the LD50 value and should be added as follows: oral: ATE = 356 mg / kg bw				

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Dossier Submitter's Response
Thank you for your comment. ATE value will be added in the Table 171 of the amended CLH Report.
RAC's response
Noted.

TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
23.10.2020	Spain		MemberState	3

Comment received
<p>ES: With respect to development, multiple malformations were seen in the developmental studies:</p> <ul style="list-style-type: none"> • In the first rat study (1993) an increased incidences of malformations (hemi vertebra from 75 mg/kg bw/d, excenphthalic head and fused ribs at 150 mg/kg bw/d) were observed; these findings showed a low incidence but were above the historical control values and showed dose relationship. • In the second rat study (1998) with respect to major malformations, one foetus was found with cleft palate at 120 mg/kg bw/d above the range of historical control. Increased incidences of variants and minor anomalies (dumb-bell shaped thoracic vertebra 6/13, hypoplasia of sternum: sternebra no.1 and rudimentary 14th rib) were shown to be statistically significant increased and above the historical control data. • In one rabbit study (1981), increase incidences of skeletal malformations associated with scoliosis like "vertebra and/or rib alteraciones" and "vertebral and other changes between upper cervical and mid-thorac regions /or rib alterations" was observed above the historical control at 32 mg/kg bw/d. • In a further rabbit study (1982) an increased incidences of major malformations [(hydrocephaly (2 fetuses), cleft palates (2 fetuses))] occurred at 32 mg/kg bw/d. Incidences were showed statistical significance and were above the range of historical control. • Finally incidence of dilation of heart ventricles in a third study in rabbits (1999) was increased above the range of historical control values from the dose level of 15 mg/kg bw/d, reaching statistical significance only at the dose of 25 mg/kg bw/d (this effect should be taken with precaution as even the control value of the study is above the range of historical control). In addition, the incidences of visceral variants (slight renal pelvis dilation) and skeletal variants (incomplete/poor ossification of fore limb) as well as skeletal anomalies (extra rib n° 13, fused sternebra n° 4,5, extra lumbar vertebra n°8 and accessory floating rib no. 13) were shown to be relevant. These malformations (some major) were found above the range of historical controls for both tested species (rat and rabbits) and in some cases in absence or with slight maternal toxicity. In any case, the available information indicates that malformations cannot not be attributed to maternal toxicity or to a mechanism of action (MoA) not relevant for humans. Additionally, the incidence was observed at low dose levels (for instance, 32 mg/kg bw/day for cleft palate (rabbits, 1981) or 25 mg/kg bw/day for dilation of heart ventricles (rabbit, 1982)) considering the experience in developmental toxicity in other CLH reports. Consequently, regarding the severe developmental effects, the Spanish CA proposes a classification as Repr. 1B (H360Df: May damage the unborn child. Suspected of damaging fertility).

Dossier Submitter's Response
Thank you for your comment.

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<p>Classification regarding adverse effects on development (Repr. 2 H361d) has been proposed based on similar findings mentioned above by Spain. Since the developmental toxicity reported in rats and mice was not consistently observed in the studies, a classification according to CLP in Repr.1B H360D is not considered appropriate.</p> <p>In addition, it should be noted that the HCD submitted for all studies under evaluation should be used with caution and acknowledgement of its lower relevance and reliability as HCD cover either a longer period (e.g. RAR B.6.6.2.1., 1993; RAR B.6.6.2.2., 1998 and RAR B.6.6.2.6., 1999) or shorter period (e.g. RAR B.6.6.2.4., 1981) than requested and no correct summary data on the HCD were submitted [e.g. ranges of values (in percentages), mean, median and standard deviation] for all studies as is required in accordance with Commission Regulation (EU) No 283/2013 (section 5; 5.6. Reproductive toxicity). Furthermore, the HCD validity is questioned (e.g. not strain, the supplier and laboratory specific) for the second developmental toxicity study in rats (RAR B.6.6.2.2., 1998). In addition, some comments concerning the findings at 15 mg/kg bw/d in a third study in rabbits (RAR B.6.6.2.6., 1999) should be submitted:</p> <p>The incidence of dilation of heart ventricles (31.4%) was statistically significantly increased in the high dose (25 mg/kg bw/day) animals only, was above the HCD and without clear dose-response relationship as there was high percentage of this finding (15.2%) in the control group. This finding in the control group and all others was above the HCD. Furthermore, the HCD validity is questioned for this study too (see above).</p>
RAC's response
Thank you for your comments. RAC has carefully considered the points raised.

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
23.10.2020	Spain		MemberState	4
Comment received				
<p>The Spanish CA supports the proposed classification of cymoxanil as Acute Tox 4 (oral) (H302: Harmful if swallowed) according to Regulation EC 1272/2008. This classification is based on to the LD50 value in female (LD50 = 356 mg/kg bw) obtained in the oral toxicity study in rats (1992a).</p>				
Dossier Submitter's Response				
Noted. Thank you for your support.				
RAC's response				
Noted.				

OTHER HAZARDS AND ENDPOINTS – Skin Hazard

Date	Country	Organisation	Type of Organisation	Comment number
16.10.2020	Germany		MemberState	5
Comment received				
<p>The classification as Skin Sens. Cat. 1A is supported. We regard the two submitted studies, the GPMT (1981, RAR B.6.2.6.1., 1992) and the second GPMT (1992) as not reliable. In the preliminary dose finding of both studies, at the highest dose for topical induction and the challenge, the concentration of 25 % could not demon-strate irritating effects. For that reason, the negative results in the main studies were ob-served in the absence of the determination of the irritating concentration. This procedure is not in accordance with OECD TG 406, where it is stated that the</p>				

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<p>concentration used for topical induction should be the highest to cause mild-to-moderate skin irritation and for the challenge exposure should be the highest non-irritant dose.</p> <p>Also in the third study according to OECD 406 (1981, RAR B.6.2.6.3., 1994) no irritating effects were observed. However, a higher concentration (40 %) was tested in a preliminary dose finding compared to the studies mentioned above. Positive findings were reported in the main test following intradermal induction using 1.0 %, topical induction with 40 % and challenge with 20 % (w/v) concentrations for 90 % animals (erythema, oedema).</p> <p>In agreement with DS Lithuania, we regard the third study (RAR B.6.2.6.3., 1994) as the most reliable and therefore we support the classification as a skin sensitizer (H317), subcategory 1A in accordance with Regulation (EC) No 1272/2008 based on positive results for > 60 % animals at intradermal induction concentrations of > 0.1 % to ≤ 1 % in GPMT.</p>
Dossier Submitter's Response
<p>Noted. Thank you for your support.</p> <p><i>"The topical induction and the challenge concentrations used in this study were apparently too low"</i> should be additionally included in "Deviations from current test guideline" in the summary table at the beginning of two studies (RAR B.6.2.6.1., 1992 and RAR B.6.2.6.2., 2003) in an amended RAR Vol.3 B-6.</p> <p>Regarding the acceptability of these two GPMT studies they will be re-considered by the Dossier Submitter (RMS LT) as 'Supportive only' instead of 'Acceptable' based on the above mentioned deviation. However, the Dossier Submitter tends to think that they cannot be considered as 'not acceptable' as they were used by it in WoE approach in assessment of skin sensitisation properties of cymoxanil. Moreover, strictly estimating, the third study (RAR B.6.2.6.3., 1994) also failed to meet the requirements of OECD Test Guideline 406 (1992): the highest concentration used for topical induction in the preliminary investigation [40% (w/v)] did not cause irritating effects.</p>
RAC's response
Noted.

OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard

Date	Country	Organisation	Type of Organisation	Comment number
23.10.2020	Spain		MemberState	6
Comment received				
The Spanish CA supports the proposed classification of cymoxanil as Skin Sens. 1A (H317: May cause an allergic skin reaction) according to Regulation EC 1272/2008. This classification is based on the results of the dermal maximisation study in guinea pigs (1994), where positive response was obtained in all test animals (100%) using 1% of test article for intradermal induction.				
Dossier Submitter's Response				
Noted. Thank you for your support.				
RAC's response				
Noted.				

OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Repeated Exposure

Date	Country	Organisation	Type of Organisation	Comment number
23.10.2020	Spain		MemberState	7
Comment received				
<p>ES: Classification as STOT RE 1, H372 Causes damage to organs (blood, thymus) through prolonged or repeated exposure (oral) according to Regulation EC 1272/2008, could be considered according to the effects observed in 90-day studies in dog below the cut off values (10 mg/kg bw/day).</p> <ul style="list-style-type: none"> • In the first 90-day dog study (1993) at 5.13 mg/kg bw/day in males haematology toxicology was observed: Middle anaemia with a decrease of RBC (15.9%), haemoglobin concentration (16.7%) and haematocrite (14.9%). • In the second 90-day dog study (1999) At 9.7 mg/kg bw/day in males thymus toxicity was observed: ↓ absolute (>55%) and relative (>45%) thymus weight and histological alterations (lymphoid atrophy) with increasing severity At 9.9 mg/kg bw/day in females haematology, liver and thymus toxicity was observed: <ul style="list-style-type: none"> □ Haematology toxicology: Middle anaemia with a decrease of RBC (13.2%) and haemoglobin concentration (10.1%) □ Liver toxicity: ↑ relative liver weight (28.6%) with alterations of clinical chemistry [↑ GGT (89%), ↑ Total Bilirubin (17%)]. □ Thymus toxicity: ↓ absolute (>56%) and relative (>50%) thymus weight and histological alterations (lymphoid atrophy). 				
Dossier Submitter's Response				
<p>Thank you for your comment. Classification regarding adverse effects on blood parameters and the thymus (Specific target organ toxicity-repeated exposure, STOT RE 2, H373) has been proposed based on the following considerations:</p> <p>First 90 days study in dogs (RAR B.6.3.2.3. Study 1, 1993)</p> <p>Haematology/Blood</p> <p>Number of red blood cells (25.6%*) and haemoglobin (22.2%*) were statistically significant reduced and mean corpuscular volume (MCV) was increased (8.7 %*) in females at high dose (10.51 mg/kg bw/day), meanwhile in mid dose (5.27 mg/kg bw/day) females number of red blood cells (11.5%), haemoglobin (12.8%) and haematocrit (9.1%) were non-statistically significant reduced.</p> <p>Males were more severely affected than females in this study and these findings in males at 5.13 mg/kg bw/day were not related to the presence of general toxicity. A statistically significant dose dependent reduction (>10%) number of red blood cells (15.9%** and 23.0%**), haemoglobin (16.7%** and 24.4%**), respectively) and haematocrit (14.9%* and 23.4%**), respectively) was observed in males of mid and high dose groups (5.13 and 10.56 mg/kg bw/day). However, a reduction in haemoglobin at ≥ 20% was observed at 10.56 mg/kg bw/day only. Furthermore, there were not changes in mean corpuscular volume (MCV) at all doses.</p> <p>According to the <i>Guidance on the Application of the CLP Criteria</i> (2017) a reduction in haemoglobin at ≥ 20% is considered a significant adverse effect in haematology. Furthermore, the increase of MCV as the most significant haematological parameter for</p>				

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assessing anaemia in about 5% should be considered as toxicologically significant change in accordance with *WHO Guidance document (WHO, Guidance document for WHO monographers and reviewers; 2015)*.

Therefore, effective dose 10.51 mg/kg bw/day was chosen for classification (see Table 28 in CLH Report). The effects on haematology reported in dogs were on the border between the guidance values for a classification in STOT RE 1 and RE 2. These effects were not reported in all short-term dog studies available for evaluation and/or in others repeated exposure studies on other species. Therefore, it is considered that the effects reported are in accordance with a classification of cymoxanil in STOT RE 2, H373.

Second 90 days study in dogs (RAR B.6.3.2.3. Study 2, 1999)

Haematology/Blood

A statistically significant dose dependant reduction (>10%) number of red blood cells (13.2%*) was observed in females from dose 9.9 mg/kg bw/ day). These values were within the HCD submitted (No of females 105; Mean 1-SD range-L: 5.88 – 7.18 x10⁶/μL); however, the HCD provided was of limited relevance with respect to the method of collection. A dose-related reduction (>10%) in haemoglobin in female was reported (10.1% and 13.9%* at 9.9 and 15.5 mg/kg bw/ day, respectively) that reached statistical significance at highest dose only. The latter Hb value (136 g/L) was lower of HCD range (No of females 105; Mean 1-SD range-L: 137.54 – 160.66 g/L). The statistically significant increase of MCV in females of the low and mid dose group (4.7%* and 3%*, respectively) could not be shown for the highest dose group (3%). The first value (67.0 fL) was higher and the second value (66.3 fL) was just at the upper edge of HCD range and all three values were above the mean of HCD (No of females 105; Mean: 63.64, Mean 1-SD range-L: 60.90 – 66.38 fL). Females were more severely affected than males with respect to haematology in this study. Based on the arguments presented above, the dose 9.9 mg/kg bw/ day was not proposed as a basis for classification in STOT RE 2, H373.

Thymus

A dose-dependent increase in male and female thymus atrophy from 9.7 mg/kg bw/day and 9.9 mg/kg bw/day, respectively, was reported in a 90 day study in dogs (RAR B.6.3.2.3. Study 2, 1999). Male thymus atrophy was repeated at 5.6 mg/kg bw/day in a 1 year dog study (RAR B.6.3.3.2., 2003). Some findings indicate that changes in thymus might be a substance-specific effect but not a result of generalised high-dose stress response. These doses were chosen for classification (see Table 28 in CLH Report). The effects on the thymus atrophy reported in dogs were on the border between the guidance values for a classification in STOT RE 1 and RE 2. These effects were not reported in all short-term dog studies available for evaluation and/or in others repeated exposure studies on other species. Therefore, it is considered that the effects reported are in accordance with a classification of cymoxanil in STOT RE 2, H373.

RAC's response

Thank you for your comment has been taken into consideration.

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
16.10.2020	Germany		MemberState	8

Comment received

We agree that cymoxanil should be classified as "Aquatic Acute 1" and "Aquatic Chronic 1". However, it is noted that the proposed classification is only based on reliable effect data for two trophic levels. Reliable data on the acute and chronic effects on algae are currently not available. The presented, not acceptable studies (e.g. Hughes 1996) suggest

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that algae could be the taxon most sensitive to cymoxanil. As stated in section 2.9.2.2.3 of the RAR - Volume 1, the applicants agreed to perform a new study on green algae with cymoxanil, which was not submitted until finalisation of the draft RAR. This new study could be vital for the final classification and labelling, and be the defining study for setting the M-factors. The acute and chronic M-factors should be updated as soon as the new study results are available.

Additionally, further remarks are:

- Chapter 2.8.2.1, page 197: Table 68 "Summary of relevant information on rapid degradability" is currently empty and should be filled.
- Chapter 2.8.2.2.6, page 200: A short description of the photolysis study in water is missing and only a summary of the hydrolysis and water/sediment studies is present-ed. Please add a short summary of the photolysis study.
- Chapter 2.8.3, page 200: For the volatility the value of the Henry's law constant is reported, please correct the unit to Pa · m³ · mol⁻¹.
- Chapter 2.9.2.4.2, page 268: It is noted that the substance is classified as not rapidly degradable. To improve the understandability of the conclusion section, please add a summarizing sentence, why the substance is classified as not rapidly degradable.

Dossier Submitter's Response

Noted. Thank you for your comment.

A new algae study has been performed and will be supplied. The study results will be provided and the acute and chronic M-factors will be updated accordingly in the amended CLH.

Table 68 Summary of relevant indormation on rapid degradability

Method	Results*	Key or Supportive study ¹	Remarks	Reference
Modified Sturm test	Biodegradation of the test substance was < 20 % after 28 days.	none	Not readily biodegradable	Luit, R., J. 2000
Modified Sturm test	Biodegradation of the test substance was < 20 % after 28 days.	none	Not readily biodegradable	Desmares-Koopmans, M. J.E., 2008
Manometric Respiratory test	Biodegradation of the test substance after 28 days in consideration of nitrification was 23% (ThOD _{NO3})	none	Not to be readily biodegradable	Feil, N. 2009

The aqueous photolysis of cymoxanil had been studied in sterile aqueous buffer at pH 5 at a temperature of 25 °C. These studies were evaluated during the previous EU review. Cymoxanil degraded rapidly under photolytic conditions at pH 5. Two major degradates were seen at >10% IN-JX915 and IN-R3273, plus a further two metabolites IN-KP533 and IN-T4226 were seen at 7.9 and 6.7 % AR respectively, several additional minor components were also seen. The DT50 for cymoxanil under continuous irradiation was 1.8 days.

The DT50 for continuous irradiation was 3.0 days which was calculated to be equivalent to 12.1 days of natural summer sunlight at 40°N. Two major degradation products were identified as IN-R3273 and IN-JX-915. The quantum yield for cymoxanil was 0.00058. The

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theoretical half-life of cymoxanil in the top layer of an aqueous system integrated over a full day in summer at 40°N latitude was 5.2 days. Photolysis model GC SOLAR was used to calculate quantum efficiencies for cymoxanil in water (pH 5). The theoretical half-life of cymoxanil in the top layer of an aqueous system integrated over a full day in summer at 40°N latitude was 17.3 days. The photolysis model GC SOLAR was used to calculate quantum efficiencies for cymoxanil, IN-R3273 and IN-JX915 in water. The theoretical half-life of cymoxanil ranged from 9.3 days in the summer at 30°N latitude to 782 days in the winter at 60°N. The half-life for IN-JX915 ranged from 44.4 days in the summer at 30°N latitude to 1250 days in the winter at 60°N. The theoretical half-life for IN-R3273 ranged from 49.0 days in the summer at 30°N latitude to 2940 days at 60°N latitude.

The volatility value of the Henry's law constant will be corrected. Thank you.

Three studies were provided for assessment of the biodegradability potential of the cymoxanil. Two modified Sturm tests and a manometric respirometry test. In modified Sturm GLP tests the results confirmed that cymoxanil is not readily biodegradable (< 20 % CO₂ evolution). Additionally, a manometric respirometry test indicated less than 23 % biodegradation of the substance with domestic sludge. Therefore, based on the available experimental data, the substance is evaluated to be not readily biodegradable according to OECD criteria. The results of the test on biodegradation of cymoxanil show that cymoxanil is considered not readily biodegradable (a degradation less than 70% within 28 days) for the purpose of classification and labelling.

RAC's response

Thank you for your comment. The support of the DS proposal for classification of the substance is noted by RAC. RAC agrees.

During the process of the preparation of the first draft opinion, RAC has received the robust summary report of the new experimental Algal Growth Inhibition Test performed with cymoxanil. The summary of the study is available in the section Additional key elements in the opinion.

Date	Country	Organisation	Type of Organisation	Comment number
23.10.2020	United Kingdom	HSE CRD	National Authority	9

Comment received

Cymoxanil (ISO); (EC: 261-043-0; CAS: 57966-95-7)

We note a harmonised classification for cymoxanil was agreed by RAC in 2011. The current CLH report proposes the same environmental classification / M-factors and we are unclear of the basis for this public consultation. We presume the current proposal considers a re-evaluation of the ecotoxicity data, leading to a different rationale for the classification – please can the DS confirm?

While we agree that the substance is not rapidly degradable due to the toxicity of the degradation products, it would be useful for the DS to consider this point with reference to CLP criteria to support the conclusion on the degradation potential of the parent substance and the relevance of new degradant ecotoxicity data.

The current proposal considers available algal ecotoxicity data for cymoxanil are not reliable. While the validity criteria were met in the algal study by Boeri (1999), the DS considers the study not acceptable because test concentrations were not maintained, and

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below the LOQ after 72 hours. The DS references an EFSA technical report (2015) to support this view that the use of half the LOD or LOQ is not acceptable to calculate geometric mean measured concentrations where intermediate measured concentrations are not available. According to ECHA's Guidance on Application of CLP Criteria(2017) section I.4.1, the use of half the LOQ or LOD is suitable in this instance for hazard classification. Therefore, reliable chronic and acute toxicity endpoints should be derived for the 72-h endpoint from this study. These endpoints would be within the same concentration range as the key endpoints used for the proposed classification and would therefore support this proposal.

Dossier Submitter's Response

Current classification was proposed based on reevaluation of all relevant old studies and new studies on acute and chronic aquatic toxicity provided for the renewal of the approval of active substance cymoxanil.

Cymoxanil is considered as not readily biodegradable based on the available experimental data (Luit, R., J. 2000, Desmares-Koopmans, M. J.E. 2008 and Feil, N. 2009). However, cymoxanil degrades very rapidly in water under neutral and alkaline conditions. The degradation is mainly driven by hydrolysis. Due to the rapid conversion of Cymoxanil to metabolites and higher toxicity of some metabolites than the parent, the acute and chronic toxicity data of metabolites are considered in the classification of the active substance.

DS agrees that according to ECHA's Guidance on Application of CLP Criteria(2017) section I.4.1, the use of half the LOQ or LOD can be considered suitable in this instance for hazard classification. However, a new algae study has been performed and will be supplied. The study results will be provided and the proposed classification will be updated accordingly in the amended CLH.

RAC's response

Thank you for your comment.

RAC agrees with commenting National Authority and DS that in line with the CLP Guidance (Version 5.0, July 2017) the use of half of the LOQ or LOD to calculate geometric mean measured concentrations can be taken into account for classification. Therefore, RAC considers that the geometric mean measured 96h E_rC₅₀ of 0.167 mg/L, 96h NOEC of 0.130 mg/L and 96h E_rC₁₀ of 0.112 mg/L derived from the algae toxicity study (Boeri, 1999) should be considered for the classification of the cymoxanil.

During the process of the preparation of the first draft opinion, RAC has received the robust summary report of the new experimental Algal Growth Inhibition Test performed with cymoxanil. The summary of the study is available in the section Additional key elements in the opinion.

Date	Country	Organisation	Type of Organisation	Comment number
23.10.2020	France		MemberState	10

Comment received

FR agrees with the classification for environmental hazards and with the acute and chronic M factor values proposed in the CLH report.

Dossier Submitter's Response

Noted. Thank you.

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RAC's response

Thank you for your comment. The support for the DS proposal for classification of the substance is noted by RAC. RAC agrees.