

Committee for Risk Assessment
RAC

Annex 2

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

sodium hypochlorite, solution ... % Cl active

EC Number: 231-668-3
CAS Number: 7681-52-9

CLH-O-0000001412-86-116/F

Adopted
3 June 2016

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON SODIUM HYPOCHLORITE, SOLUTION ... % CL ACTIVE

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: sodium hypochlorite, solution ... % Cl active

EC number: 231-668-3

CAS number: 7681-52-9

Dossier submitter: Netherlands

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
23.11.2015	United Kingdom	INOVYN Chlorvinyls Limited	Behalf Of AnOrganisation	1

Comment received

INOVYN Contribution to Sodium Hypochlorite Classification and labelling Change Consultation

As the newly formed joint venture company of INEOS and Solvay, INOVYN has a long history of manufacture, use and distribution of sodium hypochlorite for the uses disseminated in the sodium hypochlorite REACH dossier. As members of Eurochlor we are in full agreement with the AISE/Eurochlor position paper already submitted and are engaged in an assessment of the consequences of the proposed change in classification – a classification that arises from a disagreement on the quality and uncertainty of certain studies. The particular novelty of sodium hypochlorite is that the classification given by a manufacturer at the point of sale often differs from that of a downstream user or distributor since one of the first actions on receipt is to dilute the purchased solution. Hence we have experience of multiple classifications for different solution concentrations of this substance and advise our customers accordingly. An additional feature is that customers of the substance often use the substance in manufacture of mixtures and also may act as distributors of the substance itself following dilution. Therefore numerous classifications exist for sodium hypochlorite solutions already.

The two newer, reliable studies confirm that the range of invertebrate toxicities to be used for the purposes of classification and labelling is 10 – 100 micrograms per litre. When a full review of all reliable acute ecotoxicity data for the purposes of classification is made for the substance the toxicity lies in the range of 0.01 to 0.1 mg/Litre ((Acute category 1; M = 10). This is consistent with the classification reviewed in the REACH dossier and Chemical Safety Report. A review of the chronic data, coupled with the rapid

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degradation of the substance also leads to the conclusion of the classification as given in the REACH dossier and CSR.

The proposed classification may well have significant consequences not only for our own business but also for that of our customers since it may bring user and storage sites under the remit of the Seveso directive (Directive 2012/18) since the more dilute solutions of sodium hypochlorite will now come under this directive. This would impose a significant additional regulatory burden with all its associated costs. Whilst we will always implement regulations fully – including new harmonised classification – within our company and apply it to the products we sell, we feel that such a change and its potentially extensive consequences should not be based on a disagreement over the Klimish rating of certain studies.

Dossier Submitter's Response

The argumentation presented by INOVYN is not clear. Particular the statement "*The particular novelty of sodium hypochlorite is that the classification given by a manufacturer at the point of sale often differs from that of a downstream user or distributor since one of the first actions on receipt is to dilute the purchased solution.*" It seems to imply that there is problem. However, under CLP the obligations of a downstream user (incl. formulator/re-importer) is to classify in line with CLP Title II (CLP articles 5-14) in case you change the composition of the substance or mixture you place in the market. Otherwise, you may take over the classification for a substance or mixture derived in accordance with Title II of CLP already by another actor in the supply chain, provided that you do not change the composition of this substance or mixture. Guidance on the specific obligations under CLP for each of the roles in the supply chain can be found in the introductory guidance on the CLP regulation (ECHA website). The NL-CA agrees that the occurrence of numerous self-classifications for sodium hypochlorite solutions in the C&L inventory (see also table 6 of the CLH report), can indeed partially be explained by different solution concentrations.

See for the response on the AISE/Eurochlor position paper comment no. 4.

We are aware of the consequences of the current classification and labelling proposal for storage given the Seveso directive but like to point out that it should be of no influence for the derivation of the correct classification which should be purely based on the intrinsic properties (e.g. toxicity) of the substance. Hence, this argumentation is not relevant for the discussion.

RAC's response

The RAC rapporteur's opinion is that Seveso and other regulatory consequences on burden and costs are out of the scope of harmonised classification and labelling, which is based on environmental fate and effects of chemical substances.

The scientific validity of studies and the acceptance of the study results for classification purposes is an issue to discuss further in RAC.

Date	Country	Organisation	Type of Organisation	Comment number
23.11.2015	Netherlands	Unilever	Company-Downstream user	2

Comment received

Overall we support comments on the harmonised environmental classification proposal provided by EuroChlor.

Furthermore, we would like to express our concerns w.r.t. the downstream implications of the proposed environmental classifications, as these would make all products with more than 0.25% of hypochlorite fall under Seveso III Directive as of 200 tonnes of product

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stored, or potentially at lower tonnages. This may affect not only manufacturers (most of them already under Seveso) but also many retailer warehouses, and could have its impact on local spacial planning and safety measures in and around these warehouses. (Note: 200 tonnes can be reached with 8 truckloads of product)
Dossier Submitter's Response
We are aware of the consequences of the current classification and labelling proposal for storage given the Seveso directive but like to point out that it should be of no influence for the derivation of the correct classification which should be purely based on the intrinsic properties (e.g. toxicity) of the substance. Hence, this argumentation is not relevant for the discussion.
RAC's response
CLP cannot consider storage and other downstream implications.

Date	Country	Organisation	Type of Organisation	Comment number
20.11.2015	Germany		MemberState	3

Comment received
The German CA supports the proposed environmental classification and the corresponding M-factors.
Editorial Comments:
<ul style="list-style-type: none"> • In IUCLID section 1.1 CAS and IUPAC name for sodium hypochlorite are missing. Please add this information. • In IUCLID section 1.2 for none of the given impurities the CAS name, the CAS number, the EC name, the EC number or the IUPAC name is given. Furthermore, the corresponding reference substance data sets are not filled in. The missing information should be added. The same applies to one of the given additives. • Concerning the substance composition it has to be mentioned that not all of the concentration values given in the confidential annex to the CLH report attached in IUCLID section 13 are given in IUCLID section 1.2 as well. Please add the missing information on the concentration ranges concerning the constituent, impurities and additives in the IUCLID file. • In Part B, section 1.1, table 7 of the CLH report "Sodium hypochlorite, solution ... % Cl active" is given as EC name of the substance. This name should be replaced using "Hypochlorous acid, sodium salt" as EC name instead. • In Part B, section 1.1, table 7 of the CLH report "Sodium hypochlorite" is given as CAS name of the substance. This name should be replaced using "Hypochlorous acid, sodium salt (1:1)" as CAS name instead. • In Part B, section 1.2, table 8 of the CLH report the non-confidential information on the concentration range and the typical concentration of Sodium hypochlorite is presented. The given concentration values deviate from the values given in Part A, section 1.1, table 1 of the CLH report respectively the values stated in the confidential annex. Please amend the given values. The same applies to the values for the impurity Sodium chlorate given in Part B, section 1.2, table 9.

Dossier Submitter's Response
We would like to thank the DE-CA for their support on the current classification and labelling proposal and the editorial comments. We agree upon the noted inconsistencies and comments, with respect to the IUCLID and the CLH report. However, this can not be adapted in this stage of the discussion on the CLH proposal.
RAC's response
RAC rapporteur agrees with the recommended replacement of EC and CAS names.

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Date	Country	Organisation	Type of Organisation	Comment number
15.10.2015	Belgium	Euro Chlor	Industry or trade association	4
Comment received				
<p>We enclose a document which, based on weight of evidence, explains our position on the current CLH proposal. There are separate SEVESO issues as well.</p> <p><u>ECHA note</u> – The following attachment was submitted with the comment above: <i>CLH proposal for sodium hypochlorite – AISE FECC Euro Chlor position</i></p>				
Dossier Submitter's Response				
<p>In the AISE/Eurochlor position paper a 10 times lower M-factor is concluded, both for acute aquatic toxicity (M-factor of 10 instead of the proposal of 100) as for chronic aquatic toxicity (M-factor of 1 instead of the proposal of 10). For acute aquatic toxicity values a range $0.01 < L(E)C50 \leq 0.1$ mg/L is concluded, which is 10 times higher as the NL-CA concludes. The difference in M-factor for chronic aquatic toxicity is related to the conclusion that sodium hypochlorite can be considered rapidly degradable according to the industry. It is stated that the data used for the current CLH proposal presents an inaccurate opinion and higher quality studies are available.</p> <p>It should be noted that the position paper does not provide additional or new data compared to the CLH-proposal of the NL-CA, but only reflects other insights, which are set out below.</p> <p>For the recent study from Gallagher et al. 2009 other conclusions are proposed by the industry compared to the conclusions in the CLH-report. The conclusion from the NL-CA is that the EC50-48h < 48.5 µg active Cl/L, since 90% immobilisation was observed for this test substance concentration, based on the mean measured concentration. The industry prefers the conclusion EC50-48h of 141 µg active chlorine/L based on nominal concentrations or EC50-48h of 30.5 µg/L, which is calculated to be the mean measured concentration with the lower test substance concentration (which resulted in 10% immobilisation) set to the limit of quantification of 15 µg/L. The NL-CA does not support this assumption, since the mean measured concentration for the lower test substance concentration was determined to be below the LOQ, which is somewhere between 0 and 15 µg/L.</p> <p>The same accounts more or less also for the Gallagher et al. 2011 study with Cerodaphnia. The NL-CA concluded the EC50-48h to be < 25.8 µg/L (mean measured concentration) for which 100% immobilisation was observed, since the lower test substance concentration for which no immobilisation was noted, was determined to be below the LOQ of 10 µg/L. The industry prefers the conclusion EC50-48h to be 35 µg/L, based on nominal concentrations or an EC50-48h of 16 µg/L based on mean measured concentrations, for which the lower test substance concentration was set to the LOQ. The NL-CA does not agree with this conclusion since the actual test substance concentration is somewhere between 0 and 10 µg/L, which potentially can result when calculating the mean measured concentration in an EC50-48h below 10 µg/L.</p> <p>With respect to fish toxicity the industry reports as most critical toxicity value an LC50-96h of 60 µg TRC/L, while in the registration dossier a (reliable with restrictions) study of Middaugh et al. 1997 is listed, with an LC50-48h of 8.4 TRC with respect to egg hatchability for <i>Morone saxatilis</i>.</p>				

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For algae, is referred to the study of Liedtke (2013), based on nominal concentrations the ErC50-72h suggested by the industry is 0.0499 mg available chlorine/L, with as alternative ErC50-72h based on initial chlorine concentrations of 0.0365 mg available chlorine/L. The NL-CA does not support these conclusions since after 24 hours the inhibition of the growth rate for the initial measured concentration of 23.3 µg FAC/L was 60% (after one day the concentration dropped below the LOQ) and sticks to the conclusion that the ErC50-72h < 23.3 µg FAC/L. The NOECr is below the LOQ of 10,8 µg FAC/L.

It is stated by the industry that the CLH report fails to include invertebrate studies from brackish/ sea water environments. This seems to be a misunderstanding, since the study from Roberts and Gleason mentioned by industry is also listed in table 13. However, it has not been assigned to be key-study data in the CLH report, in contradiction to the RAR, since lower EC50 values have been established.

It can be concluded that the more recent studies in terms of results also have their limitations, since no fixed values can be established for the effect data. For instance, based on the study by Gallagher et al. from 2011 with Cerodaphnia an EC50-48h below 10 µg/L can not be excluded, since test substance concentrations dropped below the LOQ during the test. The NL-CA would like to emphasize that the more recent studies provided by industry have been taken into consideration, but as we have pointed out these studies also have limited use for classification purposes.

On the other hand there are two more acute aquatic toxicity values below 10 µg/L, next to the study from Taylor (see CLH-report). We agree that these are all non-standardised test protocols, which will have some limitations compared to standard test guideline studies. Still our point of view is that the weight of evidence is sufficient to conclude the most critical E(L)C50 is below below 10 µg/L. It is noted that the industry considers the acute toxicity data for invertebrates being unreliable, but not the fish study. The NL-CA therefore concludes that we agree upon one of the most critical toxicity values of 8.4 µg/L (Middaugh et al. 1977).

Next to the toxicity other issues are addressed by the industry:

- We agree with the statement from industry that sodium hypochlorite solutions are highly unstable under environmentally relevant conditions. However, the guidance (section 4.1.2.9.4 of CLP Annex I) states that "*The criteria used reflect the fact that environmental degradation may be biotic or abiotic. Hydrolysis can be considered if the hydrolysis products do not fulfil the criteria for classification as hazardous to the aquatic environment.*"
- The classification of chlorine (one of the degradation compounds) is Aquatic Acute 1 (M-factor 100). However, according to the industry the harmonized classification is based on hypochlorite data (before new data were collected). The RAC should be aware of the fact that an M-factor (of 100) has already been established with respect to hypochlorite toxicity data.
- The industry further states that reactive non-metal inorganic substances such as sodium hypochlorite are not properly addressed by the guidance, since the transformation to the mineral ion is irreversible, this in contradiction to inorganic metal compounds. The NL-CA agrees upon this statement.
- The ultimate mixture of breakdown products of sodium hypochlorite in the aquatic environment does not increase the ecotoxicity and consists predominantly the chloride ion after 28 days. The NL-CA agrees upon this statement.

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In the CLH report the reasons in favour and against considering the sodium hypochlorite solutions rapidly degradable are listed in section 5.1.3, together with the conclusion. We would like to stress that the current conclusion on rapid degradability is based on the CLP Regulation and guidance. For the time being, the NL-CA would like to leave it up to the RAC to discuss and to decide on the degradability of the substance.

We also note the additional information on mixtures presented in section 3.2.1 and annex I but consider this to be outside the scope of the current harmonised C&L proposal for sodium hypochlorite.

Taking the comments from the REACH consortium into account the NL-CA concludes that the current proposal for classification and labelling as provided in the CLH-report is the most appropriate proposal.

RAC's response

The statement on availability of higher quality studies not used by the DS has not been supported by concrete new studies. Unfortunately, none of the existing studies is entirely convincing. The fish study of Middaugh *et al.*, 1977 looks one of the best ones (Klimisch score 2) and some commenters would trust the invertebrates test of Taylor (food-free test). However, among other factors, the rapid chemical degradation of Na-hypochlorite and the differences between nominal and measured mean concentrations, as well as the detection limit of the chemical analytical methods cause high uncertainty in the results of all studies resulting an EC₅₀ close to 10 µg/L.

The quality overview of the studies shows that 16 studies, from which 11 being of good quality (Klimisch scores of 1 and 2) resulted to an EC₅₀ between 10 and 100 µg/L, and only 4 studies resulted to EC₅₀ between 1 and 10 µg/L. From these studies, one has a Klimisch score of 2, another 2 are debatable scores (disagreement between 2 or 4) and one has no score.

The second main issue mentioned is rapid degradation of Na-hypochlorite. It cannot be considered as a substance of no rapid degradation/decay in the environment. It is well known that NaOCl needs special care to prevent its degradation under experimental conditions, e.g., in toxicity studies and in treated waters. The composition of the degradation products depends on several conditions, pH, temperature, salt-concentration and the quantity and quality of organic compounds. All these may result in huge uncertainty. Rapporteur recommends discussing the problem of rapid degradation on the relevant RAC meeting.

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
23.11.2015	France		MemberState	5
Comment received				
FR agrees with the proposed classification H400 (M= 100) / H410 (M= 10)				
Dossier Submitter's Response				
We would like to thank the FR-CA for their support on the current classification and labelling proposal.				
RAC's response				
RAC thanks for the contribution.				

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Date	Country	Organisation	Type of Organisation	Comment number
11.11.2015	Finland		MemberState	6
Comment received				
<p>Based on the available information we support the conclusion made by the Dossier submitter that Sodium hypochlorite, solution ... % Cl active cannot be considered as a rapidly degradable substance. We also support the proposed classification for environmental chronic hazard Aquatic Chronic 1 – with M-factor of 10.</p> <p>Considering acute hazard we think that the M-factor of 10 is more likely warranted when using the weight of evidence approach instead of M-factor of 100 proposed by the Dossier submitter. Based on the available information presented in the CLH dossier and studies considered valid for classification purpose the acute toxicity of Sodium hypochlorite is between 10-100 µg/l which would result in classification Aquatic Acute 1 – with M-factor of 10.</p>				
Dossier Submitter's Response				
<p>We would like to thank the FI-CA for their support on the current classification and labelling proposal for chronic aquatic toxicity.</p> <p>We think that the difference in opinion for selecting the most appropriate M-factor for acute aquatic toxicity can be explained by the fact if one should focus within the derivation of the M-factor on the range of the greater part of the available toxicity data (between 10-100 µg/l) or one should focus on the most critical and lowest toxicity data (which are below 10 µg/l). Shortcomings and limitations can be noted for all available studies and are a consequence of the complex behaviour and reactions of the substance in the aquatic compartment. To our opinion the current CLH proposal should be discussed in and decided for by the RAC.</p>				
RAC's response				
<p>The RAC Rapporteur is ready to adopt a weight of evidence approach and accept the best quality studies as the decisive ones and not the questionable ones. However, several opinions support the use of the lowest EC₅₀ values (range) for the purpose of M-factor creation. The Rapporteur asks the RAC members to discuss the topic at the RAC meeting.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
23.11.2015	Netherlands	Unilever	Company-Downstream user	7
Comment received				
<p>Overall we support the Eurochlor comments on both acute and chronic toxicity. On page 24: re rapid degradability, we are of the opinion that hypochlorite due to its instable nature in the presence of organics should be considered very rapidly degradable. Arguments that pure hypochlorite solutions kept out of sunlight at 15°C are more or less stable are not relevant in this case. The fact that toxicity studies require the continuous replenishment of hypochlorite to maintain its concentration give clear indication of its instability. And the fact that a very small fraction of byproducts is formed cannot be used to invalidate the conclusion that hypochlorite is rapidly degradable without taking a thorough look at the environmental properties and occurrence of these byproducts.</p>				
Dossier Submitter's Response				
<p>The statement is noted. Please, note that no new reasons are provided next to the ones already provided in the CLH-report in section 5.1.3. See also response to comment</p>				

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number 4. The issue if sodium hypochlorite can be considered rapidly degradable should to our opinion be discussed in and decided by the RAC.
RAC's response
An open discussion at the RAC meeting can confirm one or another opinion.

Date	Country	Organisation	Type of Organisation	Comment number
23.11.2015	France	Solvay	Company-Manufacturer	8

Comment received

Sodium hypochlorite, solution ... % Cl active (CAS 7681-52-9 / EC 231-668-3) is currently listed in Annex VI to the CLP Regulation as Skin Corr. 1B, H314 and Aquatic Acute 1, H400 (no M-factor listed). Following a re-analysis of the available ecotoxicity and fate data available for the substance (including new data from the REACH registration dossier), the following harmonized environmental classification is proposed for consideration by RAC: Aquatic Acute 1, H400 (M-factor = 100) and Aquatic Chronic 1, H410 (M-factor = 10).

According to the CLH report, the following key data were retained for the assessment of acute environmental hazards:

- short-term toxicity to fish: 96h-LC50 = 0.034 mg NaOCl/l (Oncorhynchus kisutch) (Thatcher, 1978);
- short-term toxicity to aquatic invertebrates: 24h-EC50 = 0.0053 mg NaOCl/l (Ceriodaphnia dubia) (Taylor, 1993);
- short-term toxicity to aquatic plants: 24h-ErC50 < 0.0245 mg NaOCl/l (Pseudokirchneriella subcapitata) (Liedtke, 2013).

Interestingly, the toxicity data obtained on C. dubia (Taylor, 1993) was rated as Klimisch 2 in the previously issued EU Risk Assessment Report on Sodium hypochlorite (EU RAR, 2007), whereas the same data was rated as Klimisch 4 in the REACH registration dossier. First, several elements already identified in the EU RAR (2007) put doubt on the validity of the data (i.e. test concentrations calculated from measured chlorine concentration of the stock solution and dilution ratios, number of concentrations/replicates not specified, performance of controls not mentioned, 24h LC50s determined by graphical interpolation). Secondly, the industry provided detailed comments to explain the rating of the data as Klimisch 4; and yet, those comments have not been taken into account and the reliability of the C. dubia data has not been reassessed during the revision process of the harmonized classification.

It is well recognised that the dossier is complex as several data are available for the aquatic environment and as the reliability of those data is often questionable due to the instability of hypochlorite. However, in the context of the harmonized classification update, there should be no ambiguities in the reliability of the key data used to support the classification. Every data used to support the new harmonised classification should at least be reassessed. At the moment, newly generated data on Daphnia magna and C. dubia (Gallagher, Lezotte and Krueger, 2011) should be preferred as key data for the invertebrates trophic group. This would lead to an harmonized acute M-factor of 10 (instead of 100) considering that the short-term toxicity of the substance towards aquatic organisms lies in the range 0.01-0.1 mg NaOCl/l.

Dossier Submitter's Response

Next to the key-study data referred to above, there is more (supportive) data which is used in the weight-of-evidence approach as described under section 5.5 of the CLH-report to derive the most appropriate M-factor of 100.

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Indeed for the Taylor study the validity can be discussed. In addition, it has to be noted that also the Cerodaphnia study from Gallagher et al. (2011) has its limitations for deriving the M-factor, since the EC100 for that study equals to 25.8 µg active Cl/L. For the lower nominal test substance concentration, at which no effects on immobilisation were observed, no specific mean measured test substance concentration could be determined, other than is below the limit of quantification of 10 µg active Cl/L.

It is noted that the industry considers the acute toxicity data for invertebrates being unreliable, but not the fish study. The NL-CA therefore concludes that we agree upon one of the most critical toxicity values of 8.4 µg/L (Middaugh et al. 1977).

RAC's response

As the quality of many of the aquatic toxicity studies is questionable, RAC can do the following:

- (i) Accept only unequivocally good quality (e.g., Klimisch 1) studies;
- (ii) Accept studies of Klimisch score 1 and 2;
- (iii) Re-assess every available study;
- (iv) Apply the weight of evidence approach and agree on an acute M-factor of 10;
- (v) Clarify the bottlenecks of study conditions and chemical analyses – but these long term tasks cannot solve the current problem of making a good decision.

Date	Country	Organisation	Type of Organisation	Comment number
15.10.2015	Belgium	Euro Chlor	Industry or trade association	9

Comment received

When looking at all those available data in a weight of evidence approach, we believe the classification proposal should be:

For acute aquatic toxicity: Category 1, H400, M=10

Analysis of all available information, including two more recent, reliable studies indicate that the range of invertebrate acute toxicities to be used for classification and labelling purposes is 10-100 µg/L. Further studies on algae and available datasets on fish indicate that when all reliable acute ecotoxicity data are used for classification of sodium hypochlorite, toxicity is situated in the range $0.01 < L(E)C50 \leq 0.1$ mg/L, which corresponds to "Acute category 1" with M = 10.

For chronic aquatic toxicity: Category 1, H410, M=1

Given those available chronic data and the very rapid environmental degradability of sodium hypochlorite, this warrants the M=1 factor for the chronic aquatic toxicity classification of hypochlorite as per the second ATP to CLP.

We would therefore request that these M factors be used instead of the new proposed M factors for the CLH of sodium hypochlorite as explained in the attached document.

Dossier Submitter's Response

For the derivation of the most appropriate M-factors a weight-of-evidence is applied in which all data has been taken into account. Since there are more studies resulting in EC50 values between 0.001 and 0.01 mg/L, the M-factor of 100 seems more appropriate as described in section 5.5 of the CLH-report.

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The difference in opinion in M-factor for chronic aquatic toxicity relates to the issue if the substance can be considered rapidly degradable. The issue if sodium hypochlorite can be considered rapidly degradable should to our opinion be discussed in and decided by the RAC.
RAC's response
The submitted comments of MSCAs regarding the M-factors are not equivocal. Therefore, it is necessary to discuss the issue in RAC on one of the upcoming RAC-meetings.

Date	Country	Organisation	Type of Organisation	Comment number
19.11.2015	United Kingdom		MemberState	10

Comment received
<p>Based on the available information, we do not agree with the current proposal to consider sodium hypochlorite not rapidly degradable for classification. We note that under specified storage conditions sodium hypochlorite is stable. However, these conditions are not representative of the aquatic environment so are not relevant for classification. In the environment, sodium hypochlorite is considered highly reactive with transformation products including chlorine which in turn is reactive. This instability was recognised in the DAR and RAR processes which reflected the rapid dissipation and focused on chlorinated reaction products. Therefore, is there information to consider the environmental abiotic half-life of sodium hypochlorite to be >16 days for the purpose of classification? We feel this is unlikely as the substance strongly oxidises as demonstrated in ecotoxicity testing. In addition, are there data to consider the relative ecotoxicity of transformation products? Overall, we are unclear if there is sufficient detail to consider sodium hypochlorite not rapidly degradable for classification in contrast to previous assessments.</p> <p>At present we are unable to conclude if the ecotoxicity endpoints are valid for classification and derivation of M-factors. The CLH report includes endpoints considered valid in the 2007 RAR. It is unclear if all the study limitations highlighted by the Registrants for key studies were considered in the RAR process. We note the EFSA peer review conclusion on the DAR (EFSA Journal 2012;10(7):2796) considered the available ecotoxicity data did not fulfil the required endpoints and has set data gaps for all aquatic studies. Given the conflict in data validity, we feel the endpoints for key studies should be reassessed for the purpose of classification. It may be that the biocides review will provide further clarification on this.</p> <p>Finally, we note the variety of units and conversions between species. To avoid confusion, we feel the finalised classification opinion should clearly state the units with reference to active chlorine (%Cl) and sodium hypochlorite concentration.</p>

Dossier Submitter's Response
<p>We would like to thank the UK-CA for their clear-cut comments to our CLH-proposal. We agree that sodium hypochlorite solutions are highly instable in the aquatic environment, but would like to stress that the current conclusion on rapid degradability is based on CLP Regulation and guidance. The most relevant parts of the CLP Regulation and Guidance on which this proposal has been based are cited in the CLH-report in section 5.1.3. See also response to comments number 4. Again, we would like to stress it is up to RAC to discuss the issue degradability and to draw a conclusion based on the data and CLP Regulation as indicated in the CLH-report.</p>

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Next to the study limitations for some key studies, the registrant also reports an (reliable with restrictions) EC50 in the registration dossier in the range between 0.001 and 0.01 mg/L, with the study of Middaugh et al. 1977, with 48h-LC50 of 8.4 TRC with respect to egg hatchability for *Morone saxatilis*.

The EFSA peer review conclusion does not provide further clarification. The conclusion that a data gap exists for aquatic toxicity data is, without exception based on the absence of primary data.

Also we would like to leave it to RAC to select to the most appropriate unit for the finalised opinion, but feel sympathy for the proposal of the UK-CA to indicate next to the sodium hypochlorite concentration also the active chlorine content.

RAC's response

The Rapporteur agrees with the UK MSCA in many points and adds that not only the relative ecotoxicity of the transformation products is not known, but also their identity or their distribution. This is due to the complex impact of environmental conditions and water quality. The recommendation of the Rapporteur is to leave the decision to the RAC during the relevant meeting but to prepare the discussion.

NON-CONFIDENTIAL ATTACHMENTS

1. CLH proposal for sodium hypochlorite - AISE FECC Euro Chlor position. Submitted on 15/10/2015 by Euro Chlor. [Please refer to comment No 4]