Committee for Risk Assessment

RAC

# 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

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CLH-O-0000001412-86-116/F

# OPINION OF THE COMMITTEE FOR RISK ASSESSMENT ON A DOSSIER PROPOSING HARMONISED CLASSIFICATION AND LABELLING AT EU LEVEL

In accordance with Article 37 (4) of Regulation (EC) No 1272/2008, the Classification, Labelling and Packaging (CLP) Regulation, the Committee for Risk Assessment (RAC) has adopted an opinion on the proposal for harmonised classification and labelling (CLH) of:

Chemical name: sodium hypochlorite, solution ... % Cl active

EC Number: 231-668-3

CAS Number: 7681-52-9

The proposal was submitted by the Netherlands and received by RAC on 24 August 2015.

In this opinion, all classification and labelling elements are given in accordance with the CLP Regulation.

## PROCESS FOR ADOPTION OF THE OPINION

Netherlands has submitted a CLH dossier containing a proposal together with the justification and background information documented in a CLH report. The CLH report was made publicly available in accordance with the requirements of the CLP Regulation at *http://echa.europa.eu/harmonised-classification-and-labelling-consultation/* on 7 October 2015. Concerned parties and Member State Competent Authorities (MSCA) were invited to submit comments and contributions by 23 November 2015.

## ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: Katalin Gruiz

The opinion takes into account the comments provided by MSCAs and concerned parties in accordance with Article 37(4) of the CLP Regulation and the comments received are compiled in Annex 2.

The RAC opinion on the proposed harmonised classification and labelling was adopted on 3 June 2016 by consensus.

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

| | Index No | International Chemical Identification | EC No | CAS No | Classification | | Labelling | | | Specific Conc. Limits, M-factors | Notes |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Hazard Class and Category Code(s) | Hazard statement Code(s) | Pictogram, Signal Word Code(s) | Hazard state-ment Code(s) | Suppl. Hazard statement Code(s) | | |
| Current Annex VI entry | 017-011-00-1 | sodium hypochlorite, solution ... % Cl active | 231-668-3 | 7681-52-9 | Skin Corr. 1B<br>Aquatic Acute 1 | H314<br>H400 | GHS05<br>GHS09<br>Dgr | H314<br>H400 | EUH031 | EUH031: C ≥ 5 % | Note B |
| Dossier submitters proposal | 017-011-00-1 | sodium hypochlorite, solution ... % Cl active | 231-668-3 | 7681-52-9 | Retain<br>Aquatic Acute 1<br><br>Add<br>Aquatic Chronic 1 | Retain<br>H400<br><br>Add<br>H410 | Retain<br>GHS09 | Add<br>H410<br><br>Remove<br>H400 | | Add<br>M=100<br>M=10 | - |
| RAC opinion | 017-011-00-1 | sodium hypochlorite, solution ... % Cl active | 231-668-3 | 7681-52-9 | Retain<br>Aquatic Acute 1<br><br>Add<br>Aquatic Chronic 1 | Retain<br>H400<br><br>Add<br>H410 | Retain<br>GHS09 | Add<br>H410<br><br>Remove<br>H400 | | Add<br>M=10<br>M=1 | - |
| Resulting Annex VI entry if agreed by COM | 017-011-00-1 | sodium hypochlorite, solution ... % Cl active | 231-668-3 | 7681-52-9 | Skin Corr. 1B<br>Aquatic Acute 1<br>Aquatic Chronic 1 | H314<br>H400<br>H410 | GHS05<br>GHS09<br>Dgr | H314<br>H410 | EUH031 | M=10<br>M=1<br>EUH031: C ⩾ 5 % | Note B |

# GROUNDS FOR ADOPTION OF THE OPINION

## ENVIRONMENTAL HAZARD EVALUATION

### RAC evaluation of aquatic hazards (acute and chronic)

### Summary of the Dossier Submitter's proposal

Sodium hypochlorite currently has a harmonised classification as Aquatic Acute 1 (no M-factor specified) in Annex VI to the CLP Regulation. The dossier submitter (DS) proposed to add an acute M-factor of 100 to the existing harmonised entry based on lowest $LC_{50}$ values between 0.001 and 0.01 mg/L, as well as to also classify the substance as Aquatic Chronic 1 with a chronic M-factor of 10 based on non-rapid degradation and the lowest chronic NOEC values between 0.001 and 0.01 mg/L.

*Hydrolysis – stability*

Sodium hypochlorite solutions in pure water and at lower concentration levels are stable, when stored in the dark and at low temperature. At environmental pHs, only hypochlorous acid (HClO) and the hypochlorite ion ($ClO^-$) will be present.

From the half-lives reported in the CLH report (cf. Table 12), it can be concluded that, under environmentally relevant temperatures, hydrolysis is not a significant transformation route for sodium hypochlorite.

*Photodegradation*

Sodium hypochlorite solutions are very sensitive to light. Direct sunlight may cause rearrangement and decomposition resulting in the formation of chlorate ($ClO_3^-$) and oxygen (RAR, 2007).

*Biodegradation*

Sodium hypochlorite is an inorganic compound. Hence degradation studies such as the OECD TG 301 screening tests and water/sediment studies are not considered relevant.

*Overall degradation*

The DS did not consider sodium hypochlorite as rapidly degradable for the purposes of classification, based on the fact that hypochlorite solutions (kept away from sunlight and stored at low temperature) are stable and that some degradation products, such as chlorine ($Cl_2$), at low pH or organochlorine products in natural waters are hazardous to the environment. The degradation products chlorine and sodium chlorate ($NaClO_3$) have a harmonised classification as hazardous to the aquatic environment; $Cl_2$ is classified as Aquatic Acute 1 (with an M-factor of 100) and $NaClO_3$ is classified as Aquatic Chronic 2.

Whilst the DS eventually concluded that "*sodium hypochlorite cannot be considered rapidly degradable for classification purposes*" (cf. section 5.6 of the CLH report), the CLH report also contains arguments for considering the compound as being rapidly degradable.

*Bioaccumulation*

No bioaccumulation studies have been performed for sodium hypochlorite. Based on the environmental fate and behaviour of the substance, bioaccumulation in the aquatic ecosystem is not expected.

*Aquatic toxicity*

The DS collected data from the RAR (2007), DAR (2008), the REACH registration dossier (2014) and also from a number of new studies from industry not yet included in the REACH registration dossier. Furthermore, the DS clarified in the CLH report that the studies that have already been assessed and agreed upon at the EU level have not been re-assessed, but have been summarised in Table 13 of the CLH report.

New data provided in the REACH registration dossier has been assessed by the DS in more detail. Studies with critical effect data (including those which are considered invalid or not sufficiently reliable to take into account for risk assessment and classification purposes, according to the REACH registrant) have also been included in Table 13 of the CLH report. Concerning acute aquatic hazards, the DS proposed classification as Aquatic Acute 1 and an M-factor of 100, based on the results of the three most conservative studies, namely the ones by Middaugh *et al*., 1977 (48h-$LC_{50}$ = 0.0084 mg NaOCl/L) for *Morone saxatilis*, Williams *et al.,* 2003 (48h-$LC_{50}$ = 0.0053 mg NaOCl/L) for *Baetis harrisoni* and Taylor, 1993 (24h-$LC_{50}$ = 0.0053 mg NaOCl/L) for *Ceriodapnia dubia*.

Most other acute toxicity studies showed acute effect values generally between 0.01–0.1 mg/L.

Concerning long-term aquatic hazards, the DS proposed classification as Aquatic Chronic 1 and an M-factor of 10, based on the results of the majority of the available studies showing chronic toxic effects of sodium hypochlorite between 0.001 and 0.01 mg/L and on the consideration of the substance being non-rapidly degradable.

## Comments received during public consultation

Six industry-related associations and four Member State Competent Authorities (MSCAs) have submitted comments.

None of the commentators opposed the proposed classification as Aquatic Acute 1 and Aquatic Chronic 1. However, different opinions were expressed regarding the proposed M-factors reflecting the uncertainties on study selection and reliability, as well as rapid degradation.

The six industry-related organisations did not support any of the proposed M-factors: two of them referred to the consequences of the changes on business and customers, which are out of the scope of CLP and are not subject to assessment in the current regulatory context (Seveso implications).

Industry comments (AISE / Eurochlor position paper, 2015) on the potential classification of sodium hypochlorite, list several arguments disputing the reliability and overall quality of the key acute ecotoxicity studies as assigned/perceived by the DS, which represent the basis for the proposed acute M-factor of 100.

- The main objections against the study of Taylor (1993) can be summarised as follows: no information on the tested material, too little information on the analytical measurements, no indication on sample treatment, no indication whether or not tested concentrations were initial or final, no data on test design, shorter exposure periods of 24h rather than 48h, etc. The position paper concluded that the correct Klimisch score for the study should have been 3 (“not reliable”) rather than 4 (“not assignable”).

- The study of Williams *et al*. (2003) was also questioned by industry and, as an argument, the conclusion from the REACH registration dossier was cited, where the study was rated as Klimisch 4 ("not assignable") mentioning that "*The study was carried out in artificial streams, but the report lacks some key information such as hydraulic retention times and analytical measurement results. Although it is difficult to assign a Klimisch rating for the study, a rating of 3a or 4e (document insufficient for assessment) is proposed*".

As a result of the presence of newer, GLP-compliant studies (Gallagher *et al*., 2009 and 2011) and the shortcomings in the Taylor and Williams studies, the Industry position paper proposed an acute M-factor of 10 instead of 100.

Responding to the Industry comments on study reliability, the DS highlighted limitations concerning the Gallagher *et al*. (2011) study and stated that no reservations have been expressed on the Middaugh *et al*. study (1977), which can be considered as the one with "*the most critical toxicity values*" for classification purposes.

Concerning degradability, several comments referred to the fact that rapid degradation should be assessed under environmentally relevant conditions and argued that there is currently not sufficient evidence to consider the substance as non-rapidly degradable. The DS agreed 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 the CLP Regulation and guidance*.

Other commentators had similar arguments against an acute M-factor of 100 and the proposed chronic M-factor of 10, such as:

- The uncertainties in study quality and results;
- Definite knowledge on rapid transformation of sodium hypochlorite under environmentally relevant conditions.

Two MSCAs supported the DS's proposal, but one of them did not support the acute M-factor of 100, recommending an acute M-factor of 10, based on a weight-of-evidence approach (regarding study reliability) leading to acute aquatic toxicity between 10–100 µg/L.

One MSCA had editorial recommendations regarding the EC and CAS names of sodium hypochlorite and the composition of the studied substances.

In summary, the MSCAs' comments reflected the associated uncertainties (relevance and reliability of ecotoxicological studies, rapid degradability), whilst the general opinion of industry favoured an acute M-factor of 10 (based on the use of more recent, reliable study results) and a chronic M-factor of 1 (considering the substance as rapidly degradable).

## Assessment and comparison with the classification criteria

*Hydrolysis, stability*

The DS concluded in the CLH report that "*From Table 12 it can be concluded that under environmental relevant temperature hydrolysis is not a significant transformation route for sodium hypochlorite. Sodium hypochlorite solutions in pure water and at lower concentration levels are stable, when stored in the dark and at low temperature*". Hydrolysis was much faster (half-lives <16 days) for temperatures of 60°C or above.

*Photodegradation*

Sodium hypochlorite is very sensitive to photolysis. The photolysis half-life of sodium hypochlorite solution is 12 min at pH 8, 37 min at pH 7 and 60 min at pH 5 when exposed as a horizontal

water layer to solar irradiation of 1.05 kW/$m^2$. Chlorate and oxygen are formed as photolysis products.
In the Guidance on the Application of the CLP Criteria version 4.1 (Annex II. 2.3.9) it is stated that "*Information on photochemical degradation is difficult to use for classification purposes. The actual degree of photochemical degradation in the aquatic environment depends on local conditions e.g. water depth, suspended solids, turbidity as well as seasonal influences, and the hazard of the degradation products is usually not known. Probably only seldom will enough information be available for a thorough evaluation based on photochemical degradation*".

*Degradation*

Opinion of the RAC on rapid degradation of sodium hypochlorite

RAC concluded that the degradation decision scheme as in the CLP Guidance (Version 4.1, June 2015, section 4.1.3.2.3.2.) is not directly applicable for inorganic substances, as it was primarily developed for organics. Thus, points a. (ready biodegradability) and b. (simulation testing) from the decision scheme are not irrelevant for sodium hypochlorite.

Instead, a more flexible approach to rapid degradability needs to be taken in weighing the evidence, based on the rate of transformation/dissipation/"mineralisation" of the substance under environmentally relevant conditions.

Concerning environmental transformation, RAC concluded that:

(i) Transformation to the chloride ion ($Cl^-$) occurs very rapidly in natural waters.Free chlorine is very rapidly and totally transformed to combined chlorine (RAR, 2007). Combined chlorine decays somewhat less rapidly than free chlorine, however, it is also short-lived in the presence of oxidisable substrates, which are commonly present in the aquatic environment (half-lives are typically hours) and the major end-product is the chloride ion (cf. RCOM comments from industry). The reactivity and degradation is also illustrated by the fact that it is very difficult in the aquatic toxicity tests to maintain the test substance concentrations; the only way of doing so is to make use of flow-through test systems (CLH Report, section 5.1.3);

(ii) Transformation is irreversible;

(iii) Transformation leads to non-toxic (chloride, $Cl^-$) or less toxic (chlorate, $OCl_3^-$) breakdown products compared to hypochlorite. In natural waters, three chlorine species are in equilibrium: $Cl_2$, HOCl and ClO-. At pH above 4, $Cl_2$ does not exist. At environmental relevant pHs, both ClO- and HOCl would co-exist and would further be decomposed to, generally, less toxic degradation products such as sodium chloride (NaCl), sodium chlorite ($NaClO_2$), sodium chlorate ($NaClO_3$) and oxygen ($O_2$). While $NaClO_3$ (sodium chlorate) has currently a harmonised classification as Aquatic Chronic 2 and acute toxicity data from the PAN Pesticide database are well above 1 mg/L, there is currently no clarity on the likelihood of its formation;

(iv) Transformation in natural waters leads to non-persistent degradants and other reaction products.

Hence, in applying a weight of evidence approach to this specific case, RAC concludes that the substance should be considered as rapidly degradable for classification purposes.

Acute Aquatic Toxicity

Classification as Aquatic Acute 1 is indicated in all of the acute aquatic toxicity results listed in the CLH Report that show acute aquatic toxicity values below 1 mg/L. The identified uncertainties in study reliability do not dispute the environmental classification as Aquatic Acute 1, but the acute M-factor is subject to discussion.

As discussed earlier, the CLH report contains three aquatic toxicity studies which indicate an acute M-factor of 100. For two of these studies, comments during the public consultation raised reliability issues.

Table: Key study data from the CLH report (referring to short-term endpoints) - acute aquatic toxicity results from studies selected by the DS for classification purposes.

| Test organism | Standard/ method | End point | Result (µg/L) | Result in NaOCl (µg/L) | Key/supportive for CLP | Reliability: evaluation from other reports* | Reference | Origin of data |
|---|---|---|---|---|---|---|---|---|
| Fish / brackish and seawater *Oncorhynchus kisutch* | Flow-through bioassay. No guideline. No GLP reported. | 96h $LC_{50}$ | 32 (TRO) | 34 (TRO) | Key study | RAR: 2 DAR: supportive | Thatcher (1978) | RAR, 2007; DAR, 2008 |
| Fish / brackish and seawater *Morone saxatilis* | Flow-through test for early-life stages. No guideline. No GLP reported. | 48h $LC_{50}$ | 8 (TRC) | 8.4 (TRC) | Supportive study | RAR: supportive DAR: supportive REACH: 2 | Middaugh *et al.* (1977) | RAR, 2007; DAR, 2008; REACH, 2014 |
| Invertebrates / freshwater *Ceriodapnia dubia* | Continuous flow-through test without food. No guideline. No GLP reported. | 24h $LC_{50}$ Analysis of Cl-species | 5 (FAC) | 5.25 (FAC) | Key study | RAR: 2 DAR: 2 REACH: 4 | Taylor (1993) | RAR, 2007; DAR, 2008; REACH, 2014 |
| Invertebrates / freshwater *Baetis harrisoni* | Flow through artificial stream. No guideline No GLP reported. | 48h $LC_{50}$ | 5 / 6 (TRC) | 5.3 / 6.3 (TRC) | Unclear if DS intended to use the study as key or support | 2 – ??? REACH: 4 | Williams *et al.* (2003)[c] | REACH, 2014 |
| Algae / freshwater *Pseudokirchneriella subcapitata* | OECD TG 201 GLP | 24h $ErC_{50}$ | >23.3 (FAC) | <24.5 (FAC) | Key study | Industry: 1 | Liedtke (2013) | Industry, after 2014 |

FAC: free available chlorine, TRC: total residue chlorine, TRO: total residue oxidant

* Rating according to Klimisch scores. Rating in RAR and DAR is based on the recommendation of European authorities: 1: Valid without restriction; 2: valid with restriction; 3: invalid (not reliable); 4: not assignable

The DS highlighted 3 key studies as basis for acute classification, based on the most conservative (lowest) $LC/EC_{50}$ results in the CLH report. Total residue oxidant (TRO) or free available chlorine (FAC) were measured in the tests. The DS considered FAC being equivalent to TRC content for classification purposes. The $LC/EC_{50}$ results are given as the concentration of the tested substance in µg/L and are all converted to NaOCl µg/L (results shown below).

Results, rating (Klimisch score) and the standard followed by the key studies selected by the dossier submitter are further summarised below.

1: Thatcher (1978), Fish: 34 µg/L (TRO), not standardised, RAR reliability: 2; DAR: supportive;

2: Taylor (1993), Invertebrates: 5.25 µg/L (FAC), not standardised, RAR reliability: 2; DAR reliability: 2, but saying is questionable; REACH registration dossier rated as reliability 4;

3: Liedtke (2013), Algae: <24.5 µg/L (FAC), standardised, GLP, Industry rated as reliability 1.

The study of Taylor (1993) was considered as invalid in the industry position paper (AISE/Eurochlor, 2015) submitted during public consultation due to the shortcomings of the study (see details in section 'Comments received during public consultation'). Moreover the evaluation of the DAR (2008) rated the study as Klimisch 2, but questioned the study quality. As a consequence the study results can just be used as indication for toxicity. Finally, while the study was rated as Klimisch 4 in the REACH Registration dossier, it can be considered as appropriate for classification purposes according to the opinion of the DS.

The supportive studies highlighted by the DS in the CLH Report:

4: Middaugh *et al*. (1977), Fish: 8.4 µg/L (TRC), not standardised, RAR and DAR both qualified as supportive; REACH registration dossier reliability: 2;

5: Williams *et al*. (2003), Invertebrate: 5.3/6.3 µg/L (TRC) not standardized, CLH dossier reliability 2, REACH registration dossier reliability: 4

The Middaugh *et al.* (1977) study is questionable from many point of views: the evaluators in the RAR (2007) considered the result as a rough estimate, only egg relative hatchability was measured. The DAR (2008) authors did not fully recognise this study either, but recommended to take the results into consideration as supportive data. Having deeper insight into the study details: both the endpoint and testing performed with a non-standard species are without precedents and experience. The study of Williams *et al*. (2003) was also critically commented in the industry position paper (see also the previous section of the opinion) and RAC concurs with the comments made and would not base acute classification on the results of this study. In the CLP guidance is required an equivalent standard in terms of test conditions when using another species from the same trophic level, which was not completely fulfiled: e.g. the concentration of the stock solution is not specified. The flow rate of the stock solution is quantified as 15 drops/minute. It is stated in the study that the *"free residual chlorine and total residual chlorine values were the same"*, but no analytical data are published and the analysis method used does not allow to measure test concentrations, given that the colorimetric method can measure 0.1–1.0 mg/L range, which differs from the test concentration range of 0–16 µg/L, so only the stock solution could be analysed by this method, if this stock solution was concentrated enough.

It is important to note that the reliability rating of the studies has taken place for different regulatory regimes and different information (and study quality) requirements.

In the CLP Guidance (Version 4.1, June 2015) section 4.1.3.1.2 priority is given to:

- "*Preferably data shall be derived using the standardised test methods referred to in Article 8(3);*
- *[]…classification shall be based on the best available data;*
- *Regarding the use of test data, 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;*
- *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 notes that with the exception of Liedtke (2013), none of the studies presented above are standard ones and/or are rated with a Klimisch score of 1.

Table: Acute aquatic toxicity results in the CLH report from studies not selected as key or supportive studies by the DS.

| Test organism | Standard/ method | End point | Result (µg/L) | Result in NaOCl (µg/L) | Key or supportive for CLP | Reliability: evaluation from other reports | Reference | Origin of data |
|---|---|---|---|---|---|---|---|---|
| Fish /freshwater *Salmo gairdneri* | No continuous exposure<br>No guideline<br>No GLP reported | 96h $LC_{50}$ | 60 (TRC)<br>30 (FAC) | 63 (TRC)<br>32 (FAC) | Not | RAR: supportive<br>DAR: supportive<br>REACH: 2 | Bass *et al*. (1977), Heath (1978) | RAR, 2007; DAR, 2008 REACH, 2014 |
| Fish /freshwater *Ictalurus punctatus* | No continuous exposure<br>No guideline<br>No GLP reported | 96h $LC_{50}$ | 64 (TRC)<br>32 (FAC) | 67 (TRC)<br>34 (FAC) | Not | RAR: supportive<br>DAR: supportive<br>REACH: 2 | Bass *et al*. (1977), Heath (1978) | RAR, 2007; DAR, 2008 REACH, 2014 |
| Fish /freshwater (juvenils) *Salmo gairdneri* | No continuous exposure<br>No guideline<br>No GLP reported | 24h $LC_{50}$ | 430 | 452 | Not | RAR: supportive<br>DAR: supportive<br>REACH: 2 | Brooks and Seegert (1977) | RAR, 2007; DAR, 2008 REACH, 2014 |
| Fish /freshwater *Onchorhyncus kisutch*<br>*Alosa pseudoharengus*<br>*Notropis hudsonius*<br>*Osmerus mordax* | No continuous exposure<br>No guideline<br>No GLP reported | 48h $LC_{50}$ | 1260–2410 | 1323–2531 | Not | RAR: supportive<br>DAR: supportive<br>REACH: 2 | Seegert and Brooks (1978) | RAR, 2007; DAR, 2008 REACH, 2014 |
| Fish /freshwater *Pimephales promelas* | No continuous exposure<br>No guideline<br>No GLP reported | 96h $LC_{50}$ | 80 (TRC)<br>>40 (FAC) | 84 (TRC)<br>>42 (FAC) | Not | RAR: supportive<br>DAR: supportive<br>REACH: 3 | Wilde *et al*. (1983a,b) | RAR, 2007; DAR, 2008 REACH, 2014 |
| Freshwater fish *Cyprinus carpio* | No continuous exposure<br>No guideline<br>No GLP reported | 48h $LC_{50}$ | 260 | 273 | Not | RAR: supportive<br>DAR: supportive | Tsai *et al*. (1990) | RAR, 2007; DAR, 2008 |
| Fish /freshwater *Gambusia affinis* | No guideline<br>No GLP reported | 48h $LC_{50}$ | 610 | 641 | Not | RAR: supportive<br>DAR: supportive | Tsai *et al*. (1990) | RAR, 2007; DAR, 2008 |
| Fish /freshwater *Gambusia affinis* | No continuous exposure<br>No guideline<br>No GLP reported | 48h $LC_{50}$ | 840 | 882 | Not | RAR: supportive<br>DAR: supportive | Mattice *et al*. (1981) | RAR, 2007; DAR, 2008 |
| Fish /freshwater *Menidia menidia* | No guideline<br>No GLP reported | 96h $LC_{50}$ | 37 (TRC) | 39 (TRC) | Not | RAR: supportive<br>DAR: supportive<br>REACH: 3 | Roberts *et al*. (1975) | RAR, 2007; DAR, 2008 REACH, 2014 |
| Fish /brackish & sea water *Leiostomus xanthurus* | No guideline<br>No GLP reported | 96h $LC_{50}$ | 90 (TRC&FAC) | 95 (TRC&FAC) | Not | RAR: 1<br>DAR: 1<br>REACH: 2 | Bellanca and Bailey (1977) | RAR, 2007; DAR, 2008; REACH, 2014 |
| Fish / brackish & sea water *Gasterosteous aculeatus* | No guideline<br>No GLP reported | 96h $LC_{50}$ | 167 | 175 | Not | RAR: 2<br>DAR: supportive | Thatcher (1978) | RAR, 2007; DAR, 2008 |
| Invertebrate / freshwater *Ceriodapnia dubia* | Flow-through system with neo-nate *C. dubia*, OECD TG 202 GLP | 48h $EC_{50}$ | >25.8 (active chlorine, mean measured) | >27.1 (active chlorine, mean measured) | Not | REACH: 1 | Gallagher, *et al*. (2011) | REACH, 2014 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Invertebrate / freshwater *Daphnia magna* | Flow through system OECD TG 202 GLP | 48h $EC_{50}$ | >49 (active chlorine, mean measured) | >51 (active chlorine, mean measured) | Not | REACH: 1 | Gallagher, *et al*. (2009) | REACH, 2014 |
| Invertebrate / brackish & sea water *Pandalus goniurus* | No guideline No GLP reported | 96h $LC_{50}$ | 90 (TRC) | 95 (TRC) | Not | RAR: 2 DAR: supportive REACH: 2 | Thatcher (1978) | RAR, 2007; DAR, 2008 REACH, 2014 |
| Invertebrates / brackish & sea water *Brachionus plicatilis* *Acartia tonsa* *Crassostrea virginica (larvae)* | No continuous exposure, flow through system. No guideline No GLP reported | 48h $EC_{50}$ 48h $EC_{50}$ 48h $EC_{50}$ | 10–820 180 80–120 | 10.5–861 189 84–126 | Not | RAR: supportive DAR: supportive for all | Capuzzo *et al*. (1976, 1979a,b) | RAR, 2007; DAR, 2008 |
| Invertebrate / brackish & sea water *Crassostrea virginica (juveniles)* | Static and flow through systems No guideline No GLP reported | 96h $LC_{50}$ Shell deposition | 23 (TRC) | 24 (TRC) | Not | RAR: supportive DAR: supportive | Roberts *et al*. (1975) | RAR, 2007; DAR, 2008 |
| Invertebrates / brackish & sea water *Crassostrea virginica (larvae)* *Acartia tonsa* | Continuous exposure in flowing river water No guideline No GLP reported | 48h $EC_{50}$ 48h $EC_{50}$ | 26 (TRC, CaOCl) 29 (TRC, CaOCl) | 27 (TRC) 30 (TRC) | Not | RAR: 2 DAR: 2 | Roberts and Gleeson (1978) | RAR, 2007; DAR, 2008 |
| Invertebrate / brackish & sea water *Epioblasma brevidens* | No guideline No GLP reported | 24h $EC_{50}$ | 70 (TRC) | 73.5 (TRC) | Not | REACH: 2 | Valenti *et al*. (2006) | REACH, 2014 |

As a large dataset is available for sodium hypochlorite, including studies according to standard methods provided by GLP laboratories, as well as having been rated by a Klimisch score of 1 (recommended by the CLP Guidance as key) or 2 (recommended as supportive), preference for classification should be given to studies rated as 1 and 2. The following studies can be considered as key or supportive ones, even though they have not been selected as such by the DS:

6: Gallagher, *et al.* (2011), Invertebrate <27.1 µg/L (FAC, mean), OECD TG 202, GLP, REACH dossier reliability: 1;

7: Gallagher, *et al*. (2009), Invertebrate <51 µg/L (FAC, mean), OECD TG 202, GLP, REACH: dossier reliability 1;

8: Bass *et al*. (1977), Heath (1978), Fish 63 µg/L (TRC) 32 µg/L (FAC), RAR: supportive, DAR: supportive, REACH dossier reliability: 2;

9: Bass *et al*. (1977), Heath (1978), Fish 67 µg/L (TRC) 34 µg/L (FAC), RAR: supportive, DAR: supportive REACH dossier reliability: 2;

10: Bellanca and Bailey (1977), Fish 95 µg/L (TRC&FAC), RAR reliability: 1, DAR reliability: 1, REACH dossier reliability: 2;

11: Roberts and Gleeson (1978), Invertebrates $EC_{50}$ 30 µg/L (TRC), 27 µg/L (TRC), RAR reliability: 2, DAR reliability: 2;

12: Valenti *et al*. (2006), Invertebrate 73.5 µg/L (TRC), REACH dossier reliability: 2;

13: Thatcher (1978), Invertebrate 95 µg/L (TRC), RAR reliability: 2, DAR: supportive, REACH dossier reliability: 2

It is proposed that the following “weighing” is placed in the above-mentioned studies numbered in the same order :

1: Supportive

| Test organism | Standard/ method | End point | Result (µg/L) | Result in NaOCl (µg/L) | Key or supportive for CLP | Evaluation from other reports | Reference | Source of data |
|---|---|---|---|---|---|---|---|---|
| Fish / brackish & seawater *Menidia peninsulae* | Self-developed test for early life stages with 36 h eggs, flow through sea water<br>No guideline<br>No GLP reported | 28d NOEC | 40 (TRC) | 42 (TRC) | Key | RAR: 1<br>DAR: 1 | Goodman *et al.* (1983) | RAR, 2007<br>DAR, 2008 |
| Fish /freshwater *Ictalarus punctatus* | Flow-through field study with standard fish species<br>No guideline | 134d NOEC | 5 (TRC) | 5.3 (TRC) | Supportive | RAR: supportive<br>DAR: supportive | Hermanutz *et al.* (1990) | RAR, 2007<br>DAR, 2008 |

2: Questionable due to Klimisch score 4 in REACH registration dossier

3: Acceptable as key study (standardised methods, GLP-compliant, Klimisch score 1) (Liedtke, 2013)

4: Supportive

5: Questionable due to Klimisch score 4 in REACH registration dossier

6: Acceptable as key study (standardised methods, GLP-compliant, Klimisch score 1) (Gallagher, *et al.,* 2011)

7: Acceptable as key study (standardised methods, GLP-compliant, Klimisch score 1) (Gallagher, *et al*., 2009)

8: Supportive (not standardised or GLP, but rated as Klimisch score 2 by different Regulatory regimes and different purposes)

9: Supportive (not standardised or GLP, but rated as Klimisch score 2 by different Regulatory regimes and different purposes)

10: Supportive (not standardised or GLP, but rated as Klimisch score 2 by different Regulatory regimes and different purposes)

11: Supportive (not standardised or GLP, but rated as Klimisch score 2 by different Regulatory regimes and different purposes)

12: Supportive (not standardised or GLP, but rated as Klimisch score 2 by different Regulatory regimes and different purposes)

13: Supportive (not standardised or GLP, but rated as Klimisch score 2 by different Regulatory regimes and different purposes)

Given the large amount of data, RAC took only the the reliable studies into consideration as key studies and those with a Klimisch score of 2 as supportive.

Acute M-factor

Accepting only the standardised, GLP-compliant studies of reliability score 1 and 2 (studies 1, 3 and 6 to 13) and rejecting studies of reliability score 4 (studies 2, 4 and 5) would lead to an acute M-factor of 10, as all studies reveal acute concentrations between 10–100 µg/L.

Another difficulty linked to the lowest study results is the analytical uncertainty when measuring hypochlorite concentrations below 10 µg/L, with the LOQ of the most advanced measuring methods being 10 µg/L.

Chronic Aquatic Toxicity

Based on the available information (see Table below), it can be concluded that the lowest NOEC values are between 0.001 and 0.01 mg/L. Considering NaOCl to be rapidly degradable the corresponding chronic M-factor = 1.

Table: Key and supportive long-term aquatic toxicity studies highlighted by the DS due to the lowest NOEC values.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | No GLP reported | | | | | | | |
| Invertebrates / brackish & sea water /oyster *Crassostrea virginica* | Non-standard field study of shell deposition<br>No guideline<br>No GLP reported | 15d NOEC | 7 (TRO) | 7.4 (TRO) | Key | RAR: 2<br>DAR: supportive | Liden *et al.* (1980) | RAR, 2007<br>DAR, 2008 |
| Invertebrate / freshwater *Epioblasma capsaeformis* | No guideline<br>No GLP reported | 21 d NOEC | 10 (TRC, nominal, CaOCl) | 10.5 (TRC nominal, CaOCl) | Supportive | REACH: 2 | Valenti *et al.* (2006) | REACH, 2014 |
| Algae / freshwater *Pseudokirchneriella subcapitata* | Algal growth rate inhibition<br>OECD TG 201 | 24h LOErC<br>24h LOEbC | <10.8 (FAC)<br><10.8 (FAC) | <11.3 (FAC)<br><11.3 (FAC) | Key | Industry: 1 | Liedtke (2013) | Industry, after 2014 |
| Peryphytic community | Flow through microcosms<br>No guideline<br>No GLP reported | 7d NOEbC | 3 (FAC) | 3.2 (FAC) | Key | RAR: 2<br>DAR:2 | Cairns *et al.* l (1990)ab | RAR, 2007<br>DAR, 2008 |
| Zooplankton (density) | Outdoor mesocosm, daily chlorine pulse.<br>No guideline<br>No GLP reported | 24d NOEC | 1.5 (FAC) | 1.6 (FAC) | Supportive | DAR: 2<br>supportive | Pratt *et al.* (1988) | DAR, 2008 |

In summary, RAC is of the opinion that sodium hypochlorite should be classified as:

Aquatic Acute 1 (H400), M=10

Aquatic Chronic 1 (H410), M=1 based on rapid degradability.

## ANNEXES:

Annex 1 The Background Document (BD) gives the detailed scientific grounds for the opinion. The BD is based on the CLH report prepared by the Dossier Submitter; the evaluation performed by RAC is contained in 'RAC boxes'.

Annex 2 Comments received on the CLH report, response to comments provided by the Dossier Submitter and by RAC (excluding confidential information).