Committee for Risk Assessment

RAC

Annex 1

Background document

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

The background document is a compilation of information considered relevant by the dossier submitter or by RAC for the proposed classification. It includes the proposal of the dossier submitter and the conclusion of RAC. It is based on the official CLH report submitted to public consultation. RAC has not changed the text of this CLH report but inserted text which is specifically marked as 'RAC evaluation'. Only the RAC text reflects the view of RAC.

Adopted

3 June 2016

CLH report

Proposal for Harmonised Classification and Labelling

Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2

Substance Name:

Sodium hypochlorite, solution … % Cl active

EC Number: **231-668-3**

CAS Number: **7681-52-9**

Index Number: **017-011-00-1**

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Version number: 1.0 **Date: August 2015**

CONTENTS

Part A.

PART B.

Part A.

1 PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

1.1 Substance

Table 1: Substance identity

Substance name:	**Sodium hypochlorite, solution ... % Cl active**
EC number:	**231-668-3**
CAS number:	**7681-52-9**
Annex VI Index number:	**017-011-00-1**
Degree of purity:	**Maximum 25% w/w**
Impurities:	**Maximum 0.8% (w/w) sodium chlorate**

1.2 Harmonised classification and labelling proposal

Table 2: The current Annex VI entry and the proposed harmonised classification

	CLP Regulation
Current entry in Annex VI, CLP Regulation	Skin Corr. 1B H314 Aquatic Acute 1 H400
Current proposal for consideration by RAC	Aquatic Acute 1 H400 Aquatic Chronic 1 H410 Acute M-factor 100 Chronic M-factor 10
Resulting harmonised classification (future entry in Annex VI, CLP Regulation)	Skin Corr. 1B H314 Aquatic Acute 1 H400 Aquatic Chronic 1 H410 Acute M-factor 100 Chronic M-factor 10

1.3 Proposed harmonised classification and labelling based on CLP Regulation

Table 3: Proposed classification according to the CLP Regulation

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
2.1.	Explosives				Not reviewed
2.2.	Flammable gases				Not reviewed
2.3.	Flammable aerosols				Not reviewed
2.4.	Oxidising gases				Not reviewed
2.5.	Gases under pressure				Not reviewed
2.6.	Flammable liquids				Not reviewed
2.7.	Flammable solids				Not reviewed
2.8.	Self-reactive substances and mixtures				Not reviewed
2.9.	Pyrophoric liquids				Not reviewed
2.10.	Pyrophoric solids				Not reviewed
2.11.	Self-heating substances and mixtures				Not reviewed
2.12.	Substances and mixtures which in contact with water emit flammable gases				Not reviewed
2.13.	Oxidising liquids				Not reviewed
2.14.	Oxidising solids				Not reviewed
2.15.	Organic peroxides				Not reviewed
2.16.	Substance and mixtures corrosive to metals				Not reviewed
3.1.	Acute toxicity - oral				Not reviewed
	Acute toxicity - dermal				Not reviewed
	Acute toxicity - inhalation				Not reviewed
3.2.	Skin corrosion / irritation			Skin Corr. 1B	Not reviewed
3.3.	Serious eye damage / eye irritation				Not reviewed
3.4.	Respiratory sensitisation				Not reviewed
3.4.	Skin sensitisation				Not reviewed
3.5.	Germ cell mutagenicity				Not reviewed
3.6	Carcinogenicity				Not reviewed
3.7.	Reproductive toxicity				Not reviewed
3.8.	Specific target organ toxicity –single exposure				Not reviewed

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
3.9.	Specific target organ toxicity – repeated exposure				Not reviewed
3.10.	Aspiration hazard				Not reviewed
4.1.	Hazardous to the aquatic environment	Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Acute M-factor 100 Chronic M-factor 10	Aquatic Acute 1 (H400)	
5.1.	Hazardous to the ozone layer				Not reviewed

[1)] Including specific concentration limits (SCLs) and M-factors
[2)] Data lacking, inconclusive, or conclusive but not sufficient for classification

Labelling:	Signal word:	Danger
	Pictogram:	GHS05, GHS09
	Hazard statements:	H314, Causes severe skin burns and eye damage H410, Very toxic to aquatic life with long lasting effects EUH031, Contact with acids liberates toxic gas

Proposed notes assigned to an entry:

Note B is assigned to the current entry in Annex VI. No additional notes are proposed.

2 BACKGROUND TO THE CLH PROPOSAL

2.1 History of the previous classification and labelling

Sodium hypochlorite was notified as an existing active substance and assessed in accordance to Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of the substance into Annex I to the directive (Draft Assessment Report, May 2008, RMS the Netherlands).

Sodium hypochlorite was discussed at the Commission working group on the classification and labelling in December 1998 and added to Annex I of Directive 67/548/EEC in the 29th ATP with classification C; R34, R31, N; R50.

Sodium hypochlorite is currently listed (entry 017-011-00-1) in Annex VI of Regulation EC no. 1272/2008 with the same classification as was listed in the 29th ATP to Directive 67/548/EEC.

Sodium hypochlorite as a substance has been assessed extensively in the past (RAR, DAR and CAR, although that the CAR has not yet been finalised). The studies that already have been assessed and agreed upon at the EU level have not been reassessed, but have been summarized in the current harmonized classification and labelling dossier. New data which is provided in the REACH registration dossier has been assessed and summarized in more detail.

2.2 Short summary of the scientific justification for the CLH proposal

Sodium hypochlorite is currently listed in Annex VI to the CLP as acutely hazardous to the aquatic environment. However, no harmonised M-factor is listed in Annex VI. Furthermore, the currently available data suggest that sodium hypochlorite needs to be classified as Aquatic Chronic Cat 1 based on the criteria of the 2nd ATP to the CLP (Regulation 286/2011).

In this dossier, a chronic aquatic classification and M-factors for acute and chronic toxicity are proposed.

The physical hazards and human health hazards have not been evaluated, this dossier does not propose any changes to the classification of physical hazards or human health hazards.

2.3 Current harmonised classification and labelling

2.3.1 Current classification and labelling in Annex VI, Table 3.1 in the CLP Regulation

Table 4: Current classification and labelling in Annex VI, Table 3.1 in the CLP Regulation

Classification		**Labelling**			**Specific Concentration limits, M-Factors**	**Notes**
Hazard Class and Category Code(s)	**Hazard Statement Code(s)**	**Hazard Statement Code(s)**	**Supplementary Hazard Statement Code(s)**	**Pictograms, Signal Word Code(s)**		
Skin Corr. 1B Aquatic Acute 1	H314 H400	H314 H400	EUH031	GHS09 GHS05 Dgr		Note B

2.3.2 Current classification and labelling in Annex VI, Table 3.2 in the CLP Regulation

Table 5: Current classification and labelling in Annex VI, Table 3.2 in the CLP Regulation

Classification	**Labelling**
C; R34 R31 N; R50	C; N R: 31-34-50 S: (1/2-)28-45-50-61

2.4 Current self-classification and labelling

2.4.1 Current self-classification and labelling based on the CLP Regulation criteria

Table 6 shows the notifications made to the CLP Inventory for sodium hypochlorite as of 13-11-2014.

Table 6: Notifications made to the CLP Inventory for sodium hypochlorite

Classification		**Labelling**			**Specific Concentration limits, M- Factors**	**Notes**	**Number of Notifiers**
Hazard Class and Category Code(s)	**Hazard Statement Code(s)**	**Hazard Statement Code(s)**	**Supplementary Hazard Statement Code(s)**	**Pictograms Signal Word Code(s)**			
Ox. Gas	H270		EUH031	GHS09 GHS05 GHS03 Dgr		Note B	355
Skin Corr. 1B	H314	H314					
Eye Dam. 1	H318	H318					
Aquatic Acute 1	H400	H400					

<table>
<tr><th colspan="2">Classification</th><th colspan="3">Labelling</th><th rowspan="2">Specific Concentration limits, M- Factors</th><th rowspan="2">Notes</th><th rowspan="2">Number of Notifiers</th></tr>
<tr><th>Hazard Class and Category Code(s)</th><th>Hazard Statement Code(s)</th><th>Hazard Statement Code(s)</th><th>Supplementary Hazard Statement Code(s)</th><th>Pictograms Signal Word Code(s)</th></tr>
<tr><td></td><td></td><td>H272</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Skin Corr. 1B</td><td>H314</td><td>H314</td><td rowspan="2">EUH031</td><td rowspan="2">GHS09
GHS05
Dgr</td><td rowspan="2"></td><td rowspan="2">Note B</td><td rowspan="2">324</td></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td><td>H400</td></tr>
<tr><td>Skin Corr. 1B</td><td>H314</td><td>H314</td><td rowspan="2">EUH031</td><td rowspan="2">GHS09
GHS05
Dgr</td><td rowspan="2"></td><td rowspan="2">Note B</td><td rowspan="2">295</td></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td><td>H400</td></tr>
<tr><td>Met. Corr. 1</td><td>H290</td><td>H290</td><td rowspan="6"></td><td rowspan="6">GHS07
GHS09
GHS05
Dgr</td><td rowspan="6">M=10</td><td rowspan="6"></td><td rowspan="6">93</td></tr>
<tr><td>Skin Corr. 1B</td><td>H314</td><td>H314</td></tr>
<tr><td>Eye Dam. 1</td><td>H318</td><td>H318</td></tr>
<tr><td>STOT SE 3</td><td>H335 (not available)</td><td>H335</td></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td><td>H400</td></tr>
<tr><td>Aquatic Chronic 1</td><td>H410</td><td>H410</td></tr>
<tr><td>Met. Corr. 1</td><td>H290</td><td>H290</td><td rowspan="5">EUH031</td><td rowspan="5">GHS09
GHS05
Dgr</td><td rowspan="5">M=10</td><td rowspan="5"></td><td rowspan="5">78</td></tr>
<tr><td>Skin Corr. 1B</td><td>H314</td><td>H314</td></tr>
<tr><td>Eye Dam. 1</td><td>H318</td><td></td></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td><td>H400</td></tr>
<tr><td>Aquatic Chronic 2</td><td>H411</td><td>H411</td></tr>
<tr><td>Met. Corr. 1</td><td>H290</td><td>H290</td><td rowspan="6">EUH031</td><td rowspan="6">GHS07
GHS09
GHS05
Dgr</td><td rowspan="6">M=10</td><td rowspan="6"></td><td rowspan="6">78</td></tr>
<tr><td>Skin Corr. 1B</td><td>H314</td><td>H314</td></tr>
<tr><td>Eye Dam. 1</td><td>H318</td><td></td></tr>
<tr><td>STOT SE 3</td><td>H335 (Respiratory tra…) (inhalation)</td><td>H335</td></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td><td>H400</td></tr>
<tr><td>Aquatic Chronic 1</td><td>H410</td><td>H410</td></tr>
<tr><td>Skin Irrit. 2</td><td>H315</td><td>H315</td><td rowspan="4"></td><td rowspan="4">GHS07
GHS09
Wng</td><td rowspan="4">M=10</td><td rowspan="4"></td><td rowspan="4">78</td></tr>
<tr><td>Eye Irrit. 2</td><td>H319</td><td>H319</td></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td><td>H400</td></tr>
<tr><td>Aquatic Chronic 2</td><td>H411</td><td>H411</td></tr>
<tr><td>Met. Corr. 1</td><td>H290</td><td>H290</td><td rowspan="6">EUH031</td><td rowspan="6">GHS07
GHS09
GHS05
Dgr</td><td rowspan="6">M(Chronic)=1
M=10</td><td rowspan="6"></td><td rowspan="6">78</td></tr>
<tr><td>Skin Corr. 1B</td><td>H314</td><td>H314</td></tr>
<tr><td>Eye Dam. 1</td><td>H318</td><td></td></tr>
<tr><td>STOT SE 3</td><td>H335 (Respiratory tra…) (inhalation)</td><td>H335</td></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td><td></td></tr>
<tr><td>Aquatic Chronic 1</td><td>H410</td><td>H410</td></tr>
</table>

Classification		Labelling			Specific Concentration limits, M- Factors	Notes	Number of Notifiers
Hazard Class and Category Code(s)	**Hazard Statement Code(s)**	**Hazard Statement Code(s)**	**Supplementary Hazard Statement Code(s)**	**Pictograms Signal Word Code(s)**			
Skin Irrit. 2	H315	H315		GHS09 GHS05 Dgr	M=10		78
Eye Dam. 1	H318	H318					
Aquatic Acute 1	H400	H400					
Aquatic Chronic 2	H411	H411					
Aquatic Chronic 3	H412	H412					78
Skin Irrit. 2	H315	H315		GHS07 Wng			78
Eye Irrit. 2	H319	H319					
Aquatic Chronic 3	H412	H412					
Skin Corr. 1B	H314	H314		GHS09 GHS05			62
Aquatic Acute 1	H400	H400					
Skin Corr. 1B	H314	H314	EUH031	GHS09 GHS05 Dgr			47
Aquatic Acute 1	H400						
		H410					
Skin Corr. 1B	H314	H314	EUH031	Dgr			45
		H400					
		H318					
Met. Corr. 1	H290	H290	EUH031	GHS07 GHS09 GHS05 Dgr			45
Skin Corr. 1B	H314	H314					
STOT SE 1	H335 (not specified)	H335					
Aquatic Acute 1	H400	H400					
Skin Corr. 1B	H314	H314		GHS05 Dgr			37
Met. Corr. 1	H290	H290		Dgr	M=10		34
Skin Corr. 1B	H314	H314					
Eye Dam. 1	H318						
STOT SE 3	H335 (respiratory sys…)	H335					
Aquatic Acute 1	H400	H400					
Met. Corr. 1	H290		EUH031	GHS09 GHS05 Dgr		Note B	32
Skin Corr. 1B	H314	H314					
Aquatic Acute 1	H400	H400					
Skin Corr. 1B	H314	H314	EUH031	GHS09 GHS05 Dgr			29
Aquatic Acute 1	H400	H400					
		H314	EUH031	Dgr	M=10		24
		H400					

Classification		Labelling			Specific Concentration limits, M- Factors	Notes	Number of Notifiers
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	Pictograms Signal Word Code(s)			
Met. Corr. 1	H290	H290	EUH031	GHS07 GHS09 GHS05 Dgr		Note B	22
Skin Corr. 1B	H314	H314					
Eye Dam. 1	H318						
STOT SE 3	H335 (Respiratory Sys…) (Inhalation)	H335					
Aquatic Acute 1	H400	H400					
Met. Corr. 1	H290	H290	EUH031	GHS07 GHS09 GHS05 Dgr			18
Skin Corr. 1B	H314	H314					
STOT SE 3	H335 (lungs)	H335					
Aquatic Acute 1	H400	H400					
Met. Corr. 1	H290	H290	EUH031	GHS07 GHS09 GHS05 Dgr	M=10		17
Skin Corr. 1B	H314	H314					
STOT SE 3	H335 (not specified)	H335					
Aquatic Acute 1	H400	H400					
Skin Corr. 1B	H314	H314		GHS07 GHS09 GHS05 Dgr			4
Eye Irrit. 2	H319	H319					
Aquatic Acute 1	H400	H400					
Skin Corr. 1B	H314	H314 (H314)		GHS09 GHS05 Dgr		Note B	4
Aquatic Acute 1	H400	H400 (H400)					
Met. Corr. 1	H290	H290	EUH031	GHS07 GHS09 GHS05 Dgr	M=10		4
Skin Corr. 1B	H314	H314					
Eye Dam. 1	H318	H318					
STOT SE 3	H335 (Respiratory tra…) (Inhalation)	H335					
Aquatic Acute 1	H400	H400					
		H318	EUH031	GHS09 GHS05 Dgr	M=10		4
		H314					
		H400					
Met. Corr. 1	H290		EUH031	GHS07 GHS09 GHS05 Dgr	M=10	Note B	2
Skin Corr. 1B	H314	H314					
Eye Dam. 1	H318						
STOT SE 3	H335 (data lacking)						

<table>
<tr><th colspan="2">Classification</th><th colspan="3">Labelling</th><th rowspan="2">Specific Concentration limits, M- Factors</th><th rowspan="2">Notes</th><th rowspan="2">Number of Notifiers</th></tr>
<tr><th>Hazard Class and Category Code(s)</th><th>Hazard Statement Code(s)</th><th>Hazard Statement Code(s)</th><th>Supplementary Hazard Statement Code(s)</th><th>Pictograms Signal Word Code(s)</th></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td><td>H400</td><td></td><td></td><td></td><td></td><td></td></tr>
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GHS09
GHS05
Dgr</td><td rowspan="5">M=10</td><td rowspan="5">Note B</td><td rowspan="5">2</td></tr>
<tr><td>Skin Corr. 1B</td><td>H314</td><td>H314</td></tr>
<tr><td>Eye Dam. 1</td><td>H318</td><td></td></tr>
<tr><td>STOT SE 3</td><td>H335
(unknown)</td><td>H335</td></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td><td>H400</td></tr>
<tr><td>Skin Corr. 1B</td><td>H314</td><td>H314</td><td rowspan="2">EUH031</td><td rowspan="2">GHS09
GHS05
Dgr</td><td rowspan="2">M=1</td><td rowspan="2">Note B</td><td rowspan="2">2</td></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td><td>H400</td></tr>
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GHS05
Dgr</td><td rowspan="2"></td><td rowspan="2">Note B</td><td rowspan="2">2</td></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td><td>H400</td></tr>
<tr><td>Skin Corr. 1A</td><td>H314</td><td>H314
(EUH031
Contact…)</td><td rowspan="3">EUH031</td><td rowspan="3">GHS09
GHS05
Dgr</td><td rowspan="3"></td><td rowspan="3"></td><td rowspan="3">2</td></tr>
<tr><td>Eye Dam. 1</td><td>H318</td><td></td></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td><td>H400</td></tr>
<tr><td>Met. Corr. 1</td><td>H290</td><td>H290</td><td rowspan="5">EUH031</td><td rowspan="5">GHS07
GHS09
GHS05
Dgr</td><td rowspan="5"></td><td rowspan="5"></td><td rowspan="5">1</td></tr>
<tr><td>Skin Corr. 1B</td><td>H314</td><td>H314</td></tr>
<tr><td>Eye Dam. 1</td><td>H318</td><td></td></tr>
<tr><td>STOT SE 3</td><td>H335
(respiratory
sys…)
(inhalation)</td><td>H335</td></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td><td>H400</td></tr>
<tr><td>Met. Corr. 1</td><td>H290</td><td>H290</td><td rowspan="5">EUH031</td><td rowspan="5">GHS07
GHS09
GHS05
Dgr</td><td rowspan="5">M=10</td><td rowspan="5">Note B</td><td rowspan="5">1</td></tr>
<tr><td>Skin Corr. 1B</td><td>H314</td><td>H314</td></tr>
<tr><td>Eye Dam. 1</td><td>H318</td><td>H318</td></tr>
<tr><td>STOT SE 3</td><td>H335
(respiratory
sys…)
(inhalation)</td><td>H335</td></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td><td>H400</td></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td><td></td><td rowspan="2"></td><td rowspan="2">GHS09
GHS05
Dgr</td><td rowspan="2"></td><td rowspan="2"></td><td rowspan="2">1</td></tr>
<tr><td></td><td></td><td>H314</td></tr>
<tr><td>Skin Corr. 1B</td><td>H314</td><td></td><td rowspan="2"></td><td rowspan="2">Dgr</td><td rowspan="2"></td><td rowspan="2"></td><td rowspan="2">1</td></tr>
<tr><td>Aquatic Acute 1</td><td>H400</td><td></td></tr>
<tr><td>Met. Corr. 1</td><td>H290</td><td>H290</td><td rowspan="3">EUH031</td><td rowspan="3">GHS07
GHS09
GHS05
Dgr</td><td rowspan="3">M=10</td><td rowspan="3">Note B</td><td rowspan="3">1</td></tr>
<tr><td>Skin Corr. 1B</td><td>H314</td><td>H314</td></tr>
<tr><td>Eye Dam. 1</td><td>H318</td><td>H318</td></tr>
</table>

Classification		Labelling			Specific Concentration limits, M- Factors	Notes	Number of Notifiers
Hazard Class and Category Code(s)	**Hazard Statement Code(s)**	**Hazard Statement Code(s)**	**Supplementary Hazard Statement Code(s)**	**Pictograms Signal Word Code(s)**			
STOT SE 3	H335 (respiratory voi…)	H335					
Aquatic Acute 1	H400	H400					
Skin Corr. 1A	H314	H314	EUH031	GHS09 GHS05 Dgr		Note B	1
Aquatic Acute 1	H400	H400					
		H290					
		H318					
Skin Corr. 1B	H314	H314 (C>=5%)	EUH031	GHS09 GHS05 Dgr			1
Aquatic Acute 1	H400	H400					
Skin Corr. 1B	H314	H314	EUH031	GHS05 Dgr	Skin Corr. 1B: C: ≥ 5%		1
Met. Corr. 1	H290	H290	EUH031	GHS07 GHS09 GHS05 Dgr		Note B	1
Skin Corr. 1B	H314	H314					
STOT SE 3	H335 (not available)	H335					
Aquatic Acute 1	H400	H400					
Met. Corr. 1	H290	H290	EUH031	GHS07 GHS09 GHS05 Dgr	M=10	Note B	1
Skin Corr. 1B	H314	H314					
Eye Dam. 1	H318						
STOT SE 3	H335 (respiratory tra…) (inhalation)	H335					
Aquatic Acute 1	H400	H400					
Met. Corr. 1	H290	H290	EUH031	GHS07 GHS09 GHS05 Dgr	M=10	Note B	1
Skin Corr. 1B	H314	H314					
Eye Dam. 1	H318						
STOT SE 3	H335 (respiratory tra…)	H335					
Aquatic Acute 1	H400	H400					
Skin Corr. 1B	H314	H314	EUH031	GHS07 GHS09 GHS05 Dgr		Note B	1
Aquatic Acute 1	H400	H400					
		H335					
		H290					
Skin Corr. 1B	H314	H314	EUH031	GHS05 Dgr		Note B	1
Aquatic Acute 1	H400						
		H290					

3 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

Sodium hypochlorite is an active substance in the meaning of Directive 91/414/EEC and therefore subject to harmonised classification and labelling (CLP, article 36.2).

Part B.

SCIENTIFIC EVALUATION OF THE DATA

1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 7: Substance identity

EC number:	231-668-3
EC name:	Sodium hypochlorite, solution ... % Cl active
CAS number (EC inventory):	7681-52-9
CAS number:	7681-52-9
CAS name:	Sodium hypochlorite
IUPAC name:	Sodium hypochlorite
CA index name:	Hypochlorous acid, sodium salt (1:1)
CLP Annex VI Index number:	017-011-00-1
Molecular formula:	ClONa
Molecular weight range:	74.4 g/mol

Structural formula: Na^+ClO^-

1.2 Composition of the substance

Table 8: Constituents (non-confidential information)

Constituent	Typical concentration	Concentration range	Remarks
Sodium hypochlorite	12-14 % (w/w) as active or available chlorine	< 24 % (w/w) as active or available chlorine	Sodium hypochlorite, solution … % Cl active is produced as an aqueous solution (EU RAR)

See Annex for confidential information.

Current Annex VI entry:

Table 3.1: Skin Corr. 1B (H314), Aquatic Acute 1 (H400)
Table 3.2: C; R34, R31, N; R50

Table 9: Impurities

Impurity	Typical concentration	Concentration range	Remarks
Sodium chlorate		< 0.7 % (w/w)	EU-RAR

See Annex for confidential information.

Only impurities which are classified as hazardous to the aquatic environment are shown in the table. Sodium chlorate is classified in CLP Annex VI as Aquatic Chronic 2 (H411). However, it is present in quantities that will not affect the classification of the sodium hypochlorite solution.

Table 10: Additives

Additive	Function	Typical concentration	Concentration range	Remarks
Water	Stabiliser		<76 %	
Sodium hydroxide	Stabiliser			Sodium hydroxide is left as excess in the hypochlorite solution in order to stabilize the pH value at about 12 and decrease the rate of decomposition. (EU RAR)

See Annex for confidential information.

1.2.1 Composition of test material

1.3 Physico-chemical properties

Table 11: Summary of physico - chemical properties.

Property	**Value**	**Reference**	**Comment (e.g. measured or estimated)**
State of the substance at 20°C and 101,3 kPa	Liquid	EU-RAR REACH registration	In aqueous solution Sodium hypochlorite is a yellow, limpid liquid with a chlorinated odour
Melting/freezing point	-20 to -30°C -28.9°C	EU-RAR REACH registration	 Measured (24.3% available chlorine)
Boiling point	96 to 120°C ≥60.4°C	EU-RAR REACH registration	 Measured (24.3% available chlorine)
Relative density	1.23 g/cm³ at 25°C 1.3 g/cm³	EU-RAR DAR, REACH registration	15% (w/w) active chlorine solution Measured (24.3% available chlorine)
Vapour pressure	17.4 - 20 hPa at 20°C Ca. 25 hPa at 20°C	EU-RAR, DAR REACH registration	Sodium hypchlorite, solution …% Cl is an aqueous solution of an inorganic salt
Surface tension	82.4 mN/M at 20°C	REACH registration	(24.3% available chlorine) No surface tension properties
Water solubility	Miscible [29.3 g/100 g (0 °C) in water]	EU-RAR	(Merck, 2001)
Partition coefficient n-octanol/water	Not applicable	EU-RAR	
Flash point	Not applicable > 111°C	EU-RAR REACH registration	 Measured
Flammability	Not applicable	EU-RAR	
Explosive properties	Not explosive	EU-RAR	Anhydrous sodium hypochlorite is very explosive
Self-ignition temperature	Not applicable	EU-RAR	
Oxidising properties	Strong oxidizing agent but is not oxidizing when tested using methods A17 (solids) or A21 (liquids)	EU-RAR, DAR	
Granulometry	Not applicable	EU-RAR	
Stability in organic solvents and identity of relevant degradation products	No information		
Dissociation constant	In solution the sodium hypochlorite is in equilibrium with chlorine and hypochlorous acid. The equilibrium is temperature and pH dependent.	DAR	(WHO, 2000)

Property	Value	Reference	Comment (e.g. measured or estimated)
	Hypochlorous acid has a pKa of 7.5 (at 25°C)		
Viscosity	0.956 to 1.110 mPa.s (at 25° C) for 0.5-5% NaClO solution	DAR	Measured

2 MANUFACTURE AND USES

2.1 Manufacture

Sodium hypochlorite is manufactured by the absorption of chlorine in ca. 21% caustic soda solution. The chlorine and the caustic soda are made by electrolysis of brine, and the chlorine is added as gas or liquid.

2.2 Identified uses

Sodium hypochlorite is used mainly in chemical synthesis, for cleaning, disinfection and sanitation in household, for municipal water and sewage disinfection and for bleaching.

3 CLASSIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

No changes are proposed to the classification of physical hazards of sodium hypochlorite.

4 HUMAN HEALTH HAZARD ASSESSMENT

No changes are proposed to the human health classifications of sodium hypochlorite.

5 ENVIRONMENTAL HAZARD ASSESSMENT

Data from the European Risk Assessment Report (RAR), the plant protection product Draft Assessment Report (DAR) and the REACH Registration Dossiers were included in this CLH report for sodium hypochlorite, solution … % Cl active. The Competent Authority Report (CAR) for sodium hypochlorite as biocide was not finalised at the time of writing the CLH report.

Studies considered valid in the RAR and DAR (reliability score of 1 or 2) have been included in this report. Studies from the REACH registration (reliability score of 1 or 2), which were not included in the RAR and DAR were assessed for their reliability and also included in this report. Based on the behaviour of sodium hypochlorite in water, studies in which no analytical monitoring was performed were considered not sufficient reliable. In case of conflicting assignment of reliability score between the RAR, DAR and REACH registration dossier, the validity of the study was re-assessed by examination of the robust study summaries.

Different terms are used to describe the concentration of sodium hypochlorite solutions. The terms are not consequently used in the literature. The EU-RAR and DAR use the following terminology:

- *Available chlorine* measures the concentration of the three species HOCl, OCl^- and Cl_2. In practice, only HOCl and OCl^- are usually present because chlorine (Cl_2) is formed only at pH < 4;

- *Active chlorine* measures the concentration of HOCl and Cl_2. In practice, this usually includes only HOCl because chlorine (Cl_2) is formed only at pH < 4;

- HOCl or OCl^- are mostly used in cases in which one of the two species was predominant because of the pH value of the tested solution;

- *Combined chlorine* or *Bound chlorine* measures chlorine bound to amines (chloramines).

In freshwater, measured concentrations are usually expressed as Free Available Chlorine (FAC) or Total Residual Chlorine (TRC); the latter encompasses free plus combined chlorine (i.e. TRC is FAC plus combined chlorine). In chlorinated salt water, what is measured is generally called Total Residual Oxidant (TRO) including free chlorine and bromine, or Chlorine Produced Oxidant (CPO) that encompasses free and combined chlorine and bromine species.

In many aquatic toxicity studies, the results are expressed in terms other than active chlorine, such as TRC. The FAC content in TRC varies. Depending on the composition of the test media, (a part of the) FAC is bounded to amines resulting in combined chlorine. Therefore it is not possible to determine the actual active chlorine content in total residue chlorine. For classification purposes, it is assumed that TRC equals the FAC content. As the entry for sodium hypochlorite in Annex VI gives the concentration as % active chlorine, the assumption that TRC is equal to the FAC may possibly lead to an underestimation of the toxicity of sodium hypochlorite solutions.

As the results of the aquatic toxicity studies are given as mg/l active chlorine, it is necessary to convert those results to mg/l NaOCl in order to compare the results with the CLP criteria. The following assumptions and equations have been used for converting mg/L active chlorine species to mg/L NaOCl, and then back to % Cl active.

- [Cl_2]to [NaOCl]: 1.05 x Cl_2 = NaOCl
- [Cl_2]and HOCl: 0.74 x Cl_2 = HOCl
- HOCl and NaCl: 1.43 x HOCl = NaCl
- HOCl and Cl_2: 1.35 x HOCl = Cl_2
- NaOCl and HOCl: 0.70 x NaOCl = HOCl
- NaOCl and Cl_2: 0.95 x NaOCl = Cl_2

5.1 Degradation

5.1.1 Stability

Speciation forms in water

Sodium hypochlorite, solution … % Cl active exists in water as Na^+ and chlorine species. There are three species of chlorine in equilibrium in water: gaseous chlorine (Cl_2), HOCl (also a gas at room temperature and pressure), and ClO^-. An example of the distribution between them as a function of pH is shown in Figure 1 that is a reproduction of figure 2.1 from the EU-RAR. At pH values above 4.0, chlorine (Cl_2) does not exist (DAR, EU-RAR).

Figure 1.

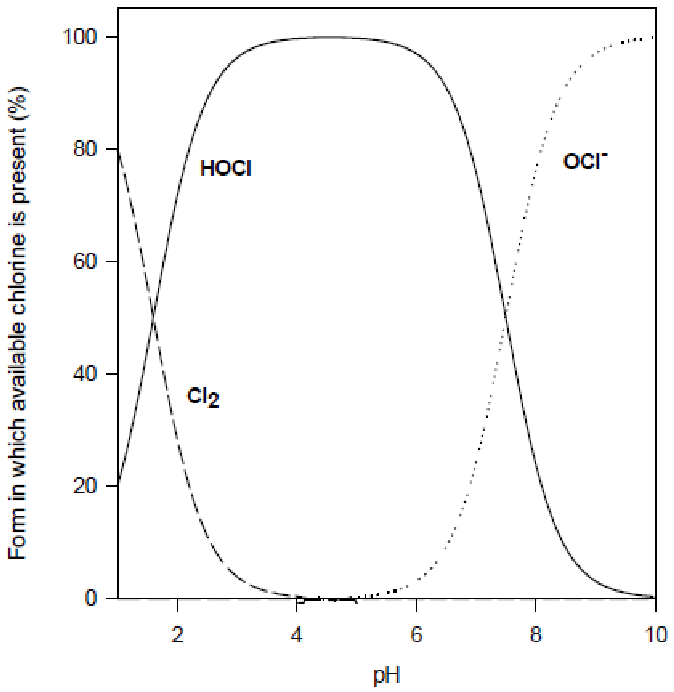

Figure 2.1. Calculated variation in composition of a chlorine solution with degree of acidity or alkalinity for 0.1 M Cl_2 in water at standard temperature and pressure (The data in this figure are based on general chemistry handbooks).

Sodium hypochlorite decay is second order with respect to NaOCl concentration. The second order rate law predicts that diluting the NaOCl by a factor of 2 should decrease the rate of NaOCl decay by a factor of 4. However, actual decay data for sodium hypochlorite solutions shows that a factor of 2 decrease in the NaOCl concentration results in an approximate factor of 5 decrease in the rate of decay. This is because of the effect of the decay rate by the decrease in the total ionic concentration of the solution. Since the dilution of a sodium hypochlorite solution not only decreases the NaOCl concentration but also decreases the concentration of all the ions in the solution (TCI, 2006, pamphlet 96; DAR).

In concentrated sodium hypochlorite solutions, the content of available chlorine decreases because NaClO tends to disproportionate to chloride and chlorate ions. The reaction is:

$$3\ NaClO \rightarrow 2\ NaCl + NaClO_3 \qquad K_{eq} = 10^{27}$$

It is the result of two reactions: a slow one with formation of chlorite and a fast one with formation of chlorate by reaction between chlorite and hypochlorite.

$2\ NaClO \rightarrow NaClO_2 + NaCl$ (slow reaction)

$NaClO + NaClO_2 \rightarrow NaClO_3 + NaCl$ (fast reaction)

The first reaction (that produces chlorite) controls the reaction rate producing chlorate. The formation rate of chlorate, at room temperature and pH = 11, is very slow. The process is dependent on the time, temperature, impurities, pH and concentration of the sodium hypochlorite solution. Also light can decompose hypochlorite solutions.

Time dependence
At constant temperature the inverse of the active product concentration is a linear function of the time. A solution dosed at 150 g/l available chlorine which is kept away from sunlight and at constant 15°C, loses 1/6 of its concentration within less than 3 months. In diluted hypochlorite solutions the losses are minor.

pH dependence
Hypochlorite should not be added to an unbuffered medium, because at low pH, the following secondary reactions could occur:

In acid media under pH 4, hypochlorite will be transformed to gaseous chlorine

$HOCl + H+ + Cl^- \rightarrow Cl_2 + H_2O$

Between pH 4 and 11, both ClO^- and HOCl are present with the latter being much more active. Degradation of HOCl is more rapid than the degradation of ClO-.

if pH <6, the main reaction is: $2HOCl \rightarrow 2HCl + O_2$
if pH >6, the main reaction is: $3NaClO \rightarrow NaClO_3 + 2\ NaCl$

Hypochlorous acid (HClO) is very unstable and it suddenly decomposes with formation of oxygen:

$2\ HOCl \rightarrow 2\ HCl + O_2$

Dependence upon impurities
Sodium hypochlorite can decompose to oxygen according to the following reaction:

$2\ NaClO \rightarrow 2\ NaCl + O_2$

The decomposition reaction is a bimolecular one and requires activation energy of 113.3 kJ/mol (26.6 kcal/mol). Although it is slower than the chlorate formation reaction, it is catalysed by trace amounts of metallic impurities. The strongest decomposition catalysts to oxygen are: Co, Ni and Cu; whereas Fe and Mn are weaker catalysts. Salts such as sodium chloride, sodium carbonate and sodium chlorate have only a very low influence on reaction rate within the range of concentration where they are normally present. Sodium hydroxide does not influence the reaction rate if its concentration is greater than 10^{-3} M (0.04 g/l).

Temperature dependence
The influence of temperature is very high. The decomposition rate doubles if the temperature increases by ~ 5.5°C. If temperature is more than 35°C, the decomposition reactions are very rapid:

$3NaClO \rightarrow NaClO_3 + 2NaCl$

In every case, the temperature of the solution must be below 55°C in order to prevent a sudden decomposition of the hypochlorite. The more stable solutions are those of low hypochlorite concentration, with a pH of 11 and low iron, copper, and nickel content, stored in the dark at low temperature.

In water containing organic matter and impurities, sodium hypochlorite may also react to form chloramines (R-NHCl, R-NCl_2 or NCl_3), monochlorophenols, chloroacetaldehydes, chloroacetonitriles and chloroacetic acids and chloroform ($CHCl_3$) (EU-RAR). In natural waters free chlorine is very rapidly and totally transformed to combined chlorine (EU-RAR).

Stability in water

The REACH registration dossier contains the following (confidential) information on the half-life of sodium hypochlorite solutions at different temperatures:

Table 12

10% available chlorine	**Temperature (°C)**	**Half-life (days)**
	15	800
	25	220
	60	3.5
	100	0.079
5% available chlorine	15	5000
	25	790
	60	13.5
	100	0.25

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.

Phototransformation in water

A photolysis study carried out in a non-guideline study (Nowell and Hoigne, 1992) is available for sodium hypochlorite. When exposed as a horizontal water layer to solar irradiation of 1.05 $kW/m^{2,}$ the photolysis half-life of sodium hypochlorite solution is 12 min at pH 8 (OCl^-), 37 min at pH 7 and 60 min at pH 5 (HOCl).

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

Phototransformation in air

The photochemical and oxidative decomposition of hypochlorous acid in air was calculated according to Atkinson (Görg and Glöckner, 2007). The reaction rate constant KOH is $0.14x10^{-12}cm^3molecule^{-1}sec^{-1}$. The DT50 for hypochlorous acid was estimated to be 114.6 days (24 hour day), corresponding to 2750 hours, using the reaction rate constant KOH. As hypochlorous acid contains no olefinic carbon-carbon and acetylenic triple bonds, it is not supposed to react with ozone.

5.1.2 Biodegradation

Sodium hypochlorite is an inorganic compound. Therefore, biodegradation studies such as the OECD301 screening tests and water/sediment studies are not relevant for sodium hypochlorite.

5.1.3 Summary and discussion of degradation

No biodegradation or water sediment studies were performed for sodium hypochlorite. Since sodium hypochlorite is an inorganic compound, these studies are not considered relevant in the degradation assessment. According to CLP Annex I section 4.1.2.10.1, for metals and inorganic compounds, the concept of degradability as applied to organic compounds has limited or no meaning. Still it has to be considered for sodium hypochlorite for the derivation of an M-factor for chronic aquatic toxicity.

The degradability of sodium hypochlorite solutions is subject of discussion. Under specific conditions sodium hypochlorite solutions are quite stable, while in aquatic test systems the test substance concentrations drop quite instantly after the beginning of the test. Below the reasoning is listed in favor or against the conclusion that sodium hypochlorite solutions can be considered rapidly degradable.

In favor:
Sodium hypochlorite, solution … % Cl active exists in water as Na^+ and chlorine species. In water, three chlorine species are in equilibrium: Cl_2, HOCl and ClO^-. The fraction of each species depends on pH, temperature and chlorine species concentration. At pH above 4, Cl_2 does not exist; Cl_2 is therefore considered to make negligible contribution to the fate and toxicity of sodium hypochlorite under environmentally relevant conditions. Between pH 4 and 11, both ClO^- and HOCl are present.
The decomposition of hypochlorite and hypochlorous acid is complex and dependent on concentration, pH, temperature and the presence of impurities. Degradation products that can be formed are Cl_2 (chlorine), sodium chloride (NaCl), sodium chlorite ($NaClO_2$), sodium chlorate ($NaOCl_3$) and oxygen (O_2), as well as chloramines and chloroform.

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 natural waters free chlorine is very rapidly and totally transformed to combined chlorine (EU-RAR). The reactivity and degradation is illustrated by the fact that it is very hard in the aquatic toxicity tests to maintain the test substance concentrations stable, the only way of doing so is to make use of a flow-through test system.

Against:
The CLP Guidance v4.0 uses the term degradation in the following way: *"Generally expressed in terms of biotic or abiotic degradation of organic substances (or transformation of inorganic substances)."* Furthermore, 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."*

In case of sodium hypochlorite, the reaction products of transformation in natural environment are at least partially unknown because of oxidation and carbon or nitrogen chlorination processes and depend on many factors, among which temperature and pH.

The degradation products chlorine and sodium chlorate have a harmonized classification as hazardous to the aquatic environment; chlorine is classified as Aquatic Acute 1 (with an M-factor of 100) and sodium chlorate is classified as Aquatic Chronic 2.

Hypochlorite solutions (kept away from sunlight) and at constant 15°C are relatively stable (rate of hydrolysis is low). Especially at low concentration levels the losses are minor.

Although that sodium hypochlorite is susceptible for photolysis, “the Guidance on the Application of the CLP criteria” in Annex II.2.3.9 states that “*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”*.

Conclusion:
The discussion if the inorganic compound sodium hypochlorite can be considered rapidly degradable is complex. Given the fact that hypochlorite solutions (kept away from sunlight and stored at low temperature) are stable and that some degradation products are also hazardous to the environment it is stated that sodium hypochlorite cannot considered being rapidly degradable for classification purposes.

5.2 Environmental distribution

5.2.1 Adsorption/Desorption

No K_{oc} value was determined for sodium hypochlorite.

5.2.2 Volatilisation

Sodium hypochlorite has negligible volatility whilst hypochlorous acid has low volatility. The equilibrium concentration of hypochlorous acid vapour in the gaseous phase above a solution depends upon the solution pH, as expected from the fact that hypochlorous acid is more volatile than the hypochlorite anion (DAR volume B8).

The volatility of the species of available chlorine in water and of three main species of combined chlorine have been studied by Holzwarth et al (1984), Blatchley et al (1992), published the Henry's constant of HOCl. These references expressed this information with different units and using different forms of Henry's law. Currently Henry's law constant is expressed in atm. and is the ratio between partial pressure in the air divided by a mole fraction in water. The figure given by Blatchley is expressed in atm and is 0.06 atm. The figures calculated by Holzwarth are without unit and expressed in mole fraction in the air divided by mole fraction in the water (for HOCl at pH 5.5 and at a temperature of 20°C, 0.076). These two expressions of Henry's law constant are not very easy to interpret. It is proposed to use a figure without unit expressing mg/l in air divided by mg/l in water. After correction of Holzwarth figures in this new unit (1 mole of air weighing 28 g and 1 mole of water 18 g; 1 m^3 of air weighing 1.2 kg and 1 litre of water weighing 1 kg), new figures of a Henry's coefficient for the different products at a temperature of 20°C are proposed:

ClO^-	pH = 8.5	H = $0.07x10^{-4}$
HOCl	pH = 5.5	H = $0.4x10^{-4}$
NH_2Cl	pH = 9	H = $2.4x10^{-4}$
$NHCl_2$	pH = 6.4	H = $8x10^{-4}$
NCl_3	pH = 1.8	H = $2300x10^{-4}$

The volatility of NCl_3 is about one thousand times the volatility of the 3 other compounds. The ClO^- Henry's coefficient is about five times lower than the coefficient of HOCl. At 40°C and pH = 1.8 the Henry's coefficient for NCl_3 is 0.6, very close to the maximum possible figure which is 1. These figures make clear that NCl_3 is completely extracted by stripping and that ClO^- is extremely difficult to extract (EU-RAR).

5.2.3 Distribution modelling

Not available.

5.3 Aquatic Bioaccumulation

Sodium hypochlorite is an inorganic substance. No log Kow value can be determined for sodium hypochlorite.

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.

5.4 Aquatic toxicity

Source of studies
Sodium hypochlorite aquatic toxicity studies have been extensively assessed in the past (RAR, DAR and CAR, although that the CAR has not yet been finalised). The studies that already have been assessed and agreed upon at the EU level have not been reassessed, but have been summarized in Table 13. New data which is provided in the REACH registration dossier has been assessed in more detail.

Studies with critical effect data (also those which are considered invalid or not sufficient reliable to take into account for risk assessment and classification purposes, according to the registrant) have also been included in Table 13. Studies with results expressed in only nominal test substance concentrations in combination with static test conditions, have been left out. In addition, many studies in the REACH registration dossier have been assigned a Klimisch score of 2, but are considered not valid in the RAR and DAR and are left out of Table 13.

Explanation with regard to relevant and reliable studies used for C&L
A large number of aquatic toxicity studies have been carried out for sodium hypochlorite and the related substance calcium hypochlorite, both in fresh water as in salt or brackish water. However, most of the studies are considered not reliable, for example due to lack of analytical monitoring and use of nominal concentrations to express the results, or give information that cannot directly be used to derive a classification. Table 13 contains a summary of all relevant and reliable studies from the information sources used. In the table it is indicated if the study has been assigned to be a key study or if it is used as supportive evidence. If sufficient information was available for sodium hypochlorite, then results from studies conducted with calcium hypochlorite were not included in the assessment. For the long term toxicity study on invertebrate (21-d study on *Epioblasma capsaerformis*), calcium hypochlorite is used due to the fact that this study is the only long-term invertebrate toxicity study available for fresh water. The use of the data on calcium hypochlorite as an alternative is justified by the fact that both substances are hypochlorite salts with comparable water solubility (ClONa; 29.3 g/ 100g and ClOCa; 21 g/l).

Furthermore, short study summaries have been included for the key studies with the lowest effect results for both acute and chronic toxicity for all three trophic levels (copied from the EU-RAR if available). Finally, a more extensive study summary have been included for a new *Ceriodaphnia dubia* and algae study which are included in the REACH registration dossier for sodium hypochlorite.

It should be noted that different Klimisch scores have been assigned to identical study data in the RAR, DAR and registration dossier. As a rule of thumb the reliability scores (notes a and b) from the previous assessment reports are leading. For some studies no Klimisch score has been derived in the previous assessments, but have been assigned to be supportive data. Also these studies have not been re-assessed.

Table 13: Summary of relevant information on aquatic toxicity (**bold faced** values indicate key study data, in addition, data which are considered supportive are in ***italics***)

Species	Criterion	Result [µg/L]	Result [µg NaOCl/L]	Reliability	Reference
Fish					
FRESH WATER – SHORT-TERM					
Salmo gairdneri	96h LC50	60 (TRC)* 30 (FAC)*	63 (TRC)* 32 (FAC)*	s[ab]/2[c]	Bass et al (1977), Heath (1978)[abc]
Ictalurus punctatus	96h LC50	64 (TRC)* 32 (FAC)*	67 (TRC)* 34 (FAC)*	s[ab]/2[c]	Bass et al (1977), Heath (1978)[abc]
Salmo gairdneri (juveniles)	24h LC50	430*	452*	s[ab]/2[c]	Brooks and Seegert (1977)[abc]
Onchorhyncus kisutch *Alosa pseudoharengus* *Notropis hudsonius* *Osmerus mordax*	48h LC50	1260-2410*	1323-2531*	s[ab]/2[c]	Seegert and Brooks (1978)[abc]
Pimephales promelas	96h LC50	80 (TRC)* >40 (FAC)*	84 (TRC)* >42 (FAC)*	s[ab]/3[c]	Wilde et al (1983a,b)[abc]
Cyprinus carpio	48h LC50	260*	273*	s	Tsai et al (1990)[ab]
Gambusia affinis	48h LC50	610*	641*	s	Tsai et al (1990)[ab]
Gambusia affinis	48h LC50	840*	882*	s	Mattice et al (1981)[ab]
Menidia menidia	96h LC50	37 (TRC)	39 (TRC)	s[ab]/3[c]	Roberts et al (1975)[abc]
BRACKISH & SEA WATER – SHORT-TERM					
Leiostomus xanthurus	96h LC50	90 (TRC & FAC)	95 (TRC & FAC)	1[ab]/2[c]	Bellanca and Bailey (1977)[abc]
Oncorhynchus kisutch	96h LC50	**32 (TRO)**	**34 (TRO)**	2[a]/s[b]	Thatcher (1978)[ab]
Gasterosteous aculeatus	96h LC50	167 (TRO)	175 (TRO)	2[a]/s[b]	Thatcher (1978)[ab]
Morone saxatilis	48h LC50	***8 (TRC)***	***8.4 (TRC)***	s[ab]/2[c]	Middaugh et al (1977)[abc]
FRESH WATER – LONG-TERM					
Ictalarus punctatus	134d NOEC 134d LOEC	***5 (TRC)*** 53 (TRC)	***5.3 (TRC)*** 56 (TRC)	s	Hermanutz et al (1990)[ab]
Oncorhynchus mykiss	48h LC50	350 (available chlorine)	368 (available chlorine)	s/2[c]	Soivo, Nukinen and Tuurala (1988)[c]
BRACKISH & SEA WATER – LONG-TERM					
Menidia peninsulae	28d NOEC	**40 (TRC)**	**42 (TRC)**	1	Goodman et al (1983)[ab]
Invertebrates					
FRESH WATER – SHORT-TERM					
Ceriodapnia dubia	24h LC50	**5 (FAC)**	**5.3 (FAC)**	2[ab]/4[c]	Taylor (1993)[abc]
Ceriodapnia dubia	48h EC50	<25.8 (active chlorine, mean measured)	<27.1 (active chlorine, mean measured)	1	Gallagher, Lezotte and Krueger (2011)[c]

Species	**Criterion**	**Result [µg/L]**	**Result [µg NaOCl/L]**	**Reliability**	**Reference**
Daphnia magna	48h EC50	<49 (active chlorine, mean measured)	<51 (active chlorine, mean measured)	1	Gallagher, Lezotte and Krueger (2009)[c]
Baetis harrisoni	48h LC50 96h LC50	***5 & 6 (TRC)*** 4.1 & 4.8 (TRC)	***5.3 & 6.3 (TRC*** 4.3 & 5 (TRC)	2 /4[c]	Williams et al (2003)[c]
BRACKISH & SEA WATER – SHORT-TERM					
Pandalus goniurus	96h LC50	90 (TRC)	95 (TRC)	2[ac]/s[b]	Thatcher (1978)[abc]
Brachionus plicatilis *Acartia tonsa* *Crassostrea virginica (larvae)*	48h LC50 48h LC50 48h LC50	10-820* 180* 80-120*	10.5-861* 189* 84-126*	s s s	Capuzzo et al (1976, 1979a,b)[ab]
Crassostrea virginica (juveniles)	96h EC50, shell deposition	23 (TRC)	24 (TRC)	s	Roberts et al (1975)[ab]
Crassostrea virginica (larvae) *Acartia tonsa*	48h EC50 48h LC50	26 (TRC, CaOCl) 29 (TRC, CaOCl)	27 (TRC) 30 (TRC)	2 2	Roberts and Gleeson (1978)[ab]
Epioblasma brevidens	24h LC50	70 (TRC)	73.5 (TRC)	2	Valenti et al (2006)[c]
FRESH WATER – LONG-TERM					
Epioblasma capsaerformis	21 d NOEC	***10 (TRC, nominal, CaOCl)***	***10.5 (TRC nominal, CaOCl)***	2	Valenti et al (2006)[c]
BRACKISH & SEA WATER – LONG-TERM					
Crassostrea virginica *Rangia cuneata*	15d NOEC, shell deposition 15d NOEC	**7 (TRO)** 62 (TRO)	**7.4 (TRO)** 65 (TRO)	2[a]/s[b]	Liden et al (1980)[ab]
Algae					
FRESH WATER – SHORT-TERM					
Pseudokirchneriella subcapitata	24h $EC50_r$	**<23.3 (FAC)**	**<24.5 (FAC)**	1	Liedtke (2013)[d]
FRESH WATER – LONG-TERM					
Pseudokirchneriella subcapitata	24h $LOEC_r$ 24h $LOEC_b$	***<10.8 (FAC)*** <10.8 (FAC)	***<11.3 (FAC)*** <11.3 (FAC)	1	Liedtke (2013)[d]
Myriophyllum spicatum	96h NOEC	20 (TRC, measured)	21 (TRC, measured)	2	Watkins and Hammerschlag (1984)[a]
Peryphytic community	7d $NOEC_b$	**3 (FAC)**	**3.2 (FAC)**	2	Cairns et al (1990)[ab]
Protozoan species	28d NOEC	2.1 (FAC)	2.2 (FAC)	s	Pratt et al (1988)[a]
Zooplankton (density)	24d NOEC	***1.5 (FAC)****	***1.6 (FAC)****	s	Pratt et al (1988)[a]
BRACKISH & SEA WATER – LONG-TERM					
Phytoplankton	21d $EC50_b$	1-10 (TRC)*	1.1-10.5 (TRC)*	s	Sanders et al (1981)[ab]
Plankton	1y $NOEC_b$	<10 (TRC)	10.5 (TRC)	s	Erickson and Foulk (1980)[a]

Remark: Klimisch scores (1-4) or s: supportive data

FAC = free available chlorine, TRC = total residue chlorine, TRO = total residue oxidant. * No continuous exposure.

[a] As summarized in the European Commission. Risk Assessment Report Sodium hypochlorite. Prepared by Italy, November 2007.

[b] As summarized in the European Commission. Draft Assessment Report Sodium hypochlorite. Prepared by the Netherlands, May, 2008.

[c] As summarized in the REACH registration for sodium hypochlorite, accessed on November 2014

[d] Provided by the industry but not yet included in the REACH registration dossier (November 2014)

5.4.1 Fish

5.4.1.1 Short-term toxicity to fish

Study 1

Thatcher (1978) conducted many laboratory flow-through bioassays on 8 species of estuarine and marine fish, belonging to different families including salmonidae, clupeidae and percidae. Since the main purpose of the study was to investigate the impact of chlorinated effluents from power plants, fish were simultaneously exposed to sodium hypochlorite and to a 5°C thermal stress. The 96h LC50 ranged from 0.032 mg/l (as TRO), for the most sensitive species (*Oncorhynchus kisutch*), to 0.167 mg/l (*Gasterosteous aculeatus*). These data were considered relevant for the assessment because heat is usually associated to chlorine in power plants effluents, but they were rated 2 because the authors report that in a previous study the addition of thermal stress resulted in a toxicity higher than chlorine alone and, moreover, LC50 was calculated pooling data from different tests.

Study 2

Middaugh et al. (1977) tested the toxicity of chlorinated brackish pond water to early-life stages of *Morone saxatilis* in a flow-through test. No indication on test guideline or GLP is reported. Only data relative to eggs hatchability could be retrieved. A rough estimate of the 48h LC50 = 8 µg/L TRC was calculated using the authors' raw data relative to percentages of hatched eggs per test concentration. This data can be used as indicative information of eggs sensitivity (EU-RAR).

5.4.1.2 Long-term toxicity to fish

Study 1

Goodman et al. (1983) developed a method for testing the early-life stages of *Menidia peninsulae*, an estuarine fish of the Atherinidae family. They carried out a 28d test starting with 36h old eggs, under flow through conditions using natural seawater diluted with freshwater to a 20‰ salinity, and measured the effects of sodium hypochlorite on eggs survival and fry survival and growth. Fry were the most sensitive stage. The authors calculated a NOEC (fry survival) = 0.04 mg CPO/l (CPO is to be considered analogous to TRC measured by other authors in saline waters), concentration at which only 5% of fish died. At this concentration no sublethal effects were evident (EU-RAR).

Study 2

The long-term toxicity to four standard fish species has been investigated by Hermanutz et al. (1990) in two field studies under flow-through conditions, lasting up to 134 days. Test guideline and GLP are not indicated. In the first study, 3 chlorine concentrations were tested with one or two replicate fish pools; in the second study, only two concentrations with no replicates were tested. In all experiments, no effect on survival was observed in any species up to 183 µg/L TRC. In the first experiment, a concentration-effect relationship, although partial, was observed only for the growth endpoint in channel catfish. At the highest concentration tested (52 and 183 µg/L), the mean weight decreased by 25% and 34%, respectively, whereas at the immediately lower concentration (5 µg/L) it was equal to that of the control group. In the second experiment, growth reduction in the same species was observed only at 62 µg/L (37% reduction) but no effect at 53 µg/L. The experiment was not conducted under standard conditions, no statistical analysis of data was carried out by the authors to identify the NOEC or LOEC, and raw data do not allow the estimation of any endpoint useful for the assessment. Therefore we cannot derive any valid endpoint, but considering that 25% effect is biologically significant we can consider the NOEC for growth 5 µg/L and use it as an indication of the long term toxicity (EU-RAR).

5.4.2 Aquatic invertebrates

5.4.2.1 Short-term toxicity to aquatic invertebrates

Study 1

The key aquatic toxicity study in the EU RAR is the study of Taylor (1993). In this study, the acute toxicity of various forms of free and combined chlorine to *Ceriodaphnia dubia* were tested in a standard 24h toxicity tests, carried out under static and flow through conditions. No test guideline was followed and no GLP statement was given. Sodium hypochlorite was tested at pH 7 for HOCl (70% HOCl and 30% OCl^-) and pH 8 for OCl^- (80% OCl^- and 20% HOCl). The toxicity tests were performed at 25°C, with 10 neonate (< 24h old) *Ceriodaphnia dubia*.

In static tests the decay of free chlorine was very rapid (1 minute and 7 hours in tests with or without food, respectively) and the results were not considered valid.

Flow-through tests (without food) were carried out to maintain a constant concentration over the exposure time. Only the results of the flow-through test can be used for classification. The 24h LC50 values from this test were found to be 5 and 6 µg/L for HOCl and OCl^-, respectively.

These data were judged valid with restriction (rated 2) because the test concentrations were calculated from measured chlorine concentration of the stock solution and dilution ratios, the number of concentrations/replicates are not specified, the performance of the controls not mentioned, and the 24h LC50s determined by graphical interpolation (EU-RAR).

The industry rated the study reliability as 4 (invalid). The reasoning provided is:

This article lacks description of several important features of the experiment, which means that this set of data cannot be used with confidence. For example:

- there is no information on the tested material: "Stock solutions containing about 20 mg/L of NH_2Cl, $NHCl_2$, or sodium hypochlorite were prepared and then diluted with DMW to make the various test solutions" (rk: DMW is 20% v/v degassed Perrier© in deionized water; hardness or other characteristics not provided);
- there is little information on the analytical measurements: "Measurements of free chlorine, NH_2Cl, and $NHCl_2$ concentrations were made with a Wallace & Tiernan (Atlanta, GA) amperometric titrator, using the procedures recommended in the instruction manual". It is stated that the detection limit of the titrator is 0.01 mg/L (no indication of whether this refers to total available chlorine, free available chlorine or even test material is given). Given the characteristics of this method and its precision in the low level range targeted here, it would have been of prime importance to get information on limit of quantification and confidence intervals. Below 0.01 mg/L, concentrations are calculated from dilution factors of the stock solutions;
- there is no indication on sample treatment: i.e. number of analytical measurements between 0 and 24 hours, and, most importantly, time between sampling and titration. A significant decay can happen in this period and result in measured concentrations that are lower than those to which the animals are actually exposed;

- it is not indicated if the concentrations mentioned are initial measured, mean of initial and final, or nominal ones. Separate stability experiments described in the same article, performed without animals, show different rates of decay according to conditions, but no information is given on stability during the flow-through exposure of animals itself;
- there is no data on test design: number of tested concentrations, range of concentrations, separation factors in the flow-through experiments, number of animals, number of replicates, lighting conditions (which plays an important role in stability);
- in contrast to the requirements of the standard OECD TG 202, exposure duration was only 24 hours instead of 48 hours.

Since no reassessment is made and the study is assigned in the EU-RAR as key-study for classification, the study is still considered as key-study despite of the shortcomings reported by industry.

Study 2

The REACH registration dossier for sodium hypochlorite contains a more recent study of the acute toxicity of sodium hypochlorite to *Ceriodaphnia dubia.* Gallagher (2011) performed an acute toxicity test with *Ceriodaphnia dubia* according to OECD guideline 202. Neonate (< 24 h old) *Ceriodaphnia dubia* were exposed to sodium hypochlorite (active chlorine content 14.5%) in concentrations of 0, 25, 50, 100, 200 and 400 µg active chlorine/L. Exposure duration was 48 hours under flow-through conditions, number of immobilised animals was determined after 3.5, 24 and 48 h. The test was performed at 25°C, pH 8.1.

Water samples were taken one day prior to the start and at the start and end of test. Analysis for chlorine by HPLC with UV detection (210 nm) after derivatisation with o-tolidine in methanol under acidic conditions (method recovery 113%, LOQ: 10 µg active Cl/L).

Measured concentrations of active chlorine in samples one day prior to the start ranged from < LOQ (for the lowest concentration) to 48% of nominal. Mean measured concentrations of active chlorine during the test ranged from < LOQ to 56% of nominal. Mean measured concentrations were: 25.8, 55.7, 106, and 181 µg active Cl/L for 50, 100, 200, and 400 µg active Cl/L, respectively.

After 48h, all but one daphnid in the control, and all daphnids in the 25 µg active Cl/L group were normal whereas all daphnids in the 50, 100, 200 µg active Cl/L groups were immobile. This suggests a steep dose-response curve. At 100 and 200 µg active Cl/L some daphnids could not be observed due to their small size. The measured concentrations were lower than 80% of nominal. Given the uncertainty in average actual measured concentrations the conclusion that the 48h EC50 <25.8 µg active Cl/L (since the 48h EC100 equals to 25.8 µg active Cl/L) seems appropriate.

Study 3

Williams et al. (2003) performed experiments (not according to established test guidelines and no GLP statement given) to determine acute chlorine tolerance of *Baetis harrisoni* (ephemeroptera) from two rivers in KwaZulu-Natal, SouthAfrica. Via a flow through artificial streams the mortality after 24, 48 and 96 hours was determined at test substance concentrations of 0 , 4, 8 and 12 µg/L TRC for the Umbilo River and at 0, 4, 6, 8, 12 and 16 µg/L TRC for Westville Stream. All test substance concentrations, including the controls were at least tested in triplicate, the test substance concentrations of the Umbilo were tested with 6 replicates. Per artificial stream 35 to 90 nymphs of the mayfly were added. The experiment was started after 48h of acclimatization and after removal of the dead nymphs. Chlorine levels were determined continuously. The 48h LC50 and 96h LC50 values were 5 and 4.1

µg/L TRC for Westville Stream and 6.5 and 4.8 µg/L TRC for the Umbilo River, respectively. Since natural waters are used in a non-standardised test-system, the study has been rated 2. This study is assigned as key-study for classification. In the registration dossier the reliability of the study was scored 4 (not assignable).

5.4.2.2 Long-term toxicity to aquatic invertebrates

Study 1

In the scientific literature, three studies investigating the long-term toxicity of sodium hypochlorite have been found. In a field study on chlorinated condenser cooling effluents using mollusk bivalves (Liden et al., 1980), the survival of oysters (*Crassostrea virginica*) and clams (*Rangia cuneata*) maintained at three TRO concentrations for 15 days was not affected at concentration as high as 62 µg/L, while oyster mean shell deposition was significantly reduced in the treated animals. The field study has not been performed according to established test guidelines and no GLP statement given. At the lowest test concentration (14 µg/L) a 14% reduction in shell deposition was observed, so that following TGD the NOEC can be estimated as LOEC/2, i.e. 7 µg/L (7.4 µg Na OCl/L). This data is rated 2 because it was obtained from a non-standard test (EU-RAR). This study is assigned as key-study for classification.

Study 2

Valenti et al. (2006) performed 21-d bioassays with two-month-old *Epioblasma capsaeformis* (oyster mussel) and three-, six-, and 12-month old *Villosa iris* (rainbow mussel) juveniles (not according to established test guidelines and no GLP statement given). Calcium hypochlorite was used as test substance, with seven (including control) test substance concentrations varying from 5 to 250 µg/L TRC for the two- and three-month-old mussels and 10-500 µg/L TRC for the older mussels. TRC was measured twice a day, FRC and CRC at the start of the experiment and weekly thereafter. The 120L test medium was composed of 50% tap water and 50% (v/v) natural water from the Sinking Creek (USA). Per concentration 20 mussels were tested. Significant declines in growth (80%) and survival (50%) were observed in the 21-d test with *E. capsaeformis* at 20 µg TRC/L. Lowest-observed-adverse-effects concentrations in bioassays with juvenile *V. iris* were higher (30–60 µg TRC/L) but showed a significant trend of declining toxicity with increased age. The NOEC with respect to growth was found to be the test substance concentration of 10 µg TRC/L (growth at this test substance concentration was reduced with 6%). Since natural waters are used in a non-standardised test-system, the study has been rated 2.

5.4.3 Algae and aquatic plants

5.4.3.1 Short-term toxicity to algae and aquatic plants

No reliable EC50 values could be determined for sodium hypochlorite for algae or aquatic plants in the past. Therefore the industry was asked to perform an algae study. Liedtke (2013) performed a standard acute aquatic toxicity test (OECD 201) on the algae *Pseudokirchneriella subcapitata*. For a standard algae test a flow-through test system cannot be applied, consequently available chlorine levels drop quite instantly after the beginning of the test. In the lowest nominal test substance concentration of 125 µg FAC/L the initial measured concentration is determined to be below the level of quantification (LOQ) of 10.8 µg FAC/L. After 24 hours only for the highest nominal test substance concentration of 2 mg/l FAC/L, some active chlorine could be detected. In all other test substance concentrations the levels are below the LOQ. After 24 hours the inhibition of the growth rate for the initial measured concentration of 23.3 µg FAC/L is 60%. After 24 hours the measured concentration is below the LOQ. Half of the LOQ is assumed for derivation of a mean measured concentration by the authors of this study, than the geometric mean measured concentration equals to 11 µg FAC/L. It can be concluded that the 24h $EC50_r$ is <23.3 µg FAC/L.

5.4.3.2 Long-term toxicity to algae and aquatic plants

Study 1

The study of Liedtke (2013) showed fast decreasing test substance concentrations. The initial measured concentration for lowest test substance concentration was at the start already below the LOQ of 10.8 µg FAC/L. Still after 24 hours for the lowest test substance concentration a 9.3% inhibition in growth rate was observed. In terms of biomass the inhibition was even higher (17.3%). The lowest test substance concentration (<10.8 µg FAC/L) can therefore be considered to be an LOEC.

Study 2

Cairns et al. (1990) used a laboratory multispecies microcosm to study the chronic effects of chlorine (alone or together with ammonia) to naturally derived periphytic communities exposed for 7 days to sodium hypochlorite in a flow-through system (not according to established test guidelines and no GLP statement given). Sodium hypochlorite concentration was expressed as TRC; FAC accounted for 73 ± 19.9%. Chlorine was tested at nominal concentration of 6 and 60 µg TRC/L. Mean measure TRC were 6.3 ± 3.9 µg/L and 56.6 ± 24.5 µg/L in the low and high treatment respectively. The reduction in protozoa species richness was statistically significant
(LOEC) at 6 µg TRC/L, while for a reduction of 20%, considered biologically significant, a concentration of 2.7 µg TRC/L was calculated. At 6 µg/L the composition of protozoa communities (number of taxa) changed significantly; since the effect was about 10% we can calculate for this endpoint a NOEC (LOEC/2) = 3 µg TRC/L. The results from this study are interesting because protozoa represent a group with a great diversity in physiology and function; data were judged reliable and relevant but rated 2 because a non-standard test system was used. Non-taxonomic responses were also measured. In vivo fluorescence, used as an index of algal biomass, was significantly reduced (22%) at 6 µg TRC/L (the lowest tested concentration). This data can be used
to calculate a NOEC = 3 µg TRC/L as an indication of long-term toxicity to algae (EU-RAR).

Study 3

Another study on the microbial community was carried out in outdoor enclosures by the same researchers (Pratt et al., 1988; (not according to established test guidelines and no GLP statement given). Each enclosure consisted of a 130L polyethylene bag containing lake water and littoral sediment, which provided immigrating pelagic and benthic microorganisms for the colonization of the artificial substrates added. In the enclosures chlorine was introduced as a daily pulse, and decay curves were used to estimate the average chlorine concentration over a 24h period. The substrates were examined once a week for protozoan species and algal genera. At the end of the exposure period (day 24) the water was sampled for zooplankton enumeration (filtered with a Wisconsin plankton net n. 10) and substrates were sampled for non-taxonomic measures (chlorophyll a, total protein, alkaline phosphatase activity) and microscopic examination.

In the 24d field test, both taxonomic and non-taxonomic parameters showed lower sensitivity than in the laboratory test, likely due to differences in test design (water, source of species and, most important, method or chlorine application). The authors comment that "Possibly the timing of dosing could have maintained communities in a constant state of recovery and therefore made them appear less sensitive to chlorine stress". At 79 µg TRC/L, neither chlorophyll a nor the number of algal genera was reduced (NOEC). Protozoan species number was not significantly reduced at the lower test concentration, i.e. NOEC = 24 µg TRC/L. The most sensitive endpoint was the zooplankton density (24d NOEC = 1.5 µg TRC/L). Anyhow, the authors report only the number of zooplankton/ml of water without providing any other information about the effects on taxonomic composition of zooplankton community, so that it is not possible to draw any conclusion about the eventual elimination of taxa from the system. Also the potential for system recovery was not evaluated. In this study FAC concentration accounted for 100% of the measured TRC so that the above endpoint can be expressed also as µg FAC/L.

Because of the uncertainty associated to the most sensitive endpoint and likely underestimation of toxicity due to the pulse dosing system, the results of this test should be interpreted with caution. This conclusion is supported by the comparison of the long term zooplankton NOEC from this test (24d NOEC = 1.5 µg FAC(or TRC)/L) with the laboratory short-term toxicity to daphnia (24h LC50 = 5 µg FAC/L) which suggests that a continuous long term exposure of 1.5 µg FAC/L might dramatically affect daphnia populations. For these reasons data from this study are not considered valid for the assessment, but have been used in the final discussion as supportive information (rated s) (EU-RAR).

5.5 Comparison with criteria for environmental hazards (sections 5.1 – 5.4)

As the entry for sodium hypochlorite in Annex VI gives the concentration as % active chlorine, the assumption that TRC is equal to the FAC may possibly lead to an underestimation of the toxicity of sodium hypochlorite solutions. In Table 13 approximately half of the key-study data is reported as TRC.

The lowest acute aquatic toxicity values for sodium hypochlorite are:

- a (supportive) 48-hour LC50 value of 8.4 µg sodium hypochlorite per litre for *Morone saxatilis*
- a 24-hour LC50 of 5.3 µg sodium hypochlorite per litre for *Ceriodaphnia dubia*
- a 48-hour LC50 of 5.3 µg sodium hypochlorite per litre for *Baetis harrisoni*
- a 24-hour $EC50_r$ of <24.5 µg sodium hypochlorite per litre for *Pseudokirchneriella subcapitata*

Most of the studies are not standardized or have at least some short-comings compared to the standard test protocol. Therefore a weight of evidence approach is applied for this data leading to the conclusion that the lowest and most critical 50% effect concentrations are between 1 and 10 µg per litre.

The lowest chronic aquatic toxicity values for sodium hypochlorite are:

- a (supportive) 134-day NOEC of 5.3 µg sodium hypochlorite per litre for *Ictalarus punctatus*
- a 15-day NOEC (shell deposition) of 7.4 µg sodium hypochlorite per litre for *Crassostrea virginica*
- a (supportive) 7-day NOEC (biomass) of 3.2 µg sodium hypochlorite per litre for the peryphytic community

- a (supportive) 24-day NOEC (density) of 1.6 µg sodium hypochlorite per litre for zooplankton

Most of the studies are not standardized or have at least some short-comings compared to the standard test protocol. Therefore a weight of evidence approach is applied for this data leading to the conclusion that the lowest no observed effect concentrations are between 1 and 10 µg per litre.

The discussion if the inorganic compound sodium hypochlorite can be considered rapidly degradable is complex. Given the fact that hypochlorite solutions (kept away from sunlight and stored at low temperature) are stable and that some degradation products are also hazardous to the environment it is stated that sodium hypochlorite cannot considered being rapidly degradable for classification purposes.

Sodium hypochlorite is not expected to bioaccumulate.

5.6 Conclusions on classification and labelling for environmental hazards (sections 5.1 – 5.4)

Aquatic acute toxicity

Acute toxicity data are available for all three trophic levels. The lowest $L(E)C_{50}$ obtained in acute aquatic toxicity studies is 5.3 µg NaOCl/L, for the invertebrates *Ceriodapnia dubia* and *Baetis harrsoni*. This value is below the classification threshold value of 1 mg/L. Based on this information, sodium hypochlorite fulfils the criteria for classification with Aquatic Acute 1. Based on a weight of evidence approach, it can be concluded that the lowest LC50 values are between 0.001 and 0.01 mg/L. Therefore an acute M-factor of 100 is assigned to sodium hypochlorite.

Aquatic chronic toxicity

Chronic toxicity data are available for all trophic levels. The lowest chronic NOEC value for sodium hypochlorite is < 1 mg/L (15d NOEC of 7.4 µg NaOCl/L for *Crassostrea virginica* (shell deposition) besides the supportive data). Sodium hypochlorite is considered not rapidly degradable in the environment.

Based on this information, sodium hypochlorite fulfils the criteria for classification as Aquatic Chronic Category 1. Based on a weight of evidence approach it can be concluded that the lowest NOEC values are between 0.001 and 0.01 mg/L. Since the substance is considered non-rapidly degradable, a chronic M-factor of 10 is assigned to sodium hypochlorite.

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 No guideline No GLP reported	96h LC_{50}	60 (TRC) 30 (FAC)	63 (TRC) 32 (FAC)	Not	RAR: supportive DAR: supportive REACH: 2	Bass *et al*. (1977), Heath (1978)	RAR, 2007; DAR, 2008 REACH, 2014
Fish /freshwater *Ictalurus punctatus*	No continuous exposure No guideline No GLP reported	96h LC_{50}	64 (TRC) 32 (FAC)	67 (TRC) 34 (FAC)	Not	RAR: supportive DAR: supportive REACH: 2	Bass *et al*. (1977), Heath (1978)	RAR, 2007; DAR, 2008 REACH, 2014
Fish /freshwater (juvenils) *Salmo gairdneri*	No continuous exposure No guideline No GLP reported	24h LC_{50}	430	452	Not	RAR: supportive DAR: supportive REACH: 2	Brooks and Seegert (1977)	RAR, 2007; DAR, 2008 REACH, 2014
Fish /freshwater *Onchorhyncus kisutch* *Alosa pseudoharengus* *Notropis hudsonius* *Osmerus mordax*	No continuous exposure No guideline No GLP reported	48h LC_{50}	1260–2410	1323–2531	Not	RAR: supportive DAR: supportive REACH: 2	Seegert and Brooks (1978)	RAR, 2007; DAR, 2008 REACH, 2014
Fish /freshwater *Pimephales promelas*	No continuous exposure No guideline No GLP reported	96h LC_{50}	80 (TRC) >40 (FAC)	84 (TRC) >42 (FAC)	Not	RAR: supportive DAR: supportive REACH: 3	Wilde *et al*. (1983a,b)	RAR, 2007; DAR, 2008 REACH, 2014
Freshwater fish *Cyprinus carpio*	No continuous exposure No guideline No GLP reported	48h LC_{50}	260	273	Not	RAR: supportive DAR: supportive	Tsai *et al*. (1990)	RAR, 2007; DAR, 2008
Fish /freshwater *Gambusia affinis*	No guideline No GLP reported	48h LC_{50}	610	641	Not	RAR: supportive DAR: supportive	Tsai *et al*. (1990)	RAR, 2007; DAR, 2008
Fish /freshwater *Gambusia affinis*	No continuous exposure No guideline No GLP reported	48h LC_{50}	840	882	Not	RAR: supportive DAR: supportive	Mattice *et al*. (1981)	RAR, 2007; DAR, 2008

Fish /freshwater *Menidia menidia*	No guideline No GLP reported	96h LC_{50}	37 (TRC)	39 (TRC)	Not	RAR: supportive DAR: supportive REACH: 3	Roberts *et al.* (1975)	RAR, 2007; DAR, 2008 REACH, 2014
Fish /brackish & sea water *Leiostomus xanthurus*	No guideline No GLP reported	96h LC_{50}	90 (TRC&FAC)	95 (TRC&FAC)	Not	RAR: 1 DAR: 1 REACH: 2	Bellanca and Bailey (1977)	RAR, 2007; DAR, 2008; REACH, 2014
Fish / brackish & sea water *Gasterosteous aculeatus*	No guideline No GLP reported	96h LC_{50}	167	175	Not	RAR: 2 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 "larger 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

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 (evidence studies 1, 3, 6-13) and rejecting studies of reliability score 4 (study numbers 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 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.

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 No guideline No GLP reported	28d NOEC	40 (TRC)	42 (TRC)	Key	RAR: 1 DAR: 1	Goodman *et al.* (1983)	RAR, 2007 DAR, 2008
Fish /freshwater *Ictalarus punctatus*	Flow-through field study with standard fish species No guideline No GLP reported	134d NOEC	5 (TRC)	5.3 (TRC)	Supportive	RAR: supportive DAR: supportive	Hermanutz *et al.* (1990)	RAR, 2007 DAR, 2008
Invertebrates / brackish & sea water /oyster *Crassostrea virginica*	Non-standard field study of shell deposition No guideline No GLP reported	15d NOEC	7 (TRO)	7.4 (TRO)	Key	RAR: 2 DAR: supportive	Liden *et al.* (1980)	RAR, 2007 DAR, 2008
Invertebrate / freshwater *Epioblasma capsaeformis*	No guideline 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 OECD TG 201	24h LOErC 24h LOEbC	<10.8 (FAC) <10.8 (FAC)	<11.3 (FAC) <11.3 (FAC)	Key	Industry: 1	Liedtke (2013)	Industry, after 2014
Peryphytic community	Flow through microcosms No guideline No GLP reported	7d NOEbC	3 (FAC)	3.2 (FAC)	Key	RAR: 2 DAR:2	Cairns *et al.* I (1990)ab	RAR, 2007 DAR, 2008
Zooplankton (density)	Outdoor mesocosm, daily chlorine pulse. No guideline No GLP reported	24d NOEC	1.5 (FAC)	1.6 (FAC)	Supportive	DAR: 2 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.

6 OTHER INFORMATION

No other relevant information available.

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8 ANNEXES

Adapted from Annex 4 in the EU RAR

ACTIVE/AVAILABLE CHLORINE AND HYPOCHLORITE

The active chlorine content of a chlorinated substance (in g/kg) is the amount of pure (100%) chlorine (in g) that has the same oxidizing power as one kg of the substance.

Example: 1 kg of a sodium hypochlorite solution containing 12.5% of active chlorine (125 g/kg) has the same oxidizing power as 125 g of pure chlorine.

The oxidizing power of a substance characterizes the number of electrons exchanged during reaction of this substance. While transforming in chloride ions (Cl^-), 1 molecule of the following substances exchanges.
- Chlorine (Cl_2) : 2 electrons
- Hypochlorite ion (ClO^-) or hypochlorous acid (HClO): 2 electrons
- > 1 mole of pure NaClO (74.5 g) has the same oxidizing power as 1mole of chlorine (71 g)

Example: The active chlorine content of a sodium hypochlorite solution containing 15 % (150 g/kg) of NaClO is : 150 * 71 / 74.5 = 143 g act. Cl_2 / kg

Two terms are used for defining the concentration of bleach in the lay-man literature and the market:

Active chlorine is by definition the amount of pure (100%) chlorine, in aqueous solution, which has the same oxidizing power as a unit quantity of that substance. In other words, the oxidizing properties of a substance are compared with chlorine and expressed as such. In practice, this corresponds to Cl_2 + HOCl (active chlorine). However, it is often used for available chlorine which is the sum of Cl_2 + HOCl + ClO^- (available chlorine). Both active and available chlorine are expressed as equivalent content of Cl_2 (molecular weight: 71g).

Sodium hypochlorite is the word used to give the concentration of bleach in North America. The molecular weight of NaOCl is 74.5 g. Since the molecular weights of Cl_2 and NaOCl are slightly different, the way of expressing the concentration is slightly different. However, the difference is small; the active chlorine equivalent content is:
- for chlorine Cl_2 :100 % (by definition)
- for sodium hypochlorite NaOCl : 95 % (by calculation: 71/74.5 = 0.95)

In the case of sodium hypochlorite, there are small difference in figures expressed in active chlorine or in weight of substance (i.e.% act.Cl_2 = % weight).

What is measured in environmental media like surface fresh water is generally expressed as free available chlorine (FAC) or total residual chlorine (TRC) which encompass free and combined chlorine (like chloramines). In saltwater what is measured is generally called total residual oxidant (TRO) including free chlorine and bromine or chlorine produced oxidant (CPO) which encompasses free and combined chlorine and bromine species.