Committee for Risk Assessment

RAC

Opinion

proposing harmonised classification and labelling
at EU level of

Glutaraldehyde

EC number: 203-856-5
CAS number: 111-30-8

CLH-O-0000004237-75-03/F

Adopted

6 June 2014

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CLH-O-0000004237-75-03/F

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

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

Chemical name:	**Glutaraldehyde**
EC number:	**203-856-5**
CAS number:	**111-30-8**

The proposal was submitted by **Finland** and received by the RAC on **13 September 2013.** All classifications are given in the form of CLP hazard classes and/or categories, the majority of which are consistent with the Globally Harmonised System (GHS); the notation of 67/548/EEC, the Dangerous Substances Directive (DSD) is no longer given.

PROCESS FOR ADOPTION OF THE OPINION

Finland has submitted a CLH dossier containing a proposal together with the justification and background information documented in a CLH report. The CLH report was made publicly available in accordance with the requirements of the CLP Regulation at ***http://echa.europa.eu/harmonised-classification-and-labelling-consultation*** on **25 September 2013**. Concerned parties and Member State Competent Authorities (MSCA) were invited to submit comments and contributions by **11 November 2013**.

ADOPTION OF THE OPINION OF THE RAC

Rapporteur, appointed by the RAC: **Peter Sørensen**

Co-rapporteur, appointed by the RAC: **Katalin Gruiz**

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

The RAC opinion on the proposed harmonised classification and labelling was reached on **6 June 2014** and the comments received are compiled in Annex 2.

The RAC Opinion was adopted by **consensus**.

OPINION OF THE RAC

The RAC adopted the opinion that **Glutaraldehyde** should be classified and labelled as follows:

Classification and labelling in accordance with the CLP Regulation

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)	
Current Annex VI entry	605-022-00-X	glutaral; glutaraldehyde; 1,5-pentanedial	203-856-5	111-30-8	Acute Tox. 3 * Acute Tox. 3 * Skin Corr. 1B Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1	H331 H301 H314 H334 H317 H400	GHS06 GHS05 GHS08 GHS09 Dgr	H331 H301 H314 H334 H317 H400		* Skin Corr. 1B; H314: C ≥ 10 % Skin Irrit. 2; H315: 0,5 % ≤ C < 10 % Eye Dam. ; H318: 2 % ≤ C < 10 % Eye Irrit. 2; H319: 0,5 % ≤ C < 2 % STOT SE; H335: C ≥ 0,5 % Skin Sens. 1; H317: C ≥ 0,5 %
Dossier submitters proposal	605-022-00-X	glutaral; glutaraldehyde; 1,5-pentanedial	203-856-5	111-30-8	**Add:** STOT SE 3 Aquatic Chronic 2 **Modify:** Acute Tox. 1 Acute Tox. 3 Skin Sens. 1A	**Add:** H335 H411 **Modify:** H330 H301		**Add:** H335 H411 H410 **Modify:** H330 H301 **Remove:** H400	**Add:** EUH071	**Add:** M (acute) = 10 **Remove:** Skin Sens. 1; H317: C ≥ 0,5 % **Modify:** STOT SE 3; H335: C ≥ 0,00005 %

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)	
RAC opinion	605-022-00-X	glutaral; glutaraldehyde; 1,5-pentanedial	203-856-5	111-30-8	**Add:** STOT SE 3 Aquatic Chronic 2 **Modify:** Acute Tox. 2 Acute Tox. 3 Skin Sens. 1A	**Add:** H335 H411 **Modify:** H330 H301		**Add:** H335 H411 H410 **Modify:** H330 H301 **Remove:** H400	**Add:** EUH071	**Add:** M (acute) = 1 **Remove:** Skin Sens. 1; H317: C ≥ 0,5 % Skin Corr. 1B; H314: C ≥ 10 % Skin Irrit. 2; H315: 0,5 % ≤ C < 10 % Eye Dam. ; H318: 2 % ≤ C < 10 % Eye Irrit. 2; H319: 0,5 % ≤ C < 2 %
Resulting Annex VI entry if agreed by COM	605-022-00-X	glutaral; glutaraldehyde; 1,5-pentanedial	203-856-5	111-30-8	Acute Tox. 2 Acute Tox. 3 STOT SE 3 Skin Corr. 1B Resp. Sens. 1 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 2	H330 H301 H335 H314 H334 H317 H400 H411	GHS06 GHS05 GHS08 GHS09 Dgr	H330 H301 H335 H314 H334 H317 H410	EUH071	* STOT SE; H335: C ≥ 0,5 % M = 1

SCIENTIFIC GROUNDS FOR THE OPINION

HUMAN HEALTH HAZARD ASSESSMENT

RAC evaluation of acute toxicity

Summary of the Dossier submitter's proposal

Oral
The CLH report included two oral rat acute toxicity studies, both conducted according to OECD TG 401 with 50% glutaraldehyde. In the first study (Myers et al., 1992) the LD_{50} values were 77 mg/kg in females and 123 mg/kg in males with a combined (males and females) LD_{50} of 100 mg/kg. In the second study (Jaeckh et al., 1994a) the LD_{50} values were 143 mg/kg in females and 158 mg/kg in males with a combined LD_{50} of 151 mg/kg. All values were presented as pure glutaraldehyde. As all LD_{50} value were within the range 50-300 mg/kg, the dossier submitter proposed to confirm the classification of Acute Tox. 3 – H301.

Inhalation
The CLH report included two rat inhalation acute toxicity studies considered reliable for classification by the dossier submitter (Klimisch et al. 1994 and 2001), conducted similar to OECD TG 403. In addition, two other studies were included as supportive information but not used for classification. The LC_{50} values in the two studies were 0.28 mg/L (females) and 0.45 mg/L (females), respectively. Necropsy revealed acute congestion, emphysema, edematization and infarctoid hyperaemia. The test substance was 50% glutaraldehyde in both cases but LC_{50} values were based on measured concentrations of glutaraldehyde in air and therefore no correction is needed. In a physical-chemical study mimicking the system used in the inhalation study, the vapour phase accounted for 65 and 68% of the measured concentration of glutaraldehyde at 0.224 and 0.349 mg/L, respectively. As the lowest LC_{50} values were below 0.5 mg/L (vapour), the dossier submitter proposed amending the classification to Acute Tox. 1 – H330. In addition, as the mechanism of toxicity was deemed to be through corrosivity, the DS proposed the addition of the supplemental hazard statement EUH071 (corrosive to the respiratory tract).

Dermal
Two dermal acute toxicity studies, conducted with 50% glutaraldehyde in rabbits, were included in the CLH report. One was conducted similar to OECD TG 402 (Jaeckh et al., 1994b) while the other was reportedly conducted according to EPA guidelines 81-2 (Kiplinger et al., 1995). Severe irritation or corrosion was seen in both studies. The LD_{50} for the test substance was >2000mg/kg in both studies, equivalent to >1000 mg/kg for pure glutaraldehyde. No classification for dermal acute toxicity was proposed.

In summary, glutaraldehyde is already classified as Acute Tox. 3* - H331 and Acute Tox. 3* - H301. This classification is based on a translation from the DSD classification and also included specific concentration limits (SCL). No SCLs are set for acute toxicity under the CLP criteria. The DS proposed to confirm the minimum classification for Acute Tox. 3 – H301 and to change the classification for acute toxicity through inhalation to Acute Tox. 1 – H330.

Comments received during public consultation

Comments were received from three Member State Competent Authorities (MSCA) and three companies. All MSCAs agreed with the proposed amendments of the acute toxicity classifications for the oral and inhalation routes, while one questioned the decision not to classify for dermal exposure. The DS explained that the dermal data were not reliable enough to base a classification on. All three companies disagreed with the acute inhalation classification, arguing that the exposure of animals was predominantly to aerosols and therefore the LC_{50} values should be compared with the criteria for dusts/mists. This would result in a classification of Acute Tox. 2 – H330. The DS disagreed with the commenting companies, arguing that the criteria for vapours are more appropriate. More information, including detailed argumentation by both the commenting parties and the DS, can be found in the RCOM.

One MSCA expressed concerns about inconsistency in assigning EUH071 to the substance compared with other similarly classified substances and raised the issue of whether SCLs would be set. Two companies also expressed disagreement with the application of EUH071, arguing that it was superfluous as the proposal already included classification as corrosive, irritant to the respiratory tract and toxic via inhalation. The DS argued that the proposed application of EUH071 was consistent with the criteria in Annex I to CLP (Note 1 in Table 3.1.3) and with previous RAC recommendations, but did not address setting SCLs.

Assessment and comparison with the classification criteria

Oral: The corrected LD_{50} values acquired from the oral rat studies ranged from 77 mg/kg in females to 158 mg/kg in males. The toxic effects were considered to be caused by the corrosive effect on the mucosal surface of the GI tract. All values were within the range 50-300 mg/kg and therefore the classification as Acute Tox. 3- H301 is warranted.

Inhalation: The corrected LC_{50} values provided were between 0.28 mg/L in females and up to 0.52 mg/L in males.

In a 50 % aqueous solution of glutaraldehyde, the Saturated Vapour Concentration (SVC) cannot be calculated using the vapour pressure of 100% glutaraldehyde. The partial vapour pressure in a 50% solution is given to be 0.13 hPa for glutaraldehyde (Olsen, 1995) instead of the standard 0.44 hPa.

A theoretical SVC for glutaraldehyde in a 50% aqueous solution can then be calculated as 0.0412 x 100.11 (g/mol) x 0.13 hPa. This results in 0.53 mg/L. But in practice this will only occur in an environment completely saturated with glutaraldehyde.

In order to clarify whether the test substance should be considered as an aerosol or vapour, the applicant under the biocidal active substance process performed a physical/chemical study mimicking the system used in the inhalation study. At measured concentrations of 0.224 and 0.349 mg glutaraldehyde/L the vapour phase accounted for around 66%. That means that two-thirds of the glutaraldehyde is presented as vapour. To take this assumption further, the saturated partial glutaraldehyde vapour phase will then be around two-thirds of 0.53 mg/L = 0.35 mg/L as determined in the physical/chemical study.
The LC_{50} values obtained from the inhalation studies are within the range 0.28 mg/L to 0.52 mg/L.

A newly submitted study (consistent with OECD TG 403) which was not reported in the CLH report but was mentioned by the industry during the public consultation and later submitted (comment No. 10 in the RCOM; Klimisch, 1981), estimated the possible risk on inhalation of a mixture of the ***vapor*** of the test substance and air. The Inhalation Hazard Test (IHT) was conducted to test saturated vapour. The atmosphere was generated by passing an air stream through a layer of test substance. Using this method, aerosols are often formed due to bubbling of the test substance. However, the fraction of aerosol is expected to be low.

Results from this study:

Exposure period		1 h	3 h	7 h
Volatile components 20 C.		0/12	1/12	6/6
Mean Conc.	Mg/l	16	17	13
	PPM	3,800	4,100	3,300

The table indicates that at an assumed vapour concentration of 0.35 mg/L, one out of 12 animals died after 3 hours of exposure.

In the CLP guidance it is stated that *"A LC50 well below the SVC will be considered for classification according to the criteria for vapours; whereas an LC50 close to or above the SVC will be considered for classification according to the criteria for mists".*

RAC concludes that the LC_{50} value of 0.28-0.52 mg/L is close to the SVC of 0.53 mg/L (theoretical calculated SVC) and the highest practically achievable vapour concentration of 0.35 mg/L and therefore the criteria for aerosols should be applied. Together with the conclusion from the new submitted study, where animals were exposed to vapours only, and only 1 animal out of 12 died within 3 hours of exposure, classification for glutaraldehyde as Acute Tox 2 – H330 is appropriate.

Dermal: LD_{50} values were reported in two studies to be > 1000 mg/kg (calculated from LD_{50} values for a 50% solution). An additional study (Myers, 1981) estimated an LD_{50} value of 875 mg/kg. However, based on the study design and on judging by the full data set, the LD_{50} value is set at above 1000 mg/kg and classification for acute dermal toxicity is not warranted.

In addition to classification for acute toxicity, the substance shall also be labelled with EUH071 (corrosive to the respiratory tract).

RAC evaluation of specific target organ toxicity – single exposure (STOT SE)

Summary of the Dossier submitter's proposal

Although glutaraldehyde is not classified for STOT SE, it currently has SCLs as STOT SE 3- H335: C ≥ 0,5 %, stemming from a translation of SCLs for Xi; R37: 0,5% ≤ C < 10 % under DSD. As the substance is considered corrosive and can be inhaled, the DS regarded classification as STOT SE 3 – H335 as appropriate. In addition, the DS argued that the substance is a sensory irritant. The CLH report included one peripheral sensory irritation (PSI) test (Werley et al., 1995). Exposure to glutaraldehyde vapour resulted in an almost immediate, dose-dependent decrease in the respiratory rate in mice, with an RD_{50} (concentration at which respiratory rate decreased by 50%) of 13.9 ppm. Five human case and epidemiology studies were also summarised in the CLH report. All documented workers' exposure to glutaraldehyde and symptoms of skin, eye, throat and lower respiratory tract irritation. As the sensory irritation RD10 was approx. 0.4 ppm and a threshold of 0.39 – 0.47 ppm for this effect was seen in human volunteers, the DS proposed SCLs of 0.00005%.

Comments received during public consultation

One MSCA expressed doubts over whether the data were sufficient for classification for respiratory irritation. Three companies expressed strong opposition to the derivation of SCLs by the DS, arguing that an atmospheric concentration of glutaraldehyde sufficient to cause symptoms in animals or humans could not be used to derive a concentration limit in an aqueous solution of glutaraldehyde. One company proposed to retain the current SCL of 0.5 % and the others did not propose an alternative SCL. The DS agreed with the comments received and provided a comparison with formaldehyde and acetaldehyde to estimate the respiratory irritation potential of glutaraldehyde. The DS proposed to retain the current SCL of 0.5 %, based on this comparison.

Assessment and comparison with the classification criteria

Glutaraldehyde is corrosive and can be inhaled. Several human case and epidemiological studies indicated respiratory irritation in humans and there were signs of peripheral sensory irritation in mice. Therefore, RAC agrees to classify glutaraldehyde as STOT SE 3 - H335 and to retain the SCL of 0.5%. In addition to this classification, the substance shall also be labelled with EUH071 (corrosive to the respiratory tract).

RAC evaluation of skin corrosion/irritation

Summary of the Dossier submitter's proposal

Glutaraldehyde is already classified as Skin Corr. 1B – H314, with specific concentration limits of Skin Irrit. 2; H315: 0.5 % ≤ C < 10 %, Eye Dam. ; H318: 2 % ≤ C < 10 % and Eye Irrit. 2; H319: 0.5 % ≤ C < 2 %. The DS presented three rabbit irritation studies; one conducted according to OECD TG 404 (Myers et al., 1988) and two non-guideline studies (Grundler et al. 1994a and

1994b). All studies were conducted with 50% glutaraldehyde. Necrosis was observed after exposure for 1h, which had not reversed by the end of the observation period (8-10 days). The DS proposed no changes to the classification or SCLs.

Comments received during public consultation

Two MSCAs and two companies offered their general agreement to no change in the classification.

Assessment and comparison with the classification criteria

As visible necrosis was seen after exposure of longer than 3 minutes but less than 1 hour, which had not fully resolved within 10 days, RAC agreed to retain the classification of Skin Corr. 1B – H314. Generic concentration limits for corrosion/irritation are different under CLP and DSD. Glutaraldehyde was classified as C;R34 under DSD, translated as Skin Corr. 1B under CLP. The entry in Table 3.2 of Annex VI showed combined GCL/SCLs, which were translated as SCLs into CLP (see table 1 below)

Table 1

C;R34/Skin Corr. 1B	**Generic concentration limits**	**Current entry for glutaraldehyde**
DSD	C;R34: C≥ 10% Xi; R36/38: 5% ≤ C10%	C;R34: C≥ 10% Xi; R37/38-41: 2% ≤ C10% Xi; R36/37/38: 0.5% ≤ C2%
CLP	Skin Corr. 1B; H314: C ≥ 5% Skin Irrit. 2; H315: 1% ≤ C < 5% Eye Dam. 1; H318: 3% ≤ C < 5% Eye Irrit. 2; H319: 1% ≤ C < 3%	Skin Corr. 1B; H314: C ≥ 10% Skin Irrit. 2; H315: 0,5% ≤ C < 10% Eye Dam. 1; H318: 2% ≤ C < 10% Eye Irrit. 2; H319: 0,5% ≤ C < 2% STOT SE 3; H335: C ≥ 0,5%

As a result of the translation, the current entry for glutaraldehyde has a higher SCL for corrosivity than the GCL under CLP. There are no data, either in the CLH report or the CAR, that would support such a conclusion. This therefore appears to be a translation error. However, glutaraldehyde also has lower SCLs for skin irritation, eye damage and eye irritation than the GCL. This may well be justified due to experimental studies for products, but there is no record in any TC C&L documents of this having been decided or of any justification in the summaries of the three studies reported.

RAC concludes that based on a lack of available data, the specific concentration limits should be removed from the entry and the generic concentration limits applied.

RAC evaluation of eye damage/irritation

Summary of the Dossier submitter's proposal

The CLH report summarised two rabbit eye irritation studies, both supporting classification as Eye Dam. 1 – H318. However, glutaraldehyde is currently classified as Skin Corr. 1B – H314 (causes severe skin burns and eye damage), covering classification for eye damage. The DS proposed no change in the classification or specific concentration limits.

Comments received during public consultation

Two MSCAs and two companies offered their general agreement to no change in the classification.

Assessment and comparison with the classification criteria

RAC agrees with the DS that glutaraldehyde is a severe eye irritant and that the classification is already covered by the classification for corrosion and that no change to the classification is needed.

RAC evaluation of respiratory sensitisation

Summary of the Dossier submitter's proposal

Glutaraldehyde is already classified as Resp. Sens. 1 – H334. The CLH report included one mouse Immunoglobulin E (IgE) study (Kimber et al., 1994) indicating a dose-dependent increase in serum IgE after exposure to glutaraldehyde. In addition, 22 human studies were summarised in the CLH report. Despite the abundance of data indicating that glutaraldehyde is a respiratory sensitiser in humans, uncertainties remained as to the concentrations causing the reactions and the frequency of response in the exposed population. Therefore, the DS concluded that no sub-categorisation is possible and proposes no change in the classification.

Comments received during public consultation

Comments were received from two companies agreeing with the proposal not to change the classification.

Assessment and comparison with the classification criteria

RAC agrees with the DS that glutaraldehyde is a respiratory sensitiser. RAC also agrees that the available data do not allow for further sub-categorisation and agrees to retain the classification of Resp. Sens. 1 – H334.

RAC evaluation of skin sensitisation

Summary of the Dossier submitter's proposal

Glutaraldehyde is already classified as Skin Sens. 1 – H317. The CLH report included one guinea pig maximisation test (GPMT) (Blaszcak, 1993), three mouse local lymph node assays (LLNA) (Kimber, 1994; Basketter, 2000 and 2003) and one guinea pig open epicutaneous test (Zeller, 1975). The four studies were used as key studies while the latter was reported as supportive information. In addition, the CLH report included short summaries of two human studies, one indicating sensitisation in human volunteers (Marzulli et al., 1974) and one indicating allergic contact dermatitis in health-care workers (Shaffer et al., 2000).

All animal studies were positive for skin sensitisation. In the GPMT study, an intradermal induction dose of 0.1% produced positive reactions in 68% of tested animals. In two LLNA studies, measured EC3 values were 0.07% and 0.2%. In Kimber (1994), the EC3 was not determined. The DS proposed sub-categorisation into Skin Sens. 1A – H317. As the GCL for subcategory 1A is 0.1%, the DS proposes removal of the SCL for skin sensitisation

Comments received during public consultation

Two MSCAs agreed with the sub-categorisation into category 1A and the removal of the SCLs. One company disagreed with the classification, arguing that the data are insufficient for sub-categorisation and that glutaraldehyde is not of significant concern in the "dermatological community". The DS disagreed and argued that the clear evidence from several independent animal studies justify classification in Skin Sens. 1A – H317. More details can be found in the RCOM.

Assessment and comparison with the classification criteria

As the result from the GPMT test was $\geq$60% with an induction dose at 0.1% together with the results from the LLNA test (EC3 values; 0.07% and 0.2% both $\leq$2%) are within the criteria for Skin Sens 1A, RAC agrees to classify glutaraldehyde as Skin Sens 1A – H317 and to remove the SCL (0.5%) and retain the GCL (0.1%) which is justified by the available data.

ENVIRONMENTAL HAZARD ASSESSMENT

RAC evaluation of environmental hazards

Summary of the Dossier submitter's proposal

The DS proposed to add the classification as aquatic chronic 2 for long-term aquatic hazard to the existing annex VI entry. Moreover, the DS proposed to add the acute M-factor = 10. Following the PC, the DS changed the proposal to acute M-factor = 1.
The proposed additions were based on the following arguments:

- Glutaraldehyde is rapidly degradable in the environment as shown by two ready biodegradability tests conducted according to the OECD guideline 301 A, providing a biological degradation of 74% after 9 days and 88% after 7 days, respectively.
- Glutaraldehyde does not have a tendency to bioaccumulate, as shown by the Log Kow values (at pH 5: –0.41; at pH 7: –0.36; at pH 9: –0.80).
- The results of an aquatic acute toxicity test on marine invertebrates (*Acartia tonsa)* provided an EC_{50} = 0.07 mg/L. Following the information submitted during the PC, the DS concluded that this value was no longer valid and should be substituted by the result of a new test on the same test organism (LC_{50} = 3.0 mg/L (nominal)). As a consequence, the most sensitive species is the algae *Scenedesmus subspicatus*, with an ErC50 of 0.6 mg/L, which was used for updating the originally proposed M-factor.
- The result of the aquatic chronic toxicity test conducted on *Scenedesmus subspicatus*, providing a NOECr (72 h) = 0.025 mg/L.

Comments received during public consultation

Two MSs supported the proposed classification. Two manufacturers recommended the modification of the proposed acute M-factor (M= 10) to M=1, according to new information on marine invertebrate toxicity. According to the commenting parties, the newly executed acute toxicity test on the marine invertebrate *Acartia tonsa* gave a more realistic result compared to the previous study, conducted under static conditions and where measured concentrations declined significantly within 48 hours (values ranged from 8–33% of the nominal concentration and the results were based on geometric mean of the measured concentrations). The new test was carried out under semi-static conditions according to GLP and ISO 14669 (1999) guidelines. The measured concentrations were within the 80–120% range of the nominal concentrations (therefore within the range of 0.7–8.1 mg a.s./L). The LC_{50} = 3.0 mg/L (nominal) corresponded to 2.7–3.3 mg/L based on measured concentrations. The test was qualified as reliable, acceptable and valid.

The newly executed test showed that marine invertebrate *Acartia tonsa* is less sensitive than was supposed based on the results of an earlier test of questionable quality. *A. tonsa* showed sensitivity similar to that of the freshwater Daphnia. The most sensitive species was therefore algae, with an ErC_{50} of 0.6 mg/L.

Assessment and comparison with the classification criteria

1. Glutaraldehyde is readily biodegradable
    - 74% and 88% DOC removal was measured within 7–9 days (a substance is readily biodegradable if a minimum of 70% DOC is removed within a 10-day time window, according to Regulation EC 1272/2008 (CLP)).

2. Glutaraldehyde is not bioaccumulative
    - The log K_{ow} was between -0.80 and -0.36 (pH 5–9, 25°C). Comparing this with the CLP criterion of K_{ow} > 4 for classification as bioaccumulative, glutaraldehyde does not fulfill the bioaccumulation criterion.

3. Acute aquatic toxicity
   - Acute aquatic toxicity measured in the new marine invertebrate *Acartia tonsa* acute toxicity test (resulting in an LC_{50} = 3.0 mg/L) does not fulfil the CLP criterion of $L(E)C_{50} \leqslant$ 1 mg/L for this hazard class. Consequently glutaraldehyde should be classified based on the algae toxicity test result. Acute aquatic toxicity measured in the algal growth test was LrC_{50}= 0.60 mg/L, which is $\leqslant$ 1 mg/L, fulfilling the criterion of $L(E)C_{50} \leqslant$ 1 mg/L and based on that, glutaraldehyde is classified as Aquatic Acute 1, H400, with an M-factor of M=1 (based on the CLP criterion of 0.1 < $L(E)C_{50} \leqslant$ 1 mg/L).

4. Chronic aquatic toxicity
   - Chronic aquatic toxicity measured by *Scenedesmus subspicatus* $NOEC_r$ (72 h) = 0.025 mg/L results in a classification of Aquatic Chronic 2; H411, fulfilling the criterion of 0.01 < NOEC $\leqslant$ 0.1 mg/L.

5. Combined labelling
   - H400 and H411 are combined (in accordance with Table 4.1.6-a of the Guidance on the Application of the CLP Criteria) resulting in Hazard Statement H410 "Very toxic to aquatic life with long lasting effects".

ANNEXES:

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

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