

# Comments on the CLH report - Proposal for Harmonised Classification and Labelling, Substance Name: 8-hydroxyquinoline, Version 3, September 2014

**Table : Proposed classification according to the CLP Regulation**

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification	Reason for no classification	Comment Notifier
<b>Hazard based on Physical/chemical Properties</b>						
2.1.	Explosives	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
2.2.	Flammable gases	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
2.3.	Flammable aerosols	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
2.4.	Oxidising gases	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
2.5.	Gases under pressure	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
2.6.	Flammable liquids	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
2.7.	Flammable solids	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
2.8.	Self-reactive substances and mixtures	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
2.9.	Pyrophoric liquids	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
2.10.	Pyrophoric solids	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
2.11.	Self-heating substances and mixtures	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
2.12.	Substances and mixtures which in contact with water emit flammable gases	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
2.13.	Oxidising liquids	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
2.14.	Oxidising solids	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
2.15.	Organic peroxides	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
2.16.	Substance and mixtures corrosive to metals	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification	Reason for no classification	Comment Notifier
<b>Human Health Hazards</b>						
3.1.	Acute toxicity - oral	Acute Tox. 3 H301: Toxic if swallowed	n.a.	R22: Harmful if swallowed	n.a.	<b>Disagreed<sup>1)</sup></b>
	Acute toxicity - dermal	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
	Acute toxicity - inhalation	n.a.	n.a.	Currently not classified	No data	Agreed
3.2.	Skin corrosion / irritation	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
3.3.	Serious eye damage / eye irritation	Eye Dam 1: H318, Causes serious eye damage,	n.a.	Currently not classified	n.a.	Agreed
3.4.	Respiratory sensitisation	n.a.	n.a.	Currently not classified	No data	Agreed
3.4.	Skin sensitisation	Skin Sens. 1; H317 May cause allergic skin reactions,	n.a.	R43: May cause sensitisation by skin contact	n.a.	Agreed
3.5.	Germ cell mutagenicity	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
3.6.	Carcinogenicity	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
3.7.	Reproductive toxicity	Repr. 2: H361d	n.a.	Currently not classified	Conclusive but not sufficient for classification	<b>Disagreed<sup>2)</sup></b>
3.8.	Specific target organ toxicity – single exposure	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
3.9.	Specific target organ toxicity – repeated exposure	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed
3.10.	Aspiration hazard	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification	Reason for no classification	Comment Notifier
<b>Environmental Hazard</b>						
4.1.	Hazardous to the aquatic environment	Aquatic acute 1 H400: Very toxic to aquatic life Aquatic chronic 1 H410: Very toxic to aquatic life with long lasting effects	Acute M = 1 Chronic M = 10	Currently not classified	n.a.	Agreed
5.1.	Hazardous to the ozone layer	n.a.	n.a.	Currently not classified	Conclusive but not sufficient for classification	Agreed

### 1) Acute oral toxicity

Classification is based on a mouse study (Dickhaus & Heisler, 1981b) LD<sub>50</sub> 177 mg/kg bw) with mortalities occurring within 24h after administration.

Please refer to the enclosed expert statement Pfau (2014).

Considering the weight of evidence the observation of the LD<sub>50</sub> in the Dickhaus & Heisler (1981b) study is considered spurious and may be due to impurities in the test item, as no specification or analysis was provided.

A more reasonable but conservative classification is proposed:

Acute Tox 4 H302, Harmful if swallowed

### 2) Reproductive toxicity

We agree with non-classification for reproductive toxicity regarding sexual function and fertility.

We disagree with the proposed classification for developmental toxicity based on findings in a rabbit developmental study (Fascineli, 2006):

Please refer to the enclosed expert statement Pfau (2014).

It is concluded that the observed effect in the rabbit is not relevant to humans.

Thus, a classification of 8-Hydroxyquinoline for developmental toxicity is not warranted.