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# CLP and the regulation of cosmetic products

This article looks at the impact that Regulation (EC) No 1272/2008 commonly referred to as 'CLP' is having on the regulation of cosmetic products. It looks at the classification of some of the ingredients listed in the annexes of Regulation (EC) No 1223/2009 and how this may affect their future use.

## What is CLP?

When referring to CLP we are referring to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures which came in to force on 20 January 2009. It replaces the Dangerous Substances Directive 67/548/EEC and the Dangerous Preparations Directive 1999/45/EC. It implements and puts into European Union law the 2nd edition of the United Nations Globally Harmonised System of classification and labelling of chemicals (GHS). It has been amended a number of times by the following Commission Regulations commonly referred to as Adaptation to Technical Progress (ATP): Commission Regulation (EC) No 790/2009; Commission Regulation (EU) No 286/2011; Commission Regulation (EU) No 618/2012; Commission Regulation (EU) No 487/2013; Commission Regulation (EU) No 944/2013 and Commission Regulation (EU) No 605/2014. It has also been amended by Commission Regulation (EU) No 758/2013 (corrections to Annex VI), Commission Regulation (EU) No 1297/2014 (liquid consumer laundry detergents in soluble packaging) and Commission Regulation 2015/491 (changing the application date for Commission Regulation (EU) No 605/2014 (6th ATP) from 1 April 2015 to 1 January 2016). Substances and their harmonised classification and labelling are listed in tables 3.1 and 3.2 in part 3 of Annex VI of Regulation (EC) No 1272/2008.

## Does CLP apply to cosmetic products?

Regulation (EC) No 1272/2008 states that it applies to all substances and mixtures supplied in the European Community except where other community legislation "lays down more specific rules on classification and labelling".[1] The labelling of cosmetics is regulated by Regulation (EC) No 1223/2009 and therefore Regulation (EC) No 1272/2008 does not apply to the labelling of most cosmetic products. The reason for saying "most" and not "all" cosmetic products is that aerosol products must be labelled in compliance with both Regulation (EC) No 1272/2008 and Regulation (EC) No 1223/2009.

## Aerosols

Commission Regulation (EU) No 487/2013 (4th ATP) covers the classification of aerosols including the criteria for flammable and non flammable aerosols. From 1 June 2015 personal care aerosol products should be labelled in compliance with Regulation (EC) No 1272/2008 as well as the labelling requirements of Regulation (EC) No 1223/2009. Labelling for aerosols is covered by Commission Directive 75/324/EEC. Commission Directive 75/324/EEC has been amended by Commission Directive 2013/10/EU to bring it in line with Regulation (EC) No 1272/2008. From 1 June 2015 labelling for aerosols must comply with the requirements of Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP). Aerosol products containing mixtures of substances placed on the market before 1 June 2015 are not required to be relabelled in accordance with commission directive 2013/10/EU until 1 June 2017.

## Material Safety Data Sheets (MSDS)

Labels and material safety data sheets are the main tools used to communicate information within the supply chain. From 1 June 2015 material safety data sheets will need to be in CLP format. Although there is not a requirement to provide a material safety data sheet when selling cosmetic products, some retailers require that companies provide them. They may also be required for transport and storage purposes.

## CMR

One of the biggest impacts that Regulation (EC) No 1272/2008 will have on cosmetic products is where it classifies substances as carcinogenic (Carc.), mutagenic (Mut.) or toxic for reproduction (Repr.). There are three categories for substances that are classified as carcinogenic, mutagenic or toxic for reproduction.

- *Category 1A:* The substance is known to be carcinogenic/mutagenic/toxic for reproduction to humans
- *Category 1B:* The substance is presumed to be carcinogenic/mutagenic/ toxic for reproduction to humans
- *Category 2:* Substances, which cause concern for humans owing to possible carcinogenic/mutagenic/toxic for reproduction effects.

## Regulation (EC) No 1223/2009

Regulation (EC) No 1223/2009 states that the use of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A, 1B and 2 under Part 3 of Annex IV of Regulation (EC) No 1272/2008 should be prohibited unless certain criteria are met. For substances of category 1A and 1B to be used in cosmetic products they must meet the following four criteria: "they comply with food safety requirements as defined in Regulation (EC) No 178/2002"; "there are no suitable alternative substances available, as documented in an analysis of alternatives"; "the application is made for a particular use of the product category with a known exposure"; and "they have been evaluated and found safe by the SCCS for use in cosmetic products".[2] For category 2 substances to be used, the Scientific Committee on Consumer Safety (SCCS) has to have evaluated them and found them to be safe for use in cosmetic products.

## Timescales

For CMR substances of category 1A and 1B Regulation (EC) No 1223/2009 states that the European Commission will amend the annexes to this regulation within 15 months of the inclusion of a substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008.[2] For CMR substances of category 2 Regulation (EC) No 1223/2009

does not specify a timescale for amending the annexes. Changes to the annexes for category 2 substances can take much longer than those for category 1A and 1B.

## COSING

COSING[3] is the European Commission database on cosmetic substances and ingredients. It is a good place to look initially if checking whether a cosmetic ingredient has been classified as a CMR. There can be a time delay between changes to a substances classification and its status being updated on COSING. COSING should not be used instead of checking the relevant regulation.

## Dichloromethane

Dichloromethane is listed in Annex III (entry 7) of Regulation (EC) No 1223/2009. It is permitted to be used as part of a mixture with 1,1,1-trichloroethane, providing that the concentration of the mixture does not exceed 35%. Dichloromethane has been classified as a Carc. 2 substance by Regulation (EC) No 1272/2008. Article 15 of Regulation (EC) No 1223/2009 prohibits the use of CMR category 2 substances in cosmetic products unless the substance has been evaluated by the Scientific Committee on Consumer Safety and found safe for use in cosmetic products. The Scientific Committee on Consumer Safety in 2012 adopted the opinion that the use of dichloromethane in hair sprays, up to a maximum concentration of 35%, is not afe for the consumer.[4] In 2015 the Scientific Committee on Consumer Safety reconfirmed its previous opinion and asked for comments.[5] The deadline for comments was 22 May 2015.

## Chloroacetamide

Chloroacetamide is listed as a preservative in Annex V (entry 41) of Regulation (EC) No 1223/2009 and is permitted to be used up to a maximum concentration of 0.3%. It is classified as Repr. 2 by Regulation (EC) No 1272/2008. The Scientific Committee on Consumer Safety has looked at the safety of chloroacetamide and concluded that it is not safe for consumers when used in cosmetic products at 0.3%.[6]

## Musk xylene

Musk xylene has been classified as Carc. 2 by Regulation (EC) No 1272/2008. It is listed in Annex III (entry 96) of Regulation (EC) No 1223/2009. According to entry 96 it can be used in all cosmetic products with the exception of oral products up to a maximum concentration of: 1.0% in fine fragrances; 0.4% in eau de toilette; and 0.03% in other products. The safety of musk xylene was evaluated by the Scientific Committee on Consumer Products and Non-Food Products (SCCNFP) in 2004 and found to be safe when used in cosmetic products excluding oral products up to a maximum concentration of 1.0% in fine fragrances; 0.4% in eau de toilette; and 0.03% in other products.[7] According to the 44th amendment to IFRA standards, musk xylene should not be used as an ingredient in fragrances as it has been identified as a very persistent and very bioccumulative (vPvB) substance by the European Chemicals Bureau.

## Musk ketone

Musk ketone has been classified as Carc. 2 by Commission Regulation (EC) No 790/2009 (1st ATP). It is listed in Annex III (entry 97) of Regulation (EC) No 1223/2009. According to entry 97 it can be used in all cosmetic products with the exception of oral products up to a maximum concentration of: 1.4% in fine fragrances; 0.56% in eau de toilette; and 0.042% in other products. The safety of musk ketone was evaluated by the Scientific Committee on Consumer Products and Non-Food Products (SCCNFP) in 2004 and found to be safe when used in cosmetic products excluding oral products up to a maximum concentration of 1.4% in fine fragrances; 0.56% in eau de toilette; and 0.042% in other products.[7] According to the 45th amendment to IFRA standards musk ketone should only be used if it contains less than 0.1% of musk xylene.

## Boric acid and borates

Boric acid and a number of boron compounds and peroxoborates have been classified as Repr. Cat 1B in Commission Regulation (EC) No 790/2009 (1st ATP). Annex III of Regulation (EC) No 1223/2009 permits the use of boric acid, borates and tetraborates (entries 1a and 1b). Entry 12 of Annex III restricts the use of compounds which release hydrogen peroxide which would include peroxoborate compounds. The Scientific Committee on Consumer Safety (SCCS) has stated in opinion SCCS/1523/13 that it is necessary to amend entries 1a, 1b and 12 in Annex III of Regulation (EC) No 1223/2009 to prohibit their use in cosmetics. The Scientific Committee on Consumer Safety is of the opinion that borates in contact with water form boric acid which is classified as Repr. Cat 1B. Therefore borates, tetraborates, octaborates as well as boric acid salts/esters such as MEA-borate, MIPA-borate, potassium borate, trioctyldodecyl borate and zinc borate should be treated in the same way as boric acid and not be permitted to be used in cosmetics. The European Commission is in the process of drafting a regulation to ban the use of boron compounds.

## Quaternium-15

Quaternium-15 is listed as a preservative in Annex V (entry 31) of Regulation (EC) No 1223/2009 which permits it to be used up to a maximum concentration of 0.2% in cosmetic products. The INCI name Quaternium-15 refers to the cis and trans isomers of 1-(3-chlorallyl)-3,5,7-triaza-1-azoniaadamantane chloride. According to information supplied to the Scientific Committee on Consumer Safety when they were assessing the safety of Quaternium-15, it is the cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (cis-CTAC) that is used in cosmetic products.[8] According to regulation 790/2009, (1st ATP) cis-1-(3-chlorallyl)-3,5,7-triaza-1-azoniaadamantane chloride has been classified as Repr. 2. The Scientific Committee on Consumer Safety were asked to consider whether the use of cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride as a preservative in cosmetic products up to a maximum concentration of 0.2% was safe for consumers. They concluded that they were unable to assess the safety of cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride because the "dermal absorption values are not sufficiently reliable to calculate the dermal uptake of cis-CTAC".[8] They were also unable to establish a no observable adverse effect level (NOAEL) and therefore could not calculate a margin of safety. They were of the opinion that its continued use in cosmetic products may not be safe. Article 15 of Regulation (EC) No 1223/2009 prohibits the use of CMR category 2 substances in cosmetic products unless the substance has been evaluated by the Scientific Committee on Consumer Safety and found safe for use in cosmetic products.

## Trimethylbenzoyl diphenylphosphine oxide

Trimethylbenzoyl diphenylphosphine oxide (TPO) has been classified as Repr. 2 by Commission Regulation (EU) No 618/2012 (3rd ATP). It is not listed in any of the annexes of Regulation (EC) No 1223/2009. In cosmetics it is used either in photo cured nail polishes or for nail enhancement products. Cosmetics Europe supplied the European Commission with a dossier to support its safe use as "a key processing aid in topically applied artificial nail systems"[9] in September 2013. The European Commission asked the Scientific Committee on Consumer Safety to give an opinion on the safety of trimethylbenzoyl diphenylphosphine oxide when used as a nail modelling product at a maximum concentration of 5%. The Scientific Committee on Consumer Safety is of the opinion that trimethylbenzoyl diphenylphosphine oxide is safe up to a maximum concentration of 5.0% when used

in nail modelling products.[9] The Scientific Committee on Consumer Safety also stated that trimethylbenzoyl diphenylphosphine oxide is a moderate skin sensitiser and that they would require further documentation in order to evaluate other uses.

## Polyaminopropyl biguanide

Poly(hexamethylene) biguanide hydrochloride has been classified as Carc. 2 by Regulation (EU) No. 944/2013 (5th ATP). This classification came in to force on 1 January 2015. Poly(hexamethylene) biguanide hydrochloride (INCI name: Polyaminopropyl Biguanide) is a preservative listed in Annex V (entry 28) of Regulation (EC) No. 1223/2009 and may be used up to a maximum concentration of 0.3% in cosmetic products. As a consequence of the Carc. 2 classification and that Article 15 of Regulation (EC) No 1223/2009 has not been met the use of polyaminopropyl biguanide is prohibited from 1 January 2015. However in Article 15 of Regulation (EC) No 1223/2009 provision is made for the Scientific Committee on Consumer Safety to evaluate the safety of Carc. 2 substances and for them to be used in cosmetic products if the Scientific Committee on Consumer Safety finds that they are safe. In 2014 the Scientific Committee on Consumer Safety considered if polyaminopropyl biguanide could be safely used as a preservative in cosmetic products up to a maximum concentration of 0.3% and if it is safe to be used in spray formulations. In their opinion on the safety of poly(hexamethylene) biguanide hydrochloride (PHMB) the Scientific Committee on Consumer Safety declared that: "Polyaminopropyl biguanide (PHMB) is not safe for consumers when used as a preservative in all cosmetic products up to the maximum concentration of 0.3%".[10] They state in their opinion that the safe use for polyaminopropyl biguanide could be based on a lower use concentration or by restricting the types of products that it is used in. They have requested additional dermal absorption studies on representative cosmetic formulations. The Scientific Committee on Consumer Safety has concluded that polyaminopropyl biguanide is not safe for consumers when used as a preservative in spray formulations up to a concentration of 0.3%.

The European Commission formally considers the use of polyaminopropyl biguanide in cosmetics as prohibited from 1 January 2015.[11] However it acknowledges the need to differentiate between safe and unsafe levels of use. The Commission took the exceptional measure of conducting another public consultation on the revised opinion (SCCS/1535/14). The opinion was open to public comment up to 30 January 2015. The Commission cannot ask Member States to refrain from enforcing the legislation but has committed to provide clarification to Member States that the evaluation process is ongoing. Cosmetic Europe, the cosmetic trade body, continues to defend the safe use of polyaminopropyl biguanide in cosmetics but has decided not to defend its use in spray formulations.

## Formaldehyde

Regulation (EC) No 1223/2009 permits the use of formaldehyde in nail hardeners up to a maximum concentration of 5% (Annex III entry 13). Formaldehyde is also listed in Annex V (entry 5) and is permitted to be used in oral products up to a maximum concentration of 0.1%, and in other products up to a maximum concentration of 0.2%. It is not permitted to be used in aerosol spray products. Formaldehyde was classified as Carc. 2 in Regulation (EC) No 1272/2008. It was reclassified as Carc. 1B and Mut. 2 by Commission Regulation (EU) No 655/2014 (6th ATP). This classification was to apply from 1 April 2015 but the European Commission has decided to delay adopting this classification until 1 January 2016.[12] For formaldehyde to continue to be used in cosmetics the criteria for CMR 1A and 1B substances specified in Article 15 of Regulation (EC) No 1223/2009 must be met. One of the criteria is for the Scientific Committee on Consumer Safety to declare them safe for use in cosmetic products. The Scientific Committee on Consumer Safety (SCCS) has published an opinion that states that: "nail hardeners with a maximum concentration of about 2.2% free formaldehyde can be used safely to harden or strengthen nails".[13] Another of the criteria is that there are no suitable alternative substances available. According to the European Commission working group on cosmetics, Member States are aware of alternative substances to formaldehyde which could be used in nail hardening substances. Member States have been requested by the European Commission working group to pass this information on to the European Commission.[14] An opinion on the use of formaldehyde as a preservative has not yet been published. According to Article 15 of Regulation (EC) No 1223/2009 the entries for formaldehyde must be amended by 27 September 2015.

## Other substances

Other substances which have an INCI name that have been classified as CMR by Commission Regulation (EU) No 944/2013 (5th ATP) are ethyl pyrrolidone and vinyl acetate. Ethyl pyrrolidone is classified as Repr. 1B and vinyl acetate is classified as Carc. 2. The classification applies from 1 January 2015. As the requirements of Article 15 of Regulation (EC) No 1223/2009 have not been met ethyl pyrrolidone and vinyl acetate cannot be used in cosmetic products from 1 January 2015. Commission Regulation (EU) No 605/2014 (6th ATP) has classified styrene as Repr. 2 and tetrahydrofurfuryl alcohol as Repr. 1B. Styrene is not known to be used in cosmetics but is used as a monomer in the production of styrene polymers. The styrene polymers will still be permitted to be used in cosmetic products providing Article 17 (traces of prohibited substances) is complied with. The CLP classification for these substances applies from 1 January 2016. Imidazole has been included in the draft of the 7th ATP and classified as Repr. 1B. The 7th ATP to Regulation (EC) No 1272/2008 is expected to be published later in 2015.

## Conclusion

This article has looked at the impact that CLP is having on the regulation of cosmetic products. Some substances in Annexes III and V have been classified as CMRs. For substances that are in categories 1A and 1B the European Commission is amending Regulation (EC) No 1223/2009 within the 15 months allowed. For substances in category 2 the European Commission is taking much longer to amend the annexes. For some of the category 2 substances the Scientific Committee on Consumer Safety is unable to give an opinion that these substances are safe to use in cosmetic products. Further regulation of these substances is required. PC

## References


1 Regulation (EC) No 1272/2008 paragraph 11.
2 Regulation (EC) No 1223/2009 Article 15.
3 http://ec.europa.eu/consumers/cosmetics/cosing.
4 SCCS/1408/11 Opinion on Dichloromethane.
5 SCCS/1547/15 Opinion on Dichloromethane Submission IV.
6 SCCS/1360/10 Opinion on Chloroacetamide Colipa n° P27.
7 SCCNFP/0817/04 Opinion of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers concerning Musk Xylene and Musk Ketone.
8 SCCS/1344/10 Opinion on Quaternium-15 (cis-isomer).
9 SCCS/1528/14 Opinion on Trimethylbenzoyl diphenylphosphine oxide (TPO).
10 SCCS/1535/14 Opinion on the safety of poly(hexamethylene) biguanide hydrochloride (PHMB) Revision of 16 December 2014.
11 CTPA Website Important: Revised PHMB Opinion – Open for Comment [March 2015].
12 Commission Regulation (EU) 2015/491.
13 SCCS/1538/14 Opinion on the safety of the use of formaldehyde in nail hardeners.
14 The Cosmetic Toiletry & Perfumery Association News April 2015.