SCIENTIFIC ADVISORY GROUP ON CHEMICAL SAFETY OF NON-FOOD AND NON-MEDICINAL CONSUMER PRODUCTS (SAG-CS)

Final Opinion on Formaldehyde Releasing Substances.

1. Summary

1.1. Formaldehyde (CAS No 50-00-0) has a harmonised classification as a Category 1B carcinogen under the GB Classification, Labelling and Packaging (CLP) regulation No 1272/2008 (as amended).[1] A Category 1B substance is presumed to have carcinogenic potential for humans based on animal studies. Formaldehyde also has a harmonised classification under CLP as a Category 2 Mutagen, Category 1B Skin Corrosive, Category 1 Skin Sensitiser and is classified as toxic when swallowed, inhaled, or when in contact with the skin. The rationale for this harmonised classification can be seen in the Committee for Risk Assessment's (RAC) Opinion on the Proposed Harmonised Classification for Formaldehyde (RAC, 2012).

1.2. Formaldehyde is currently included on the list of substances prohibited for use in cosmetic products within Annex II (Entry 1577) of the Cosmetic Products Regulation UK No 1223/2009 (as amended).[2] Previously, formaldehyde was listed under Annexes III and V (Entries 13 and 5 respectively) of the equivalent EU cosmetics regulations for restricted use in nail hardening products and as an allowed preservative in cosmetic products, respectively. Formaldehyde was delisted from Annexes III and V in 2019 following categorisation as a Category 1B carcinogen and publication of Commission Regulation (EU) No

[1] The GB CLP Regulation No 1272/2008 as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019.

[2] The UK Regulation currently consists of the Regulation UK No 1223/2009 as amended by SI 696/2019 Product Safety and Metrology (EU Exit) Regulations.

831/2019. Simultaneously, formaldehyde was added to the list of prohibited substances in cosmetic products under Entry 1577 of Annex II to the Cosmetic Regulation.

1.3. Despite the removal of formaldehyde from Annexes III and V of the Cosmetic Regulation, formaldehyde may still be present in cosmetic products through the inclusion of formaldehyde releasers permitted within Annex V. Examples of formaldehyde releasing substances include: DMDM hydantoin (Annex V, Entry 33), imidazolidinyl urea (Annex V, Entry 27), diazolidinyl urea (Annex V, Entry 46), polyoxymethylene urea (not listed in Annex V), sodium hydroxymethylglycinate (Annex V, Entry 51), bronopol (Annex V, Entry 21), benzylhemiformal (Annex V, Entry 55), methenamine (Annex V, Entry 30), and glyoxal (Annex III, Entry 194). As such, Point 2 within the preamble to Annex V contains the statement: "All finished products containing substances in this Annex and which release formaldehyde must be labelled with the warning 'contains formaldehyde' where the concentration of formaldehyde in the finished product exceeds 0.05%". This label was introduced by the Eighth Commission Directive 86/199/EEC, dated 26th March 1986, with the intention to inform consumers of the presence of a substance that could cause an allergy through release of formaldehyde.

1.4. It has been suggested that formaldehyde exposure to levels below 0.05% could cause contact dermatitis in persons with a formaldehyde allergy, hence bringing into question the provisions described above relating to the labelling of formaldehyde releasing substances listed in Annex V of the Cosmetic Regulation.

2. Presentation and Discussion by The Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products (SAG-CS)

2.1. At their February 2022 meeting, the SAG-CS discussed a paper which focussed on risks posed to health by the current labelling threshold of formaldehyde releasing substances.

2.2. Members discussed the origin of the current 0.05% labelling threshold and previous opinions from other scientific advisory groups.

2.3. Members concluded that the current threshold of 0.05% for labelling formaldehyde releasing preservatives was insufficient to protect consumers.

2.4. Members agreed that a threshold for labelling formaldehyde releasing preservatives up to 10 ppm (0.001%), which did not elicit an allergic reaction, would be adequate to protect consumers if used for leave-on products. Members stated that such a level would likely be sufficiently protective for use

in rinse-off products also. This threshold level of up to 10ppm (0.001%) is based upon the Repeat Open Application Test (ROAT)[3] performed by Hauksson *et al*. (Hauksson, 2016).

2.5. Members agreed that the analytical methods available for determination of formaldehyde are well known, however it was noted that analysis of some formaldehyde releasing substances is difficult owing to their decomposition in certain aqueous systems used.

2.6. Members discussed the differences between leave-on and rinse-off cosmetic products. Cumulative exposure of consumers to formaldehyde was also discussed.

3. Conclusions

Members were satisfied that there was sufficient evidence to form an opinion at this stage.

Members concluded that the current threshold of 0.05% for labelling formaldehyde releasing preservatives was insufficient to protect consumers.

Members agreed that a threshold for labelling formaldehyde releasing preservatives of 10 ppm (0.001%) would be adequate to protect consumers if used for leave-on products. Members agreed that such a level would likely be sufficiently protective for use in rinse-off products also.

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[3] A Repeat Open Application Test (ROAT) is a method of testing a substance to establish its potential to induce allergic contact dermatitis. It is designed to simulate the exposure pattern to an allergen in daily life. Typically, the test substance is applied, without occlusion, to an area of the skin several times over a defined time period to simulate daily usage. The treated area of skin is then observed for any allergenic reactions.

References

Commission Regulation (EU) 2019/831 of 22 May 2019 amending Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.137.01.0029.01.ENG

Committee for Risk Assessment (RAC) – Opinion proposing harmonised classification and labelling at EU level of Formaldehyde, 2012 - Opinion on the Proposed Harmonised Classification for Formaldehyde.

Eighth Commission Directive 86/199/EEC of 26 March 1986 adapting to technical progress Annexes II, IV and VI to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products - https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A31986L0199

Hauksson I, Pontén A, Gruvberger B, Isaksson M, Engfeldt M, Bruze M. Skincare products containing low concentrations of formaldehyde detected by the chromotropic acid method cannot be safely used in formaldehyde-allergic patients. British Journal of Dermatology. 2016 Feb;174(2):371-9.