Personal Care Products Council
Committed to Safety, Quality & Innovation

April 11, 2025

Via Electronic Submission
Washington State Department of Ecology
P.O. Box 47600
Olympia, WA 98504-7600
Attn: Stacey Callaway

Re: Formaldehyde in Cosmetics Rulemaking (173-339 WAC)

The Personal Care Products Council ("PCPC") is pleased to submit the following comments on Washington State Department of Ecology's ("Ecology") WAC-173-339-10 to WAC-173-339-110, released February 6, 2025. Founded in 1894, PCPC is the leading national trade association representing the cosmetic and personal care products industry. PCPC is dedicated to promoting product safety, quality, and innovation, serving as a unifying voice that champions science-based standards and responsible practices to support health, well-being, and economic growth. PCPC's global members are some of the beloved and trusted brands in beauty and personal care today, providing millions of consumers with the diverse products they rely on every day –from sunscreens, toothpaste and shampoo to moisturizers, makeup, and fragrance.

Our members are therefore impacted by Ecology's implementation of the Toxic-Free Cosmetics Act ("TFCA"). We have a strong interest in the scope and applicability of Ecology's proposed rule on formaldehyde and formaldehyde releasing agents ("FRAs"). FRAs have important technical functions in cosmetic and personal care products. This includes functioning as preservatives, antistatic and straightening agents, and pH adjusters. FRAs are not equivalent to formaldehyde. Formaldehyde is not added to cosmetics or personal care products, and FRAs do not present the concerns associated with breathing formaldehyde.

We appreciate this opportunity to provide Ecology, and other stakeholders, with critical information on the safety and technical functionalities of ingredients and manufacturing processes of formaldehyde and FRAs, as discussed below.

General Comments

1. Definition of "Intentionally Added"

Ecology "defined 'intentionally added' to clarify restrictions on the toxic chemicals in the Toxic-Free Cosmetics Act." The proposed rule defines "intentionally added" as "a chemical that serves an intended function in: [t]he final product[,] [t]he manufacturing of the product[, or a]n ingredient in the final product." Ecology described their definition as "more protective" than other definitions of intentionally added because it "includes chemicals that serve an intended function in the manufacturing of the product or in an ingredient in the final product."

Rather than being protective, the proposed definition of intentionally added is problematic and lacks clarity. The definition as currently written is too broad and does not account for incidental or trace contaminants, which are an inevitable part of the manufacturing process.

Existing definitions of "intentionally added" that address incidental or trace contaminants can be found in other regulatory bodies such as the European Union ("EU") and the Food and Drug Administration ("FDA").[1] The current definition used by Ecology does not align with any pre-existing definition. The FDA defines ingredient as "any single chemical entity or mixture used as a component in the manufacture of a cosmetic product." 21 CFR 700.3(e). The FDA defines "incidental ingredients" as

1. Substances that have no technical or functional effect in the cosmetic but are present by reason of having been incorporated into the cosmetic as an ingredient of another cosmetic ingredient.
2. Processing aids, which are as follows:
    i. Substances that are added to a cosmetic during the processing of such cosmetic but are removed from the cosmetic in accordance with good manufacturing practices before it is packaged in its finished form.
    ii. Substances that are added to a cosmetic during processing for their technical or functional effect in the processing, are converted to substances the same as constituents of declared ingredients, and do not significantly increase the concentration of those constituents.
    iii. Substances that are added to a cosmetic during the processing of such cosmetic for their technical and functional effect in the processing but are present in the finished cosmetic at insignificant levels and do not have any technical or functional effect in that cosmetic.

[1] European Union Cosmetic Regulation No 1223/2009 defines ingredient as "any substance or mixture intentionally used in the cosmetic product during the process of manufacturing." However, "impurities in the raw materials used" and "subsidiary technical materials used in the mixture but not present in the final product" are considered "incidentals" and not ingredients.

21 CFR 701.3(l). The Food and Drug Administration's definitions have been incorporated into state regulations in California and Maine.[2]

PCPC strongly encourages Ecology to revise the definition of "intentionally added" to align with pre-existing definition of "ingredient" and "incidental ingredient" as defined by the FDA. By proposing a new, broad definition of intentionally added, rather than aligning with a pre-existing definition of intentionally added that companies are already complying with, Ecology is imposing a burden that would be difficult for industry to comply with and lead to uncertainty in compliance obligations. For example, in section 2.a.ii the proposed rule states:

> Applying the definition of "intentionally added" in WAC 173-339-020 that takes effect on January 1, 2027:
> Formaldehyde is intentionally added to a cosmetic product or ingredient when it functions as an antimicrobial, a preservative, a denaturant, a cross linker, or serves another purpose. This includes the direct addition of formaldehyde, or the addition of a chemical selected to release formaldehyde, to the product or ingredient over time.

When formaldehyde is used in the manufacturing of an ingredient as a cross linker the intent often is that the formaldehyde becomes chemically bonded during the cross-linking process and is no longer present in the ingredient or the final cosmetic product. Therefore, any formaldehyde remaining would be a residual impurity with no function in the ingredient or any final cosmetic product in which the ingredient may be used. In this example the formaldehyde used to create the ingredient is not intentionally added to the finished product and any remaining is as an impurity.

In sum, the current scope of the definition of "intentionally added" is too broad. Ecology should revise the definition of "intentionally added" to exclude incidental or trace contaminants that have no function in the finished product.

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[2] The California State Cosmetic Act states that ingredient "has the same meaning as that term is defined in subdivision (e) of Section 700.3 of Part 700 of Chapter 1 of Title 21 of the Code of Federal Regulations and does not include any incidental ingredient as defined in subdivision (*l*) of Section 701.3 of Part 701 of Chapter 1 of Title 21 of the Code of Federal Regulations. 2005 Cal ALS 729; 2005 Cal SB 484; 2005 Cal Stats. ch. 729.

In February 2025, legislators in Maine introduced an "Act to Enact Safe Cosmetics." The proposed legislation defines ingredient as "a single chemical entity or mixture used as a component in the manufacture of a cosmetic product. "Ingredient" does not include an incidental ingredient as described in 21 Code of Federal Regulations, Section 701.3(l)." 2025 Bill Text ME LD 317, HP 217. The legislation further specifies that an "intentionally added ingredient" means an ingredient added during the manufacture of a cosmetic product or a component of a cosmetic product to provide a specific characteristic, appearance or quality or to perform a specific function.

2. Compliance

Currently Ecology "may infer" from "reviewing ingredient lists[,] sampling for formaldehyde in cosmetic products[, or] considering other relevant information" that formaldehyde or FRAs were intentionally added to a product.

First, any inference that formaldehyde or FRA is intentionally added to a product because the product tests positive for even the smallest amount of formaldehyde is an inappropriate conclusion. Formaldehyde is an easy molecule to be made as a byproduct or an impurity. Formaldehyde impurities which show up on tests in trace amounts cannot be considered as evidence that formaldehyde or formaldehyde releasing preservatives were intentionally added to a cosmetic product, but rather a more appropriate conclusion would be that there is an unavoidable impurity which is part of the product which is measurable due to the use of advanced tests which can measure very low levels of formaldehyde. Finally, the current inference of intentionally added formaldehyde or FRAs does not account for false positive tests that could occur because of cross-contamination during the testing process. The testing method itself could cause false positive results, rather than formaldehyde or FRAs being present in the actual product.

Second, allowing Ecology to infer intentionally added formaldehyde or FRAs by "considering other relevant information" is extremely broad and extremely vague. PCPC strongly urges Ecology to build in greater flexibility on test methodology used to measure FRA in finished products and to narrow the scope of "other relevant information."

3. Formaldehyde Releasing Agents (FRAs)

PCPC recommends that Ecology apply the restriction limits placed on FRA ingredients by regulatory and expert panels (see below and Appendix 1). FRAs, which are intended to release minimal amounts of formaldehyde through chemical reactions over time, have been used for many decades as a well-studied product preservative method, resin and antistatic/smoothing agent that are internationally recognized as safe. The safety of FRAs is supported by extensive scientific data and regulatory reviews – these agents have been evaluated by multiple independent bodies, including the Cosmetic Ingredient Review ("CIR"), EU's European Commission and the Australian Industrial Chemicals Introduction Scheme ("AICIS"), which have confirmed their safety under specified conditions of use. FRAs used to preserve product integrity are widely considered not only safe but also effective in protecting consumer personal care products against a broad spectrum of microbial contamination.

Chemical Name	**CIR**	**Other Regulatory Agencies**
Preservatives		
DMDM Hydantoin	Safe in the present practices of use up to 1%	EU Annex V-33 Preservatives: 0.6%
Diazolidinyl Urea	Safe in the present practices of use up to 0.5%	EU Annex V-46 Preservatives: 0.5%

Imidiazolidinyl Urea (Should be Imidazolidinyl Urea)	Safe in the present practices of use at concentration ranges of ~0.1, >0.1 to 1, and >l to 5%	EU Annex V-27 Preservatives: 0.6%
Quaternium-15	Safe in the present practices of use up to 0.2%	EU Annex II-1385 Prohibited
2-Bromo-2-Nitropropane-1,3-Diol (Bronopol)	Safe in the present practices of use up to 0.1%	EU Annex V-21 Preservatives 0.1% avoid formation of nitrosamines Canada Cosmetic Ingredient Hotlist: restricted 0.1%; not permitted in cosmetics that contain amines or amides
Sodium Hydroxymethylglycinate	Not reviewed	EU Annex V-51 0.5%
Polyoxymethylene Urea	Safe in the present practices of use up to 0.2%. It cannot be concluded that Polyoxymethylene Urea is safe for use in cosmetic products intended to be aerosolized	
Glyoxal	Safe for use in products intended to be applied to the nail at concentrations <1.25%. The available data are insufficient to support the safety for other uses	EU Annex III-194 restricted 100 mg/kg maximum concentration
Polyoxymethylene Melamine	CIR: [Insufficient data] (it had no uses in past VCRP data)	
5-Bromo-5-Nitro-1,3-Dioxane (Bronidoz)	Safe as a cosmetic ingredient at concentrations up to and including 0.1% except under circumstances where its action with amines or amides can result in the formation of nitrosamines or nitrosamides	EU Annex V-20 Preservatives limited to rinse-off products 0.1%; avoid formation of nitrosamines Canada Cosmetic Ingredient Hotlist: restricted 0.1%; not permitted in cosmetics that contain amines or amides
7-Ethylbicyclooxazolidine (Bioban CS1246)	Not reviewed	EU Annex V-49 Preservatives 0.3%; not to be used in oral products and in products applied on mucous membranes
Benzylhemiformal	Not reviewed	EU Annex V-55 Preservatives 0.15% rinse-off products
Dimethyl Oxazolidine	Not reviewed	EU Annex V-45 Preservatives 0.1% pH >6
Methenamine	Safe for cosmetic use at concentrations not to exceed 0.16% in formulation. It cannot be concluded that Methenamine is safe for use in cosmetic products intended to be aerosolized	EU Annex V-30 Preservatives 0.15%
Heat-activated hair straighteners		
Glyoxylic Acid	Not reviewed	AICIS EVA00110 evaluated for human health at a use concentration up to 12% (sold in hair straighteners at concentrations up to 50%)
Miscellaneous		
Tosylamide/Formaldehyde Resin (PTSAF)	Safe in the present practices of use up to 10%	

Of the 28 FRAs identified, 11 have been fully reviewed by the Expert Panel for Cosmetic Ingredient Safety (CIR Expert Panel) and determined to be safe under the conditions of use and concentrations indicated (see above and Appendix 1). The CIR Expert Panel is an independent panel of experts that assesses the safety of individual ingredients as used in cosmetic products through critical consideration of publicly available information and submitted, unpublished data. The CIR was established in 1976 by PCPC (then the Cosmetic, Toiletry, and Fragrance Association), with the support of the U.S. FDA and the Consumer Federation of America. CIR and the Expert Panel for Cosmetic Ingredient Safety operate under a set of procedures defining their purpose, responsibilities, relative expertise of panelists, liaison representation, etc. General policy and direction are given by a 7-member Steering Committee chaired by the President and CEO of the PCPC, with a dermatologist representing the American Academy of Dermatology, a toxicologist representing the Society of Toxicology, a consumer representative representing the Consumer Federation of America, an industry scientist, Chair of the Expert Panel for Cosmetic Ingredient Safety, and the PCPC's Executive Vice President for Science.

The members of the CIR Expert Panel are recognized experts in their fields of medicine and scientific study. The CIR Expert Panel includes multiple dermatologists, toxicologists, and pharmacologists. Additional information regarding the biographies and curriculum vitae of the CIR Expert Panel members is publicly available and can be found here. CIR Expert Panel members are subject to the same conflict of interest rules as USFDA advisory committee members.

Selection of the ingredients the CIR reviews is based on several factors. These factors include the frequency with which an ingredient is used, reports of potential adverse effects, or nomination of an ingredient by a stakeholder. Ingredients are also systematically re-reviewed after a fifteen-year period. Draft priority lists for ingredient review are made available for public comment and are discussed in open Expert Panel meetings before finalization.

The CIR review process involves comprehensive review of the published scientific literature. Unpublished reports or data are accepted to inform the overall assessment, and are made available on the CIR website or by request. Four meetings of the CIR Expert Panel are held each year, and the meetings are open to the public. The CIR Expert Panel members vote and determine the overall conclusions for the reviewed ingredient. Following this, the CIR Expert Panel issues a tentative report which is then subject to a public comment period. At the conclusion of the comment period, there is an opportunity for revisions after which there is a final review by the CIR Expert Panel. The CIR Expert Panel then typically issues a final report. Historically, the CIR Expert Panel provides final reports to the US FDA and submits the final reports for publication in the *International Journal of Toxicology.* Additional information regarding the CIR, the CIR Expert Panel, and its process are available in the Boyer et al. (2017) publication, available here.

In the EU, cosmetic preservatives must be safe for use within the required concentration limits. Cosmetic preservatives must comply with stringent evaluation to conform to the EU safety standards. Preservatives must undergo rigorous evaluation, including safety assessments and quality testing, before they are approved for use in the EU market.

Cosmetic products are regulated by the EC under the Cosmetics Regulation EC No. 1223/2009, and preservatives used in cosmetics must also comply with the EU Regulatory guidelines. The list of substances that can be used as preservatives in cosmetics marketed in the EU is included in Annex V of the regulation. The list contains maximum concentration limits along with other restrictions for preservatives. It also contains specific warnings for product labeling and 60 unique substances permissible for use in the EU as preservatives for cosmetics.

The Australian Industrial Chemicals Introduction Scheme (AICIS) oversees the import and manufacture of chemicals in cosmetics. The guidelines include registration, categorization, record-keeping, and compliance with government standards. AICIS evaluated glyoxylic acid in 2022, noting it is not only safe under intended usage conditions, but necessary when used as a semi-permanent hair straightener, a pH adjuster and an anti-static agent. Based on the available data the chemicals, AICIS determined that glyoxylic acid and its monohydrate have low acute and dermal toxicity, are not expected to cause systemic health effects following repeated oral exposure and are not expected to cause specific reproductive or developmental toxicity effects.

In addition, a number of these ingredients have also been reviewed under The United Kingdom Office for Product Safety & Standards Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products (SAG-CS) – Final Opinion on Formaldehyde Releasing Substances. In addition, many of these ingredients are regulated under the European Union's Cosmetic Products Regulation (Annex V – Allowed Preservatives) including maximum concentration limits and other restrictions. In light of these safety assessments, we would recommend that Ecology reevaluate their restriction under the Toxic-Free Cosmetics Act. Our review also revealed a number of identified FRAs are not currently used in products. This information can also be found in Appendix 1.

FRAs are important preservatives, antistatic and straightening agents, and pH adjusters, which are not equivalent to formaldehyde. Formaldehyde is not added to cosmetics or personal care products, and FRAs do not present the concerns associated with breathing formaldehyde. Products are formulated so that the releases are minimal and controlled, and that the risk associated with exposure to formaldehyde in cosmetic products is significantly lower than that associated with direct inhalation exposure to formaldehyde gas. The cosmetics industry follows the science on these ingredients: as example, when the CIR Expert Panel concluded an unsafe use of methylene glycol in hair straighteners, the industry suspended its presence in these products.

FRAs are formulated into thousands of cosmetic products including hair shampoos, conditioners and rinses, eye lotions, bubble bath, makeup foundations, makeup bases, nail products (basecoats, undercoats, polish and enamels), skin moisturizers, eyeliners, eye shadows, mascaras, eyebrow pencils, etc.

Preservatives such as FRAs prevent the growth of mold, yeast, bacteria, fungi, and other contaminants. Products without adequate preservative protection could become moldy or discolored, develop an unpleasant smell, or even cause serious health problems like irritation or infection. Preservation Efficacy Testing (PET) also known as Antimicrobial Effectiveness

Testing (AET), or more specifically for the cosmetics industry, the Cosmetic Challenge Testing, are used to test the efficacy of the preservation system for controlling microbial growth which is a critical measure for safety and quality assurance for manufacturers. We encourage Washington Ecology to become familiar with the current procedure for validating a preservation system following the application of good manufacturing practices (GMPs), the control of the raw material, and the verification of the preservative effect by suitable methodologies, including the challenge test (Halla et al. 2018).

Formaldehyde is a chemical that naturally occurs in the environment. According to the Centre for Food Safety (Hong Kong), formaldehyde is present at low levels in most living organisms as a metabolic intermediate. Formaldehyde can be found naturally in food up to the levels of 300 to 400 mg/kg including fruits and vegetables, meats, fish, crustaceans, etc. (Foods Known to Contain Naturally Occurring Formaldehyde).

Consumer safety is a top PCPC priority, and we strongly encourage the Department of Ecology to reconsider banning these ingredients that are not only safe but necessary when used as preservatives to maintain product stability and shelf life and deliver performance when these ingredients are used as hair-straightening products.

PCPC would like to sit down virtually with Washington Ecology to discuss these ingredients further.

Conclusion

Thank you for your continued opportunity to engage in this process and provide comments on the proposed draft. Should you have any questions or wish to discuss any of the above points with us, please do not hesitate to contact us.

Sincerely,

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Appendix 1.

Formaldehyde Releasing Agents (Washington State – Toxic-Free Cosmetic Act)

Chemical Name	CAS RN	CIR Report	Comments
Preservatives			
DMDM Hydantoin	6440-58-0	CIR: [S]1988 confirmed in a rereview published in 2008 https://cir-reports.cir-safety.org/view-attachment/?id=2c52792c-8d74-ec11-8943-0022482f06a6 Conclusion reached from review of 80 references	2023 VCRP 936 2024 RLD 5728 EU Annex V-33 Preservatives: 0.6% AICIS 2023 evaluation statement EVA00149 for Hydroxymethylated imidazolidinones (this is an environmental assessment) https://www.industrialchemicals.gov.au/sites/default/files/2023-12/EVA00149%20-%20Evaluation%20statement%20-%2014%20December%202023.pdf Conclusion: The Executive Director is satisfied that the identified risks to the environment from the introduction and use of the industrial chemicals can be managed.
Diazolidinyl Urea	78491-02-8	CIR: [SQ up to 0.5%] 1990 confirmed in a rereview published in 2008 https://cir-reports.cir-safety.org/view-attachment/?id=9bda0d14-8d74-ec11-8943-0022482f06a6 Conclusion reached from review of 47 references	2023 VCRP 1219 2024 RLD 3372 EU Annex V-46 Preservatives: 0.5% AICIS 2023 evaluation statement EVA00149 for Hydroxymethylated imidazolidinones (this is an environmental assessment) (see description under DMDM Hydantoin for more details)
Imidiazolidinyl Urea Should be Imidazolidinyl Urea	39236-46-9	CIR [S] 1980 confirmed in rereviews published in 2003 and 2023 https://cir-reports.cir-safety.org/view-attachment/?id=370cd0b0-8d74-ec11-8943-0022482f06a6	2023 VCRP 210 2024 RLD 1358 EU Annex V-27 Preservatives: 0.6% AICIS 2023 evaluation statement EVA00149 for Hydroxymethylated imidazolidinones (this is an environmental assessment) (see description under DMDM Hydantoin for more details)

		Conclusion reached from review of 49 references	
Quaternium-15	4080-31-3; 51229-78-8	CIR: [SQ up to 0.2%] 2010 confirmed in a rereview published in 2017 https://cir-reports.cir-safety.org/view-attachment/?id=5b307d65-8e74-ec11-8943-0022482f06a6 Conclusion reached from review of 112 references	2023 VCRP 6 2024 RLD 64 EU Annex II-1385 Prohibited
Tosylamide/Formaldehyde Resin (PTSAF)	25035-71-6	CIR: [S] 1986 confirmed in a rereview published in 2006 https://cir-reports.cir-safety.org/view-attachment/?id=b1b96d44-8d74-ec11-8943-0022482f06a6 Conclusion reached from review of 62 references	2023 VCRP 16 2024 RLD 0
2-Bromo-2-Nitropropane-1,3-Diol (Bronopol)	52-51-7	CIR: [SQ up to 0.1%] 1984 confirmed in a rereview published in 2006; this report is currently being rereviews (the report is open) https://cir-reports.cir-safety.org/view-attachment/?id=ba229680-8d74-ec11-8943-0022482f06a6 Conclusion reached from review of 40 references	2023 VCRP 36 2024 RLD 167 EU Annex V-21 Preservatives 0.1% avoid formation of nitrosamines Canada Cosmetic Ingredient Hotlist: restricted 0.1% Not permitted in cosmetics that contain amines or amides AICIS Evaluation statement 2022 EVA00058 (environmental assessment) https://www.industrialchemicals.gov.au/sites/default/files/2022-01/EVA00058%20-%20Evaluation%20statement%20-%2014%20January%202022%20%5B1801%20KB%5D.pdf Conclusion: "The Executive Director is satisfied that the identified environment risks can be managed within existing risk management frameworks. This is provided that all requirements are met under environmental, workplace health and safety and poisons legislation as adopted by the

			relevant state or territory."
Sodium Hydroxymethylglycinate	70161-44-3	Not reviewed	2023 VCRP 33 2024 RLD 172 EU Annex V-51 0.5% AICIS included in EVA00063 January 2022 Chemicals unlikely to require further regulation to manage risks to environment
Polyoxymethylene Urea	9011-05-6; 68611-64-3	CIR: [SQ free formaldehyde not exceed 0.2%. It cannot be concluded that Polyoxymethylene Urea is safe for use in cosmetic products intended to be aerosolized] 1995 confirmed in a re-review published in 2011 https://cir-reports.cir-safety.org/view-attachment/?id=7d211ed5-8d74-ec11-8943-0022482f06a6 Conclusion reached from review of 73 references	2023 VCRP 1 2024 RLD 6
Glyoxal	107-22-2	CIR: [SQ safe for use in products intended to be applied to the nail at concentrations <1.25%. The available data are insufficient to support the safety for other uses] 2000 confirmed in a rereview published in 2023 https://cir-reports.cir-safety.org/view-attachment/?id=307fc8b6-8d74-ec11-8943-0022482f06a6	2023 VCRP 11 2024 RLD 230 EU Annex III-194 restricted 100 mg/kg maximum concentration NTP has a 3-month study in rats and mice; data are available, but the final report is not yet available

		Conclusion reached from review of 96 references	
Polyoxymethylene Melamine	9003-01-8	CIR: [Insufficient data] (it had no uses in past VCRP data) 1995 https://cir-reports.cir-safety.org/view-attachment/?id=64201ed5-8d74-ec11-8943-0022482f06a6 Conclusion reached from review of 39 references	2023 VCRP 0 2024 RLD 125 (this may be an underestimate as it may also be listed without a space between the two words)
5-Bromo-5-Nitro-1,3-Dioxane (Bronidoz)	30007-47-7	CIR: [SQ safe as a cosmetic ingredient at concentrations up to and including 0.1% except under circumstances where its action with amines or amides can result in the formation of nitrosamines or nitrosamides] 1990 confirmed in a rereview published in 2011 https://cir-reports.cir-safety.org/view-attachment/?id=7e98591a-8d74-ec11-8943-0022482f06a6 Conclusion reached from review of 30 references	2023 VCRP 0 2024 RLD 1 EU Annex V-20 Preservatives limited to rinse-off products 0.1%; avoid formation of nitrosamines Canada cosmetic ingredient hotlist restricted 0.1% not permitted in cosmetics that contain amines or amides AICIS Evaluation statement 2022 EVA00058 (environmental assessment) https://www.industrialchemicals.gov.au/sites/default/files/2022-01/EVA00058%20-%20Evaluation%20statement%20-%2014%20January%202022%20%5B1801%20KB%5D.pdf See 2-Bromo-2-Nitroproane-1,3-Diol for more details
7-Ethylbicyclooxazolidine (Bioban CS1246)	7747-35-5	Not reviewed	2023 VCRP 0 2024 RLD 0 EU Annex V-49 Preservatives 0.3% Not to be used in oral products and in products applied on mucous membranes
Benzylhemiformal	14548-60-8	Not reviewed	2023 VCRP 0 2024 RLD 0

			EU Annex V-55 Preservatives 0.15% rinse-off products
Dimethylhydantoin formaldehyde (INCI name: DMHF)	26811-08-5;9065-13-8	Not reviewed	2023 VCRP 0 2024 RLD 0
Dimethylol Glycol	3586-55-8	Not reviewed	2023 VCRP 0 2024 RLD 1
Dimethylol Urea	140-95-4	Not reviewed	2023 VCRP 0 2024 RLD 3
Dimethyl Oxazolidine	51200-87-4	Not reviewed	2023 VCRP 0 2024 RLD 0 EU Annex V-45 Preservatives 0.1% pH >6
MDM Hydantoin	116-25-6; 27636-82-4: 16228-00-5	Not reviewed	2023 VCRP 1 2024 RLD word search picks up MDMD AICIS 2023 evaluation statement EVA00149 for Hydroxymethylated imidazolidinones (this is an environmental assessment) (see description under DMDM Hydantoin for more details)
Methenamine	100-97-0	CIR: [SQ safe for cosmetic use at concentrations not to exceed 0.16% in formulation. It cannot be concluded that Methenamine is safe for use in cosmetic products intended to be aerosolized] 1992 confirmed in a rereview published in 2011 https://cir-reports.cir-safety.org/view-attachment/?id=5678eaf5-8c74-ec11-8943-0022482f06a6 Conclusion reached from review of 64 references	2023 VCRP 1 2024 RLD 8 EU Annex V-30 Preservatives 0.15%
Methylal	109-87-5	Not reviewed	2023 VCRP 9 2024 RLD 89
Paraformaldehyde	30525-89-4	Not reviewed	NOT AN INCI NAME 2023 VCRP 0 2024 RLD 0

Polyoxymethylene	9002-81-7	Not reviewed	NOT AN INCI NAME this is polyformaldehyde and is a part of other polymers in the Dictionary (2 (not listed below) are listed in this table) Butylated Polyoxymethylene Urea Calcium Polyoxymethylene Pyrrolidone Methoxypolyoxymethylene Melamine Polyacryloyldimethyltaurate Polyoxymethylene Melamine Polyoxymethylene Cyanoguanidine Urea Polyoxymethylene Glycol Urea Polyoxymethylene Melamine Urea Polyoxymethylene Resorcinol 2023 VCRP the word Polyoxymethylene is in one ingredient in the 2023 VCRP Polyoxymethylene Urea with one use 2024 RLD 135 Polyoxymethylene (but 125 are Polyoxymethylene Melamine)
Tetramethylolglycoluril	5395-50-6	Not reviewed	2023 VCRP 0 2024 RLD 0 AICIS 2023 evaluation statement EVA00149 for Hydroxymethylated imidazolidinones (this is an environmental assessment) (see description under DMDM Hydantoin for more details)
Tris-Hydroxymethylnitromethane	126-11-4	Not reviewed	2023 VCRP 0 2024 RLD 0
Urea, polymer with formaldehyde, isobutylated	68002-18-6	Not reviewed	NOT AN INCI NAME 2023 VCRP 0 2024 RLD not searched
Heat-activated hair straighteners			
Glyoxylic Acid (when used in heat-activated hair straighteners)	298-12-4	Not reviewed	2023 VCRP 19 (5 hair straighteners) 2024 RLD 176 French Authorities concerned about the use of Glyoxylic Acid in hair straighteners because of kidney effect (oxalic acid crystals) AICIS EVA00110 evaluated for human health at a use concentration up to 12% (sold in hair straighteners at concentrations up to 50%) https://www.industrialchemicals.gov.au/sites/default/files/2022-12/EVA00110%20-%20Evaluation%20statement%20-%2022%20December%202022.pdf
Glyoxylol Carbocysteine (when used in heat-activated hair straighteners)	1268868-51-4	Not reviewed	2023 VCRP 0 2024 RLD 0
Timonacic (when used in heat-activated hair straighteners)	444-27-9	Not reviewed	2023 VCRP 0 2024 RLD 6

The Introduction to Annex V of the EU cosmetic regulations states: “All finished products containing substances which are listed in this Annex and which release formaldehyde shall be labelled with the warning "releases formaldehyde" where the total concentration of formaldehyde released in the finished product exceeds 0.001% (10 ppm), irrespective of whether the finished product contains one or more substances releasing formaldehyde.”

2023 VCRP indicates the number of cosmetic products reported to FDA’s Voluntary Cosmetic Registration Program (VCRP) containing a particular ingredient.

2024 RLD (Registration and Listing Data) (December 18, 2023-July 10, 2024) was a name search; the search results were not checked to see if the ingredient declarations contained the search word as part of another ingredient.