Independent Beauty Association

The attached is submitted by the Independent Beauty Association.

INDEPENDENT BEAUTY ASSOCIATION®

April 11, 2025

Washington State Department of Ecology
300 Desmond Drive SE,
Lacey, WA 98503

RE: Formaldehyde in Cosmetics Rulemaking

The Independent Beauty Association (IBA), a non-profit trade association representing over 600 companies spanning the North American beauty industry, respectfully submits the following comments in response to the rulemaking to develop Cosmetic Product Restrictions (Chapter 173-339 WAC) – Formaldehyde in Cosmetics Rulemaking.

IBA was founded in 1974 with the mission to foster the success of entrepreneurial companies in the independent cosmetic and personal care industries operating in the U.S. market. IBA's membership represents a broad cross-section of the independent beauty industry including brands, raw material and packaging suppliers, finished product manufacturers and retailers, as well as providers of essential business services such as legal, regulatory, technical, operational, and business advice.

IBA has been serving small to medium-sized businesses since its launch as Independent Cosmetic Manufacturers and Distributors (ICMAD) in 1974. We are pleased to support the Washington State Department of Ecology's rulemaking efforts on draft restrictions on intentionally added formaldehyde and formaldehyde releasers.

Formaldehyde releasers have historically played a critical role in cosmetic product preservation, helping extend shelf life and prevent harmful microbial growth in cosmetic products. They are cost-effective, well-researched, and have been widely used within safety limits defined by regulatory agencies. For many small businesses, they offer a practical way to ensure product safety without significantly driving up costs. That said, IBA recognizes the growing concern among consumers regarding potential formaldehyde exposure, and IBA strives to collaborate with the Department to achieve a reasonable balance between formaldehyde releaser restriction, and finished products that are safely and sufficiently preserved to protect consumers from the risks associated with microbial contamination.

IBA provides the following commentary for consideration in regards to the Formaldehyde in Cosmetics Rulemaking Proposed Rule:

Clarification of "Intentionally Added"

The language of "intentionally added" in the proposed legislation is inconsistent with existing federal and state level regulated definitions of cosmetic "ingredient," including the US FD&C Act and current US state definitions; furthermore, the proposed language is excessively broad and unclear on what is not considered an "intentionally added ingredient." This is likely to lead to inconsistent interpretation, misapplication, and uncertainty of what constitutes adequate substantiation for compliance.

The proposed rule contains three qualifiers:

- *Serves an intended function in the product.*
    - This is consistent with current definitions by other regulatory bodies.
- *Serves an intended function in the manufacturing of the product.*
    - This qualifier is less clear. Does it include cleaning and sanitization of equipment, contamination from raw material packaging or finished product packaging?
- *Serves an intended function in an ingredient in the final product.*
    - This qualifier is less clear and creates potential conflicts with ingredient suppliers as they are not obligated to divulge trade secrets. There are also residual ingredient precursors, monomers and reactants present as impurities, processing aids, anti-microbial agents, stabilizers and growth media. How far back in the supply chain is it reasonable to expect data exchange?

There appears to be no exclusion for incidental trace substances which may be present in ingredients, packaging and finished products. This is also inconsistent with current regulated definitions of cosmetic "ingredient."

Regarding the justification that is being used to extend the proposed "intentionally added ingredient" definition; the section of regulation *Preliminary Regulatory Analyses: Chapter 173-339 WAC, Cosmetic Products Restrictions Section 2.2.2 of the Preliminary Regulatory Analysis for the proposed rule 173-339 WAC* states that the WA Safer Products Restrictions

and Reporting Rule (default.aspx) "restricts intentionally added chemicals in cosmetic products." That is not exactly accurate. It restricts a specific set of substances (ortho-phthalates) which are intentionally added as solvents or fixatives of fragrance ingredients to be used in specified consumer products. Other uses of phthalates in the products in scope are explicitly exempted from the "intentionally added" restriction.

Data Availability

It should also be noted that most companies receive information from their vendors or suppliers and rely upon that information as the guide to determine whether or not a product is compliant with the requirements. Recognizing that there are situations in which information may not have been provided to the company, e.g. the vendor preserves a raw material with a potential formaldehyde donor preservative but fails to disclose this to the manufacturing company, there should be an exemption for companies who obtain and review the requisite data to determine that there is no reason to believe that the product has any formaldehyde or formaldehyde donor chemicals contained therein. Even without the exemption envisioned here, the use of a raw material with a small amount of a preservative that is otherwise problematic would lead many to the interpretation that the ingredient, especially at lower than active levels for functionality within the formula, would be "intentionally added". We recommend that the Department consider this as part of a reasonable system within which to best manage the needs of both the safety of consumers within Washington State as well as the needs of industry to have a workable and concrete regulation that can best inform the industry of their responsibility under this new requirement.

Safety In Use

For decades, formaldehyde releasers have been subjected to rigorous toxicological studies, and these studies consistently demonstrate that when used in low concentrations—as is standard in the cosmetic industry—these ingredients do not pose a risk to consumers.

Glyoxal is a dialdehyde that occurs naturally in the human body and in food. In the body, it is produced by a variety of non-enzymic oxidation reactions such as sugar autooxidation, DNA oxidation and peroxidation of polyunsaturated fatty acids.[i] It is also produced by the microsomal oxidation of glycolaldehyde, ethylene glycol and other chemicals. Its

concentration in blood plasma of healthy individuals ranges between 13 and 67 ng / ml, of which approximately 90% is bound to proteins. Glyoxal is readily metabolized by GSH dependent glyoxalase I and II. In patients with diabetes or end stage kidney disease, blood plasma concentrations of glyoxal are much higher.

The main routes of human exposure to glyoxal are through ingestion, inhalation and for some occupations, dermal exposure. People may ingest more than 10 mg glyoxal per day from food.[ii] Sources include coffee, toast, stir fried meals that include rice, soy source, beer, fermented foods such as dairy products and vegetables. This is the primary route of exogenous exposure except in cases of occupational exposure, especially to disinfectants. Glyoxal is also approved for use in food packaging in the USA and the EU. However, maximum levels are set due to safety concerns.

In the EU, in Annex III (restricted ingredients, no. 194) the EU has set a maximum level of 100 ppm (100 ug /ml) glyoxal in cosmetic products.[iii] If a consumer uses 18 grams of cosmetics a day and each product contains 100 ppm glyoxal (a very unlikely quantity) then exposure would be 1.8 mg of glyoxal per day.[iv] This is much less than potential exposure from food (see below).

In the USA, the Cosmetic Ingredient Review (CIR) has found that glyoxal is safe up to 1.25% in nail products.[v] However, there was insufficient data for all other cosmetic products. In Australia, NICNAS reported that glyoxal could be used in consumer products as long as appropriate usage instructions were provided and followed. Stricter guidelines should be provided for occupational usage.

Glyoxal also has been used as a processing aid to support cold-process dispersion of starches like hydroxyethylcellulose (HEC). Without the addition of glyoxal to the cellulose, the manufacture must heat the product to disperse the starch. HEC is often used at 0.5% or less, but no more than 1% in cosmetic products. As the level of glyoxal in HEC is approximately 0.01%, this yields a final concentration of 1 ppm glyoxal in the final product. If all the glyoxal converts into formaldehyde at one time, which is highly unlikely, then the formaldehyde level in the final product would be 1.03 ppm. This compares with 16 ppm in bananas and between 30 and 60 ppm in pears.[vi]

Preservatives may be another source of formaldehyde in cosmetics products, notably DMDM hydantoin, which has been used for decades to preserve cosmetic products. It's use in extremely small quantities for a preservative, typically less than 0.20% by weight in a formulation. DMDM Hydantoin is included in EU Cosmetic Regulations Annex V, that relates to approved preservatives[iii]. Its maximum use level is restricted to 0.6 %.

In the US, the Cosmetic Ingredient Review has found that DMDM Hydantoin is safe up to the practices and conditions of use in cosmetic products, as of 2008, i.e. up to 0.8%.[vii] At that DMDM Hydantoin level, the concentration of free formaldehyde in the cosmetic product is unlikely to exceed 200 ppm.

The enclosed Table shows the toxicological profile of glyoxal and compares it was that of the formaldehyde donor preservative most commonly used in cosmetics - DMDM Hydantoin: according the FDA's Voluntary Cosmetic Registration Program (VCRP). In 2017, glyoxal was used as an ingredient in 2 products whereas DMDM Hydantoin was used as an ingredient in more than 1,500 products.

Like glyoxal, only a minute amount of formaldehyde is present. In DMDM Hydantoin, only 2% maximum of the molecule exists as free aldehyde in equilibrium with the hydantoin. If all 2% converts to formaldehyde at one time, which is highly unlikely, and the average use level of DMDM Hydantoin is 0.25%, only 0.005% would exist as formaldehyde. This is an extremely small quantity.

Conclusion:

IBA believes in enabling innovation and helping companies meet the evolving needs of the beauty and personal care consumer, while ensuring safe products are brought to market. IBA also supports the growth and success of independent beauty businesses, as the cosmetic and personal care sector offers opportunity and access to entrepreneurism in ways that many other industries cannot—many of the small business founders in the beauty industry represent diverse backgrounds and create products and services unique to their specific consumer or community needs. The businesses that make up the independent beauty industry are also employment generators, employing many people across the state in development, retail, manufacturing, professional services, and more. IBA supports practical legislative and regulatory policies that preserve innovation and free enterprise across the industry, and that are based on common sense and sound science.

IBA is thankful for the forum to submit these comments on the Proposed Rule and welcomes further opportunity to engage with the Department of Ecology to foster a better understanding of the beauty industry and to provide additional context and perspective on

the interpretation, implementation, and impact of this potential regulation on independent businesses in the sector.

After careful review, our recommendation is to maintain the intentionally added formaldehyde requirement included in the Proposed Rule, but provide an accommodation for cosmetic products that contain formaldehyde donors as they contribute negligible quantities of formaldehyde to cosmetic products, in quantities less than a piece of fruit.

Respectfully Submitted,

Don Frey
President & CEO
Independent Beauty Association

Table Comparing the Toxicological Profiles Relating to Human Safety of Glyoxal and DMDM Hydantoin.

	Glyoxal			**DMDM Hydantoin**	
CAS Number	107-22-2			6440-58-0	
EC Number	203-474-9			229-222-8	
Other name(s)	Ethandial, oxaldehyde			Glydant, 1,3-bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione	
Human Safety					
Toxicological Endpoint	**Value**	**Data Source**		**Value**	**Data Source**
Acute Toxicity (Oral: LD_{50})	> 2,000 but < 5,000 mg / kg bw (rats) 3,300 mg / kg bw	ECHA Registration Portal[viii]		1752 mg / kg bw (rats)	ECHA Registration Portal[ix]
Acute Toxicity (Dermal LD_{50})	> 2,000 mg / kg bw (rats)	ECHA Registration Portal		> 1052 mg / kg bw (rabbits)	ECHA Registration Portal

Skin Irritation / corrosivity	Category 2 irritant based on GHS criteria (rabbit)	ECHA Registration Portal		Slightly irritating in rabbits but officially designated as “not classified”.	ECHA Registration Portal
Eye Irritation	Variable results in rabbits – pure glyoxal or depending on solvent produced transient irritation that had disappeared with 8 days (GHS: not classified). Technical grade glyoxal – GHS Category 2.	ECHA Registration Portal		Slightly irritating in rabbits but officially designated as “not classified”,	ECHA Registration Portal
Skin Sensitization	Sensitizer in all studies (LLNA, GPMT and Buehler)	ECHA Registration Portal		Non-sensitizing in Buehler test. Confirmed in LLNA and GPMT assays.	ECHA Registration Portal
Repeated Dose Toxicity (Oral)	In a 90-day study: NOAEL = 72 mg / kg bw / day in male rats (93 mg / kg bw/ day in female rats).	ECHA Registration Portal		DMDMH readily undergoes hydrolysis to DMH and therefore in long term testing, the data on DMH is considered more relevant. In a 90-day study with DMH in rats, the NOAEL was >1000 mg/kg. For DMDM Hydantoin, the NOAEL exceeded 220 mg / kg bw / day.	ECHA Registration Portal

Repeated Dose Toxicity (Dermal)	Data from a dosage estimation for Dermal carcinogenesis study (mice). Systemic NOAEL = 125 mg / kg bw / day for systemic effects but 63 mg / kg bw / day for local effects (skin lesions).	ECHA Registration Portal		In 9- day dermal study the NOEL was 390 mg/kg (limited by solubility) in rats.	ECHA Registration Portal
Genotoxicity	In *in vitro* tests as the Ames test and the in vitro chromosomal aberration assay, glyoxal was genotoxic. However, in the higher-level *in vivo* studies, such as the Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays (OCED TG 488) and Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells in vivo (OECD TG 486) glyoxal was non-genotoxic.	ECHA Registration Portal		DMDM Hydantoin gave mixed results in the in vitro testing. In the higher-level *in vivo* testing (micronucleus and a DNA strand break assay), the results were negative. DMDM Hydantoin's breakdown product DMH, produced negative results in the in vitro testing.	ECHA Registration Portal
Carcinogenicity	Glyoxal was reported to be non-carcinogenic in a 2-year	ECHA Registration Portal		DMDM Hydantoin readily undergoes	ECHA Registration Portal

	carcinogenicity study run in rats. The NOAEL for oral administration was 300 mg / kg bw / day. Separately in mice, a NOAEL of 63 mg / kg bw / day was observed for dermal exposure.			hydrolysis to DMH so long-term studies on this compound are more relevant. DMH did not demonstrate a carcinogenic response in either the rat or the mouse.	
Reproductive Toxicity	Neither developmental toxicity and teratogenicity nor effects on fertility and reproductive performance was seen up to the highest dose tested in rats. (NOAEL > 400 mg/kg bw/day). OECD TG 416 was used	ECHA Registration Portal		Again DMH (the breakdown product of DMDMH) was judged to be the more appropriate test material for this long-term study. Using OECD TG 416, the NO(A)ELs in rats were: Parent males = 20000 ppm (~1395 mg/kg bw/day) Parent females = 20000 ppm (~1774 mg/kg bw/day) F1 males = 6000 ppm (~379 mg/kg bw/day) F1 females = 6000 ppm (~475 mg/kg bw/day) F2 males = 6000ppm	ECHA Registration Portal

				F2 females = 6000ppm.	

REFERENCES

[i] Concise International Chemical Assessment Document 57: Glyoxal (2004). https://www.inchem.org/documents/cicads/cicads/cicad57.htm Accessed March 26, 2025.

[ii] EU Scientific Committee on Consumer Products (SCCP) Opinion on Glyoxal (2005). https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_023.pdf Accessed March 26, 2025.

[iii] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1223 Accessed March 26, 2025.

[iv]SCCS Notes of guidance for the testing of cosmetic ingredients and their safety evaluation - 12th revision. https://health.ec.europa.eu/publications/sccs-notes-guidance-testing-cosmetic-ingredients-and-their-safety-evaluation-12th-revision_en Accessed March 26, 2025

[v] Glyoxal. Becker L.C. et al International Journal of Toxicology Volume 42, Issue 3 Suppl, pp 47S-48S December 2023. https://journals.sagepub.com/doi/epub/10.1177/10915818231204261

[vi] Risk In Brief Formaldehyde in Food https://www.cfs.gov.hk/english/programme/programme_rafs/programme_rafs_fa_02_09.html Accessed March 27, 2025.

[vii] Annual Review of Cosmetic Ingredient Safety Assessments: 2005/2006. International Journal of Toxicology, v27 (Suppl. 1): pp 77–142 (2008).

[viii] ECHACHEM ECHA Chemical Database. https://chem.echa.europa.eu/100.003.160/dossier-view/895e89c1-1ba7-4f9d-b55c-a5971f21b8e4/IUC5-99ca3a20-a1e3-43f9-b438-529c7b00cc3d_518f8623-fa23-46d8-9072-917599915481?searchText=Glyoxal Accessed March 25, 2025.

[ix] ECHACHEM ECHA Chemical Database https://chem.echa.europa.eu/100.026.566/dossier-view/b4247d81-db63-460e-ae47-

5abf6fbc9cde/4c8f577e-99cc-4e2d-920e-bcb6b0345b17_4c8f577e-99cc-4e2d-920e-bcb6b0345b17?searchText=DMDM%20Hydantoin Accessed March 27, 2025.