

USA TBT Enquiry Point

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BY EMAIL

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USA WTO TBT Enquiry Point

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Response to G/TBT/N/USA/2187 Chapter 173-339 WAC Cosmetic Products Restrictions (Formaldehyde in Cosmetics)

Dear Madam, Sir,

Since 1962, Cosmetics Europe has been the voice of Europe's cosmetic, toiletry and perfumery industry with a representative membership consisting of more than 20 major international cosmetic companies and 27 cosmetic associations from the EU member states representing more than 5000 cosmetic companies. Cosmetics Europe is the recognised industry stakeholder in policy discussions on the development and practical implementation of the harmonised EU legislation affecting cosmetics.

Cosmetics Europe is aware that the proposed rule will ban total 28 substances to be used as cosmetic ingredients due to their identified formaldehyde releasing properties, ten of which have been evaluated as safe at certain concentration by the Scientific Committee on Consumer Safety (SCCS) in the European Union (EU).

These ten preservatives are legally approved ingredients in the EU for their preserving function for the cosmetic products (in the table below). Banning these ingredients creates technical barriers to trade. It is not justified to ban these ingredients when their use is demonstrated as safe.

Note that banning these ten preservatives also reduces the preservatives palette for cosmetics and personal care products. Consumers in Washington State would likely have higher exposure to the remaining preservatives than before. From a consumer safety perspective, it is better to spread the exposure patterns, meaning it is better to expose to smaller amounts of various substances than expose to higher amounts of fewer substances.

Item	Chemical name	CAS RN	Maximum concentration in ready for use preparation in EU Cosmetic Product Regulation (CPR) Annex V
1	DMDM Hydantoin	6440-58-0	0,6 %
2	Diazolidinyl Urea	78491-02-8	0,5 %
3	Imidiazolidinyl Urea	39236-46-9	0,6 %
6	2-Bromo-2-Nitropropane-1,3-Diol (Bronopol)	52-51-7	0,1 %
7	Sodium Hydroxymethyl-glycinate	70161-44-3	0,5 % (Not to be used if the maximum theoretical

			concentration of releasable formaldehyde, irrespective of the source, if the mixture as placed on the market is $\geq 0,1$ % w/w)
11	5-Bromo-5-Nitro-1,3-Dioxane (Bronidox)	30007-47-7	0,1 % in Rinse-off products
12	7-Ethylbicyclo-oxazolidine (Bioban CS1246)	7747-35-5	0,3 % (Not to be used in oral products and in products applied on mucous membranes)
13	Benzylhemiformal	14548-60-8	0,15 % in Rinse-off products
17	Dimethyl Oxazolidine	51200-87-4	0,1 % pH > 6
21	Methenamine	100-97-0	0,15 %

Other substances proposed to be banned in this draft rule may contain or generate during use negligible levels of formaldehyde that are of no toxicological relevance. Hence their ban would constitute a disproportional measure if the objective is to protect human health.

Those include for example Tosylamide/Formaldehyde resin, which is a large molecular weight polymer, hence not even bioavailable when applied through topical applications which is the case of cosmetics. The potential presence of minimal amounts of formaldehyde leads to negligible exposures in the context of cosmetic uses.

Another example is “glyoxylic acid when used in heat-activated hair straighteners”. These products do not contain formaldehyde, but very small amounts can be released into the air from the heated hair, that are equivalent to the amounts released without the product being used, and orders of magnitude lower than the air concentrations established to be safe as workplace exposure levels. For example, by the US occupational safety and health administration¹, and well within the guideline for indoor air quality from the WHO².

Note that formaldehyde is formed endogenously in humans by oxidative metabolism (EFSA, 2014). Formaldehyde can also occur naturally in some foods (e.g. fruits, vegetables, fish, and meat).

These ten preservatives that have been demonstrated as safe should not be banned. They are not equal to formaldehyde and there is actually a way for Washington State to regulate them safely. We strongly encourage Washington State to consider regulating these ten preservatives with another approach, for which specific concentration and use conditions can be referenced.

Definition of “intentionally added”

The draft rule proposes:

<p>"Intentionally added chemical" or "intentionally added" means a chemical that serves an intended function in:</p> <ul style="list-style-type: none"> • The final product.

¹ Occupational Safety and Health (OSHA):29 CFR 1910.1048 / OSHA 1992

² World Health Organization (WHO): WHO Guidelines for Indoor Air Quality: Selected Pollutants 2010

- The manufacturing of the product.
- An ingredient in the final product.

This definition applies to the chemicals restricted in chapter 70A.560 RCW. This definition takes effect January 1, 2027.

We think the definition of "**Intentionally added chemical**" or "**intentionally added**" is too broad to be applicable. For instance, a substance banned for use as cosmetic ingredient (e.g., formaldehyde) may be used in one of steps during the manufacturing process, and such use is not intended to be present in the final product. Nevertheless, a trace quantity of this substance may still be present in the final product as impurity even when cosmetic good manufacturing practices (cGMP) is complied.

It is necessary to include the following exclusion criteria in this rule to clarify the scope of ban of unintended substances:

Exclusion: The distribution, sale or offering for sale of a cosmetic product in this State does not violate the prohibition in subsection 1 if the cosmetic product contains a technically unavoidable trace quantity of a substance identified in subsection 1 and that trace quantity is present due to:

A. Impurities or contamination:

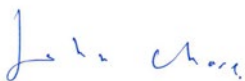
- (1) From a natural or synthetic ingredient used in the manufacture of the cosmetic product;
- (2) From the manufacturing process; or
- (3) From the storage of the cosmetic product; or

B. Due to migration of the ingredient from the packaging of the cosmetic product into the cosmetic product.

The non-intended presence of a small quantity of a prohibited substance should be permitted, when companies can demonstrate compliance of good manufacturing practice (GMP) and the presence of trace is technically unavoidable, and such presence is demonstrated as safe for human health. This approach is in line with international practice on managing non-intended presence of substance in the finished cosmetic product.

Cosmetic Europe and its experts stand ready to answer any question that you should have in relation to our comments.

Yours sincerely,



John Chave

Director General
Cosmetics Europe