Cosmetics Regulatory Newsletter

Winter 2024 **Keystone Industries**

EU Microplastics Ban

Microplastics restrictions have been published and adopted by the European Commission under Regulation (EU) 2023/2055. The Regulation reads:

Polymers that are solid and fulfil the two following conditions shall not be placed on the market as substances on their own or, where the synthetic polymer microparticles are present to confer a sought-after characteristic, in mixtures in a concentration ≥ 0,01% by weight.

Substance Conditions:

1) Are contained in particles and constitute at least 1% by weight of those particles; or build a continuous surface coating on particles;
2) At least 1% of these particles have dimensions ≤ 5 mm or have length ≤ 15 mm and their length to diameter ratio is greater than 3.

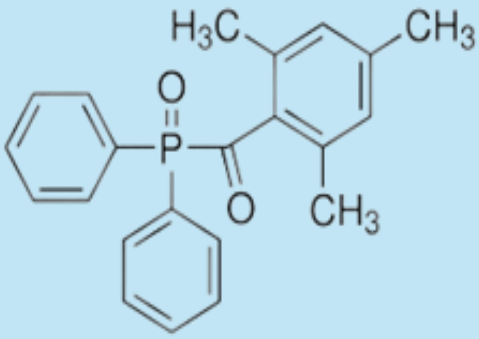
What does this mean for Keystone Nail Products? No immediate impact! While microplastics are extensively utilized in cosmetic items, the initial regulation implemented last year primarily targeted microbeads, synthetic polymer microparticles used for abrasion purposes such as exfoliation, polishing, or cleaning. However, the use of microplastics in nail products, given its minimal contribution to overall microplastic emissions, is permitted until October 17, 2035. Starting from October 17, 2031, nail products containing microplastics must explicitly state "This product contains microplastics" on its label until the ban comes into effect in 2035. This timeline affords us the opportunity to efficiently reformulate and transition to suitable alternatives as needed.

It's crucial to emphasize that there isn't a comprehensive list of cosmetic ingredients affected by this regulation. Each substance must undergo individual assessment to determine if it qualifies as a synthetic polymer microparticle. Furthermore, not all glitters used in cosmetic products fall under the category of microplastics. Our Research and Development team specialists will evaluate formulas containing potentially classified microplastics and will communicate any necessary regulatory adjustments needed for compliance within the designated transition.

Newsletter Topics

Reclassification of TPO

Effective **September 1, 2025**, Diphenyl(2,4,6-trimethylbenzoyl) phosphine oxide (TPO)(CAS: 75980-60-8, EINECS: 278-355-8), a common photo initiator in Keystone's UV/LED curable systems, will be prohibited in cosmetic products within the EU. The European Commission enacted Regulation (EU) 2024/197 on January 5, 2024 reclassifying TPO as a category 1B CMR substance due to reproductive toxicity concerns, leading to TPO's inclusion in the List of Substances Prohibited in Cosmetic Products (Annex II of EU Cosmetic Regulations 1223/2009).



In anticipation of compliance needs, Keystone's R&D and Regulatory teams collaborated to develop an alternative TPO-free formula that preserves the color vibrancy and curing properties valued by customers. New products launched will no longer contain TPO and a selection of existing formulas containing TPO will undergo reformulation. Customers using TPO-containing products will receive notifications from Keystone Sales Representatives about available alternatives. Regulatory support will be provided to ensure the quality documentation necessary for labeling and notifications.

EU Banned Substances Update

Article 15 of Regulation (EC) No.1223/2009 states that substances classified as CMR substances of category 1A, 1B or 2 under Part 3 of Annex VI to Regulation (EC) No. 1272/2008 (CMR substances) are to be prohibited from use in cosmetic products. However, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the Scientific Committee on Consumer Safety (SCCS) and found safe for use in cosmetic products.

Below is a list of substances with updated hazard classification per EU Classification, Labeling and Packaging (CLP) regulation. Keystone Industries is actively working on removing these substances from our formulations before the effective deadlines.

EU substance with updated cosmetic hazard classifications

INCI (CAS)	Regulation/EU reg. entry	Regulation Date	Effective Keystone product(s)	Current Activities
Benzophenone (119-61-9)	EU CLP (Carc 1B) – Annex II/1703^1	12/2023	Monomer, UV gel top & base coats, UV gels	Reformulations ongoing
Trimethylolpropane Triacrylate (TMPTA) (15625-89-5)	EU CLP (Carc 2) – Annex II/1718^2	12/2023	Not in EU cosmetic products	Not in EU cosmetic products
Trimethylbenzoyl diphenylphosphine oxide (TPO) (75980-60-8)	EU CLP (Reprotoxic 1B) – No Annex entry yet	09/2025	UV gels	Reformulations ongoing
Dimethyltolylamine(n,n-DMPT) (99-97-8)	EU CLP (Carc 1B) – No Annex entry yet	09/2025	Monomers	Reformulations ongoing

*Date that the regulation will apply from, enters into force.

Link to EU regulation 2023/1490 (^1&^2): https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R1490

FRAGRANCE UPDATE

The term "fragrance" on ingredient lists often represents a blend of multiple components. Cosmetic companies may not disclose the specific ingredients for proprietary reasons, but some people may have sensitivities or allergies to certain fragrance ingredients. In the European Union (EU) there is a requirement for cosmetic manufacturers to list allergens from fragrances on the product label. Currently under annex iii to regulation (EC) 1223/2009 on cosmetic products, 24 fragrance allergens are required to be named in the list of ingredients. Allergens must be declared on the label when they are present in a concentration that exceeds 0,001% in leave-on products and 0,01% in rinse-off products.

On July 26th, 2023, the European union (EU) adopted regulation (EU) 2023/1545 to update labelling of fragrance allergens. It expands the list to over 80+ allergens that are required to be listed on the product label if present in the concentrations listed previously. For new cosmetic products to be placed onto the EU market, they shall comply with the new requirement by July 31st, 2026 (within 3 years). For existing cosmetic products already on the EU market, they shall comply with the new requirement by July 31st, 2028 (within 5 years).

Stay fragrant! Stay informed!

Modernization of Cosmetic Regulation

First major update to FDA cosmetic regulations since FD&C Act of 1938. The Modernization of Cosmetics Regulation Act (MoCRA) was signed into law on 12/29/22 with new provisions to both FDA and cosmetic industry, including the following:

Currently Enforced

- Tracking and reporting serious adverse events
- Record retention of adverse events
- FDA recall authority
- Safety substantiation

Pending Enforcement and/or Guidance

- Facility registration and cosmetic listings (July 1, 2024)
- Good manufacturing processes (GMP) (December 29, 2025)
- Improved labeling (June 29, 2024)

Regulatory has concluded gap assessment and identified next steps to be compliant with MoCRA regulations. All Keystone cosmetic facilities (Cherry Hill, Gibbstown, C7, and Interfilling) have FDA Establishment Identifier (FEI) numbers; number assigned by FDA to identify firms associated with FDA regulated products. Per MoCRA, facility registration and product listing must be completed by July 1, 2024. Any cosmetic manufacturer that sales product in the US marketplace must register that facility with FDA. The responsible person (RP), manufacturer, packer or distributor name that appears on the label of the cosmetic product must complete the product listing with FDA. Regulatory will continue to provide further details as certain deadline approach.

Link to FDA MoCRA regulations: https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022-mocra