



Müller + Krempel AG
Schützenmattstrasse 46
8180 Bülach
Switzerland

Zeewolde, 1-7-2019

Re: Cosmetic regulation 1223/2009

Dear customer,

We are pleased to respond to your inquiry regarding our PE/PP/PET-E bottles, closures, jars and Silgan Dispensing Systems pumps (i.e., packaging components listed Annex I) and provide information to that can be used by “responsible persons” of cosmetics products to fulfill their obligations under the new EC Regulation on Cosmetics Regulation (1223/2009). This information is intended to provide information that can be used by the “responsible person” to conduct a “safety assessment” of their cosmetic product as is required under EC 1223/2009 (articles 3, 5, 6, 10, 11 and 17).

The following provides information about raw materials used to make packaging components of listed PE/PP/PET-E bottles, closures, jars and Silgan Dispensing Systems pumps that directly will contact packaged cosmetics. This information is provided to assist the “responsible person” to conduct a safety assessment and prepare a Cosmetics Product Safety Report - Section 4. Impurities & Traces Information about Packaging Materials” (refer to Annex I Part A of 1223/2009):

- List of “Prohibited substances” in Cosmetics Products (1223/2009 - Annex II)
- Substances classified as CMR substances - carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A, 1B and 2, under Part 3 of Annex VI to Regulation (EC) No 1272/2008
- Suitable Purity for Food Contact Articles per EU Food Contact Regulations or Directives (1935/2004; 10/2011; 2002/72/EC and as amended)

This following disclosure is based on our product formulations, technical knowledge of material science, our qualified raw material manufacturers’ product regulatory declarations and composition/ impurity disclosures (received to date), and our targeted validation testing to determine if there are detectable concentrations of key “chemicals of concern” in select product components. The above is done in accordance with supplier Product Stewardship and Good manufacturing Practices (GMP) commitments.

Absence of “Prohibited substances” listed (1223/2009 - Annex II):

- Supplier does not intentionally add any prohibited substances listed in Annex II of EC Regulation 1223/2009
- Supplier does not know of the presence of any prohibited substances in our packaging components based on our targeted testing, disclosures and certifications received to date from raw material manufacturers

Absence of CMR Classified Substances (Article 15)

- Supplier does not intentionally add any CMR substances listed as category 1A, 1B and 2, under Part 3 of Annex VI to Regulation (EC) No 1272/2008
- Supplier does not know of the presence of any such CMR substances in our packaging components based on our targeted testing, disclosure and certifications received to date from raw material manufacturers



Suitable Purity for Food Contact Articles

Resins used to make the packaging components are of suitable purity for direct food contact packaging applications. The materials that are used to make components that come in direct contact with packaged cosmetics meet the following food contact suitability requirements:

- EC Regulation 1935/2004/EC
- EC Regulation 1895/2005/EC
- EC Directive 2002/72/EC and subsequent updates
- EC Regulation 10/2011/EU (as indicates in art. 22 and 23)

The materials may contain substances regulated by Directives 89/107/EC, 88/388/EC, EC Regulation 10/2011/EU and Commission Decision 1999/217/EC.

The user of the material intended for contact with food has a responsibility to inform the company in writing of any restrictions because of the compositional characteristics (presence of additives and flavor) of food to be packed.

This statement is valid from the date above and will be replaced when significant changes occur in the production of material capable of changing the essential requirements for compliance or where legislative references in paragraph 1 shall be modified and updated to require a new verification of compliance.

Ultimately customers must make their own determination that their use of our product is safe, lawful and technically suitable in their intended applications, as required in the article no. 3 of the European Regulation 1935/2004.

Frapak packaging is not responsible for any contamination that could take place in the subsequent processing of the product carried out by cosmetics product packagers or customers.

Frapak packaging b.v.
Quality Manager



Mr. J. Cornelisse

The product composition information provided above is provided in "good faith" for customers to consider when performing their own determinations of the fitness for use of the packaging components for their product and its intended uses. Ultimately customers must make their own determination and conduct appropriate testing to assure that the use of the packaging and packaging components are safe, lawful and technically suitable in their intended end use applications. This information in no way modifies, amends, enlarges, or creates any specification or warranty, and ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE HEREBY EXCLUDED.

