

Compilation of submission on Cosmetics

Information provided by EU, Uganda, the United States and other stakeholders (IPEN)

Eye makeup, cleansing products and mascara containing thiomersal

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| 1. Category of mercury-added product | Cosmetics |
| 2. Further description of the product (if any) | Eye makeup, cleansing products and mascara containing thiomersal |
| 3. Information on the use of the product | <ul style="list-style-type: none">• Thiomersal is an organic compound, containing ethyl mercury, which is often used as a preservative in mascara, eye makeup and cleansing products (WHO, 2011). Thiomersal provides a useful role, extending the shelf life of cosmetics and limiting the risk of infection to cosmetic users. However, due to the risk of allergic reaction and the wider health impacts associated with exposure to mercury, the concentration of mercury in eye makeup products is restricted by legislation internationally.• The majority of purchased cosmetic products are stored at room temperature in households, in relatively moist conditions. These conditions, combined with repeated, regular use by consumers, leave cosmetic products susceptible to microorganism growth (ICCR, 2016). For eye makeup products, which have a high water content, such as mascara and liquid eyeliner, preservatives are required to limit microbial growth and extend the shelf life of these products.• Thiomersal is a key preservative used in eye makeup products, to prevent fungal and bacterial growth and limit the risk of infection for consumers. Although thiomersal serves reduces the spread of microorganisms, mercury compounds can cause skin irritation, neurotoxicity and kidney damage (EWG, 2019a). The North American Contact Dermatitis Group reported thiomersal as the fifth most common allergen, with 11% of patch-test patients experiencing allergic reactions, despite its low clinical relevance (Fonacier & Boguniewicz, 2016). In spite of these concerns, WHO scientist, Tempowski, states that ‘the risk-benefit analysis favours the use of these preservatives’, due to their ability to inhibit bacterial and fungal growth (Scientific American, 2013).• Mercury concentrations in eye makeup products vary depending on the product yet usually do not exceed 1 ppm. According to information provided by an industry group, thiomersal is no longer used by the European cosmetics industry, based on knowledge of the 2016 Cosmetics Europe Preservative Use Survey for the preservation of cosmetic products. This Survey was completed by 85 organisations in the sector, including multinational organisations and SMEs. In addition, over 60,000 product types were analyses, accounting for over 60,000 product formulations. |

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| <p>4. Information on the availability of mercury-free (or less-mercury) alternatives</p> | <p><u>Main alternatives: Parabens, organic alternatives</u></p> <p>COWI (2008) suggests that, for the use of mercury as a preservative in cosmetics, ‘alternatives dominate the market, but new products with mercury also have significant market share’.</p> <p>Phenoxyethanol, methylisothiazolinone and parabens are mercury-free substitutes used to replace thiomersal in eye makeup products. However, these alternatives are also associated with detrimental health impacts, from allergic reactions to toxicity (Scientific American, 2013). Organic preservatives, such as benzoic acid and sorbic acid, as well as organic ingredients, such as honey and sea salt, are also used by some cosmetic companies. Dermosoft multifunctionals, which combine organic acids and chemical compounds, can also offer an alternative to thiomersal, effectively tackling microbial growth through combining multiple preservatives (Thiemann & Jänichen, 2014).</p> <p>Some companies also choose to use sterilisation as an alternative to preservatives, using the Ultra-High-Temperature process (UHT) to heat and sterilise the product, before quickly cooling it. In addition, as high water-content is one of the key causes of microbial growth, some brands are innovating to replace water with a gelled substitute, removing the need for preservatives altogether (EcoMundo, 2019).</p> <p>There are a number of mercury-free alternatives available, and according to the Environmental Working Group’s (EWG) Skip Deep Cosmetics Database, there are no eye makeup products currently available in the US that contain thiomersal (EWG, 2019b).</p> |
| <p>5.(i) Information on the technical feasibility of alternatives</p> | <p>Several factors are considered when selecting the most suitable preservative to use in cosmetic products. This decision is linked to the expected performance of the product, consumer behaviour and the specific requirements of the product (ICCR, 2016). Alongside these key factors, preservatives must be determined as safe, and aim to use the minimum concentration of preservatives required to ensure the product does not spoil. A consideration of the interaction between preservatives and other product ingredients is essential, to ensure the preservative operates effectively. Therefore, the technical feasibility of alternatives is product-specific, as it depends on the interaction of substitute preservatives with other product ingredients.</p> |

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| | <p>Organic preservatives, such as sorbic or benzoic acid, are effective against most fungi. However, they tend not to be particularly effective against bacterial growth (Microchem Laboratory, 2018). Multiple organic preservatives can be combined to achieve wider success in limiting microbial growth. However, these alternatives also precipitate in products with high water content, which diminishes their effectiveness (ibid). Phenoxyethanol is particularly stable and not pH dependent, unlike some organic preservatives, which require a pH range of 2-6. Parabens are most widely used, in both rinse-off products and makeup products used throughout the day, providing a suitable alternative to thiomersal (ibid). It can also be useful to combine preservatives, as is the case with dermosoft multifunctionals, to achieve a more cohesive antimicrobial effect (Thiemann & Jänichen, 2014). Therefore, there are a number of technically feasible alternatives that are already commercially available. However, it is important to also consider practical and health-related factors, to ensure the preservative is suitable for the product.</p> |
| <p>5.(ii) Information on the economic feasibility of alternatives</p> | <p>The cost of non-mercury alternatives varies depending on the preservative. The cost of cosmetic ingredients is an important consideration, as it greatly influences the marketing of products. Although consumers are moving towards more affordable cosmetics, the cost of antimicrobials is not necessarily negative, as consumers are generally willing to pay to avoid negative health outcomes (Halla, et al., 2018).</p> |
| <p>6. Information on environmental and health risks and benefits of alternatives</p> | <p>The health and environmental risks associated with non-mercury alternatives vary depending on the substitute. Parabens are often used in cleansing products. However, these preservatives are linked to a number of health concerns, including damage to skin cells, reproductive toxicity and endocrine disruption. Phenoxyethanol is also used as a preservative in cosmetic products, yet it has been linked to allergic reactions, including eczema and anaphylaxis. However, it is a viable alternative, if individuals are not allergic to the preservative.</p> <p>Methylisothiazolinone is another preservative used in mascara and cleansing products. However, it is linked to inhalation toxicity and allergic reactions (Breast Cancer Prevention Partners, 2019). In 2015, 75 000 metric tonnes of preservatives were used in cosmetic products globally.</p> <p>Therefore, organic alternatives, such as honey and sea salt, which naturally break down without causing harm to the environment, are preferable (LUSH, 2019).</p> |

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| <p>7. If any, additional information being submitted on mercury-added products pursuant to Article 4.4 of the Convention not addressed above (e.g. manufacture, general trade information, etc.)</p> | <p>NA</p> |
| <p>8. Other relevant information pursuant to Decision MC-3/1</p> | <p>In Europe, Regulation (EC) 1223/2009 is the primary piece of legislation governing the use of mercury in eye makeup, cleansing products and mascara. Under Article 14(1)(a), restrictions are placed on the use of certain substances in cosmetic products, listed under Annex II. Mercury and its compounds are banned, with the exception of special cases outlined in Annex V. The use of thiomersal in eye makeup products is one of the special cases identified by the Regulation, where a maximum concentration of 0,007 % of mercury is permitted in eye makeup, mascara and cleansing products. If thiomersal is combined with other mercury compounds permitted under Regulation (EC) 1223/2009, the maximum concentration of mercury in eye products remains the same (i.e. 0,007 %). Phenylmercuric salts (including borate) found in eye products are also subject to the same maximum concentration. In addition, through the introduction of a ‘date of minimum durability’ or a ‘period after opening’ date in Europe, consumers are more aware of the appropriate shelf life of cosmetic products (Cosmetics Europe, 2019).</p> <p>During the ad hoc group’s meeting, an expert confirmed that, to his knowledge, the European cosmetics industry no longer use mercury preservatives.</p> <p>In the US, the Food and Drug Administration (FDA) leads on legislative development for cosmetics. The concentration of mercury compounds in eye makeup products is limited to 0,0065%, and is only permitted in the case that no mercury-free alternatives are available (US FDA, 2017). All other cosmetic products must have a mercury concentration of less than 1 mg per kg. Mercury is listed in 21 CFR. § 700.13 as a banned ingredient for cosmetic uses, with the exception of “<i>de minimis</i>” use as a preservative in eye-area cosmetics if no other alternatives are available. A search of FDA’s Voluntary Cosmetic Registration Program (VCRP, 21 CR 720) in October of 2020 found no cosmetic products containing either organic or inorganic Hg-containing ingredients currently registered.</p> <p>Skin bleaching products, generally, especially those containing ammoniated mercury are deemed unapproved over-the-counter (OTC) drug products and are unapproved new drugs in the United States.</p> |

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| | <p>Cosmetic products containing Hg that do not comply with the above noted regulation would be deemed to be “adulterated” and the FDA has the authority to enjoin and criminally prosecute offenses relating to such products (see, 21 U.S.C. §§ 331(a), 332, 333). FDA Import Alert # 53-18 (“Detention Without Physical Examination of Skin Whitening Creams Containing Mercury”; https://www.accessdata.fda.gov/cms_ia/importalert_137.html) is the basis for surveillance by inspectors at U.S. ports of entry for imported cosmetics that may contain Hg in violation of FDA regulations at 21 CFR 700.13. In the past few years, FDA and state health officials have discovered and analyzed some products marketed as skin lighteners that contain mercury; FDA’s internet website posted an article, “Skin Products Containing Mercury”, which presents the Hg content found in seven 2019 skin products along with the products names and images. (See, https://www.fda.gov/consumers/health-fraud-scams/skin-products-containing-mercury). All cosmetic products covered by the Convention are also subject to the labeling requirements of the Federal Food, Drug, and Cosmetic Act and, if marketed at retail for consumers, the Fair Packaging and Labeling Act. The ASEAN Cosmetic Directive reflects EU legislation, with thiomersal permitted as a preservative in eye makeup and cleansing products, as long as the concentration of mercury does not exceed 0,007 %. The maximum concentration of mercury remains 0,007 % if other mercury compounds are contained in the product (Health Sciences Authority, 2018). All 10 Member States³ were required to implement the Directive by January 2018.</p> |
| 9. References | |

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Other cosmetics

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| 1. Category of mercury-added product | Cosmetics |
| 2. Further description of the product (if any) | Other cosmetics |
| 3. Information on the use of the product | <p>Uganda There are mercury containing cosmetics and related products in use in Uganda as revealed in the National Minamata Initial Assessments report, 2018. <u>Estimated Mercury input in the environment (MIAs report, 2018)</u></p> <ul style="list-style-type: none"> • At use and disposal phase fused together, cosmetics and related products contribute to 104 kg/Hg/Yr <p><u>Use of the product</u></p> <ul style="list-style-type: none"> • Available in various forms such as sprays, gels, lotions, creams, soaps, powders, etc., cosmetics cover a wide range of products intended for contact with the body. Of particular concern are skin-lightening (or fairness) creams and soaps exceeding that level. |
| 4. Information on the availability of mercury-free (or less-mercury) alternatives | <p><u>Existing less-mercury products</u></p> <ul style="list-style-type: none"> • <i>Cosmetics with trace levels of mercury (< 1ppm)</i> • <i>Beautysoaps and creams without mercury, e.g., cosmetic products based on natural products, vegetable oils, or essential oil formulations</i> <p>Information from experts In Indonesia, mercury has been banned since 1998 for cosmetic products by MOH and 2011 by NADFC. Since mercury has been banned for many years, the cosmetics industry was able to replace mercury with other alternative ingredients.</p> |
| 5.(i) Information on the technical feasibility of alternatives | <p>Uganda</p> <ul style="list-style-type: none"> • There is limited knowledge by consumers in Uganda on existence of alternatives • There is limited policy restrictions on importation of listed Non-electronic measuring devices |

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| | <ul style="list-style-type: none"> • There are no incentives on use/importation of alternatives <p>IPEN Many manufacturers have now moved to formulations that are mercury free demonstrating that alternatives are available and accepted (COWI, 2008) by the cosmetics industry.</p> |
| 5.(ii) Information on the economic feasibility of alternatives | <p>Uganda</p> <ul style="list-style-type: none"> • The alternatives usually cost higher than the more toxic ones. • Alternatives are mainly imported, hence transferring taxation costs to the consumer. |
| 6. Information on environmental and health risks and benefits of alternatives | |
| 7. If any, additional information being submitted on mercury-added products pursuant to Article 4.4 of the Convention not addressed above (e.g. manufacture, general trade information, etc.) | |
| 8. Other relevant information pursuant to Decision MC-3/1 | |
| 9. References | <ul style="list-style-type: none"> • Developing National Strategies for Phasing Out Mercury Containing Thermometers and Sphygmomanometers in Health Care, Including in the Context of the Minamata Convention on Mercury, World Health Organization, 2015. Available at http://www.who.int/ipcs/assessment/public_health/WHOGuidanceReportonMercury2015.pdf?ua= • UNEP (2013): Minamata Convention on Mercury. Available at http://www.mercuryconvention.org • Minamata Initial Assessments report, 2018 • Mercury Learn - HS codes (2015); COMTRADE database <p>Information from experts</p> |

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| | <p>Peraturan Menteri Kesehatan Nomor 445/MENKES/Per/V/1998 tentang Pelarangan Penggunaan Merkuri dalam Sediaan Kosmetika;</p> <p>Badan Pengawas Obat dan Makanan Republik Indonesia Nomor HK.03.1.23.08.11.07517 Tahun 2011 tentang larangan penggunaan Merkuri dalam sediaan kosmetik;</p> <p>Peraturan Badan POM 23 Tahun 2019 Persyaratan Teknis Bahan Kosmetika.</p> <p>PERATURAN BADAN PENGAWAS OBAT DAN MAKANAN NOMOR 12 TAHUN 2019 TENTANG CEMARAN DALAM KOSMETIKA</p> |
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