

LANETH-9 ACETATE and LANETH-10 ACETATE

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of Laneth-10 Acetate Group in 1982 (this report contained both Laneth-9 Acetate and Laneth-10 Acetate).¹ The Panel concluded that these ingredients are safe for topical application to humans in the present practices of use and concentration, as stated in that report. Upon re-review in 2002, the Panel reaffirmed the original conclusion, as published in 2005.² These two ingredients were originally reviewed with three other ingredients (Laneth-5, Laneth-16, and Laneth-25); however, these other three ingredients are not being reviewed herein as they have since been included in the Alkyl PEG Ethers report.

Because it has been at least 15 years since the prior re-review was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel again determined whether the safety assessment should be reopened. At the September 2023 meeting, the Panel considered updated information regarding product types and ingredient use frequencies as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database in 2023³ and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council in 2022.⁴ In 2001, Laneth-10 Acetate was reported to be used in 44 formulations, but concentration of use data were not reported. Additionally, no uses were reported for Laneth-9 Acetate in either the VCRP or the concentration of use survey. Currently, Laneth-9 Acetate and Laneth-10 Acetate have no reported uses, according to both 2022 concentration of use and 2023 FDA VCRP data. The cumulative frequency and concentration of use data for Laneth-10 Acetate are presented in Table 1. Because Laneth-9 Acetate had no previous (2001) or current (2022/2023) reported uses, it has not been included in the use table.

In July 2023, an extensive search of the world's literature was performed for studies dated 2000 forward, and no relevant new data were found.

In summary, the Panel reviewed 2023 frequency and 2022 concentration of use data, noting the lack of use. The Panel also noted the lack of any new, available, relevant safety data. Considering this information, as well as the information provided in the original safety assessment and the prior re-review document, the Panel reaffirmed the 1982 conclusion.

Table 1. Frequency (2023/2001) and concentration (2022/2001) of use of Laneth-10 Acetate according to likely duration and exposure and by product category

| | # of Uses | | Max Conc of Use (%) | |
|-----------------------------------------------------|-------------------|------------------------------------|---------------------|-------------------|
| | 2023 ³ | 2001 ² | 2022 ⁴ | 2001 ² |
| Totals* | NR | 44 | NR | NR |
| summarized by likely duration and exposure** | | | | |
| Duration of Use | | | | |
| Leave-On | NR | 27 | NR | NR |
| Rinse-Off | NR | 17 | NR | NR |
| Diluted for (Bath) Use | NR | NR | NR | NR |
| Exposure Type | | | | |
| Eye Area | NR | NR | NR | NR |
| Incidental Ingestion | NR | NR | NR | NR |
| Incidental Inhalation-Spray | NR | 5; 2 ^a ; 9 ^b | NR | NR |
| Incidental Inhalation-Powder | NR | 9 ^b | NR | NR |
| Dermal Contact | NR | 35 | NR | NR |
| Deodorant (underarm) | NR | NR | NR | NR |
| Hair - Non-Coloring | NR | 8 | NR | NR |
| Hair-Coloring | NR | NR | NR | NR |
| Nail | NR | 1 | NR | NR |
| Mucous Membrane | NR | 11 | NR | NR |
| Baby Products | NR | 2 | NR | NR |
| as reported by product category | | | | |
| Baby Products | | | | |
| Other Baby Products | NR | 2 | NR | NR |
| Hair Preparations (non-coloring) | | | | |
| Hair Spray (aerosol fixatives) | NR | 5 | NR | NR |
| Shampoos (non-coloring) | NR | 2 | NR | NR |
| Tonics, Dressings, and Other Hair Grooming Aids | NR | 1 | NR | NR |
| Makeup Preparations | | | | |
| Foundations | NR | 3 | NR | NR |
| Makeup Bases | NR | 1 | NR | NR |
| Manicuring Preparations (Nail) | | | | |
| Nail Polish and Enamel Removers | NR | 1 | NR | NR |
| Personal Cleanliness Products | | | | |
| Bath Soaps and Detergents | NR | 7 | NR | NR |
| Other Personal Cleanliness Products | NR | 4 | NR | NR |
| Shaving Preparations | | | | |
| Aftershave Lotion | NR | 3 | NR | NR |
| Skin Care Preparations | | | | |
| Cleansing | NR | 3 | NR | NR |
| Body and Hand (exc shave) | NR | 9 | NR | NR |
| Skin Fresheners | NR | 1 | NR | NR |
| Other Skin Care Preparations | NR | 2 | NR | NR |

NR – not reported

*Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

**likely duration and exposure are derived based on product category (see Use Categorization <https://www.cir-safety.org/cir-findings>)

^a It is possible these products are sprays, but it is not specified whether the reported uses are sprays.

^b Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories

REFERENCES

1. Andersen FA (ed). Final Report on the Safety Assessment of Laneth-10 Acetate Group. *J Am Coll Toxicol*. 1982;1(4).
2. Andersen FA (ed). Annual review of cosmetic ingredient safety assessments - 2002/2003. *IJT*. 2005;24:56-59.
3. US Food and Drug Administration (FDA) Center for Food Safety & Applied Nutrition (CFSAN). 2023. Voluntary Cosmetic Registration Program - Frequency of Use of Cosmetic Ingredients. (Obtained under the Freedom of Information Act from CFSAN; requested as "Frequency of Use Data" January 4, 2023; received February 2, 2023). College Park, MD.
4. Personal Care Products Council. 2022. Concentration of Use by FDA Product Category: Laneth-9 Acetate and Laneth-10 Acetate. (Unpublished data submitted by Personal Care Products Council on October 31, 2022.)