Addendum to the Safety Assessment of Brown Algae-Derived Ingredients

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Samuel M. Cohen, M.D., Ph.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D., and the Senior Director is Monice Fiume, M.B.A. This safety assessment was prepared by Priya Ferguson, M.S., Associate Toxicologist and Senior Scientific Analyst/Writer, CIR.

The Expert Panel for Cosmetic Ingredient Safety (Panel) assessed the safety of 82 brown algae-derived ingredients.[1] The Panel reviewed the available data to determine the safety of these ingredients, which are frequently reported to function in cosmetics as skin-conditioning agents. Impurities, particularly arsenic, may be present in these aquatic organisms. Therefore, industry should continue to use good manufacturing practices to monitor and limit these possible impurities. The Panel concluded that 68 of these brown algae-derived ingredients are safe in cosmetics in the present practices of use and concentration described in this safety assessment. The Panel also concluded that the data are insufficient to determine the safety of the remaining ingredients, including Cladosiphon Novae-Caledoniae Extract, under the intended conditions of use in cosmetic formulations. Subsequent to completion of the original safety assessment, the Panel received and reviewed additional data on Cladosiphon Novae-Caledoniae Extract, including information on its preparation, chemical properties, composition, acute oral toxicity, genotoxicity, dermal irritation and sensitization, ocular irritation, phototoxicity, and photosensitization. In particular, the composition and dermal sensitization data addressed the key information gaps identified in the original assessment.[2,3]

Preparation information described harvesting of the algae, followed by washing, hot-water extraction, and filtration to produce the cosmetic ingredient. The material was described as a pale-yellow liquid that was freely soluble in water. Compositional analysis of a spray-dried sample prepared from Cladosiphon Novae-Caledoniae Extract identified fucose (39.1%), sulfate (19.3%), and glucuronic acid (14.2%) as the major reported constituents, together with smaller amounts of other monosaccharides and inorganic constituents.

The toxicological studies were conducted using undiluted Cladosiphon Novae-Caledonia Extract (approximately 1.2% fucoidan preserved with 0.5% phenoxyethanol). In an acute oral toxicity study, the oral LD_{50} in rats was $\geq$ 2000 mg/kg. The extract was not mutagenic in an Ames assay at concentrations up to 5000 µg/plate, with or without metabolic activation, and did not induce structural or numerical chromosomal abnormalities in CHL/IU cells at concentrations up to 5 mg/ml under treatment conditions without S9. No evidence of dermal irritation, ocular irritation, phototoxicity, or photosensitization was observed in studies using the undiluted test material, and the extract was not a sensitizer in a guinea pig maximization test.

Additionally, an HRIPT conducted in 107 subjects using undiluted Cladosiphon Novae-Caledoniae Extract (approximately 1.2% fucoidan preserved with 0.5% phenoxyethanol) under occlusive or semi-occlusive conditions, with nine induction applications followed by a challenge application, produced no evidence of dermal irritation or sensitization.

The Panel reviewed these additional data and determined that the available information is sufficient to assess the safety of Cladosiphon Novae-Caledoniae Extract in the present practices of use and concentration described in the original safety assessment. In particular, the Panel considered the composition data, which adequately characterized the ingredient, together with the negative findings from the HRIPT, to address the data gaps identified in the original safety assessment. Accordingly, the Panel concluded that Cladosiphon Novae-Caledoniae Extract is safe in cosmetics in the present practices of use and concentration described in the safety assessment.

References

1. Ferguson P, Becker L, Bergfeld WF, et al. Safety Assessment of Brown Algae-Derived Ingredients as Used in Cosmetics. *Int J Toxicol*. 2026;45(2_suppl):5S–86S.

2. Anonymous. 2024. Safety study summary - Cladosiphon Novae-Caledoniae Extract. [Unpublished data submitted by Personal Care Products Council on December 5, 2024].

3. Anonymous. 2022. Preparation and composition of Cladosiphon Novae-Caledonia Extract. [Unpublished data submitted by Personal Care Products Council on December 5, 2024].