
Safety Assessment of Alkyl Amide MIPA ingredients as Used in Cosmetics

Status: Draft Report for Panel Review
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The 2019 Cosmetic Ingredient Review Expert Panel members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Ronald A. Hill, Ph.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Alice Akinsulie, Scientific Analyst/Writer.

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review (CIR)

FROM: Alexandra Kowcz, MS, MBA
Industry Liaison to the CIR Expert Panel

DATE: February 15, 2019

SUBJECT: Scientific Literature Review: Safety Assessment of Alkyl Amide MIPA
Ingredients (release date January 28, 2019)

The Council respectfully submits the following comments on the scientific literature review, Safety Assessment of Alkyl Amide MIPA Ingredients as Used in Cosmetics.

The Council has no suppliers listed for the following ingredients included in this report:

Linoleamide MIPA	Ricinoleamide MIPA
Myristamide MIPA	Stearamide MIPA
Palmamide MIPA	MIPA-Myristate
Palm Kernelamide MIPA	

Key Issues

As much of the information in the report is from the ECHA dossier on Oleamide MIPA, in the Introduction, it would be helpful to indicate that a source of information was the third party summaries found in the dossier.

Additional Considerations

Introduction - Please define MIPA in the Introduction.

Cosmetic Use - It should be made clear that the only ingredient in the CIR report associated with EU Annex III number 61 (monoalkanolamines) is MIPA-Myristate.

DART - Please indicate that the second study was an OECD 422 guideline study.

Effect on Cell Proliferation and Apoptosis, Summary - The OECD 408 guideline study is a 90-day oral study. This study should be presented in the Subchronic section, not in a separate section under other relevant studies. Although the Summary states: "There were no changes in cell proliferation and apoptosis attributed to the test article." There is no statement regarding cell proliferation and apoptosis earlier in the report. More details about the results of this study (especially about liver and bone marrow histopathologic changes) should be included in the CIR report.

Summary - The concentration tested in the guinea pig maximization study should be stated in the Summary.

Reference 8 - Please correct "dossiee"

Reference 11 - Please correct "nomoalkanolamines"