
Safety Assessment of Hydrolyzed Wheat Protein and Hydrolyzed Wheat Gluten as Used in Cosmetics

Status: Draft Final Report for Panel Review
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The 2014 Cosmetic Ingredient Review Expert Panel members are: Chairman, 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 Director is Lillian J. Gill, DPA. This report was prepared by Christina Burnett, Scientific Analyst/Writer, Bart Heldreth, Ph.D., Chemist CIR, and Ivan Boyer, Ph.D., Toxicologist CIR.

Cosmetic Ingredient Review

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Memorandum

To: CIR Expert Panel Members and Liaisons
From: Christina L. Burnett, Scientific Writer/Analyst
Ivan Boyer, Senior Toxicologist
Date: February 21, 2014
Subject: Draft Final Safety Assessment of Hydrolyzed Wheat Protein and Hydrolyzed Wheat Gluten

At the September 2013 meeting, the Panel issued a tentative safety assessment of hydrolyzed wheat gluten and hydrolyzed wheat protein with the conclusion that these ingredients are safe for use in cosmetics when formulated to minimize peptide lengths greater than 30 amino acids. Additionally, these ingredients should not be used on damaged skin or in products that may come into contact with mucous membranes or may be incidentally inhaled.

The Panel asked that the cosmetics industry continue to provide additional data on manufacturing practices, characterization methods, and composition, including peptide size distributions, to enable better characterization of the nature and variability of these ingredients as used in cosmetic products and to enable the Panel to refine its conclusion. Since the September meeting, no additional new unpublished data were received.

Comments received from the Council prior to the September meeting and on the tentative safety assessment have been considered. These comments are in the panel book package for your review. The Council requested that information on wheat gluten (non-hydrolyzed) be incorporated into this report and that the Panel consider a re-review of the safety assessment of *Triticum Vulgare* (wheat) protein and *Triticum Vulgare* (wheat) germ protein.

CIR staff disagrees with the Council's suggestion that the Panel's conclusion for hydrolyzed wheat protein and hydrolyzed wheat gluten indicates that a re-review may be warranted for wheat protein and wheat germ protein, as used in cosmetics. This is because hydrolysis, particularly acid hydrolysis, can be expected to yield products that are significantly different in their chemical properties and potential bioavailability and bioactivity from the starting material (i.e., "whole" or "intact" wheat protein or gluten prepared by extraction methods that typically would be mild compared to hydrolysis). These products will likely differ from the relatively "intact" or "whole" proteins from which they were derived, in water solubility, degree of deamidation, molecular weights, and other properties. Such differences are reflected, for example, in the extensive spreading in electrophoresis gels of the products of hydrolysis, compared with the "whole" or "intact" proteins of the corresponding starting materials in the gels.

Further, the current evidence indicates that the potential for developing wheat-dependent exercise-induced type 1 hypersensitivity through percutaneous and rhinoconjunctival exposures is associated specifically with the use of hydrolyzed wheat protein or hydrolyzed wheat gluten, not with wheat protein and wheat germ protein, in cosmetics or other personal care products. There is no evidence that we could find that topical application of "whole" or "intact" wheat protein or gluten preparations can sensitize people, or elicit hypersensitivity responses from people already sensitized to "whole" or "intact" wheat proteins or gluten. In contrast, all of the available evidence indicates that hydrolyzed wheat protein or hydrolyzed wheat gluten preparations, particularly those with substantial fractions of products having relatively "high" molecular weights (e.g., enzyme hydrolysis products with MW >1050 Da, in one study) appear to have non-negligible capacities to sensitize and elicit hypersensitivity responses from people.

Per the Panel's request for expert insight on reports of type 1 hypersensitivity reactions to hydrolyzed wheat protein/gluten through percutaneous/rhinoconjunctival exposure, two speakers have been scheduled to speak prior to the team deliberations: Dr. Dass Chahal, Research & Technology Director of Sun Care & Biotechnology, Croda Europe, Ltd. and Dr. Kayoko Matsunaga, Professor and Chairperson of the Department of Dermatology at Fujita Health University School of

Medicine. Following the presentations and Q&A of the speakers, the Panel should carefully review the abstract and discussion, and determine if the conclusion is appropriate. The Panel should issue a Final Safety Assessment.

Hydrolyzed Wheat Protein and Hydrolyzed Wheat Gluten Data Profile* – March 2014
Writer, Christina Burnett

	Reported Use	Composition/ Impurities	Method of Manufacturing	Irritation/ Sensitization - Animal	Irritation/ Sensitization - Human	Ocular/ Mucousal	Case Studies
Hydrolyzed Wheat Gluten	X						
Hydrolyzed Wheat Protein	X	X	X	X	X	X	X

*"X" indicates that data were available in a category for the ingredient

