
Safety Assessment of Benzyl Salicylate As Used in Cosmetics

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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 Writer/Analyst.

Cross-Reactivity, Summary - This section says the subjects were induced with "hexyl salicylate". In contrast, the Summary states that the subjects were induced with "cyclohexyl salicylate". Which compound was studied?

Phototoxicity/Photosensitization, Table 5 - The table number needs to be added to the sentence that refers to the table. The study in humans should be added to Table 5. If this study is not added to Table 5, the sentence indicating that the studies are presented in the table should be moved after the Animal subheading.

Please provide references and a description of the light exposure for the studies in Dunkin Hartley guinea pigs (20 in the phototoxicity test; 25 in the photosensitization study).

Retrospective and Multicenter Studies - Is reference 36 the correct reference for the perfume screening study in 241 patients? The title given in the reference section is: "Cinnamic aldehyde test concentration".

Retrospective and Multicenter Studies, Summary - The section summarizing retrospective and multicenter studies describes a study with Oxisoralen, while the Summary describes a study with trioxsalen. Are these supposed to be the same study?

Clinical Studies, Photoallergy - The light exposure should be described.

Summary - What species was used in a maximization pre-test in which 30% Benzyl Salicylate was administered in closed patch for 48 hours?

Table 4, Sensitization, Animal - In the description of reference 30, it is not clear that there was an intradermal injection. The first column describes an intradermal concentration, but the Procedure column only describes dermal induction patches.

Table 4, Sensitization, Human - If available, please provide patch sizes or mg/cm² doses. In the first study in this section, it is not clear why the duration of "approximately three weeks" needs to be stated twice. In the second study, please correct: "administrated"

Table 5 - The time of examination and the method of grading should be in the Procedure column not the Results column. Hartley Dunkin needs to be corrected to Dunkin Hartley. The light exposure should be stated for each study in this table.