
Safety Assessment of Capryloyl Salicylic Acid as Used in Cosmetics

Status: Draft Amended Report for Panel Review
Release Date: May 10, 2019
Panel Date: June 6-7, 2019

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 report was prepared by Wilbur Johnson, Jr., M.S., Senior Scientific Analyst.

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In Vitro

The genotoxicity of Capryloyl Salicylic Acid (in ethanol) was evaluated in the Ames test using the following bacterial strains, with and without metabolic activation: *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA1537 and *Escherichia coli* strain WP2 uvr A.³ Doses up to 1000 µg/plate were tested, and the test material was classified as non-genotoxic. The mammalian chromosome aberration test involving Chinese hamster ovary cells (with and without metabolic activation) was used to evaluate the genotoxicity of Capryloyl Salicylic Acid (in ethanol) at concentrations of 50 µg/mL and 80 µg/mL.⁴ The test material was classified as clastogenic with, but not without, metabolic activation.

In Vivo

The genotoxicity of Capryloyl Salicylic Acid (in 0.5% carboxymethylcellulose aqueous vehicle) was evaluated in the micronucleus test using groups of 10 (5 males, 5 females per group) mice of the CD-1 strain.³ A single dose of the test substance (250, 500, and 1000 mg/kg) was administered by gavage to the 3 groups, respectively. The test material was classified as non-clastogenic. In a second micronucleus test, Capryloyl Salicylic Acid (in 0.5% aqueous carboxymethylcellulose) was administered to groups of 10 (5 males, 5 females per group) Swiss CD-1 mice.⁴ A single dose of the test material (500, 1000, and 2000 mg/kg) was administered by gavage to the 3 groups, respectively. A slight increase in the polychromatic erythrocytes (PCEs)/normochromatic erythrocytes (NCEs) ratio was observed in males of the 2000 mg/kg dose group, only at the 24-h sampling time. This finding was indicative of an inhibitory effect on erythropoietic cell division. Results indicated that the test material was non-clastogenic in this assay. (Results relating to the acute oral toxicity of this test material are included in that section of this report.) The unscheduled DNA synthesis test was also used to evaluate the genotoxicity of Capryloyl Salicylic Acid (in 0.5% aqueous carboxymethylcellulose), using groups of 4 Sprague-Dawley rats.⁴ In 2 tests, single doses of 500, 1000, and 2000 mg/kg were administered by gavage, and the test material was classified as non-clastogenic in both. (Results relating to acute oral toxicity are included in that section of this report.)

CARCINOGENICITY STUDIES

Data on the carcinogenicity of Capryloyl Salicylic Acid were neither found in the published literature, nor were these data submitted.

DERMAL IRRITATION AND SENSITIZATION STUDIES

The skin irritation and sensitization studies summarized below are presented in detail in Table 4.

The skin irritation potential of Capryloyl Salicylic Acid was evaluated in an occlusive patch test using 3 male New Zealand White rabbits.³ The animals were patch tested with 0.5 g of the test material, and results were negative. In a study involving groups of 5 female rats of the CrI:CD(SD)BR (VAF plus) strain, Capryloyl Salicylic Acid (in PEG-6) was applied to the back (constant volume of 2 mL/kg) once daily for 10 days. The test material was applied at concentrations of 2% and 5%; only the 5% concentration caused very slight erythema (in 2 to 5 rats) and edema (3 or 4 rats). Minimal/moderate scabbing at the application site was also observed. (Additional results from this study are included in the Short-Term Dermal Toxicity section of this report.) Skin irritation data are reported in a developmental toxicity study (described previously) on Capryloyl Salicylic Acid (in PEG-6) involving 2 groups of 24 pregnant female Sprague-Dawley rats.³ The test material was applied to skin of the back (2 groups) at doses of 40 mg/kg/day and 100 mg/kg/day, respectively, on gestation days 6 to 15. Erythema and eschar formation were observed in both groups (number of animals not stated), the severity of which was dose-related. Slight edema was also reported, and scabbing and/or reddening at test sites was observed at necropsy.

Reactions described as cutaneous signs of slight intensity were observed in 5 of 49 subjects after application of a face product containing 0.3% Capryloyl Salicylic Acid to the face and eye contour twice daily for 4 weeks.⁴

The skin sensitization potential of Capryloyl Salicylic Acid (in peanut oil) was evaluated in the guinea pig maximization test, using 20 female Dunkin-Hartley guinea pigs.³ Induction involved intradermal injection and topical application of 1% and 0.5% concentrations, respectively. This was followed by challenge with 0.5% (occlusive patch). The test material was classified as a skin sensitizer. In another maximization test, 20 guinea pigs were tested with Capryloyl Salicylic Acid (in ethanol).⁴ Induction involved intradermal injection and topical application of 0.5% and 10% concentrations, respectively. There were no signs of skin irritation during induction at concentrations of 0.5% (injected intradermally) and 10% (topical application). The animals were challenged with 2%. Sensitization reactions were observed (at 24 h and 48 h) at the application sites of 5 guinea pigs. However, these findings were classified as limited evidence of skin sensitization. The skin sensitization potential of Capryloyl Salicylic Acid (in PEG-300) was also evaluated in the maximization test, using 20 guinea pigs.⁴ The induction phase involved concentrations of 25%, 15%, and 10%. When a

Table 3. Genotoxicity Studies on Capryloyl Salicylic Acid.

Ingredient	Strain/cell type	Assay	Dose/Concentration	Results
<i>In Vitro</i>				
Capryloyl Salicylic Acid (in ethanol)	<i>Salmonella typhimurium</i> strains TA98, TA100, TA1535, and TA1537 and <i>Escherichia coli</i> strain WP2 uvr A.	Ames test, with and without metabolic activation. Test protocol equivalent or similar to OECD TG 471. Controls: vehicle (ethanol); positive, without metabolic activation (2-aminoacridine, 2-nitrofluorene, and sodium azide); and positive, with metabolic activation (2-aminoanthracene and 4-nitroquinoline-1-oxide)	1 st experiment: doses up to 1000 µg/plate (with and without metabolic activation). 2 nd experiment: doses up to 100 and 200 µg/plate (without metabolic activation)	No substantial increases in revertant colony numbers over vehicle control count in any bacterial strain. Non-genotoxic. ³
Capryloyl Salicylic Acid (in ethanol)	Chinese hamster ovary cells	Mammalian chromosome aberration test, with and without metabolic activation. Controls: vehicle (ethanol) and positive (mitomycin C and cyclophosphamide). Exposure and harvest times not reported.	Two experiments performed at concentrations up to 50 mg/mL and 80 mg/mL, respectively.	1 st test (with metabolic activation): statistically significant increases in chromosome aberrations at 1 st harvest observed at 50 µg/mL. (actual frequency was within background for this cell line). 2 nd test (with metabolic activation): statistically significant increases in chromosome aberrations at 1 st harvest observed at 80 µg/mL (actual frequency was above background for this cell line). No statistically significant increases in chromosome aberrations without metabolic activation. Results for positive controls confirmed validity of the test system. Clastogenic to Chinese hamster ovary cells. ⁴
<i>In Vivo</i>				
Capryloyl Salicylic Acid (0.5% in carboxymethylcellulose)	Groups of 10 (5 males, 5 females per group) mice of the CD-1 strain	Micronucleus test. Protocol similar to OECD TG 474, with minor deviations. Vehicle control group dosed with carboxymethylcellulose, and positive control group dosed with mitomycin C (injected intraperitoneally). Animals killed at 24 h, 48 h, and 72 h post-dosing. Bone marrow cells obtained and analyzed for micronuclei. Minimum of 1000 polychromatic erythrocytes (PCE) counted per animal.	3 groups received single oral doses (by gavage) of 250, 500, and 1000 mg/kg, respectively.	Micronuclei not induced at any administered dose of test material, despite decrease in PCE/normochromatic erythrocytes at dose of 1000 mg/kg at 24 h. Test material was non-clastogenic. Positive control induced appropriate increase in number of PCE. ³
Capryloyl Salicylic Acid (in 0.5% aqueous carboxymethylcellulose)	Groups of 10 (5 males, 5 females per group) Swiss CD-1 mice	Micronucleus test. Performed in accordance with OECD TG 474. Vehicle control group dosed with carboxymethyl-cellulose, and positive control group dosed with mitomycin C.	3 groups received single oral doses (by gavage) of 500, 1000, and 2000 mg/kg, respectively.	A slight increase in the polychromatic erythrocytes (PCEs)/normochromatic erythrocytes (NCEs) ratio was observed in males of the 2000 mg/kg dose group, only at the 24-h sampling time. No statistically significant increases in frequency of micronucleated PCEs. Test material was non-clastogenic. Positive and negative controls yielded satisfactory response, confirming validity of test system. ⁴

Table 3. Genotoxicity Studies on Capryloyl Salicylic Acid.

Ingredient	Strain/cell type	Assay	Dose/Concentration	Results
Capryloyl Salicylic Acid (in 0.5% aqueous carboxymethylcellulose)	Groups of 4 Sprague-Dawley rats	Unscheduled DNA synthesis test. Performed in accordance with OECD TG 486. Vehicle control group dosed with carboxymethylcellulose, and 2-acetamidofluorene and methylnitrosourea served as positive controls.	In 2 tests, single doses of 500, 1000, and 2000 mg/kg were administered by gavage. In the 2 tests, animals were killed at 14 h and 2 h, respectively.	Treatment with the test material did not produce group mean net grain value that was greater than -0.88, and no more than 6% of the cells were found in repair. Test material was non-clastogenic. Positive and negative controls yielded satisfactory response, confirming validity of test system. ⁴

Table 4. Skin Irritation and Sanitization Studies on Capryloyl Salicylic Acid.

Test Substance	Animals/Subjects	Test Protocol	Results
Irritation (Animal)			
Capryloyl Salicylic Acid	3 male New Zealand White rabbits	OECD TG 404. Occlusive patch containing test material (0.5 g moistened with distilled water (0.5 ml)) applied for 4 h to 6.25 cm ² area on dorsal flank. Skin irritation evaluated according to Draize scale at 24 h, 48 h, and 72 h after patch application.	No skin irritation at any time after patch application. Test material classified as non-irritant. ³
Capryloyl Salicylic Acid (in PEG 300) tested at concentrations of 2% and 5%.	5 female rats of the CrI:CD(SD)BR (VAF plus) strain	Test protocol similar to OECD TG 410. Applied for 6 h directly to the back (not less than 10% of body area; constant volume of 2 ml/kg) once daily (for 10 days) at each concentration	In group that received 5% concentration, very slight erythema observed in 2 to 5 animals throughout dosing period (beginning at day 6), and well-defined erythema observed in 1 female between days 8 and 10 of dosing period. Very slight edema observed in 3 or 4 animals treated with 5%, beginning at day 7, and scabbing (minimal/moderate; observed at necropsy) at application site observed in all animals treated with 5%. ³
Irritation (Human)			
Face product containing a 0.3% Capryloyl Salicylic Acid	49 subjects	Product applied to face and eye contour twice a day for 4 weeks.	Cutaneous signs of slight intensity were observed in 5 subjects. ⁴
Sensitization (Animal)			
Capryloyl Salicylic Acid (in arachis oil), tested during induction (1% and 0.5%) and challenge (2%)	30 female Dunkin-Hartley guinea pigs (20 test and 10 controls)	OECD TG 406. Guinea pig maximization test. Initially, following 3 pairs of intradermal induction injections (0.1 ml per injection) made in group of 20 animals: 1:1 mixture of Freund's complete Adjuvant in distilled water; 1% (w/v) dilution of test material in arachis oil; and 1% (w/v) dilution of test material in a 1:1 preparation of Freund's complete Adjuvant and arachis oil. These intradermal injections comprise 2 induction exposures during an exposure period of 7 days + 48 h. One week later, a 48-h topical application (induction) of 0.2 to 0.3 ml of 0.5% (w/w) test material in arachis oil over injection sites (shoulder region). At 2 weeks post-topical induction, a 24-h epicutaneous challenge with 2% (w/w) test material in arachis oil (occlusive patch) involved the left flank. Dose per cm ² for induction and challenge applications not stated. Challenge reactions scored at 24 h and 48 h. Positive and vehicle controls were 2,4-dinitrochlorobenzene and arachis oil, respectively.	Positive reactions observed in 14 of 20 guinea pigs at 24 h after challenge. At 48 h, 4 guinea pigs had positive reactions. Test material classified as skin sensitizer because more than 30% of total number of guinea pigs tested (i.e., 70%) had positive response. Control animals treated with arachis oil did not have positive reactions. Positive control (2,4-dinitrochlorobenzene) induced sensitization. ³

Table 4. Skin Irritation and Sanitization Studies on Capryloyl Salicylic Acid.

Test Substance	Animals/Subjects	Test Protocol	Results
Capryloyl Salicylic Acid (in ethanol), tested during induction (10% and 0.5%) and challenge (2%)	30 female Dunkin-Hartley guinea pigs (20 test and 10 controls)	Method similar to OECD TG 406. Guinea pig maximization test. During induction, animals injected intradermally with concentration of 0.5%, and received topical applications at a concentration of 10%. Challenged with a concentration of 2%. The dose per cm ² for induction and challenge applications was not stated. Challenge reactions were scored at 24 h and 48 h.	No signs of skin irritation during induction at concentrations of 0.5% (injected intradermally) and 10% (topical application). Positive (sensitization) reactions observed (at 24 h and 48 h) at the application sites of 5 guinea pigs. Classified as limited evidence of reactions indicative of skin sensitization. Adverse skin reactions not observed in control animals. ⁴
Capryloyl Salicylic Acid (in PEG 300), tested during induction (25%, 15%, and 10%) and challenge (5%)	30 female Dunkin-Hartley guinea pigs (20 test and 10 controls)	OECD TG 406 (no significant protocol deviations). Guinea pig maximization test. During induction, test material applied topically at concentration of 25%. Due to severity of skin reactions after first induction application, concentration reduced to 15% for 2 nd induction, and to 10% for last induction. Animals challenged topically with a test substance concentration of 5%. Dose per cm ² for induction and challenge applications not stated. Challenge reactions scored at 24 h and 48 h.	When a concentration of 25% was applied, several test animals (number not stated) had erythema scores of 2 or more at the application site after the first induction application. At 24 h, positive (sensitization) reactions observed at application sites of 2 animals. Positive reactions not observed in any animals at 48 h. Reactions classified as limited evidence of reactions indicative of skin sensitization. Adverse skin reactions not observed in control animals. ⁴
Capryloyl Salicylic Acid (in 0.5% aqueous methylcellulose), tested at 1% (induction and challenge)	Dunkin-Hartley guinea pigs (test: 10 males, 10 females; controls: 5 males, 5 females)	OECD TG 406. Guinea pig maximization test. Topical application during induction, followed by topical challenge. Dose per cm ² for induction and challenge applications not stated. Challenge reactions scored at 24 h and 48 h. Ten positive control animals tested with 2,4-dinitrochlorobenzene.	Skin reactions not observed in any test animals during induction or challenge. No evidence of adverse skin reactions in negative control animals. Test material classified as non-sensitizer. Sensitization in 3 of 10 positive control animals. ⁴ [Results relating to short-term dermal toxicity in that section of this report.]
Sensitization (Human)			
Face serum product containing a 0.5% Capryloyl Salicylic Acid	106 subjects	HRIPT. During induction, occlusive patches containing 0.02 mL of product applied (50 mm ² area; application site not stated) 3 times per week (Tuesdays, Thursdays, and Saturdays) for total of 9 applications. Patches removed after 48 h (or 72 h for patches applied on Saturday). Sites graded 15 to 20 min after patch removal. Challenge phase initiated after 13-day non-treatment period. Challenge patch containing 0.02 mL of product applied to previously treated site and to new site for 48 h. Patch alone applied to new site served as negative control. Reactions scored at least 30 min and ~ 48 h after patch removal.	Slight skin irritation observed in a few subjects (number not stated) during induction phase and at first challenge reading. Sensitization not observed at 1 st challenge reading, and no adverse responses observed at final challenge reading. Product classified as non-sensitizer. ⁴ [
Face serum product containing a 0.5% Capryloyl Salicylic Acid	105 subjects.	HRIPT. During induction, occlusive patches containing 0.02 mL of product applied (50 mm ² area; application site not stated) 3 times per week (Mondays, Wednesdays, and Fridays) for total of 9 applications. Patches removed after 48 h, and reactions scored prior to next patch application. Challenge phase initiated after 10 to 14-day non-treatment period. Challenge patch containing 0.02 ml of product applied to previously treated site and to new site for 48 h, after which reactions. Reactions also scored at 72 h and 96 h post-application.	No evidence of adverse responses during induction or challenge. Product classified as non-sensitizer. ⁴

Table 4. Skin Irritation and Sanitization Studies on Capryloyl Salicylic Acid.

Test Substance	Animals/Subjects	Test Protocol	Results
Cream product containing a 0.5% Capryloyl Salicylic Acid	104 subjects	HRIPT performed according to L'Oreal general protocol. Occlusive patches containing 0.02 mL of product applied to 50 mm ² area. Details relating to test protocol not included.	No evidence of adverse responses during induction or challenge. Product classified as non-sensitizer. ⁴
Fluid cream product containing a 0.5% Capryloyl Salicylic Acid	106 subjects	HRIPT performed according to L'Oreal general protocol. Occlusive patches containing 0.02 mL of product applied to 50 mm ² area. Details relating to test protocol not included.	No evidence of adverse responses during induction or challenge. Product classified as non-sensitizer. ⁴
Cosmetic product containing a 2% Capryloyl Salicylic Acid	102 subjects	HRIPT. During induction, semi-occlusive patches containing 0.2 mL of product applied (4 cm ² area; application site not stated) 3 times per week (Tuesdays, Thursdays, and Saturdays) for total of 9 applications. Patches removed after 48 ± 4 h (or 72 ± 4 h for patches applied on Saturday). Sites graded 15 to 30 min after patch removal. Challenge phase initiated after 13-day non-treatment period. Challenge patch containing 0.2 ml of product applied to previously treated site and to a new site for 48 ± 4 h. Patch alone applied to new site served as negative control. Reactions scored 30 to 35 min and ~ 48 ± 4 h after patch removal.	Slight skin irritation observed in a few subjects (number not stated) during induction phase and at first challenge reading. Sensitization not observed at 1 st challenge reading, and no adverse responses observed at final challenge reading. Product classified as non-sensitizer. ⁴
Face powder containing a 2 % Capryloyl Salicylic Acid	105 subjects	During induction, occlusive patches containing 0.02 mL of product applied (50 mm ² area; application site not stated) 3 times per week (Mondays, Wednesdays, and Fridays) for total of 9 applications. Patches removed after 48 h, and reactions scored prior to next patch application. Challenge phase initiated after 10- to 14-day non-treatment period. Challenge patch containing 0.02 ml of product applied to previously treated site and to new site for 48 h, after which reactions scored. Reactions also scored at 72 h and 96 h post-application.	No evidence of adverse responses during induction or challenge phases. Product classified as non-sensitizer. ⁴
Deodorant aerosol product containing a 2% Capryloyl Salicylic Acid	103 subjects	HRIPT. During induction, occlusive patches containing 0.02 mL of product applied (50 mm ² area; application site not stated) 9 times over period of 3 consecutive weeks. Patches removed after 48 h, and reactions scored prior to next patch application. Challenge phase initiated after 2-week non-treatment period. Challenge patch containing 0.02 ml of product applied to previously treated site and to new site for 48 h, after which reactions scored. Reactions also scored at 72 h and 96 h post-application. Patch alone applied to new site served as negative control.	No evidence of adverse responses during induction or challenge. Product classified as non-sensitizer. ⁴

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2019 VCRP Data

Capryloyl Salicylic Acid

03D - Eye Lotion	5
03G - Other Eye Makeup Preparations	4
07I - Other Makeup Preparations	1
11G - Other Shaving Preparation Products	2
12A - Cleansing	9
12C - Face and Neck (exc shave)	24
12D - Body and Hand (exc shave)	4
12F - Moisturizing	24
12G - Night	10
12J - Other Skin Care Preps	20
13C - Other Suntan Preparations	1
Total	104