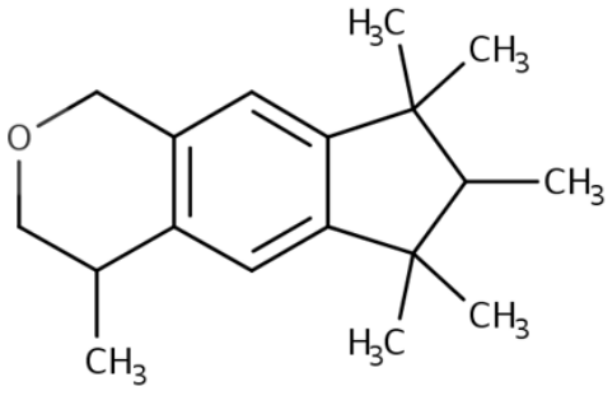
United States
Environmental Protection Agency

March 2026
Office of Chemical Safety and
Pollution Prevention

Draft Data Quality Evaluation Information for Human Health Hazard Epidemiology for 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[γ]-2-benzopyran (HHCB)

Systematic Review Support Document for the Draft Risk Evaluation

CASRN: 1222-05-5



March 2026

This supplemental file contains the data quality evaluation results for epidemiology data sources that met the PECO screening criteria and further filtering criteria for the *Draft Human Health and Environmental Hazard Assessment for 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [γ]-2-benzopyran (HHCB)* . EPA conducted data quality evaluation based on author-reported descriptions and results; additional analyses (*e.g.*, statistical analyses performed during data integration into the risk evaluation) potentially conducted by EPA are not contained in this supplemental file. EPA used the TSCA systematic review process described in the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (also referred to as '2021 Draft Systematic Review Protocol'). Any updated steps in the systematic review process since the publication of the 2021 Draft Systematic Review Protocol are described in the *Draft Systematic Review Protocol for 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [γ]-2-benzopyran (HHCB)*.

Table of Contents

Study Citation:	An, S. S., Lee, A. Y., Lee, C. H., Kim, D. W., Hahm, J. H., Kim, K. J., Moon, K. C., Won, Y. H., Ro, Y. S., Eun, H. C. (2005). Fragrance contact dermatitis in Korea: a joint study. Contact Dermatitis 53(6):320-323.
Health Outcome(s) Assessed:	Sensitization-Irritation
Reported Health Effect(s):	Irritation
Chemical:	HHCB- Parent compound
HERO ID:	2910944

Domain	Metric		Rating	Comments
Domain 1: Randomization				
	Metric 1A:	Was an adequate method used to randomize the administered dose or exposure level?	Medium	Randomization is not applicable; in this study all participants were exposed to each of the study chemicals. There was no randomization to a placebo group.
Domain 2: Allocation Concealment and Blinding				
	Metric 2A:	Was allocation to study groups adequately concealed until recruitment was complete?	Medium	In this intentional dosing study, participants were exposed to each study chemical using the same protocol. There was no allocation to different groups. However,
	Metric 2B:	Were the research personnel and human subjects blinded to the study group during the study?	Low	Insufficient information is provided on blinding of outcome assessors. Patch test results are interpreted results rather than a measured or machine-reported value, thus a lack of blinding could potentially bias the results. Participants were exposed to the same chemicals using the same study protocols.
Domain 3: Attrition				
	Metric 3A:	Were outcome data complete without attrition or exclusion from analysis?	High	No attrition was reported. All 422 participants appear to have been exposed to each of the study chemicals and there were no reported exclusions.
Domain 4: Exposure Measurement Bias				
	Metric 4A:	Can we be confident in the exposure characterization?	Low	Insufficient information was provided on the purity and stability of the test substance. HHCB was supplied by “International Flavours and Fragrances” at a concentration of 5%. No further information on the test substance is provided. HHCB (galaxolide) was applied via skin patch.
Domain 5: Outcome Assessment				
	Metric 5A:	Can we be confident in the outcome assessment?	Low	Insufficient information is provided regarding the patch-testing procedures. The authors note only that “Finn Chambers on Scanpor tape (Epitest, Tuusula, Finland)” were used. No further details are given and the timing of outcome evaluation is not reported. Although the authors state that “results were evaluated according to the recommendations of the International Contact Dermatitis Research Group,” the study does not provide the specific criteria nor definitions of positive cases. It is also unclear whether outcome assessors received any training. It is unclear whether the outcomes were assessed as irritation or sensitization responses, as results are only reported as ”positive” reactions with no clear point in time.

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Chemical:	HHCB- Parent compound
HERO ID:	2910944

Domain	Metric	Rating	Comments
	Metric 5B: Selective Reporting: Were all measured outcomes reported?	Medium	Outcomes (number and percentage of positive cases) are reported for HHCB and other "commonly positive fragrance materials."

Additional Comments: In this intentional dosing study, patch tests were conducted on 422 participants in 9 university hospitals in Korea and 1 cosmetics company between April 2002 to June 2003. Insufficient information on the study protocol, including blinding and purity of the test substance, was provided. Positive patch test results were observed in 1.2% of participants following exposure to HHCB; however it is not clear whether the positive patch test results represent an irritation or sensitization response.

Overall Quality Determination Low

Study Citation:	An, S. S., Lee, A. Y., Lee, C. H., Kim, D. W., Hahm, J. H., Kim, K. J., Moon, K. C., Won, Y. H., Ro, Y. S., Eun, H. C. (2005). Fragrance contact dermatitis in Korea: a joint study. Contact Dermatitis 53(6):320-323.
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Reported Health Effect(s):	Irritation
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HERO ID:	2910944

Domain	Metric		Rating	Comments
Domain 1: Randomization				
	Metric 1A:	Was an adequate method used to randomize the administered dose or exposure level?	Medium	Randomization is not applicable; in this study all participants were exposed to each of the study chemicals. There was no randomization to a placebo group.
Domain 2: Allocation Concealment and Blinding				
	Metric 2A:	Was allocation to study groups adequately concealed until recruitment was complete?	Medium	In this intentional dosing study, participants were exposed to each study chemical using the same protocol. There was no allocation to different groups. However,
	Metric 2B:	Were the research personnel and human subjects blinded to the study group during the study?	Low	Insufficient information is provided on blinding of outcome assessors. Patch test results are interpreted results rather than a measured or machine-reported value, thus a lack of blinding could potentially bias the results. Participants were exposed to the same chemicals using the same study protocols.
Domain 3: Attrition				
	Metric 3A:	Were outcome data complete without attrition or exclusion from analysis?	High	No attrition was reported. All 422 participants appear to have been exposed to each of the study chemicals and there were no reported exclusions.
Domain 4: Exposure Measurement Bias				
	Metric 4A:	Can we be confident in the exposure characterization?	Low	Insufficient information was provided on the purity and stability of the test substance. HHCB was supplied by “International Flavours and Fragrances” at a concentration of 5%. No further information on the test substance is provided. HHCB (galaxolide) was applied via skin patch.
Domain 5: Outcome Assessment				
	Metric 5A:	Can we be confident in the outcome assessment?	Low	Insufficient information is provided regarding the patch-testing procedures. The authors note only that “Finn Chambers on Scanpor tape (Epitest, Tuusula, Finland)” were used. No further details are given and the timing of outcome evaluation is not reported. Although the authors state that “results were evaluated according to the recommendations of the International Contact Dermatitis Research Group,” the study does not provide the specific criteria nor definitions of positive cases. It is also unclear whether outcome assessors received any training. It is unclear whether the outcomes were assessed as irritation or sensitization responses, as results are only reported as ”positive” reactions with no clear point in time.
	Metric 5B:	Selective Reporting: Were all measured outcomes reported?	Medium	Outcomes (number and percentage of positive cases) are reported for HHCB and other “commonly positive fragrance materials.”

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Domain	Metric	Rating	Comments
Additional Comments:	In this intentional dosing study, patch tests were conducted on 422 participants in 9 university hospitals in Korea and 1 cosmetics company between April 2002 to June 2003. Insufficient information on the study protocol, including blinding and purity of the test substance, was provided. Positive patch test results were observed in 1.2% of participants following exposure to HHCB; however it is not clear whether the positive patch test results represent an irritation or sensitization response.		

Overall Quality Determination Low

Study Citation:	Larsen, W., Nakayama, H., Fischer, T., Elsner, P., Frosch, P., Burrows, D., Jordan, W., Shaw, S., Wilkinson, J., Marks, J., Sugawara, M., Nethercott, M., Nethercott, J. (2001). Fragrance contact dermatitis: a worldwide multicenter investigation (Part II). Contact Dermatitis 44(6):344-346.
Health Outcome(s) Assessed:	Sensitization-Irritation
Reported Health Effect(s):	Irritation
Chemical:	HHCB- Parent compound
HERO ID:	5428193 Linked HERO ID(s): 5428193, 8900562, 8900573

Domain	Metric		Rating	Comments
Domain 1: Randomization				
	Metric 1A:	Was an adequate method used to randomize the administered dose or exposure level?	Medium	Randomization is not applicable; in this study all participants were exposed to each of the study chemicals. There was no randomization to a placebo group.
Domain 2: Allocation Concealment and Blinding				
	Metric 2A:	Was allocation to study groups adequately concealed until recruitment was complete?	Medium	In this intentional dosing study, participants were exposed to each study chemical using the same protocol. There was no allocation to different groups. Therefore, lack of adequate allocation concealment would not appreciably bias results.
	Metric 2B:	Were the research personnel and human subjects blinded to the study group during the study?	Low	Insufficient information is provided on blinding of outcome assessors. Participants were exposed to the same chemicals using the same study protocols.
Domain 3: Attrition				
	Metric 3A:	Were outcome data complete without attrition or exclusion from analysis?	High	No attrition was reported. All 178 participants were exposed to each of the study chemicals and there were no reported exclusions.
Domain 4: Exposure Measurement Bias				
	Metric 4A:	Can we be confident in the exposure characterization?	Low	Insufficient information was provided on the purity and stability of the test substance. The study only states that “test materials used in the investigation were prepared in batches in Japan by 3 major perfume companies and distributed to all the test centers.” HHCB was formulated in 7% petrolatum for testing.
Domain 5: Outcome Assessment				
	Metric 5A:	Can we be confident in the outcome assessment?	Low	The authors state that “internationally accepted criteria” were used for patch test methods and reading. Initial examinations were conducted 2-3 days after testing, with a follow-up conducted “in the majority of cases” between 2-5 days after the initial examination. There is no description of where patches were placed and there is no description of whether outcome assessors were trained. It is unclear whether the outcomes were assessed as irritation or sensitization responses, as results are only reported as ”positive” reactions with no clear point in time. In Part 1 of this series of patch test studies (HEROID: 8900562), results are discussed separately as either irritation or sensitization responses, but the criteria used to distinguish between the two is not specified.

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Health Outcome(s) Assessed:	Sensitization-Irritation
Reported Health Effect(s):	Irritation
Chemical:	HHCB- Parent compound
HERO ID:	5428193 Linked HERO ID(s): 5428193, 8900562, 8900573

Domain	Metric		Rating	Comments
	Metric 5B:	Selective Reporting: Were all measured outcomes reported?	Medium	All measured outcomes appear to have been reported in the results. Table 1 provides results of patch testing for all chemicals across all study sites.

Additional Comments: In this intentional dosing study, patch tests were conducted on 178 participants in 8 centers in Japan, Northern Ireland, United States, England, Switzerland, and Sweden over a 3-month period. Insufficient information on the study protocol, including blinding and purity of the test substance, was provided. Positive patch test results were observed in 3.4% of participants following exposure to HHCB.

Overall Quality Determination Low

Study Citation:	Larsen, W., Nakayama, H., Fischer, T., Elsner, P., Frosch, P., Burrows, D., Jordan, W., Shaw, S., Wilkinson, J., Marks, J., Sugawara, M., Nethercott, M., Nethercott, J. (2001). Fragrance contact dermatitis: a worldwide multicenter investigation (Part II). Contact Dermatitis 44(6):344-346.
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HERO ID:	5428193 Linked HERO ID(s): 5428193, 8900562, 8900573

Domain	Metric		Rating	Comments
Domain 1: Randomization				
	Metric 1A:	Was an adequate method used to randomize the administered dose or exposure level?	Medium	Randomization is not applicable; in this study all participants were exposed to each of the study chemicals. There was no randomization to a placebo group.
Domain 2: Allocation Concealment and Blinding				
	Metric 2A:	Was allocation to study groups adequately concealed until recruitment was complete?	Medium	In this intentional dosing study, participants were exposed to each study chemical using the same protocol. There was no allocation to different groups. Therefore, lack of adequate allocation concealment would not appreciably bias results.
	Metric 2B:	Were the research personnel and human subjects blinded to the study group during the study?	Low	Insufficient information is provided on blinding of outcome assessors. Participants were exposed to the same chemicals using the same study protocols.
Domain 3: Attrition				
	Metric 3A:	Were outcome data complete without attrition or exclusion from analysis?	High	No attrition was reported. All 178 participants were exposed to each of the study chemicals and there were no reported exclusions.
Domain 4: Exposure Measurement Bias				
	Metric 4A:	Can we be confident in the exposure characterization?	Low	Insufficient information was provided on the purity and stability of the test substance. The study only states that “test materials used in the investigation were prepared in batches in Japan by 3 major perfume companies and distributed to all the test centers.” HHCB was formulated in 7% petrolatum for testing.
Domain 5: Outcome Assessment				
	Metric 5A:	Can we be confident in the outcome assessment?	Low	The authors state that “internationally accepted criteria” were used for patch test methods and reading. Initial examinations were conducted 2-3 days after testing, with a follow-up conducted “in the majority of cases” between 2-5 days after the initial examination. There is no description of where patches were placed and there is no description of whether outcome assessors were trained. It is unclear whether the outcomes were assessed as irritation or sensitization responses, as results are only reported as ”positive” reactions with no clear point in time. In Part 1 of this series of patch test studies (HEROID: 8900562), results are discussed separately as either irritation or sensitization responses, but the criteria used to distinguish between the two is not specified.
	Metric 5B:	Selective Reporting: Were all measured outcomes reported?	Medium	All measured outcomes appear to have been reported in the results. Table 1 provides results of patch testing for all chemicals across all study sites.

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Chemical:	HHCB- Parent compound
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Domain	Metric	Rating	Comments
Additional Comments:	In this intentional dosing study, patch tests were conducted on 178 participants in 8 centers in Japan, Northern Ireland, United States, England, Switzerland, and Sweden over a 3-month period. Insufficient information on the study protocol, including blinding and purity of the test substance, was provided. Positive patch test results were observed in 3.4% of participants following exposure to HHCB.		

Overall Quality Determination Low

Study Citation:	Bell, I.R., Szarek, M.J., Dicenso, D.R., Baldwin, C.M., Schwartz, G.E., Bootzin, R.R. (1999). Patterns of waking EEG spectral power in chemically intolerant individuals during repeated chemical exposures. International Journal of Neuroscience 97(1-2):41-59.
Health Outcome(s) Assessed:	Neurological/Behavioral
Reported Health Effect(s):	EEG test results
Chemical:	HHCB- Parent compound
HERO ID:	5431388

Domain	Metric		Rating	Comments
Domain 1: Randomization				
	Metric 1A:	Was an adequate method used to randomize the administered dose or exposure level?	Medium	All study participants served as their own control and all received the same exposure dose following the same procedures. Subjects received exposure to galaxolide via foil-covered tubes on a stand below their noses. Some tubes contained galaxolide, while others contained distilled water, were empty, or contained propylene glycol. The order in which subjects received these tubes was randomized, although no specific randomization process is specified.
Domain 2: Allocation Concealment and Blinding				
	Metric 2A:	Was allocation to study groups adequately concealed until recruitment was complete?	Medium	The exposure protocol was the same for all participants. Lack of adequate allocation concealment would not appreciably bias results.
	Metric 2B:	Were the research personnel and human subjects blinded to the study group during the study?	High	In this study, subjects were exposed to a series of foil-covered tubes, some of which contained galaxolide. Both subjects and researchers were stated to be blinded to the order of tubes. The outcome of interest was the results of EEG tests, which would not be expected to be significantly biased by knowledge of exposure. Lack of adequate blinding during the study would not appreciably bias results.
Domain 3: Attrition				
	Metric 3A:	Were outcome data complete without attrition or exclusion from analysis?	Medium	After exclusions were made, the final number of subjects was n=40 (18 controls, 12 with chemical intolerance with associated lifestyle changes, and 10 with chemical intolerance). Ten participants dropped out of the study for unknown reasons prior to the first sleep laboratory session, and two more subjects dropped out of the study after the first sleep laboratory session. The final number of subjects was thus 28 (11 controls, 9 with chemical intolerance with associated lifestyle changes, and 8 with chemical intolerance). The ten subjects who dropped out prior to the first session were excluded. While the percentage lost to follow-up among the excluded 10 is greater than 20% for the control group, exclusion is an appropriate method to address missingness. For the two subjects who dropped out after the first night, their EEG data "were replaced with their respective group means for the second session" and thus they were kept for analysis.
Domain 4: Exposure Measurement Bias				
	Metric 4A:	Can we be confident in the exposure characterization?	Low	There is insufficient information provided on the purity of galaxolide, leading to the inability to determine the validity of the exposure assessment.

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Study Citation:	Bell, I.R., Szarek, M.J., Dicenso, D.R., Baldwin, C.M., Schwartz, G.E., Bootzin, R.R. (1999). Patterns of waking EEG spectral power in chemically intolerant individuals during repeated chemical exposures. International Journal of Neuroscience 97(1-2):41-59.
Health Outcome(s) Assessed:	Neurological/Behavioral
Reported Health Effect(s):	EEG test results
Chemical:	HHCB- Parent compound
HERO ID:	5431388

Domain	Metric		Rating	Comments
Domain 5: Outcome Assessment				
	Metric 5A:	Can we be confident in the outcome assessment?	Medium	Absolute delta power using EEG sensitization was assessed in the same time frame for all subjects. While subjects and assessors were not reported to be blinded, a lack of adequate blinding of outcome assessors would not appreciably bias results. Neural sensitization by absolute delta power was assessed using EEG monitored by technicians.
	Metric 5B:	Selective Reporting: Were all measured outcomes reported?	High	All of the study's measured outcomes outlined in the protocol, methods, abstract, and/or introduction have been reported.

Additional Comments: In this intentional dosing study, participants breathed in 6 vials of sham or varying levels of galaxolide and absolute delta power using EEG sensitization responses were assessed. There were a few key limitations in the study, notably that the galaxolide was of unknown purity. However, there is no significant evidence to suggest that the results of the study are solely due to bias. The study reported significant EEG energy changes following exposure to galaoxlide. Significant changes in delta power, as an EEG reading, were observed after exposure to galaxolide.

Overall Quality Determination Medium

Study Citation:	IFF, (1964). Repeated patch test. Galaxolide. (sanitized).
Health Outcome(s) Assessed:	Irritation-Sensitization
Reported Health Effect(s):	Sensitization (patch test)
Chemical:	HHCB- Parent compound
HERO ID:	8785221

Domain	Metric		Rating	Comments
Domain 1: Randomization				
	Metric 1A:	Was an adequate method used to randomize the administered dose or exposure level?	Medium	In this dermal patch test study, each participant served as their own control. All participants received the same exposure and control dose, following the same procedure. Six to nine different samples were tested simultaneously on each subject, with the order applied being rotated from one subject to the next. The test patch was applied to the same site each test time for a 24-hour exposure period on a Monday-Wednesday-Friday sequence for three successive weeks, except for the sixth week where the test patch was applied to a site not previously exposed.
Domain 2: Allocation Concealment and Blinding				
	Metric 2A:	Was allocation to study groups adequately concealed until recruitment was complete?	Medium	Participants served as their own controls. The exposure protocol was the same for all participants, so lack of adequate allocation concealment would not appreciably bias results.
	Metric 2B:	Were the research personnel and human subjects blinded to the study group during the study?	Medium	In this patch test study, participants served as their own controls. Lack of adequate allocation concealment would not appreciably bias results.
Domain 3: Attrition				
	Metric 3A:	Were outcome data complete without attrition or exclusion from analysis?	Medium	From the original sample of 47 participants, there were 7 participants who were excluded from the analytic sample. Participants were removed due to "loss of interest, nausea or respiratory distress attributed to sample oders, unexpected other obligations, and so on." The authors noted that removed subjects exhibited no significant differences in reactions from other subjects in the group, during the time they were under observation. The amount of attrition would likely not appreciably bias results.
Domain 4: Exposure Measurement Bias				
	Metric 4A:	Can we be confident in the exposure characterization?	Low	The study reported using "Final test concentration: Galaxolide 3.75% + Alcohol 96.25%," but this is does not refer to the purity and stability of galaxolide. The precise purity of galaxolide is not provided or discussed. 0.5 mL of the solution was applied to a 1x3-inch Webril swatch and the bandage was placed on participants' upper arms. The patch test was repeated for a series of 9 application sessions for three successive weeks.
Domain 5: Outcome Assessment				

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Study Citation:	IFF, (1964). Repeated patch test. Galaxolide. (sanitized).
Health Outcome(s) Assessed:	Irritation-Sensitization
Reported Health Effect(s):	Sensitization (patch test)
Chemical:	HHCB- Parent compound
HERO ID:	8785221

Domain	Metric		Rating	Comments
	Metric 5A:	Can we be confident in the outcome assessment?	Medium	The study used an adaptation of the Draize dermal patch test protocol. Skin reaction was assessed for 9 patches after 24 hours each for all subjects simultaneously. Scoring reaction criteria were outlined in the report. No information is provided regarding blinding of outcome assessors. However, the absence of blinding is not expected to appreciably bias the results because the study used standardized and clearly defined scoring criteria for assessing reactions.
	Metric 5B:	Selective Reporting: Were all measured outcomes reported?	High	All outcomes described in the methods are reported, including the individual irritation and sensitization scores for all individual participants and applications.

Additional Comments: In this patch-test study, 40 participants received 9 patches containing Galaxolide in a Webril swatch. Skin irritation or sensitization responses were assessed at after 24 hours for each of the three-week patch tests. However, there were no other significant concerns for bias, notably due to the sufficient description of the outcome assessment process. The primary potential source of bias is the lack of information on the purity of galaxolide. The study did not report whether outcome assessors were blinded; however, any potential bias is likely minimal due to the use of standardized and clearly defined scoring criteria. The study reported no irritation or sensitization reactions following exposure to galaxolide.

Overall Quality Determination Medium

Study Citation:	IFF, (1964). Repeated patch test. Galaxolide. (sanitized).
Health Outcome(s) Assessed:	Irritation-Sensitization
Reported Health Effect(s):	Sensitization (patch test)
Chemical:	HHCB- Parent compound
HERO ID:	8785221

Domain	Metric		Rating	Comments
Domain 1: Randomization				
	Metric 1A:	Was an adequate method used to randomize the administered dose or exposure level?	Medium	In this dermal patch test study, each participant served as their own control. All participants received the same exposure and control dose, following the same procedure. Six to nine different samples were tested simultaneously on each subject, with the order applied being rotated from one subject to the next. The test patch was applied to the same site each test time for a 24-hour exposure period on a Monday-Wednesday-Friday sequence for three successive weeks, except for the sixth week where the test patch was applied to a site not previously exposed.
Domain 2: Allocation Concealment and Blinding				
	Metric 2A:	Was allocation to study groups adequately concealed until recruitment was complete?	Medium	Participants served as their own controls. The exposure protocol was the same for all participants, so lack of adequate allocation concealment would not appreciably bias results.
	Metric 2B:	Were the research personnel and human subjects blinded to the study group during the study?	Medium	In this patch test study, participants served as their own controls. Lack of adequate allocation concealment would not appreciably bias results.
Domain 3: Attrition				
	Metric 3A:	Were outcome data complete without attrition or exclusion from analysis?	Medium	From the original sample of 47 participants, there were 7 participants who were excluded from the analytic sample. Participants were removed due to ”loss of interest, nausea or respiratory distress attributed to sample oders, unexpected other obligations, and so on.” The authors noted that removed subjects exhibited no significant differences in reactions from other subjects in the group, during the time they were under observation. The amount of attrition would likely not appreciably bias results.
Domain 4: Exposure Measurement Bias				
	Metric 4A:	Can we be confident in the exposure characterization?	Low	The study reported using ”Final test concentration: Galaxolide 3.75% + Alcohol 96.25%,” but this is does not refer to the purity and stability of galaxolide. The precise purity of galaxolide is not provided or discussed. 0.5 mL of the solution was applied to a 1x3-inch Webril swatch and the bandage was placed on participants’ upper arms. The patch test was repeated for a series of 9 application sessions for three successive weeks.
Domain 5: Outcome Assessment				

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Study Citation:	IFF, (1964). Repeated patch test. Galaxolide. (sanitized).
Health Outcome(s) Assessed:	Irritation-Sensitization
Reported Health Effect(s):	Sensitization (patch test)
Chemical:	HHCB- Parent compound
HERO ID:	8785221

Domain	Metric		Rating	Comments
	Metric 5A:	Can we be confident in the outcome assessment?	Medium	The study used an adaptation of the Draize dermal patch test protocol. Skin reaction was assessed for 9 patches after 24 hours each for all subjects simultaneously. Scoring reaction criteria were outlined in the report. No information is provided regarding blinding of outcome assessors. However, the absence of blinding is not expected to appreciably bias the results because the study used standardized and clearly defined scoring criteria for assessing reactions.
	Metric 5B:	Selective Reporting: Were all measured outcomes reported?	High	All outcomes described in the methods are reported, including the individual irritation and sensitization scores for all individual participants and applications.

Additional Comments: In this patch-test study, 40 participants received 9 patches containing Galaxolide in a Webril swatch. Skin irritation or sensitization responses were assessed at after 24 hours for each of the three-week patch tests. However, there were no other significant concerns for bias, notably due to the sufficient description of the outcome assessment process. The primary potential source of bias is the lack of information on the purity of galaxolide. The study did not report whether outcome assessors were blinded; however, any potential bias is likely minimal due to the use of standardized and clearly defined scoring criteria. The study reported no irritation or sensitization reactions following exposure to galaxolide.

Overall Quality Determination Medium