JOHNSON & JOHNSON CONSUMER INC.

SUMMARY CLINICAL STUDY REPORT

PROTOCOL TITLE:	A Single-Center, Clinical Study to Evaluate the Whitening Effect of Mineral Sunscreens in Multi-Cultural Skin Tones thru Instrumentation Measurements, Imaging, and Self-Assessments
PROTOCOL NUMBER:	CCSSKA004479 Final Version 1.0, 06 December 2021
SPONSOR:	Johnson & Johnson Consumer Inc. 199 Grandview Road, Skillman, NJ 08558 USA
STUDY SITE:	Validated Claim Support (VCS) 400 Frank W Burr Blvd Teaneck, NJ 07666
PRINCIPAL INVESTIGATOR:	David Wrone, M.D., FAAD Address: Refer to Study Site address Phone: 201-331-9300, Email: dwrone@validatedcs.om
STUDY INITIATION DATE (First Subject First Visit):	29-DEC-2021
STUDY COMPLETION DATE (Last Subject Completed):	30-MAR-2022
SITE APPROVAL:	[redacted]
SPONSOR REVIEW AND APPROVAL:	[redacted]

The principles of the International Council for Harmonisation (ICH) Guidelines for Good Clinical Practice (GCP E6 (R2)) were applied to this study.

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1. STUDY SYNOPSIS

The principles of the International Council for Harmonisation (ICH) Guidelines for Good Clinical Practice (GCP E6 (R2)) were applied to this study.

INTRODUCTION	There is a need to evaluate and understand the whitening potential of mineral sunscreens across multi-cultural skin tones as we become more diverse and inclusive in our product benefit assessments. Based on the two-layer optical model, the whitening potential of sunscreen increases with darker skin tone and with higher amount of product application[1]. It is unclear how much sunscreen consumers apply and whether or not the whitening potential of the sunscreen itself affects their application behavior and ultimately their sun protection. The study aims to objectively measure the whitening effect of different mineral sunscreens with standardized application through instrumentation and imaging, and to capture consumer application behavior and perception through self-application and questionnaire. The data will also be used to develop and validate an in vitro whitening model. The relation of whitening and sun protection level under standardized application and consumer application behavior can be implemented noninvasively through a reflectance spectroscopy in the ultraviolet region using a hybrid diffuse reflectance spectroscopy (HDRS) method.
OBJECTIVE(S)	The objectives of the study were to: Primary objectives: • evaluate the whitening potential of mineral sunscreens across multi-cultural skin tones through instrumentation, imaging, and self-assessment. • evaluate the relationship between self-perception and objective measurement of whitening. Secondary objectives: • evaluate whether the whitening effect from a sunscreen impacts consumer application behavior and ultimately their sun protection. • evaluate new methodology in assessing SPF.
STUDY DESIGN	This was a single center, randomized, open label clinical study. A sufficient number of subjects were enrolled to complete the study with at least 90 subjects. The target population was 18- to 55-year-old, female subjects who had a history of using or is a current user of sunscreens.

<table>
<tr><td></td><td>Subjects were assessed at a single visit (Visit 1), comprised of Baseline and post IP application time points.

At Visit 1, each enrolled subject had instrumental measurements and imaging completed at Baseline and post IP application time points. After Baseline instrumental measurements and imaging were completed, each subject was randomly assigned two of the six IPs to apply to her whole lower legs, between the knee and ankle. The subject then selected one of the two IPs randomly assigned to her lower legs and applied the selected IP to her full face.

After lower legs and facial IP applications were completed, a trained designee delineated six 4 cm x 4 cm test sites on the subject's volar forearms (3 test sites per volar forearm). The six IPs were randomly assigned to the six test sites and applied by a trained designee. The subject immediately completed a self-assessment questionnaire (Part A) after each IP application on the lower legs, facial skin, and volar forearms. After all volar forearms IP applications and self-Assessment questionnaire (Part A) were completed, the subject completed the self-Assessment questionnaire (Part B).</td></tr>
<tr><td>SUBJECT INFORMATION</td><td>The complete eligibility criteria for this study were followed as defined in the study protocol referenced on page 1 of this report.

The main criteria were:
• Female
• 18 to 55 years old
• Had a history of using or was a user of sunscreens at the time of the visit.</td></tr>
<tr><td>INVESTIGATIONAL STUDY MATERIALS</td><td><table>
<tr><th>Identification</th><th>Product #</th><th>Product type</th></tr>
<tr><td>Sunscreen A</td><td rowspan="6">[redacted]</td><td>Investigational Product (IP)</td></tr>
<tr><td>Sunscreen B</td><td>IP</td></tr>
<tr><td>Sunscreen C</td><td>IP</td></tr>
<tr><td>Sunscreen D</td><td>IP</td></tr>
<tr><td>Sunscreen E</td><td>IP</td></tr>
<tr><td>Sunscreen F</td><td>IP</td></tr>
</table></td></tr>
<tr><td>DOSE AND MODE OF APPLICATION</td><td>At Visit 1, each enrolled subject was randomly assigned two of the six IPs to apply to her whole lower legs (1 IP per lower leg), between the knee and ankle. The subject then</td></tr>
</table>

	selected one of the two IPs randomly assigned to her lower legs and applied the selected IP to her full face. After lower legs and facial IP applications were completed, a trained designee delineated six 4 cm x 4 cm test sites on the subject's volar forearms (3 test sites per volar forearm). The six IPs was randomly assigned to the six test sites and applied by a trained designee.
METHODOLOGY	• Instrumental measurements: ➢ SkinSkan measurements (face and volar forearms) • Imaging (face and volar forearms) • Self-assessment questionnaires (parts A and B)
MEASUREMENT AND/OR EVALUATION SCHEDULE	The instrumental measurements and imaging were completed at Baseline and post IP application time points. The self-assessment questionnaire (part A) was completed immediately after each IP application on the lower legs, facial skin, and volar forearms. The self-assessment questionnaire (part B) was completed after all IP applications.
INSTITUTIONAL REVIEW BOARD (IRB)	This study was reviewed and approved by the following IRB: • Name: Advarra IRB • Address: 6100 Merriweather Dr., Suite 600, Columbia, MD 21044 • Contact details: o Phone: 877-992-4724 o Email: adviser@advarra.com o Web: https://www.advarra.com/ • Approval date: 13-DEC-2021 • IRB Closeout date: 12-SEP-2022 There were no amendments to the study.
SAFETY AND ADVERSE EVENTS	All Adverse Events (AEs/SAEs) were collected regardless of causal relationship to the subject's participation in the study. The information was collected/reported within the reporting timelines specified in the protocol. 1 subject - Subject ID 1098: • Mild erythema on volar forearm sites 1 and 2 (possible relationship the IPs) No other significant adverse events were reported and/or observed in this study.

MONITORING, QUALITY CONTROL, AND QUALITY ASSURANCE	The study monitoring was conducted as per the Sponsor´s requirements. The Study Site is subject to review by the IRB (if applicable), to quality assurance audits performed by the Sponsor, and/or to inspection by appropriate regulatory authorities.
CONCLUSIONS	This research study supports that on skin whitening of sunscreen is the key attribute influencing likeability, and usage across all skin tones. Whitening assessment through image analysis were consistent with consumer perception, likeability, and choice. There is a significant disparity between measured whitening across skin tones, with sunscreen on average appearing 3x whiter on dark skin tone than light skin tone. Choice of sunscreen for facial application is consistent with measured whitening and perception with 100% of subjects choosing the least whitening sunscreen. There is indication that consumers avoid sunscreens with negative whitening aesthetics or compensate with reduced application, which compromise the ability to achieve their sun protection needs, particularly for populations of darker skin tones.

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