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# Safety Assessment of *Butyrospermum parkii* (Shea)- Derived Ingredients as Used in Cosmetics

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Status: Draft Final Report for Panel Review  
Release Date: March 17, 2017  
Panel Meeting Date: April 10-11, 2017

The 2017 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 safety assessment was prepared by Christina L. Burnett, Scientific Analyst/Writer and Bart Heldreth, Ph.D., Chemist CIR.

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Memorandum

To: CIR Expert Panel Members and Liaisons  
From: Christina Burnett, Senior Scientific Writer/Analyst  
Date: March 17, 2017  
Subject: Draft Final Report of the Safety Assessment of *Butyrospermum parkii* (Shea)-Derived Ingredients

Enclosed is the draft final report of the Safety Assessment of *Butyrospermum parkii* (Shea)-Derived Ingredients as Used in Cosmetics. (It is identified as *shea042017rep* in the pdf document.)

At the September 2016 meeting, the Panel issued a tentative report for the 13 *Butyrospermum parkii* (shea)-derived ingredients described in the safety assessment with the conclusion that that the following 9 ingredients are safe as used in the present practices of use and concentration as described in the safety assessment.

Butyrospermum Parkii (Shea) Butter	Hydrogenated Shea Oil
Buyrospemum Parkii (Shea) Oil	Shea Butter Glyceride
Butyrospermum Parkii (Shea) Butter Extract	Shea Butter Glycerides
Butyrospermum Parkii (Shea) Butter Unsaponifiables	Shea Oleine
Hydrogenated Shea Butter	

The Panel concluded that the data on the 4 ingredients listed below are insufficient to determine safety.

Butyrospermum Parkii (Shea) Nut Extract	Butyrospermum Parkii (Shea) Seedcake Extract
Butyrospermum Parkii (Shea) Nut Shell Powder	Hydrolyzed Shea Seedcake Extract*

Data needs included:

- Method of manufacturing for Butyrospermum Parkii (Shea) Nut Extract, Butyrospermum Nut Shell Powder, Butyrospermum Parkii (Shea) Seedcake Extract, and Hydrolyzed Shea Seedcake Extract
- Composition and impurities data on the above listed nut and seedcake ingredients
- Sensitization data on the above listed nut and seedcake ingredients

Since the September meeting, data on method of manufacturing and composition/impurities on Butyrospermum Parkii (Shea) Nut Shell Powder and Butyrospermum Parkii (Shea) Seedcake Extract were received in addition to irritation and sensitization data on Butyrospermum Parkii (Shea) Seedcake Extract. These data have been incorporated into the report and highlighted with brackets in text or shaded in tables. The Council has also informed CIR staff that no uses of shea oleine were reported in a concentration of use survey. No other requested data have been received by CIR staff. Comments received from the Council prior to the September meeting and on the tentative report have been considered. The comments and the unpublished data can be found in this report's package (*shea042017pcpc1* and *shea042017pcpc2* and *shea042017data1* through *shea042017data4*, respectively).

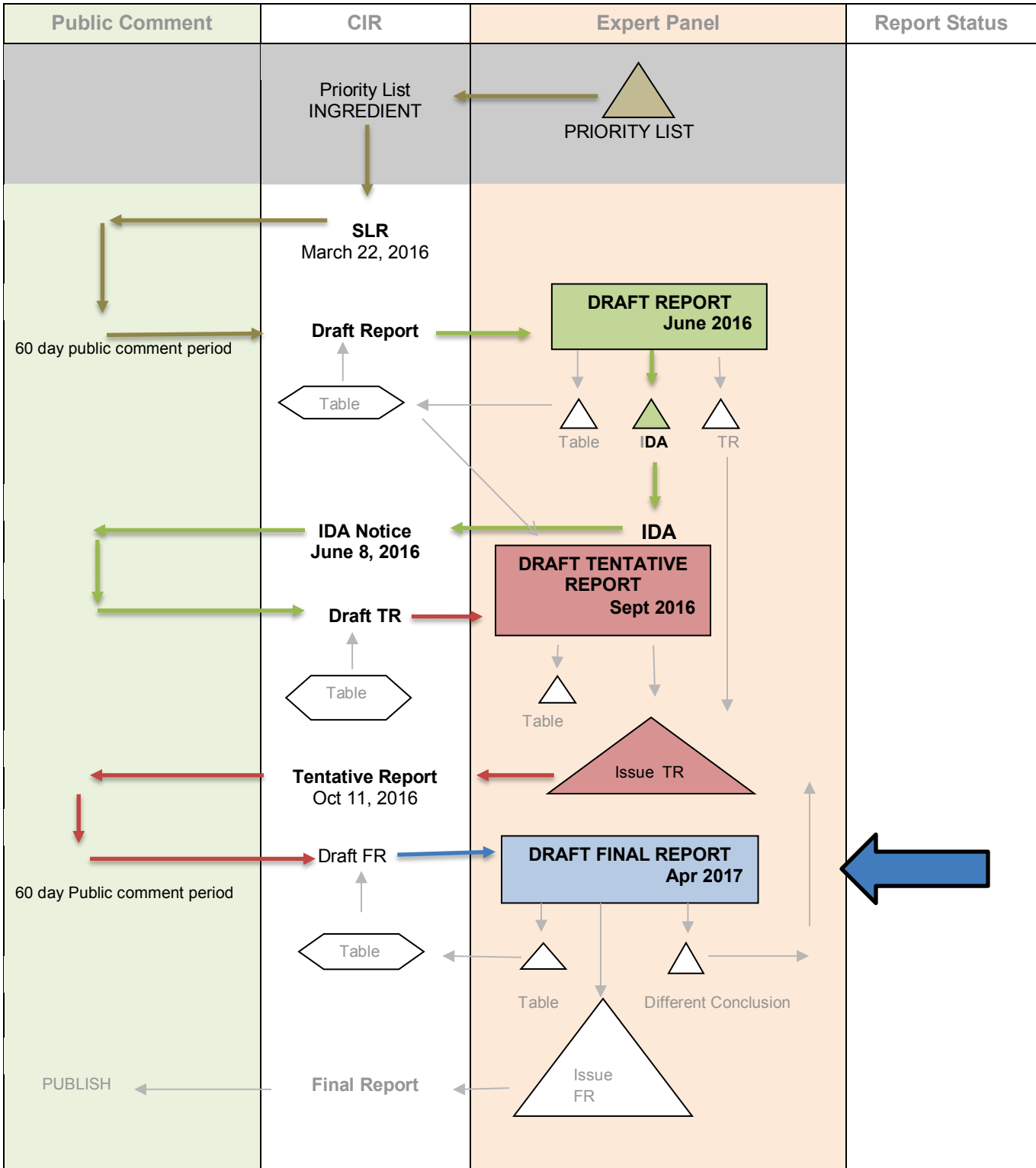
According to the recently obtained 2017 VCRP data, uses for most of the ingredients have increased with the most significant increase occurring in Butyrospermum Parkii (Shea) Butter. Use for this ingredient has increased from 4358 to 5447, with the majority of the uses reported in leave-on products.

The Panel should carefully review all new information, and the Abstract, Discussion, and Conclusion of this report. If the data are now sufficient, the Panel should issue a revised Tentative Safety Assessment with an appropriate discussion and new conclusion. If the data are still insufficient, the Panel should issue a Final Safety Assessment a split conclusion.

# SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY Butyrospermum Parkii (Shea)-Derived Ingredients

MEETING April 2017



**Butyrospermum parkii (Shea)-Derived Ingredients History**

**March 2016** – Scientific Literature Review announced.

**June 2016** - The Panel issued an Insufficient Data Announcement for the 13 *Butyrospermum parkii* (shea)-derived ingredients described in the safety assessment. Data needs included:

- Method of manufacturing for Butyrospermum Parkii (Shea) Nut Extract, Butyrospermum Nut Shell Powder, Butyrospermum Parkii (Shea) Seedcake Extract, and Hydrolyzed Shea Seedcake Extract
- Additional information on method of manufacturing, composition and impurities data, and sensitization data on Butyrospermum Parkii (Shea) Butter Unsaponifiables.
- Composition and impurities data on the above listed nut and seedcake ingredients
- Sensitization data on the above listed nut and seedcake ingredients

**September 2016** – The Panel issued a tentative report for the 13 *Butyrospermum parkii* (shea)-derived ingredients described in the safety assessment with the conclusion that the following 9 ingredients are safe as used in the present practices of use and concentration as described in the safety assessment.

Butyrospermum Parkii (Shea) Butter	Hydrogenated Shea Butter
Buyrospemum Parkii (Shea) Oil	Hydrogenated Shea Oil
Butyrospermum Parkii (Shea) Butter Extract	Shea Butter Glyceride
Butyrospermum Parkii (Shea) Butter Unsaponifiables	Shea Butter Glycerides
	Shea Oleine

The Panel concluded that the data on the 4 ingredients listed below are insufficient to determine safety.

Butyrospermum Parkii (Shea) Nut Extract	Butyrospermum Parkii (Shea) Seedcake Extract
Butyrospermum Parkii (Shea) Nut Shell Powder	Hydrolyzed Shea Seedcake Extract*

Data needs included:

- Method of manufacturing for Butyrospermum Parkii (Shea) Nut Extract, Butyrospermum Nut Shell Powder, Butyrospermum Parkii (Shea) Seedcake Extract, and Hydrolyzed Shea Seedcake Extract
- Composition and impurities data on the above listed nut and seedcake ingredients
- Sensitization data on the above listed nut and seedcake ingredients

<b>Butyrospermum parkii (Shea)-Derived Ingredients Data Profile - April 2017 - Writer, Christina Burnett</b>															
	<b>In-Use</b>	<b>Physical/Chemical Properties</b>	<b>Method of Manufacturing</b>	<b>Composition/Impurities</b>	<b>Toxicokinetics</b>	<b>Acute Toxicity</b>	<b>Repeated Dose Toxicity</b>	<b>Reproductive and Developmental Toxicity</b>	<b>Genotoxicity</b>	<b>Carcinogenicity</b>	<b>Irritation/Sensitization - Nonhuman</b>	<b>Irritation/Sensitization - Clinical</b>	<b>Ocular/Mucosal</b>	<b>Phototoxicity</b>	<b>Case Studies</b>
Butyrospermum Parkii (Shea) Butter	X	X	X	X							X	X	X	X	
Butyrospermum Parkii (Shea) Butter Extract	X											X			
Butyrospermum Parkii (Shea) Butter Unsaponifiables	X		X	X					X		X		X	X	
Butyrospermum Parkii (Shea) Nut Extract	X														
Butyrospermum Parkii (Shea) Nut Shell Powder	X		X	X											
Butyrospermum Parkii (Shea) Oil	X	X	X	X			X	X		X					
Butyrospermum Parkii (Shea) Seedcake Extract	X		X	X								X			
Hydrogenated Shea Butter	X														
Hydrogenated Shea Oil															
Hydrolyzed Shea Seedcake Extract															
Shea Butter Glyceride	X														
Shea Butter Glycerides	X														
Shea Oleine (not an INCI ingredient)	X		X	X	X		X	X		X					

“X” indicates that data were available in the category for that ingredient.

**Search Strategy for *Butyrospermum parkii* (Shea)-Derived Ingredients**  
**(Performed by Christina Burnett)**

- SciFinder – January 2016
  - Search for ingredients by INCI names, only Shea Glyceride(s) in system –0 reference hits

Search Terms	TOXLINE Hits (excluding PUBMED)	PUBMED Hits	SCCS/SCCP Opinion	ECHA Hits	NICNAS
Butyrospermum parkii	5	9	0	0	0
Vitellaria paradoxa	1	37	0	0	0
Shea	*	*	0	0	0

\*Reference searches for “shea” were not very successful because hits with authors named “Shea” would come up, even with qualifiers.

Total references ordered or downloaded: 24

Search updated April 15, 2016 = 0 relevant references found.

Search updated August 2, 2016 = 0 relevant references found.

**Search updated February 16, 2017 = 0 relevant references found.**

**Butyrospermum parkii (Shea)-Derived Ingredients**  
**September 26-27, 2016**

**Dr. Marks' Team**

DR. MARKS: Okay. Next is shea butyrospermum parkii and there's a draft tentative report at the June meeting this year. We issued an insufficient data announcement for these 13 shea derived ingredients including method of manufacturing for several of the ingredients, composition impurities for several of them, sensitization data. So team, what did you feel? I thought we perhaps could go with a tentative conclusion, or a tentative report with a conclusion safe for eight butter oil and glyceride ingredients, insufficient for the four nut and seed cake, and we need method of manufacture that's composition, impurities and sensitization data.

DR. SHANK: I agree.

DR. SLAGA: I agree too.

DR. HILL: Yes.

DR. MARKS: Does that sound good? And then I wondered, the shea oleine, how do you, o-l-e-i-n-e include, it's not an INCI ingredient, so kind of up to--

MS. BURNETT: There are VCRP data and some of the data used in the report, by the report are for that compound.

DR. MARKS: Okay. So, keep it in. That would be one of the, since that's not a butter oil or glyceride ingredient, that would be one of the included in the insufficient. Is that correct, then? Because I had insufficient for the four nut and seed cake. That would be -- would that also come under the insufficient?

DR. MARKS: When you look at the table, it's the last ingredient, Ron Hill.

DR. HILL: In which -- where are you at?

DR. MARKS: This would be, it's probably about the page four or five. Let's see.

DR. HILL: Of the PDF?

DR. MARKS: Yes.

DR. HILL: All right.

DR. MARKS: It's the shea oleine.

DR. HILL: Yeah.

DR. MARKS: Oleine, if you pronounce all the vowels.

MS. BURNETT: PDF five.

DR. MARKS: Yeah, five.

DR. HILL: I got it. I'm on five or four?

MS. BURNETT: Five.

DR. HILL: I'm on five.

DR. MARKS: Yeah. And we don't--

DR. EISENMANN: One thing about ingredient, I have not surveyed it yet.

DR. HELDRETH: Also, if you look on PDF page 25, the shea oleine is a fraction of the shea oil.

DR. MARKS: Oh, so if we feel the oil is sort of safe, then as a fraction of it, you would think that would be safe.

DR. SHANK: You would think.

DR. MARKS: Butter oil and glyceride ingredients. So that would be nine, if we, if that's part of the oil. So I'm going to increase that from eight to nine. Does that sound good, team?

DR. SHANK: Yes.

DR. MARKS: And then the only other question I had, and I would be interested what Ron, Ron, and Tom, what your feeling is. The shea butter is used at 100 percent. We have a guinea maximum of 60 percent, which it leaves a non- sensitizer, but I mean shea oil is used all the time. There are no clinical reports that you found Christina of allergy to it.

MS. BURNETT: Mm-hmm.

DR. MARKS: So I think between our clinical experience, I even know it's used 100 percent as safe as a butter at 100 percent since that's one of the use concentrations. Did I read that correctly? It goes up to 100 percent?

MS. BURNETT: Mm-hmm.

DR. MARKS: Well, I'll ask Don about that tomorrow, but that was my feeling that even though we don't have a sensitization data to confirm lack of sensitivity at 100 percent, our clinical experience would suggest that's fine. Does that sound reasonable, Tom, Ron, and Ron?

DR. SHANK: Yes.

DR. HILL: Yes.

DR. SLAGA: Yes.

DR. MARKS: Okay. Clinical experience, okay. Okay. So, tomorrow I'll move a tentative report be issued with the conclusion safe for the nine butter oil and glyceride ingredients insufficient for the four nut and seed cake ingredients. We need the method of manufacture, composition impurities and sensitization data. Sound good?

DR. SHANK: Yes.

DR. MARKS: Okay.



**Dr. Belsito's Team**

DR. BELSITO: So shea butter. At the June meeting another insufficient data announcement for these ingredients. Additional data: Method of manufacture for the nut extract, nut shell powder, seedcake extract, hydrolyzed seedcake extract; additional information on method of manufacturing, composition and impurities data, sensitization data on shea butter unsaponifiables; composition and impurities data on the above-listed nut and seedcake ingredients; and sensitization data on the above-listed nut and seedcake ingredients. We did get additional irritation and sensitization data, but we didn't get data on method of manufacture, composition and impurities, irritation and sensitization for those specific ingredients. And we did get a DPRA, and we got updated frequency of use.

DR. SNYDER: So on this one under the intro you say that the sunflower is a member of a family that is known to contain potential sensitizing agents.

DR. BELSITO: We're not on helianthus.

DR. SNYDER: Oh, we're not? Oh, I'm sorry.

DR. BELSITO: We're on butyrospermum. We're on shea butter.

DR. LIEBLER: But now we know what Paul's going to say about sunflowers. Showing your cards there, Snyder.

DR. BELSITO: I thought all the butter components were okay and the nut seedcake insufficient for the reasons we asked.

DR. LIEBLER: Right. I'm exactly in the same place.

DR. SNYDER: So we asked for sensitization on the nut and seedcake, and we got sensitization data at 5 percent on the butter extract?

DR. BELSITO: Right.

DR. SNYDER: Okay. It's used up to 100 percent.

DR. LIEBLER: Are you looking for an answer to your question?

DR. SNYDER: No, I'm just reiterating -- I'm only pointing out in most instances where we have discrepancies for what we asked for and what we got. So we asked for sensitization data on the nut and seedcake, and we got irritation and sensitization on the butter extract at 5 percent. So is that sufficient for the data request of sensitization on the nut and seedcake?

DR. ANSELL: I don't think it was provided for that purpose.

DR. BELSITO: I mean all we have for the undiluted is the DPRA. Otherwise for sensitization data the highest we have is 5 percent in a face cream.

DR. LIEBLER: Yeah, I think we're still insufficient for the nut shell and seedcake ingredients, same data needs.

DR. BELSITO: I mean I think what Paul is saying is even the butter cleared based upon the fact that it's used up to 100 percent. We don't have sensitization data to 100 percent.

DR. SNYDER: In moisturizers and that's a leave- on.

DR. BELSITO: I mean I'm okay with it. I mean shea butter is in everything. I've never seen an allergic reaction to shea butter. I forget. Do we have composition data on the shea butter? No?

DR. LIEBLER: Yeah.

MS. BURNETT: From a previous report we do have sensitization data up to like 50 or 75 percent, but not quite 100 percent.

DR. BELSITO: I mean you look at what's in shea butter -- myristic, palmitic, stearic, oleic, linolenic, arachidic. I mean there's nothing that bothers me there and it's got tocopherols. So I'm not concerned that we don't have sensitization data at 100 percent.

DR. ANSELL: We also wanted to point out that the percent shea butter unsaponifiables be a vehicle to use to suspend it with shea butter.

DR. BELSITO: Which study was that, Jay?

DR. ANSELL: Carol notes that we have some 30 percent shea butter unsaponifiables.

DR. LIEBLER: What type of test?

MS. BURNETT: It's either the irritation or the --

DR. BELSITO: Yeah, 30. It's irritation. So 30 percent -- but it says here diluted in paraffin oil, Jay, not shea butter.

DR. ANSELL: Yeah, I'm looking at that, too, at the genotox --

MS. BURNETT: Material tested low assay in a human tested at 70 percent shea butter and 30 percent shea butter unsaponifiables. That's what her note is.

DR. BELSITO: I'm sorry. I missed what you said, Christina.

MS. BURNETT: Her note to me says "the material tested in both the episkin assay and the human cutaneous tolerance test was 70 percent shea butter and 30 percent shea butter unsaponifiables." And then in the human study a percent dilution of the mixture was used, resulting in test concentrations of 21 percent shea butter and 90 percent shea butter unsaponifiables.

DR. ANSELL: And sensitization in the --

MS. BURNETT: In the DPRA it was also 70 percent shea butter and 30 percent shea butter unsaponifiables.

DR. LIEBLER: So the unsaponifiables, just to clarify, are the sterols, waxes, and large hydrocarbons, anything that doesn't have an ester in it, because saponification is a process that cleaves the esters, basically cuts the fatty acids off any kind of alcohols that they are attached to. So the unsaponifiables was listed as an insufficiency in the last meeting and I don't think that is necessary. We know enough about what unsaponifiables would be of shea butter to remove that insufficiency. And there's a short description under method of manufacture. So I'm fine with that. And this distinction of the shea butter and the shea butter unsaponifiables as a mix in these tests is kind of a useless distinction. Shea butter would contain the unsaponifiables --

DR. SNYDER: 30 percent --

DR. LIEBLER: But if you wanted to saponify it and then extract what's left, you'd get the unsaponifiables.

DR. BELSITO: So then if I'm hearing you, Dan, you're saying that the butter and unsaponifiables are safe?

DR. LIEBLER: Yes.

DR. BELSITO: And all the others are insufficient for all the reasons that we've previously expressed?

DR. LIEBLER: Correct.

DR. BELSITO: I'm fine with that.

MS. BURNETT: So anything that says nut or seedcake is the --

DR. SNYDER: Nut extract, nut seed powder, cake extract, hydrogenated seedcake extract, all those.

DR. LIEBLER: And if you tell me that we have some bitter orange seedcake data, I'll jump out a window.

MS. BURNETT: Should anything be added to the current discussion? I have botanical.

DR. BELSITO: I didn't have anything for it.

MS. BURNETT: Inhalation, pesticide, heavy metal.

DR. BELSITO: I made no comments on your discussion.

DR. SNYDER: Yep, I was fine.

DR. LIEBLER: Right.

DR. BELSITO: I mean I just wanted to go back and look -- I mean it's interesting that when you look at VCRP reporting, the nut extract is not reported to be used at all. We just have concentrations of use. The nut shell powder has two uses. The shea oil has 58. The seedcake has two. Now what about the hydrogenated shea butter? Is that okay?

DR. LIEBLER: I would have no problem with that.

DR. BELSITO: Okay. So then just looking at the ingredients we have here --

MS. BURNETT: And that was already previously reported, the hydrogenated.

DR. BELSITO: It was?

MS. BURNETT: Yes. That was part of the plant oils report.

DR. BELSITO: And the shea oleine was also part of the -- no?

MS. BURNETT: No, that was -- I was able to find data on that and I think I found that it was in the VCRP, but it's not an INCI ingredient. We included it because of similarity and that we have data.

DR. BELSITO: Okay. So then let's look at our list here. So going to PDF page 24, the list of ingredients we're looking at. Everyone there? So we're saying the shea butter, the shea butter extract, the shea butter unsaponifiables are safe as used. What about the shea oil? Yes?

MS. BURNETT: Yes, you already found that to be safe.

DR. BELSITO: Right, okay. The hydrogenated shea butter and the hydrogenated shea oil?

DR. SNYDER: Good.

DR. BELSITO: The shea butter glyceride and the shea oleine?

DR. LIEBLER: Those are fine.

DR. SNYDER: Fine.

DR. BELSITO: Okay. So basically then to repeat what's not fine is --

DR. SNYDER: Nut extract.

DR. BELSITO: -- is the shea nut extract, nut shell powder, seedcake extract, and hydrolyzed seedcake extract.

DR. LIEBLER: Right.

DR. BELSITO: So we have four insufficient. All the others are sufficient.

DR. LIEBLER: Correct. The way I look at this is if you go to PDF 26, there's a little scheme under method of manufacture and it goes from shea tree nut to shea oil. Almost all of our ingredients, other than the nut stuff and seedcake, are downstream of shea oil, which is fine.

DR. BELSITO: Okay.

DR. SNYDER: Makes sense.

DR. BELSITO: I like that downstream effect.

DR. LIEBLER: Yeah, downstream.

DR. BELSITO: Anything else on these? We're clear on what we're going sufficient and what we're going insufficient for? Okay, so do you want a 10 minute break? Okay, it's 10:43. We'll reconvene at 10:55.

**Full Panel Meeting**

DR. MARKS: So in June of this year, the panel issued an insufficient data announcement for these 18 *Butyrospermum parkii*, or shea, ingredients. We did receive a fair amount of data. We felt we could move on to issue a tentative report at this point with a conclusion that they're safe for the nine butter/oil ingredients and glyceride insufficient for the four nut and seedcake ingredients. And what we needed for that was method of manufacture, composition, impurities, and sensitization data. So that's a motion.

DR. BELSITO: Second.

DR. BERGFELD: Any further discussion? Any editorial remarks?

DR. MARKS: Yes, as I mentioned yesterday in our team meeting, shea butter is used at 100 percent. We had a guinea pig maximization confirming that 60 percent was safe concerning sensitization, but I think, Don, your experience and mine -- I'm assuming your experience -- we just don't see sensitization to shea butter and there have not been clinical reports. So I felt that it would be okay from a sensitization point of view.

DR. BELSITO: I agree.

DR. BERGFELD: Any other comments? Seeing none, I'll call the question.

All those in favor of the conclusion? Thank you. Unanimous.

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## Safety Assessment of *Butyrospermum parkii* (Shea)- Derived Ingredients as Used in Cosmetics

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## ABSTRACT

The Cosmetic Ingredient Review (CIR) Expert Panel (Panel) assessed the safety of 13 *Butyrospermum parkii* (shea)-derived ingredients, which are most frequently reported to function in cosmetics as skin and hair conditioning agents. The Panel reviewed the available data to determine the safety of these ingredients. Because final product formulations may contain multiple botanicals, each containing similar constituents of concern, formulators are advised to be aware of these constituents and to avoid reaching levels that may be hazardous to consumers. Industry should use good manufacturing practices to limit impurities that could be present in botanical ingredients. The Panel concluded that the 9 butter, oil, and glyceride ingredients are safe as used in the present practices of use and concentration as described in this safety assessment, while the data on the 4 nut and seedcake ingredients are insufficient to determine safety.

## INTRODUCTION

The *Butyrospermum parkii* (shea)-derived ingredients detailed in this report function mainly as skin and hair conditioning agents in personal care products according to the *International Cosmetic Ingredient Dictionary and Handbook (Dictionary)*.<sup>1</sup> This report assesses the safety of the following 13 *Butyrospermum parkii* (shea)-derived ingredients:

Butyrospermum Parkii (Shea) Butter	Hydrogenated Shea Butter
Butyrospermum Parkii (Shea) Butter Extract	Hydrogenated Shea Oil
Butyrospermum Parkii (Shea) Butter Unsaponifiables	Hydrolyzed Shea Seedcake Extract
Butyrospermum Parkii (Shea) Nut Extract	Shea Butter Glyceride
Butyrospermum Parkii (Shea) Nut Shell Powder	Shea Butter Glycerides
Butyrospermum Parkii (Shea) Oil	Shea Oleine
Butyrospermum Parkii (Shea) Seedcake Extract	

The Panel previously reviewed the safety of Butyrospermum Parkii (Shea) Oil, Butyrospermum Parkii (Shea) Butter, Butyrospermum Parkii (Shea) Butter Unsaponifiables, and Hydrogenated Shea Butter in the 2011 safety assessment of plant-derived fatty acid oils and found these ingredients to be safe as used in cosmetics.<sup>2</sup> Because data from the previous assessment may help to inform the safety of the ingredients listed in this current assessment, the relevant information has been summarized here in italics.

Botanicals such as *Butyrospermum parkii* (shea)-derived ingredients may contain hundreds of constituents, some of which may have the potential to cause toxic effects. In this assessment, CIR is reviewing the potential toxicity of each of the *Butyrospermum parkii* (shea)-derived ingredients as a whole, complex mixture. Except for specific constituents of concern, CIR will not review the potential toxicity of the individual constituents found in *Butyrospermum parkii* from which the ingredients in this report are derived.

The ingredient names, according to the *Dictionary*, are written as listed above, without italics and without abbreviations. When referring to the tree from which these ingredients are derived, the standard scientific practice of using italics will be followed (e.g., *Butyrospermum parkii*). The shea tree is also known taxonomically as *Vitellaria paradoxa* and is referred to as such by many references and by the Food and Drug Administration (FDA).

Shea oleine (“oleine” is an oleate triglyceride) is listed as a cosmetic ingredient in the FDA Voluntary Cosmetic Registration Program (VCRP) database, but it is not an ingredient listed in the *Dictionary*. This chemical has been included in this report because use as a cosmetic ingredient may be demonstrated. (Triolein, the triester of glycerin and oleic acid, was previously reviewed by the Panel and was found safe as used in cosmetics.)<sup>3</sup>

## CHEMISTRY

### Definition

The definitions and functions of the *Butyrospermum parkii* (shea)-derived ingredients included in this report are provided in Table 1.

### Plant Identification

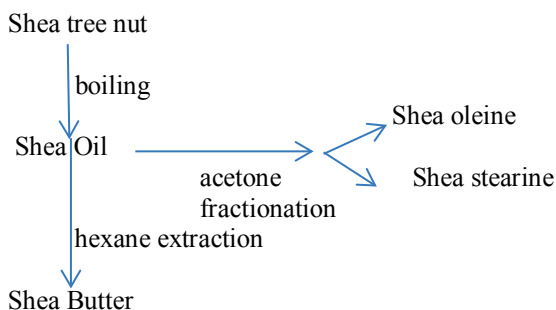
The raw materials for the *Butyrospermum parkii* (shea)-derived ingredients found in this report are obtained from the tree *Butyrospermum parkii*, which grows mainly in equatorial Africa.<sup>4-6</sup>

### Physical and Chemical Properties

Butyrospermum Parkii (Shea) Butter, depending on level of refinement, is an off-white or grey to yellowish-cream tallow-like solid, with a specific gravity of 0.918 at 15 °C and a melting point of 37.8 °C (reported range: 28-46 °C).<sup>7-12</sup> Butyrospermum Parkii (Shea) Oil is a pale yellow liquid.<sup>13</sup> Shea Oleine is a clear yellow liquid, with a characteristic fatty odor and a density of 0.922-0.928 at 20 °C.<sup>14</sup>

### Method of Manufacture

The general description of the method of manufacturing of several *Butyrospermum parkii* (shea)-derived ingredients is described in the following schematic:<sup>15</sup>



**Figure 1.** General description of the manufacturing of *Butyrospermum parkii* (shea)-derived ingredients

#### ***Butyrospermum Parkii* (Shea) Butter Unsaponifiables**

Butyrospermum Parkii (Shea) Butter Unsaponifiables is obtained by molecular distillation and supercritical carbon dioxide extraction of Butyrospermum Parkii (Shea) Butter.<sup>16</sup>

#### ***Butyrospermum Parkii* (Shea) Nut Shell Powder**

According to a supplier, Butyrospermum Parkii (Shea) Nut Shell Powder is obtained by removing the shea seed from the shell and drying the shell in the sun, followed by grinding and sieving the resultant product.<sup>17</sup> The ground shell is then sterilized and examined by quality control.

#### ***Butyrospermum Parkii* (Shea) Seedcake Extract**

Butyrospermum Parkii (Shea) Seedcake Extract is produced by solubilizing the seedcake of *Butyrospermum parkii* in a mixture of water and butylene glycol (50%/50% -v/v), and then separating the soluble and insoluble phases, filtrating, and sterilizing.<sup>18</sup>

### Composition/Impurities

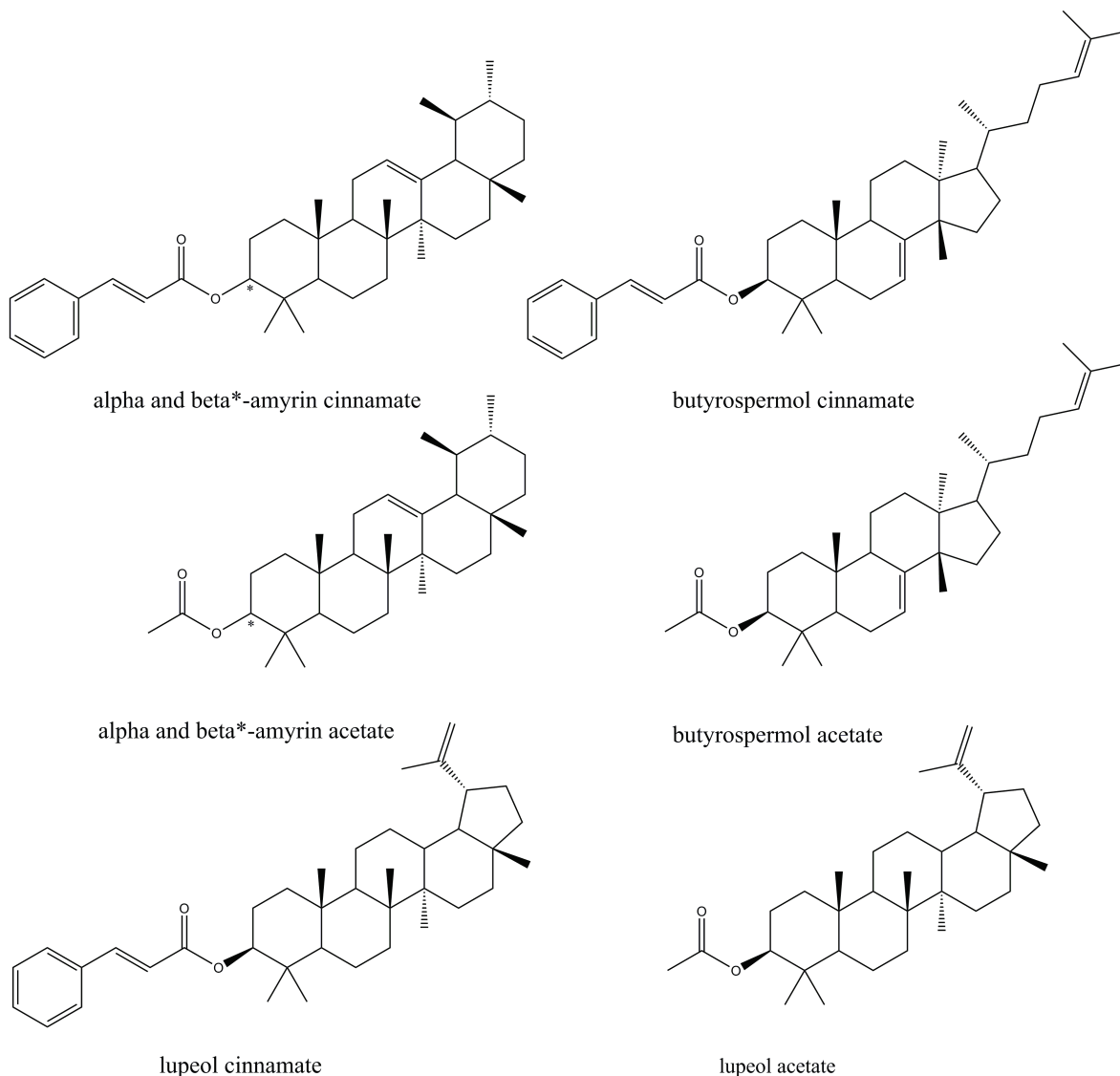
The mean tocopherol concentrations and fatty acid compositions of *Butyrospermum parkii* (shea)-derived ingredients are provided in Table 2 and Table 3, respectively. While *Butyrospermum parkii* grows mainly in equatorial Africa, subtle differences in geographic location and climate affect the levels of the natural compounds, such as tocopherol and fatty acids, in *Butyrospermum parkii* (shea)-derived ingredients.<sup>4,5</sup>

A study of Butyrospermum Parkii (Shea) Butter (described as kernel fats; n-hexane extraction) from 36 samples from seven different countries found the principal triacylglycerols to be stearic-oleic-stearic (mean 31.2% of total triacylglycerols), stearic-oleic-oleic (27.7%), and oleic-oleic-oleic (10.8%).<sup>19</sup> Triterpene ester contents ranged from 0.5% to 6.5% and consisted of  $\alpha$ -amyrin cinnamate (mean 29.3% of total triterpene esters), butyrospermol cinnamate (14.8%),  $\alpha$ -amyrin acetate (14.1%), lupeol cinnamate (9.0%),  $\beta$ -amyrin cinnamate (7.6%), lupeol acetate (7.2%), butyrospermol acetate (5.8%), and  $\beta$ -amyrin acetate (4.9%) (Figure 2).

The same researchers identified the content and composition of triterpene alcohol fractions of the non-saponifiable lipids of Butyrospermum Parkii (Shea) Butter from 36 samples.<sup>20</sup> The shea kernels contained 30%-54% fat, of which 2%-12% were non-saponifiable lipids. Triterpene alcohol content in the non-saponifiable lipids was 22%-72%. The triterpene alcohol fractions contained  $\alpha$ -amyrin,  $\beta$ -amyrin, lupeol, and butyrospermol with minor or trace amounts of  $\psi$ -taraxasterol, taraxasterol, parkeol, 24-methylene-24-dihydroparkeol, 24-methylene-cycloartanol, dammaradienol, and 24-methylenedammarenol.



An analysis of the phenolic constituents of shea kernels by liquid chromatography-mass spectrometry (LC-MS) identified the following catechin compounds: gallic acid, catechin, epicatechin, epicatechin gallate, gallocatechin, epigallocatechin, gallocatechin gallate, and epigallocatechin gallate.<sup>6</sup> Quercetin and *trans*-cinnamic acid were also identified. The mean kernel content of the catechin compounds was 4000 ppm with a range of 2100-9500 ppm.



**Figure 2.** Triterpene esters.

### ***Butyrospermum Parkii (Shea) Butter Unsaponifiables***

Butyrospermum Parkii (Shea) Butter Unsaponifiables mainly contain terpene alcohols present in the butter in the form of cinnamic acid esters (including  $\alpha$ - and  $\beta$ -amyrin lupeol, butyrospermol, and cycloartenol) and phytosterols including  $\alpha$ -spinasterol,  $\Delta^7$ -stigmasterol, and stigmasterol).<sup>16</sup>

### ***Butyrospermum Parkii (Shea) Nut Shell Powder***

A supplier has reported that Butyrospermum Parkii (Shea) Nut Shell Powder does not contain any fragment or pieces of shea seed.<sup>17</sup> Butyrospermum Parkii (Shea) Nut Shell Powder does not contain Butyrospermum Parkii (Shea) Butter Unsaponifiables. This ingredient consists of woody tissues and does not contain asbestos, free amines,

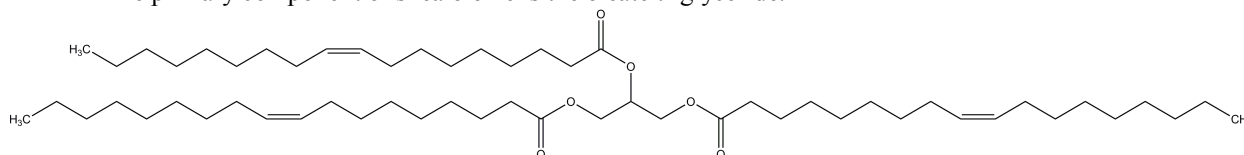
antioxidants, formaldehyde, monomers, nitrosamines, ethylene oxide, triethanolamine, 1,4-dioxane, or volatile organic compounds.

### ***Butyrospermum Parkii (Shea) Seedcake Extract***

According to a supplier, *Butyrospermum Parkii* (Shea) Seedcake Extract is composed of 2.8% of the named ingredient, 50.0% butylene glycol, and 47.2% water.<sup>18</sup> This supplier also reported that alkaloids were less than the limit of sensitivity (0.05 g/l in Dragendorff reagent), heavy metal composition included trace levels of nickel (0.049 ppm) and lead (0.478 ppm), and the sum of the concentrations of aflatoxins B1, B2, G1, and G2 was less than 1.0 µg/kg. The supplier also reported that neither the 26 allergenic compounds regulated by the European Union nor any pesticides were detected in this ingredient.

### ***Shea Oleine***

The primary component of shea oleine is the oleate triglyceride.



**Figure 3.** Oleate triglyceride.

However, the sterol component of shea oleine is approximately 8% (w/w), of which approximately 97% is 4,4-dimethylsterols (mostly as esters of cinnamic acid), 2% is 4-demethylsterols and 0.5% is 4- $\alpha$ -methylsterols.<sup>15</sup>

## **USE** **Cosmetic**

The safety of the cosmetic ingredients included in this assessment is evaluated based on data received from the U.S. FDA and the cosmetics industry on the expected use of these ingredients in cosmetics. Use frequencies of individual ingredients in cosmetics are collected from manufacturers and reported by cosmetic product category in FDA's VCRP database. Use concentration data are submitted by Industry in response to surveys, conducted by the Personal Care Products Council (Council), of maximum reported use concentrations by product category.

According to 2017 VCRP data, *Butyrospermum Parkii* (Shea) Butter has the most reported uses of the ingredients listed in this safety assessment in cosmetic products, with a total of 5447; nearly three-fourths of the uses are in leave-on formulations (Table 4).<sup>21,22</sup> *Butyrospermum Parkii* (Shea) Butter Extract has the second greatest number of overall uses reported, with a total of 560; two-thirds of the uses are in leave-on formulations. The results of the concentration of use survey conducted in 2016 by the Council indicate *Butyrospermum Parkii* (Shea) Butter has the highest reported maximum concentration of use; it is used at up to 100% in moisturizers.<sup>23</sup> *Butyrospermum Parkii* (Shea) Oil is used at up to 11% in lipsticks.<sup>24</sup> No uses were reported for Hydrogenated Shea Oil or Hydrolyzed Shea Seedcake Extract.

In some cases, reports of uses were received from the VCRP, but no concentration of use data were provided. For example, Hydrogenated Shea Butter is reported to be used in 22 formulations, but no use concentration data were provided. In other cases, no uses were reported to the VCRP, but a maximum use concentration was provided in the industry survey. For example, Shea Butter Glyceride was not reported in the VCRP database to be in use, but the industry survey indicated that it is used at concentrations up to 0.49%. It should be presumed that Shea Butter Glyceride is used in at least one cosmetic formulation.

Some of these ingredients may be used in products that can be incidentally ingested or come into contact with mucous membranes. For example, *Butyrospermum Parkii* (Shea) Oil is used in lipsticks at up to 11%.<sup>24</sup> Additionally, some of these ingredients were reported to be used in hair sprays, face powders, fragrances and body and hand sprays and could possibly be inhaled. For example, *Butyrospermum Parkii* (Shea) Seedcake Extract was reported to be used in fragrance preparations at a maximum concentration of 4% and *Butyrospermum Parkii* (Shea) Unsaponifiables was reported to be used in a face powder at 0.06%.<sup>23</sup> In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters >10 µm, with propellant sprays yielding a greater fraction of droplets/particles below 10 µm compared with pump sprays. Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and bronchial regions and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount. Conservative estimates

of inhalation exposures to respirable particles during the use of loose powder cosmetic products are 400-fold to 1000-fold less than protective regulatory and guidance limits for inert airborne respirable particles in the workplace.<sup>25-27</sup>

The *Butyrospermum parkii* (shea)-derived ingredients described in this safety assessment are not restricted from use in any way under the rules governing cosmetic products in the European Union.<sup>28</sup>

### **Non-Cosmetic**

Butyrospermum Parkii (Shea) Oil (sheanut oil), from which many of the ingredients of this report are derived, is generally recognized as safe (GRAS) in the U.S. as a direct food additive (21CFR§184.1702). It is used in confections and frostings, coatings of soft candy, and sweet sauces and toppings.

Refined sheanut oil is described as a component of a mixture of oils used as a cocoa butter substitute, as a coating agent, and in margarine and shortening in the *Food Chemicals Codex*, a compendium of internationally recognized standards published by the United States Pharmacopeia (USP) for the purity and identity of food ingredients.<sup>13</sup>

A triterpene-rich extract of *Butyrospermum parkii* has been reported to be used as a dietary supplement for the treatment of osteoarthritis.<sup>29</sup> Other studies have found that components of shea extracts potentially have anti-inflammatory, antioxidant, and anti-tumor effects.<sup>30-33</sup>

## **TOXICOKINETIC STUDIES**

### **Absorption, Distribution, Metabolism, and Excretion (ADME)**

#### ***Animal***

##### ***Oral***

##### **Shea Oleine**

In an oral absorption and excretion study, groups of Colworth Wistar male rats were fed shea oleine in a semisynthetic diet.<sup>34</sup> In a low-dose experiment, groups of 24 rats received control feed, feed containing 0.5% shea oleine, or feed containing 5% shea oleine for 1 week, with control feed administered to all rats the week prior and the week following the exposure week. In a high-dose experiment, 2 groups of 15 male and 15 female rats received either 10% or 20% shea oleine in the feed for 3 weeks. In the first experiment, feces were collected and pooled weekly for each treatment group throughout weeks 2 and 3. In the second experiment, feces were collected and pooled for each treatment group in week 3 only. The dried fecal matter of the rats was then analyzed with thin-layer and gas-liquid chromatography for fecal lipid, total sterol, differential sterol levels, and, specifically, 4,4-dimethylsterols (the main sterol constituent (~97%) of shea oleine). Excretion of 4,4-dimethylsterols increased with the consumption of shea oleine. Apparent absorption was 27% to 52% and was estimated from the disappearance of 4,4-dimethylsterols from the feces. The majority of the 4,4-dimethylsterols was excreted unchanged.

#### ***Human***

##### ***Oral***

##### **Shea Oleine**

The oral absorption and excretion of shea oleine was studied in 4 male volunteers.<sup>34</sup> On day 3 of an 8 day period, the subjects consumed a single 25 g portion (approximately 0.4 g/kg) of shea oleine in mayonnaise. No other vegetable fats were consumed during the course of the study. Feces were collected on days 3 to 8 inclusively, freeze-dried, and weighed. The dried fecal matter was analyzed in the manner described above. Excretion of 4,4-dimethylsterols increased with the consumption of shea oleine, with a marked increase from baseline on days 4 and 5 and a return to approximate baseline on day 8. Absorption of 4,4-dimethylsterols was estimated to be 13% to 49%. The majority of the 4,4-dimethylsterols was excreted unchanged.

## **TOXICOLOGICAL STUDIES**

### **Acute Toxicity Studies**

No relevant published acute toxicity studies on *Butyrospermum parkii* (shea)-derived ingredients were identified in a literature search for these ingredients, and no unpublished data were submitted.

## Subchronic Toxicity Studies

### *Shea Oleine*

In a 13-week rat feeding study, Colworth-Wistar rats received a diet containing 20% (w/w; 10 to 15 g/kg/day) shea oleine or hydrogenated shea oleine.<sup>35</sup> Groups of 15 male and 15 female rats were fed either 20% (w/w) palm oil, soy bean oil, or the hydrogenated equivalents. During the exposure period, body weight, food and water consumption, urine chemistry, and clinical pathology were assessed. Gross necropsy and microscopic examination of select tissues and organs were performed at study completion.

Results showed that shea oleine diets produced biological effects similar to those of palm oil and soy bean oil diets. Slightly reduced body weight gain was observed in rats fed either of the shea oleine diets when compared to diets with palm oil and soy bean oil. No significant differences in body weight gains were observed between rats fed hydrogenated shea oleine versus non-hydrogenated shea oleine. Slightly reduced cholesterol levels, increased aminotransferase levels, and lower triglyceride and alanine aminotransferase values were observed in rats fed non-hydrogenated diets, as were increased liver weights and reduced liver-lipid values. These changes were not considered to be biologically significant. Also considered biologically insignificant by the authors were raised alkaline phosphatase levels and increased food consumption in rats fed hydrogenated shea oleine. The authors concluded that all diets were well tolerated in the rats and considered none of the findings in this study to be adverse.<sup>35</sup>

## Chronic Toxicity Studies

### *Butyrospermum Parkii (Shea) Oil and Shea Oleine*

See Carcinogenicity section below.

## DEVELOPMENTAL AND REPRODUCTIVE TOXICITY (DART) STUDIES

### Oral

### *Butyrospermum Parkii (Shea) Oil and Shea Oleine*

The reproductive toxicity potential of shea oleine and hydrogenated shea oleine was assessed in two dietary studies in rats.<sup>36</sup> In study 1, groups of 20 male and 20 female Colworth-Wistar rats received 7% (w/w; 3.5 g/kg/day) of either type of shea oleine in their diet for 20 weeks (breeding began at week 12 and lasted for 2 weeks). In study 2, groups of 50 male and 50 female Colworth-Wistar rats received 15% (w/w; 7.5 g/kg/day) of either type of shea oleine in their diets for 10 weeks (breeding began at week 2 and lasted for 1 week). Both studies also evaluated other commercially available materials, such as *Butyrospermum Parkii* (Shea) Oil (15% w/w, in study 2), palm oil, and cocoa butter. The rats received the test materials during pre-mating, mating, pregnancy and offspring weaning. Reproduction was assessed by counting the number of litters, pups born, and pups surviving, and measuring body weights at birth and at weaning on day 21. Skeletal evaluation using X-ray, clinical pathology and macroscopic examination were performed on F<sub>1</sub> rats. Parental animal parameters assessed were body weight, food consumption, clinical pathology, organ weights and macroscopic examination. Fatty acids and hydrocarbon levels were measured, and various tissues were evaluated in F<sub>0</sub> animals for lipogranulomata in Study 2.

Slightly reduced body weight gain, reduced cholesterol, and increased alkaline phosphatase levels were observed in rats treated with either shea oleine or hydrogenated shea oleine. No adverse effects on reproduction from any shea materials were observed in either study for any parameter. Results showed that shea oleine and hydrogenated shea oleine were toxicologically comparable to the other commercially available materials used in this study. The authors concluded that there was no evidence of reproductive toxicity following dietary exposure to shea oleine and hydrogenated shea oleine in rats at concentrations equating to greater than 15% (7.5 g/kg/day).<sup>36</sup>

## GENOTOXICITY

### In Vitro

### *Butyrospermum Parkii (Shea) Butter and Butyrospermum Parkii (Shea) Butter Unsaponifiables*

A material containing *Butyrospermum Parkii* (Shea) Butter (70%) and *Butyrospermum Parkii* (Shea) Butter Unsaponifiables (30%) was not mutagenic in an Ames test.<sup>16</sup> The material was tested at 50 to 5000 µg/plate, with and without metabolic activation. No further details were provided.

## CARCINOGENICITY

### Oral

#### ***Butyrospermum Parkii (Shea) Oil and Shea Oleine***

The carcinogenic potential of shea oleine was evaluated in a dietary study in Colworth-Wistar rats for 104 weeks.<sup>15</sup> The study also evaluated Butyrospermum Parkii (Shea) Oil and palm oil. Groups of 50 male and 50 female rats received diets containing 15% (w/w; approximately equivalent to 7.5 g/kg/day) shea oleine, 15% (w/w) Butyrospermum Parkii (Shea) Oil, or 15% (w/w) palm oil. The rats were the offspring of the animals used in the reproduction study described above (study 2) and the test diets began at weaning (21 days of age). The following parameters were assessed: mortality, clinical signs of toxicity, body weight, food intake, clinical pathology, organ weights and macroscopic and histopathological changes plus tumor type and incidence evaluation.

Final mortality rates for both sexes for shea oleine and Butyrospermum Parkii (Shea) Oil were in the range of 28% to 30% each, while the mortality rates for both sexes exposed to palm oil was 40%. No clinical signs of toxicity were found after exposure to either shea test material. Reduced body weight gain and increased feed intake were observed in rats of both sexes fed either shea diets, while reduced cholesterol was observed in females fed the shea oleine diet. Increased alkaline phosphatase levels were observed in both sexes fed the Butyrospermum Parkii (Shea) Oil diet, but this value was only increased in females fed the shea oleine diet. Reduced heart weight and an increased incidence of pulmonary lipidosis were observed in rats of both sexes fed either shea diet. In females fed either shea diet, an increase in the number of hepatomas was observed, while in males fed shea oleine, increases in pancreatic exocrine adenomas and skin keratoacanthomas were observed. The increase in the incidence of hepatomas was thought to be related to the high fat content of the diets. The authors concluded that none of the findings in this study were adverse effects and that shea oleine showed no tumorigenic potential in the rat at 15% in the diet (7.5 g/kg/day) when compared to Butyrospermum Parkii (Shea) Oil and palm oil.<sup>15</sup>

## DERMAL IRRITATION AND SENSITIZATION STUDIES

### Irritation

Dermal irritation studies are summarized in Table 5.<sup>16,18,37-39</sup> A material containing Butyrospermum Parkii (Shea) Butter (70%) and Butyrospermum Parkii (Shea) Butter Unsaponifiables (30%) was non-irritating in an EpiSkin™ assay when tested undiluted and in a human primary cutaneous tolerance test at a 30% dilution in paraffin oil. Butyrospermum Parkii (Shea) Butter Extract at 5% in a moisturizer and Butyrospermum Parkii (Shea) Seedcake Extract at up to 0.14% were not irritating in human irritation studies.

#### ***Butyrospermum Parkii (Shea) Butter***

*In an EpiSkin™ in vitro assay, 24.1% Butyrospermum Parkii (Shea) Butter in a lip wax was not an irritant.<sup>2</sup> In animal study, Butyrospermum Parkii (Shea) Butter (concentration not reported) produced very slight erythema with or without edema in 2/3 rabbits exposed to the test material for 4 h in an irritation study utilizing occlusive patches. The erythema was resolved 3 or 4 days after patching. Butyrospermum Parkii (Shea) Butter did not cause primary cutaneous irritation when tested at up to 2%. No irritation to Butyrospermum Parkii (Shea) Butter was observed in human volunteers for in-use studies of lip gloss or body/hand massage oils at concentrations up to 45%.*

### Sensitization

Dermal sensitization studies are summarized in Table 6.<sup>16,18,40-44</sup> A material containing Butyrospermum Parkii (Shea) Butter (70%) and Butyrospermum Parkii (Shea) Butter Unsaponifiables (30%) was considered non-sensitizing in a direct peptide reactivity assay when tested undiluted. Butyrospermum Parkii (Shea) Butter Extract was non-sensitizing in human patch tests up to 5% in formulation. Butyrospermum Parkii (Shea) Seedcake Extract at up to 0.14% did not produce sensitization reaction in humans.

#### ***Butyrospermum Parkii (Shea) Butter***

*Butyrospermum Parkii (Shea) Butter was not sensitizing in a guinea pig maximization study.<sup>2</sup> The induction concentration was 75% and the challenge concentrations were 20% and 50%. No sensitization was observed in multiple HRIPTs with products containing Butyrospermum Parkii (Shea) Butter. Concentrations tested were up to 60%.*

## Phototoxicity and Photosensitization

### *In Vitro*

#### ***Butyrospermum Parkii (Shea) Butter and Butyrospermum Parkii (Shea) Butter Unsaponifiables***

A material containing Butyrospermum Parkii (Shea) Butter (70%) and Butyrospermum Parkii (Shea) Butter Unsaponifiables (30%) was considered non-phototoxic in a 3T3 NRU assay when tested at 0.005 to 1 mg/ml.<sup>16</sup> This study was performed in accordance to Organization for Economic Co-operation and Development's (OECD) TG 432. No further details were provided.

### *Animal*

#### ***Butyrospermum Parkii (Shea) Butter***

*Butyrospermum Parkii (Shea) Butter was not phototoxic in guinea pigs when tested at 10 and 20% in acetone.<sup>2</sup> The test sites were irradiated with UV-B light for 80 seconds followed by UV-A light for 80 min.*

## OCULAR IRRITATION STUDIES

### *Animal*

#### ***Butyrospermum Parkii (Shea) Butter***

*While mild conjunctival reactions were observed, undiluted Butyrospermum Parkii (Shea) Butter was considered not irritating when tested in the eyes of male rabbits.<sup>2</sup>*

## MUCOUS MEMBRANE IRRITATION STUDIES

### *In Vitro*

#### ***Butyrospermum Parkii (Shea) Butter and Butyrospermum Parkii (Shea) Butter Unsaponifiables***

A balm containing 1.5% of the mixture Butyrospermum Parkii (Shea) Butter (70%) and Butyrospermum Parkii (Shea) Butter Unsaponifiables (30%) was considered non-irritating in a Skinethic reconstituted mucous membrane model.<sup>16</sup> Approximately 10 µl of the balm was applied undiluted for 24 h. The negative control was phosphate buffer saline and the positive control was 0.1% and 3% sodium dodecyl sulfate). No further details were provided.

## SUMMARY

The 13 *Butyrospermum parkii* (shea)-derived ingredients detailed in this report function mainly as skin and hair conditioning agents in personal care products. Studies on Butyrospermum Parkii (Shea) Butter and Butyrospermum Parkii (Shea) Butter Unsaponifiables included in the 2011 safety assessment of plant-derived fatty acid oils are not included in this summary.

According to 2017 VCRP data, Butyrospermum Parkii (Shea) Butter has the most reported uses of the ingredients listed in this safety assessment in cosmetic products, with a total of 5447; nearly three-fourths of the uses are in leave-on formulations. Butyrospermum Parkii (Shea) Butter Extract has the second greatest number of overall reported, with a total of 560; about two-thirds of the uses are in leave-on formulations. The results of the concentration of use survey conducted in 2016 by the Council indicate Butyrospermum Parkii (Shea) Butter has the highest reported maximum concentration of use; it is used at up to 100% in moisturizers. Butyrospermum Parkii (Shea) Oil is used at up to 11% in a lipstick. No uses were reported for Hydrogenated Shea Oil or Hydrolyzed Shea Seedcake Extract.

Butyrospermum Parkii (Shea) Oil is a GRAS direct food additive in the U.S. It is used as a cocoa butter substitute in confections and frostings, coatings of soft candy, and sweet sauces and toppings. It is also used as a margarine or shortening. Components of shea extracts have potential anti-inflammatory, antioxidant, and anti-tumor effects.

Oral absorption and excretion studies of rats fed up to 20% shea oleine in a semisynthetic diet found excretion of 4,4-dimethylsterols increased with the consumption of shea oleine. Apparent absorption of shea oleine was 27% to 52%, as measured by 4,4-dimethylsterols. The majority of the 4,4-dimethylsterols was excreted unchanged. The findings for the absorption and excretion of approximately 0.4 g/kg in a single dose study of human volunteers were similar, with the absorption of shea oleine estimated to be 13% to 49%, as measured by 4,4-dimethylsterols.

In a 13-week rat feeding study, shea oleine or hydrogenated shea oleine (20% w/w, equivalent to 10-15 g/kg/day, for both test materials) did not produce adverse effects. No reproductive effects were observed in rats fed shea oleine or hydrogenated shea oleine (up to 15% w/w, equivalent to 7.5 g/kg/day, for both test materials) for

up to 20 weeks. No tumorigenic potential or adverse effects to shea oleine (15% w/w, equivalent to 7.5 g/kg/day) was observed in a carcinogenicity study in the offspring of the rats from the reproductive study.

A material containing Butyrospermum Parkii (Shea) Butter (70%) and Butyrospermum Parkii (Shea) Butter Unsaponifiables (30%) was not mutagenic in an Ames test.

A material containing Butyrospermum Parkii (Shea) Butter (70%) and Butyrospermum Parkii (Shea) Butter Unsaponifiables (30%) was non-irritating in an EpiSkin™ assay when tested undiluted and in a human primary cutaneous tolerance tested at a 30% dilution in paraffin oil. Butyrospermum Parkii (Shea) Butter Extract at 5% in a moisturizer and Butyrospermum Parkii (Shea) Seedcake Extract at up to 0.14% were not irritating in human irritation studies.

A material containing Butyrospermum Parkii (Shea) Butter (70%) and Butyrospermum Parkii (Shea) Butter Unsaponifiables (30%) was considered non-sensitizing in a direct peptide reactivity assay when tested undiluted. Butyrospermum Parkii (Shea) Butter Extract was non-sensitizing in human patch tests at up to 5% in formulation. Butyrospermum Parkii (Shea) Seedcake Extract at up to 0.14% did not produce sensitization reaction in humans.

A material containing Butyrospermum Parkii (Shea) Butter (70%) and Butyrospermum Parkii (Shea) Butter Unsaponifiables (30%) was considered non-phototoxic in a 3T3 NRU assay when tested at 0.005 to 1 mg/ml.

A balm containing 1.5% of the mixture Butyrospermum Parkii (Shea) Butter (70%) and Butyrospermum Parkii (Shea) Butter Unsaponifiables (30%) was considered non-irritating in a Skinethic reconstituted mucous model.

No relevant published acute toxicity or case reports on *Butyrospermum parkii* (shea)-derived ingredients were identified in a literature search for these ingredients and no unpublished data were submitted.

## **DISCUSSION**

The Panel noted that, because botanical ingredients are complex mixtures, there is concern that multiple botanical ingredients in one formulation may each contribute to the final concentration of a single constituent. Therefore, when formulating products, manufacturers should avoid reaching levels in final formulation of botanical constituents that may cause sensitization or other adverse effects.

The Panel discussed the issue of incidental inhalation exposure from hair sprays, fragrance preparations, body and hand sprays, and face powders. There were no inhalation toxicity data available. The Panel noted that droplets/particles from spray and loose-powder cosmetic products would not be respirable to any appreciable amount. The potential for inhalation toxicity is not limited to respirable droplets/particles deposited in the lungs. In principle, inhaled droplets/particles deposited in the nasopharyngeal and thoracic regions of the respiratory tract may cause toxic effects depending on their chemical and other properties. However, coupled with the small actual exposure in the breathing zone and the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at <http://www.cir-safety.org/cir-findings>.

The Panel also expressed concern about pesticide residues, heavy metals, and other plant species that may be present in botanical ingredients. They stressed that the cosmetics industry should continue to use current good manufacturing practices (cGMPs) to limit impurities.

The ingredient Butyrospermum Parkii (Shea) Butter is reported to be used at concentrations up to 100%. While there are no safety test data for this ingredient at this maximum concentration, the Panel noted that sensitization studies summarized in the 2011 safety assessment of plant-derived fatty acid oils were negative for products containing up to 60% Butyrospermum Parkii (Shea) Butter. Based on this information, the clinical experience of the Panel, and the absence of adverse event reports, the Panel was not concerned about dermal irritation or sensitization. The Panel considered the available data on the remaining butter, oil, and glyceride ingredients and found that data were adequate to support the safety of these ingredients as they are used in cosmetics. However, the Panel found that the data are insufficient to make a conclusion on the safety of the 4 nut- and seedcake-derived ingredients in this safety assessment. The data that are needed to properly evaluate the safety of these ingredients are:

- Method of manufacturing for Butyrospermum Parkii (Shea) Nut Extract, Butyrospermum Nut Shell Powder, Butyrospermum Parkii (Shea) Seedcake Extract, and Hydrolyzed Shea Seedcake Extract
- Composition and impurities data on the above listed nut and seedcake ingredients
- Sensitization data on the above listed nut and seedcake ingredients.

**CONCLUSION**

The CIR Expert Panel concluded that the following 9 ingredients are safe as used in the present practices of use and concentration as described in this safety assessment.

Butyrospermum Parkii (Shea) Butter	Hydrogenated Shea Butter
Buyrospemum Parkii (Shea) Oil	Hydrogenated Shea Oil*
Butyrospermum Parkii (Shea) Butter Extract	Shea Butter Glyceride
Butyrospermum Parkii (Shea) Butter	Shea Butter Glycerides
Unsaponifiables	Shea Oleine

The Panel concluded that the data on the 4 ingredients listed below are insufficient to determine safety.

Butyrospermum Parkii (Shea) Nut Extract  
Butyrospermum Parkii (Shea) Nut Shell Powder  
Butyrospermum Parkii (Shea) Seedcake Extract  
Hydrolyzed Shea Seedcake Extract\*

\*Not reported to be in current use. Were ingredients in this group not in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group.



**TABLES****Table 1.** Definitions and functions of the ingredients in this safety assessment.<sup>1</sup>

<b>Ingredient/CAS No.</b>	<b>Definition</b>	<b>Function</b>
Butyrospermum Parkii (Shea) Butter CAS No. 91080-23-8; 194043-92-0	Butyrospermum Parkii (Shea) Butter is a fat obtained from the fruit of <i>Butyrospermum parkii</i> . The accepted scientific name for <i>Butyrospermum parkii</i> is <i>Vitellaria paradoxa</i> .	skin-conditioning agents – miscellaneous; skin-conditioning agents – occlusive; viscosity increasing agents - nonaqueous
Butyrospermum Parkii (Shea) Butter Extract CAS No. 91080-23-8	Butyrospermum Parkii (Shea) Butter Extract is the extract of Butyrospermum Parkii (Shea) Butter. The accepted scientific name for <i>Butyrospermum parkii</i> is <i>Vitellaria paradoxa</i> .	skin-conditioning agents - miscellaneous
Butyrospermum Parkii (Shea) Butter Unsaponifiables CAS No. 194043-92-0; 225234-14-0	Butyrospermum Parkii (Shea) Butter Unsaponifiables is the fraction of shea butter which is not saponified in the refining recovery of shea butter fatty acids. The accepted name for <i>Butyrospermum parkii</i> is <i>Vitellaria paradoxa</i> .	hair conditioning agents; skin-conditioning agents - miscellaneous
Butyrospermum Parkii (Shea) Nut Extract CAS No. 91080-23-8	Butyrospermum Parkii (Shea) Nut Extract is the extract of the nuts of <i>Butyrospermum parkii</i> . The accepted name for <i>Butyrospermum parkii</i> is <i>Vitellaria paradoxa</i> .	skin-conditioning agents - emollient
Butyrospermum Parkii (Shea) Nut Shell Powder CAS No. 91080-23-8	Butyrospermum Parkii (Shea) Nut Shell Powder is the powder obtained from the dried, ground nut shells of <i>Butyrospermum parkii</i> . The accepted scientific name for <i>Butyrospermum parkii</i> is <i>Vitellaria paradoxa</i> .	abrasives
Butyrospermum Parkii (Shea) Oil CAS No. 91080-23-8	Butyrospermum Parkii (Shea) Oil is the liquid fraction obtained from Butyrospermum Parkii (Shea) Butter. The accepted name for <i>Butyrospermum parkii</i> is <i>Vitellaria paradoxa</i> .	skin-conditioning agents – miscellaneous; skin-conditioning agents - occlusive
Butyrospermum Parkii (Shea) Seedcake Extract CAS No. 91080-23-8	Butyrospermum Parkii (Shea) Seedcake Extract is the extract of the seedcake of <i>Butyrospermum parkii</i> . The accepted name for <i>Butyrospermum parkii</i> is <i>Vitellaria paradoxa</i> .	skin protectants
Hydrogenated Shea Butter	Hydrogenated Shea Butter is the end product of the controlled hydrogenation of Butyrospermum Parkii (Shea) Butter.	skin-conditioning agents – occlusive; viscosity increasing agents - nonaqueous
Hydrogenated Shea Oil CAS No. 93333-83-6	Hydrogenated Shea Oil is the product obtained by the hydrogenation of Butyrospermum Parkii (Shea) Oil.	skin conditioning agents – emollient; skin-conditioning agents - occlusive
Hydrolyzed Shea Seedcake Extract	Hydrolyzed Shea Seedcake Extract is the hydrolysate of an extract of shea seedcake derived by acid, enzyme, or other method of hydrolysis.	not reported
Shea Butter Glyceride	Shea Butter Glyceride is the monoglyceride derived from Butyrospermum Parkii (Shea) Butter.	skin-conditioning agents – emollient; surfactants – emulsifying agents
Shea Butter Glycerides CAS No. 194043-92-0; 1016637-12-9	Shea Butter Glycerides are a mixture of mono-, di-, and triglycerides derived from Butyrospermum Parkii (Shea) Butter.	emulsion stabilizers; hair conditioning agents; skin-conditioning agents – miscellaneous; slip modifiers; surfactants – emulsifying agents; viscosity increasing agents - aqueous
Shea Oleine	Not in <i>Dictionary</i> .	Not in <i>Dictionary</i> .

**Table 2.** Mean concentrations of tocopherols in 102 *Butyrospermum Parkii* (Shea) Butter samples by HPLC analysis ( $\mu\text{g/g}$ )<sup>4</sup>

$\alpha$ -tocopherol	$\beta$ -tocopherol	$\gamma$ -tocopherol	$\delta$ -tocopherol	total tocopherol
112	16	38	34	208

**Table 3.** Total fatty acid composition of *Butyrospermum parkii* (Shea)-derived ingredients (%)<sup>2,5,45</sup>

Fatty Acids	Butyrospermum	
	Parkii (Shea) Oil	Butyrospermum Parkii (Shea) Butter
Myristic (C14)	NR	0.5
Palmitic (C16)	3.8-4.1	2.6-9
Stearic (C18)	41.2-56.8	25.6-50.2
Oleic (C18:1)	34.0-46.9	37.1-62.1
Linoleic (C18:2)	3.7-6.5	0.6-10.8
Linolenic (C18:3)	NR	0.5 max
Arachidic (C20)	1-2	0-3.5

NR-Not reported.

**Table 4.** Frequency and concentration of use according to duration and type of exposure for shea ingredients.<sup>21-24,46</sup>

	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>
	<b>Butyrospermum Parkii (Shea) Butter</b>		<b>Butyrospermum Parkii (Shea) Butter Extract</b>		<b>Butyrospermum Parkii (Shea) Butter Unsaponifiables</b>		<b>Butyrospermum Parkii (Shea) Nut Extract</b>	
<b>Totals<sup>†</sup></b>	<b>5447*</b>	<b>0.0001-100</b>	<b>560</b>	<b>0.0000095-5</b>	<b>75</b>	<b>0.01-4.5</b>	<b>NR</b>	<b>0.0003-1</b>
<b><i>Duration of Use</i></b>								
Leave-On	4146	0.001-100	384	0.0000095-5	72	0.015-4.5	NR	0.01-1
Rinse Off	1266	0.0001-10	169	0.00028-0.96	3	0.01-2	NR	0.0003-0.51
Diluted for (Bath) Use	35	0.05-3	7	0.05	NR	NR	NR	NR
<b><i>Exposure Type</i></b>								
Eye Area	249	0.1-8	25	0.5	39	0.16-0.5	NR	NR
Incidental Ingestion	510	0.01-9.4	39	0.075-1.9	3	0.25-2.5	NR	NR
Incidental Inhalation -Sprays	23; 1751 <sup>a</sup> ; 1124 <sup>b</sup>	0.1-0.33; 0.001-8 <sup>a</sup> ; 0.59 <sup>b</sup>	14; 132 <sup>a</sup> ; 111 <sup>b</sup>	0.001-0.025; 0.001-0.8 <sup>a</sup> ; 0.0001 <sup>b</sup>	6 <sup>a</sup> ; 7 <sup>b</sup>	0.5 <sup>a</sup>	NR	NR
Incidental Inhalation - Powders	9; 36 <sup>c</sup> ; 1124 <sup>b</sup>	3; 0.59 <sup>b</sup> ; 0.05-8 <sup>c</sup>	2; 8 <sup>c</sup> ; 111 <sup>b</sup>	0.015; 0.0000095-5 <sup>c</sup> ; 0.0001 <sup>b</sup>	4; 1 <sup>c</sup> ; 7 <sup>b</sup>	0.06	NR	NR
Dermal Contact	4625	0.0004-100	489	0.0001-5	67	0.051-4.5	NR	0.0003-1
Deodorant (underarm)	21 <sup>a</sup>	NR	1 <sup>a</sup>	0.05	NR	NR	NR	NR
Hair - Non-Coloring	268	0.0001-8	31	0.001-0.96	5	0.01-0.5	NR	0.01
Hair-Coloring	23	0.004-3.5	NR	NR	NR	NR	NR	NR
Nail	10	0.1-5	NR	0.01	NR	NR	NR	NR
Mucous Membrane	1422	0.0004-9.4	137	0.00028-1.9	3	0.051-2.5	NR	0.0003-0.51
Baby Products	46	0.005-7	10	0.1	1	4	NR	NR
<b><i>Butyrospermum Parkii (Shea) Nut Shell Powder</i></b>								
<b>Totals<sup>†</sup></b>	<b>2</b>	<b>0.00028-1</b>	<b>82</b>	<b>0.001-11</b>	<b>3</b>	<b>0.0002-5.5</b>	<b>23</b>	<b>NR</b>
<b><i>Duration of Use</i></b>								
Leave-On	2	0.01-1	47	0.01-11	2	0.0002-5.5	12	NR
Rinse Off	NR	0.00028-0.5	32	0.001-2.5	1	0.0003-2	11	NR
Diluted for (Bath) Use	NR	NR	3	NR	NR	NR	NR	NR
<b><i>Exposure Type</i></b>								
Eye Area	NR	NR	2	0.5-8	NR	0.0002-5.5	NR	NR
Incidental Ingestion	NR	NR	1	0.5-11	NR	3	1	NR
Incidental Inhalation -Sprays	1 <sup>b</sup>	NR	33 <sup>a</sup> ; 6 <sup>b</sup>	1; 0.2 <sup>a</sup>	2 <sup>a</sup>	0.0095-4; 0.01 <sup>a</sup>	1; 5 <sup>a</sup> ; 3 <sup>b</sup>	NR
Incidental Inhalation - Powders	1 <sup>b</sup>	NR	1; 1 <sup>c</sup> ; 6 <sup>b</sup>	0.95-8 <sup>c</sup>	NR	0.0012-5 <sup>c</sup>	3 <sup>b</sup>	NR
Dermal Contact	2	0.00028-1	75	0.005-8	2	0.0002-5.5	15	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	0.01	6	0.001-0.4	1	0.001-0.99	7	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	0.1-2	NR	3-5	NR	NR
Mucous Membrane	NR	0.00028-0.0011	29	0.005-11	NR	0.0003-3	4	NR
Baby Products	NR	NR	1	NR	NR	5	NR	NR
<b>Shea Butter Glyceride</b>			<b>Shea Butter Glycerides</b>			<b>Shea Oleine</b>		

**Table 4.** Frequency and concentration of use according to duration and type of exposure for shea ingredients.<sup>21-24,46</sup>

	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>	<i># of Uses</i>	<i>Max Conc of Use (%)</i>
<b>Totals<sup>†</sup></b>	<b>NR</b>	<b>0.49</b>	<b>39</b>	<b>0.49-6.5</b>	<b>3</b>	<b>NR</b>		
<b><i>Duration of Use</i></b>								
Leave-On	NR	NR	29	6.5	3	NR		
Rinse Off	NR	0.49	10	0.49-2	NR	NR		
Diluted for (Bath) Use	NR	NR	NR	NR	NR	NR		
<b><i>Exposure Type</i></b>								
Eye Area	NR	NR	4	NR	NR	NR		
Incidental Ingestion	NR	NR	1	NR	NR	NR		
Incidental Inhalation -Sprays	NR	NR	13 <sup>a</sup> ; 5 <sup>b</sup>	NR	1; 1 <sup>a</sup>	NR		
Incidental Inhalation - Powders	NR	NR	5 <sup>b</sup>	0.49-6.5	NR	NR		
Dermal Contact	NR	0.49	31	NR	1	NR		
Deodorant (underarm)	NR	NR	NR	NR	NR	NR		
Hair - Non-Coloring	NR	NR	7	NR	2	NR		
Hair-Coloring	NR	NR	NR	NR	NR	NR		
Nail	NR	NR	NR	NR	NR	NR		
Mucous Membrane	NR	NR	3	2	NR	NR		
Baby Products	NR	NR	1	NR	NR	NR		

NR = No reported use

† Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

\* Number of uses includes VCRP entries for Vitellaria Paradoxa Nilotica (Shea) Butter.

<sup>a</sup> It is possible these products may be sprays, but it is not specified whether the reported uses are sprays.<sup>b</sup> Not specified whether a powder or a spray, so this information is captured for both categories of incidental inhalation.<sup>c</sup> It is possible these products may be powders, but it is not specified whether the reported uses are powders.

**Table 5.** Dermal irritation studies for *Butyrospermum parkii* (shea)-derived ingredients.

Test Article	Concentration/Dose	Test Population	Procedure	Results	Reference
<b>In Vitro</b>					
70% Butyrospermum Parkii (Shea) Butter and 30% Butyrospermum Parkii (Shea) Butter Unsaponifiables	undiluted	N/A	EpiSkin™ assay in accordance with OECD TG 439; no further details provided	Non-irritating	<sup>16</sup>
<b>Human</b>					
Butyrospermum Parkii (Shea) Butter Extract	5% in a moisturizer	46 subjects	Single-blind, 4-week clinical use study; test material applied twice daily in place of regular moisturizer; study supervised by a dermatologist who conducted baseline, 2-week interim, and final exams.	No irritation	<sup>37</sup>
Butyrospermum Parkii (Shea) Butter Extract	5% in a moisturizer	18 subjects	24-h single insult patch test; undiluted; occluded (Blenderm patch); no further details provided	No irritation	<sup>38</sup>
70% Butyrospermum Parkii (Shea) Butter and 30% Butyrospermum Parkii (Shea) Butter Unsaponifiables	30% diluted in paraffin oil	10 subjects	48-h primary cutaneous tolerance test; single patch; treated sites examined 30 min and 24 h post-patch removal; no further details provided	No irritation	<sup>16</sup>
2.8% Butyrospermum Parkii (Shea) Seedcake Extract in mixture with water and butylene glycol	product diluted to 5%	23 subjects	48-h primary cutaneous tolerance test; single occlusive patch; no further details provided	48-h after application, one skin reaction observed on the treated site and one on the control site; mean irritation index = 0.04; product was considered non-irritating	<sup>18</sup>
Butyrospermum Parkii (Shea) Seedcake Extract	0.006% in a SPF 50 cream	41 subjects	4-week cutaneous “in-use” test; once daily application to face, neck, and neckline; no sun exposure; study supervised by a dermatologist who conducted baseline and final exams.	Good cutaneous acceptability	<sup>39</sup>

**Table 6.** Dermal sensitization studies for *Butyrospermum parkii* (shea)-derived ingredients.

Test Article	Concentration/Dose	Test Population	Procedure	Results	References
<b>In Vitro</b>					
70% Butyrospermum Parkii (Shea) Butter and 30% Butyrospermum Parkii (Shea) Butter Unsaponifiables	undiluted	N/A	Direct peptide reactivity assay; performed in accordance with the European Centre for the Validation of Alternative Methods (ECVAM) protocol; reactivity of test material evaluated by monitoring peptide depletion following 24-h contact between test material and synthetic cysteine and lysine peptides; no further details were provided.	Non-reactive and considered non-sensitizing	<sup>16</sup>
<b>Human</b>					
Butyrospermum Parkii (Shea) Butter Extract	2% in a body lotion	28 healthy subjects	Maximization test; 0.05ml test material applied neat under an occlusive dressing to a sodium lauryl sulfate (SLS) pre-treated site on the upper arm; five 48-h induction patches were followed 7-10 days later with challenge on naïve site	Not sensitizing	<sup>40</sup>
Butyrospermum Parkii (Shea) Butter Extract	2% in a body lotion	26 healthy subjects	Maximization test; 0.05ml test material applied neat under an occlusive dressing to a SLS pre-treated site on the upper arm; five 48-h induction patches were followed 7-10 days later with challenge on naïve site	Not sensitizing	<sup>41</sup>
Butyrospermum Parkii (Shea) Butter Extract	5% in a face cream	25 healthy subjects	Maximization test; 0.05ml test material applied neat under an occlusive dressing to a SLS pre-treated site on the upper arm; five 48-h induction patches were followed 7-10 days later with challenge on naïve site	Not sensitizing	<sup>42</sup>
Butyrospermum Parkii(Shea) Butter Extract	1.7975% in a lipstick	104 subjects	HRIPT; 0.2 g test material applied to area 1 in <sup>2</sup> on upper back ; semi-occluded	Not a dermal irritant or dermal sensitizer	<sup>43</sup>
2.8% Butyrospermum Parkii (Shea) Seedcake Extract in mixture with water and butylene glycol	product diluted to 5%	15 subjects	Subjects were those of the cutaneous tolerance study described above, in which the cutaneous tolerance test was considered the induction phase of the sensitization test; after a 6-8 week rest period, subjects were challenged with a single occlusive patch for 48 h; no further details provided	No reactions were observed	<sup>18</sup>
Butyrospermum Parkii (Shea) Seedcake Extract	0.006% in a SPF 50 cream	103 subjects	HRIPT; 0.02 ml test material applied over a 50 mm <sup>2</sup> area via occlusive patch (Finn Chambers on Scanpor) on back	Not irritating or sensitizing	<sup>44</sup>

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## 2017 FDA VCRP Raw Data

01B - Baby Lotions, Oils, Powders, and Creams	VITELLARIA PARADOXA (SHEA) BUTTER	36
01C - Other Baby Products	VITELLARIA PARADOXA (SHEA) BUTTER	10
02A - Bath Oils, Tablets, and Salts	VITELLARIA PARADOXA (SHEA) BUTTER	14
02B - Bubble Baths	VITELLARIA PARADOXA (SHEA) BUTTER	14
02C - Bath Capsules	VITELLARIA PARADOXA (SHEA) BUTTER	1
02D - Other Bath Preparations	VITELLARIA PARADOXA (SHEA) BUTTER	6
03A - Eyebrow Pencil	VITELLARIA PARADOXA (SHEA) BUTTER	3
03B - Eyeliner	VITELLARIA PARADOXA (SHEA) BUTTER	17
03C - Eye Shadow	VITELLARIA PARADOXA (SHEA) BUTTER	34
03D - Eye Lotion	VITELLARIA PARADOXA (SHEA) BUTTER	132
03E - Eye Makeup Remover	VITELLARIA PARADOXA (SHEA) BUTTER	1
03F - Mascara	VITELLARIA PARADOXA (SHEA) BUTTER	11
03G - Other Eye Makeup Preparations	VITELLARIA PARADOXA (SHEA) BUTTER	51
04E - Other Fragrance Preparation	VITELLARIA PARADOXA (SHEA) BUTTER	23
05A - Hair Conditioner	VITELLARIA PARADOXA (SHEA) BUTTER	122
05C - Hair Straighteners	VITELLARIA PARADOXA (SHEA) BUTTER	14
05E - Rinses (non-coloring)	VITELLARIA PARADOXA (SHEA) BUTTER	2
05F - Shampoos (non-coloring)	VITELLARIA PARADOXA (SHEA) BUTTER	41
05G - Tonics, Dressings, and Other Hair Grooming Aids	VITELLARIA PARADOXA (SHEA) BUTTER	43
05I - Other Hair Preparations	VITELLARIA PARADOXA (SHEA) BUTTER	46
06A - Hair Dyes and Colors (all types requiring caution statements and patch tests)	VITELLARIA PARADOXA (SHEA) BUTTER	22
06D - Hair Shampoos (coloring)	VITELLARIA PARADOXA (SHEA) BUTTER	1
07A - Blushers (all types)	VITELLARIA PARADOXA (SHEA) BUTTER	10
07B - Face Powders	VITELLARIA PARADOXA (SHEA) BUTTER	9
07C - Foundations	VITELLARIA PARADOXA (SHEA) BUTTER	23
07E - Lipstick	VITELLARIA PARADOXA (SHEA) BUTTER	510
07F - Makeup Bases	VITELLARIA PARADOXA (SHEA) BUTTER	6
07G - Rouges	VITELLARIA PARADOXA (SHEA) BUTTER	1
07I - Other Makeup Preparations	VITELLARIA PARADOXA (SHEA) BUTTER	127
08B - Cuticle Softeners	VITELLARIA PARADOXA (SHEA) BUTTER	4
08C - Nail Creams and Lotions	VITELLARIA PARADOXA (SHEA) BUTTER	4
08G - Other Manicuring Preparations	VITELLARIA PARADOXA (SHEA) BUTTER	2
10A - Bath Soaps and Detergents	VITELLARIA PARADOXA (SHEA) BUTTER	751
10B - Deodorants (underarm)	VITELLARIA PARADOXA (SHEA) BUTTER	21
10E - Other Personal Cleanliness Products	VITELLARIA PARADOXA (SHEA) BUTTER	126
11A - Aftershave Lotion	VITELLARIA PARADOXA (SHEA) BUTTER	44
11B - Beard Softeners	VITELLARIA PARADOXA (SHEA) BUTTER	12
11D - Preshave Lotions (all types)	VITELLARIA PARADOXA (SHEA) BUTTER	1
11E - Shaving Cream	VITELLARIA PARADOXA (SHEA) BUTTER	11
11F - Shaving Soap	VITELLARIA PARADOXA (SHEA) BUTTER	8
11G - Other Shaving Preparation Products	VITELLARIA PARADOXA (SHEA) BUTTER	5
12A - Cleansing	VITELLARIA PARADOXA (SHEA) BUTTER	83
12B - Depilatories	VITELLARIA PARADOXA (SHEA) BUTTER	5

12C - Face and Neck (exc shave)	VITELLARIA PARADOXA (SHEA) BUTTER	375
12D - Body and Hand (exc shave)	VITELLARIA PARADOXA (SHEA) BUTTER	741
12E - Foot Powders and Sprays	VITELLARIA PARADOXA (SHEA) BUTTER	7
12F - Moisturizing	VITELLARIA PARADOXA (SHEA) BUTTER	1480
12G - Night	VITELLARIA PARADOXA (SHEA) BUTTER	165
12H - Paste Masks (mud packs)	VITELLARIA PARADOXA (SHEA) BUTTER	72
12I - Skin Fresheners	VITELLARIA PARADOXA (SHEA) BUTTER	6
12J - Other Skin Care Preps	VITELLARIA PARADOXA (SHEA) BUTTER	135
13A - Suntan Gels, Creams, and Liquids	VITELLARIA PARADOXA (SHEA) BUTTER	10
13B - Indoor Tanning Preparations	VITELLARIA PARADOXA (SHEA) BUTTER	40
13C - Other Suntan Preparations	VITELLARIA PARADOXA (SHEA) BUTTER	6
01A - Baby Shampoos	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	1
01B - Baby Lotions, Oils, Powders, and Creams	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	8
01C - Other Baby Products	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	1
02A - Bath Oils, Tablets, and Salts	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	1
02B - Bubble Baths	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	3
02D - Other Bath Preparations	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	3
03A - Eyebrow Pencil	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	1
03C - Eye Shadow	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	7
03D - Eye Lotion	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	11
03F - Mascara	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	1
03G - Other Eye Makeup Preparations	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	5
04A - Cologne and Toilet waters	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	4
04E - Other Fragrance Preparation	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	10
05A - Hair Conditioner	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	17
05F - Shampoos (non-coloring)	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	9
05I - Other Hair Preparations	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	4
07A - Blushers (all types)	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	1
07B - Face Powders	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	2
07C - Foundations	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	4
07E - Lipstick	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	39

07G - Rouges	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	1
07I - Other Makeup Preparations	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	11
10A - Bath Soaps and Detergents	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	64
10B - Deodorants (underarm)	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	1
10E - Other Personal Cleanliness Products	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	27
11E - Shaving Cream	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	8
11G - Other Shaving Preparation Products	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	4
12A - Cleansing	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	26
12B - Depilatories	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	8
12C - Face and Neck (exc shave)	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	51
12D - Body and Hand (exc shave)	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	60
12F - Moisturizing	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	100
12G - Night	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	25
12H - Paste Masks (mud packs)	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	5
12I - Skin Fresheners	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	4
12J - Other Skin Care Preps	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	30
13B - Indoor Tanning Preparations	VITELLARIA PARADOXA (SHEA) BUTTER EXTRACT	3
01B - Baby Lotions, Oils, Powders, and Creams	VITELLARIA PARADOXA (SHEA) BUTTER UNSAPONIFIABLES	1
03B - Eyeliner	VITELLARIA PARADOXA (SHEA) BUTTER UNSAPONIFIABLES	6
03C - Eye Shadow	VITELLARIA PARADOXA (SHEA) BUTTER UNSAPONIFIABLES	32
03G - Other Eye Makeup Preparations	VITELLARIA PARADOXA (SHEA) BUTTER UNSAPONIFIABLES	1
05A - Hair Conditioner	VITELLARIA PARADOXA (SHEA) BUTTER UNSAPONIFIABLES	1
05F - Shampoos (non-coloring)	VITELLARIA PARADOXA (SHEA) BUTTER UNSAPONIFIABLES	2
05I - Other Hair Preparations	VITELLARIA PARADOXA (SHEA) BUTTER UNSAPONIFIABLES	2
07A - Blushers (all types)	VITELLARIA PARADOXA (SHEA) BUTTER UNSAPONIFIABLES	4
07B - Face Powders	VITELLARIA PARADOXA (SHEA) BUTTER UNSAPONIFIABLES	4
07C - Foundations	VITELLARIA PARADOXA (SHEA) BUTTER	1

	UNSAPONIFIABLES	
07E - Lipstick	VITELLARIA PARADOXA (SHEA) BUTTER UNSAPONIFIABLES	3
07I - Other Makeup Preparations	VITELLARIA PARADOXA (SHEA) BUTTER UNSAPONIFIABLES	4
12C - Face and Neck (exc shave)	VITELLARIA PARADOXA (SHEA) BUTTER UNSAPONIFIABLES	1
12D - Body and Hand (exc shave)	VITELLARIA PARADOXA (SHEA) BUTTER UNSAPONIFIABLES	6
12F - Moisturizing	VITELLARIA PARADOXA (SHEA) BUTTER UNSAPONIFIABLES	5
12G - Night	VITELLARIA PARADOXA (SHEA) BUTTER UNSAPONIFIABLES	1
12J - Other Skin Care Preps	VITELLARIA PARADOXA (SHEA) BUTTER UNSAPONIFIABLES	1
12D - Body and Hand (exc shave)	VITELLARIA PARADOXA (SHEA) NUT SHELL POWDER	1
12J - Other Skin Care Preps	VITELLARIA PARADOXA (SHEA) NUT SHELL POWDER	1
01B - Baby Lotions, Oils, Powders, and Creams	VITELLARIA PARADOXA (SHEA) OIL	1
02A - Bath Oils, Tablets, and Salts	VITELLARIA PARADOXA (SHEA) OIL	1
02B - Bubble Baths	VITELLARIA PARADOXA (SHEA) OIL	2
03D - Eye Lotion	VITELLARIA PARADOXA (SHEA) OIL	1
03G - Other Eye Makeup Preparations	VITELLARIA PARADOXA (SHEA) OIL	1
05A - Hair Conditioner	VITELLARIA PARADOXA (SHEA) OIL	2
05G - Tonics, Dressings, and Other Hair Grooming Aids	VITELLARIA PARADOXA (SHEA) OIL	2
05I - Other Hair Preparations	VITELLARIA PARADOXA (SHEA) OIL	2
07B - Face Powders	VITELLARIA PARADOXA (SHEA) OIL	1
07E - Lipstick	VITELLARIA PARADOXA (SHEA) OIL	1
10A - Bath Soaps and Detergents	VITELLARIA PARADOXA (SHEA) OIL	23
10E - Other Personal Cleanliness Products	VITELLARIA PARADOXA (SHEA) OIL	2
12A - Cleansing	VITELLARIA PARADOXA (SHEA) OIL	5
12C - Face and Neck (exc shave)	VITELLARIA PARADOXA (SHEA) OIL	5
12D - Body and Hand (exc shave)	VITELLARIA PARADOXA (SHEA) OIL	1
12F - Moisturizing	VITELLARIA PARADOXA (SHEA) OIL	28
12G - Night	VITELLARIA PARADOXA (SHEA) OIL	2
12I - Skin Fresheners	VITELLARIA PARADOXA (SHEA) OIL	1
12J - Other Skin Care Preps	VITELLARIA PARADOXA (SHEA) OIL	1
05F - Shampoos (non-coloring)	VITELLARIA PARADOXA (SHEA) SEEDCAKE EXTRACT	1
12F - Moisturizing	VITELLARIA PARADOXA (SHEA) SEEDCAKE EXTRACT	2
12C - Face and Neck (exc shave)	VITELLARIA PARADOXA NILOTICA (SHEA) BUTTER	1
12F - Moisturizing	VITELLARIA PARADOXA NILOTICA (SHEA)	1

	BUTTER	
12H - Paste Masks (mud packs)	VITELLARIA PARADOXA NILOTICA (SHEA) BUTTER	1
04E - Other Fragrance Preparation	HYDROGENATED SHEA BUTTER	1
05A - Hair Conditioner	HYDROGENATED SHEA BUTTER	7
07C - Foundations	HYDROGENATED SHEA BUTTER	2
07E - Lipstick	HYDROGENATED SHEA BUTTER	1
10A - Bath Soaps and Detergents	HYDROGENATED SHEA BUTTER	3
12C - Face and Neck (exc shave)	HYDROGENATED SHEA BUTTER	3
12F - Moisturizing	HYDROGENATED SHEA BUTTER	5
12H - Paste Masks (mud packs)	HYDROGENATED SHEA BUTTER	1
01A - Baby Shampoos	SHEA BUTTER GLYCERIDES	1
03C - Eye Shadow	SHEA BUTTER GLYCERIDES	4
05A - Hair Conditioner	SHEA BUTTER GLYCERIDES	3
05F - Shampoos (non-coloring)	SHEA BUTTER GLYCERIDES	1
05I - Other Hair Preparations	SHEA BUTTER GLYCERIDES	2
07E - Lipstick	SHEA BUTTER GLYCERIDES	1
07I - Other Makeup Preparations	SHEA BUTTER GLYCERIDES	1
10A - Bath Soaps and Detergents	SHEA BUTTER GLYCERIDES	1
10E - Other Personal Cleanliness Products	SHEA BUTTER GLYCERIDES	1
11A - Aftershave Lotion	SHEA BUTTER GLYCERIDES	1
12A - Cleansing	SHEA BUTTER GLYCERIDES	3
12C - Face and Neck (exc shave)	SHEA BUTTER GLYCERIDES	3
12D - Body and Hand (exc shave)	SHEA BUTTER GLYCERIDES	2
12F - Moisturizing	SHEA BUTTER GLYCERIDES	12
12J - Other Skin Care Preps	SHEA BUTTER GLYCERIDES	2
13B - Indoor Tanning Preparations	SHEA BUTTER GLYCERIDES	1
04E - Other Fragrance Preparation	SHEA OLEINE	1
05G - Tonics, Dressings, and Other Hair Grooming Aids	SHEA OLEINE	1
05I - Other Hair Preparations	SHEA OLEINE	1



**Memorandum**

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Jonas, Ph.D.  
Industry Liaison to the CIR Expert Panel

A handwritten signature in black ink that reads "Beth A. Jonas".

**DATE:** September 27, 2016

**SUBJECT:** Butyrospermum Parkii (Shea) Nut Shell Powder

Anonymous. 2016. Summary information Butyrospermum Parkii (Shea) Nut Shell Powder.

September 2016

## Summary Information Butyrospermum Parkii (Shea) Nut Shell Powder

### Method of Manufacture

After the seed of the shea nut has been removed, the shell is dried in the sun, ground and sieved. The ground shell is then sterilized, examined by quality control and released for sale.

### Composition

Butyrospermum Parkii (Shea) Nut Shell Powder does not contain any fragments or pieces from the shea seed. It consists of woody tissues constituting the shell and does not contain Butyrospermum Parkii (Shea) Butter Unsaponifiables found in shea butter.

The supplier certifies that Butyrospermum Parkii (Shea) Nut Shell Powder does not contain: asbestos, free amines, antioxidants, formaldehyde, monomers, nitrosamines, ethylene oxide, triethanolamine, 1,4-dioxane or volatile organic compounds.

### Use

Used as an abrasive in wash products at a concentration of approximately 0.5%.





**Memorandum**

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Jonas, Ph.D.  
Industry Liaison to the CIR Expert Panel

**DATE:** November 16, 2016

**SUBJECT:** Butyrospermum Parkii (Shea) Seedcake Extract

Institut d'Expertise Clinique. 2009. Clinical study for the appraisal of the cutaneous acceptability of a cosmetic investigational product, applied under normal conditions of use, (without sun exposure), for 4 weeks, in the Asian adult subject (SPF 50 creme containing 0.006% Butyrospermum Parkii (Shea) Seedcake Extract).

Institut d'Expertise Clinique. 2009. Verification of the absence of sensitising potential and of the good cutaneous compatibility of a cosmetic investigational product, by repeated epicutaneous applications under occlusive patch (SPF 50 creme containing 0.006% Butyrospermum Parkii (Shea) Seedcake Extract).



**i e c**  
**IN**  
 INSTITUT  
 d'EXPERTISE  
 CLINIQUE

## REPORT: ACCEPTABILITY STUDY IN CHINA

DT032183

### IN-USE TEST UNDER DERMATOLOGICAL CONTROL

CLINICAL STUDY FOR THE APPRAISAL OF THE CUTANEOUS  
 ACCEPTABILITY OF A COSMETIC INVESTIGATIONAL PRODUCT,  
 APPLIED UNDER NORMAL CONDITIONS OF USE, (WITHOUT SUN  
 EXPOSURE), FOR 4 WEEKS, IN THE ASIAN ADULT SUBJECT

**INVESTIGATIONAL PRODUCT:** CREMESP50  
 (formula n° BUTYROSPERMUM PARKII (SHEA) SEEDCAKE  
 EXTRACT 0.006%- batch n° FPF1 du 05/02/09)

**PROTOCOLS:** Specific N° C090342PE, of 9 March 2009  
 Standard N° 052067D - Version 2 Subsidiaries, of 9 March  
 2007

**REPORT:** N° C090342RDT- Version 1, of 10 June 2009

**BEGINNING OF OBSERVATIONS:** 16 March 2009  
**END OF OBSERVATIONS:** 13 April 2009

STUDY MONITOR	RESPONSIBLE FOR THE STUDY	INVESTIGATOR
Miss A.M. ESCOFFIER RNERPLAZA 25-29, quai Aulagnier 92665 ASNIERES-SUR-SEINE CEDEX-FRANCE	Miss I. SAGARDOY Post Graduate in Molecular Biology I.E.C. 88, boulevard des Belges 69006 LYON - FRANCE	Dr. S. XIE, M.D. Dermatologist Address of Investigations: I.E.C. China BE room,20F,Guangfa Baili Commercial Center 498,Huanshi Dong Road 510075 GUANGZHOU PEOPLE'S REPUBLIC OF CHINA

document of 44 pages

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## AUTHENTICATION

The study subject of the present report was conducted under my responsibility, in compliance with the standard and specific study protocols, in accordance with the standard operating procedures of the Clinical Research Centre, and in the spirit of the general principles of the Good Clinical Practices published by I.C.H. (Topic E6: CPMP/ICH/135/95).

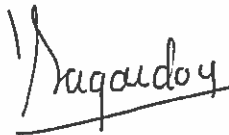
All observations and numerical data obtained during this study are reported in the present document.



Handwritten signature of Dr. Shuxia XIE, M.D. The signature is written in black ink and includes the date '20.6.9' below the name.

Dr. Shuxia XIE, M.D.  
Dermatologist Investigator

I have read this report, I certify that these data are an accurate reflection of the results obtained and I agree with its content.



Handwritten signature of Isabelle SAGARDOY in black ink.

Isabelle SAGARDOY  
Responsible for the Study

10106109

## PERSONNEL INVOLVED IN THE REALISATION OF THE STUDY

<p><b>President</b>  Name: J.P. GUILLOT  Senior Toxicologist- Pharmacologist  (Eurotox Registered Toxicologist)  Address: Route de Bibost  69690 Bessenay - France  if: +33 (0) 4.74.70.93.39</p>	<p><b>Deputy General Director- Vice President</b>  Name: E. CAMEL  Pharm. D., D.E.A. in Skin Biology and  Cosmetology, Senior Toxicologist  (Eurotox Registered Toxicologist)  Address: 88, boulevard des Belges  69006 Lyon - France  if: +33 (0) 4.72.69.89.61</p>
<p><b>Deputy General Director- Vice-President,  in charge of Operations Management</b>  Name: F. GUILLOT  Toxicologist, Masters in Management and  International Law  Address: 88, boulevard des Belges  69006 Lyon- France  if: +33 (0) 4.72.69.89.77</p>	<p><b>Administration, Finance and Human Resources  Director</b>  Name: Y. POHLMANN  D.U.E.L. in English  Address: 88, boulevard des Belges  69006 Lyon - France  2: +33 (0) 4.72.69.70.91</p>
<p><b>Head of Management for Clinical Studies and  Consumer Tests</b> Name:  E. MARQUIS Master in  Biochemistry  Post graduate in Industrial Cosmetology (I.P.I.L)  Address: 88, boulevard des Belges  69006 Lyon - France  if: +33 (0) 4.72.69.89.73</p>	<p><b>Head of Clinical Safety Studies</b>  Name: B. GRANGER  Post graduate in "Metabolism, Endocrinology and  Nutrition", and Training to Clinical Trials  Address: 88, boulevard des Belges  69006 Lyon - France  2: +33 (0) 4.72.69.89.70</p>
<p><b>Responsible for the Quality Control</b>  Name: C. AUZEAU  Management Systems Quality - Environment and  Security - Diploma level II  Address: 88, boulevard des Belges  69006 Lyon - France  if: +33 (0) 4.72.69.90.93</p>	<p><b>Responsibles for the Data Management and  Statistical Analysis</b>  Names:- Y. CHIPIER,  Senior technician in Biochemistry  -N. REY,  Master in Statistical and Infonnatics Data Analysis  Post graduate in Epidemiologic Statistics  Address: 88, boulevard des Belges  69006 Lyon - France  2: +33 (0) 4.72.69.89.72</p>
<p><b>Responsible for the Study</b>  Name: I. SAGARDOY  Post Graduate in Molecular Biology  Address: 88, boulevard des Belges  69006 Lyon - France  if: +33 (0) 4.72.69.77.45</p>	<p><b>I.E.C. China General Director</b>  Name: C. WU  M.B.A.  Address: I.E.C. China  BE room,20F,Guangfa Baili  Commercial Center  498, Huanshi Dong Road  510075 Guangzhou  People's Republic of China</p>

<u>Technical and Scientific Manager</u> Name: P. RUAN Bachelor in Pharmaceutics Analysis Address: I.E.C. China BE room,20F,Guangfa Baili Commercial Center 498, Huanshi Dong Road 510075 Guangzhou People's Republic of China	<u>Investigator</u> Name: Dr. S. XIE, M.D., Dermatologist Address: I.E.C. China BE room,20F,Guangfa Baili Commercial Center 498, Huanshi Dong Road 510075 Guangzhou People's Republic of China
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<u>Secretary / Technicians</u> Names: -H. CHEN -H. CHEN - S. LIANG - J. TANG -M. XU Address: I.E.C. China BE room,20F,Guangfa Baili Commercial Center 498, Huanshi Dong Road 510075 Guangzhou People's Republic of China
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**INSTITUT D'EXPERTISE CLINIQUE  
C H I N A**

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I. E. C. CHINA, B-E room, 20F, Guangfa Baili Commercial Center  
498, Huanshi Dong Road, 510075 Guangzhou- PEOPLE'S REPUBLIC OF CHINA

**ENGLISH SUMMARY OF THE REPORT**

SPONSOR:

INVESTIGATIONAL PRODUCT: CREME SPF 50  
(formula n° BUTYROSPERMUM PARKII (SHEA)  
SEEDCAKE EXTRACT 0.006% -batch n° PPF1 du  
05/02/09)

DT032183

**ACCEPTABILITY STUDY: IN-USE TEST  
UNDER DERMATOLOGICAL CONTROL**

**CLINICAL STUDY FOR THE APPRAISAL OF THE CUTANEOUS  
ACCEPTABILITY OF A COSMETIC INVESTIGATIONAL PRODUCT,  
APPLIED UNDER NORMAL CONDITIONS OF USE, (WITHOUT SUN  
EXPOSURE), FOR 4 WEEKS, IN THE ASIAN ADULT SUBJECT**

<b>STUDY OBJECTIVE</b>	To appraise the cutaneous acceptability of a cosmetic investigational product, applied under the normal conditions of use (without sun exposure), in the Asian adult subject.	
<b>TYPE OF STUDY</b>	Acceptability study ("in-use test"), under Dermatological control, in "open".	
<b>INCLUSION CRITERIA SPECIFIC TO THE STUDY</b> (in addition to the criteria given in the standard study protocol)	<ul style="list-style-type: none"> <li>. <i>Number of subjects:</i> 40</li> <li>. <i>Sex:</i> female</li> <li>. <i>Origin:</i> Asian (Chinese)</li> <li>. <i>Age:</i> 18 to 70 years old</li> <li>. <i>Face skin:</i> all types</li> </ul>	<ul style="list-style-type: none"> <li>. <i>"Sensitive" skin:</i> 20 to 30%* maximum</li> <li>. <i>"Healthy subjects with history of atopy":</i> 20 to 25%* maximum</li> <li>. <i>Other:</i> subject presenting with pigmented spots on the face and neckline</li> </ul> <p>*proportion currently admitted for this population</p>
<b>METHODOLOGY</b>	<ul style="list-style-type: none"> <li>- Application modalities of the investigational product: <ul style="list-style-type: none"> <li>. <i>areas:</i> face, neck and neckline (insisting on pigmented spots)</li> <li>. <i>frequency and duration:</i> once a day (in the morning) for 4 weeks</li> <li>. <i>application conditions:</i> by the subject him/herself, at home (starting on D0 and ending on D27), under the normal conditions of use (without sun exposure) (as much as necessary).</li> </ul> </li> <li>- Modalities of evaluations: <ul style="list-style-type: none"> <li>. <i>cutaneous acceptability:</i> <ul style="list-style-type: none"> <li>7 cutaneous clinical examinations by the Dermatologist Investigator on D0 and on D28</li> <li>7 questionnaire including a daily log filled in by the subject</li> </ul> </li> <li>. <i>cosmetic qualities:</i> questionnaire prepared in collaboration with the Study Monitor, filled in by the subject, at home, before his/her last visit to I.E.C. and complemented by a global appraisal given in the presence of the Dermatologist Investigator on D28.</li> </ul> </li> </ul>	

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## RESULTS AND CONCLUSION

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### STUDIED POPULATION

Number of subjects recruited	58
Number of subjects who came to I.E.C.	44
Number of subjects included by the Dermatologist Investigator	43
Number of subjects discontinued from the study	2
Number of subjects for the analysis of the results	41

The physical characteristics of the Asian (Chinese) subjects are summarized in the following table:

Subjects	Face skin nature	Body skin nature	Healthy subjects with history of atopy
Number : 41	Normal : 4 (10 %)	Normal : 13 (32 %)	5 (12 %)
Females : 41 (100 %)	Mixed Oily : 13 (32 %)	Dry : 23 (56%)	
Males : 0 (0 %)	Oily : 0 (0 %)	Very Dry : 5 (12 %)	
Mean age : 41.6	Mixed Dry : 8 (20 %)		
Age min : 20	Dry : 10 (24 %)		
Age max : 59	Very Dry : 6 (15 %)		
	Sensitivity : 6 (15%)	Sensitivity : 1 (2%)	

All these subjects presented with pigmented spots.

## CONCLUSION

Analysis of the results obtained revealed, on the whole:

- As regards to irritation or discomfort, a very good acceptability of the investigational product in 32 out of the 41 subjects who took part in the whole study.

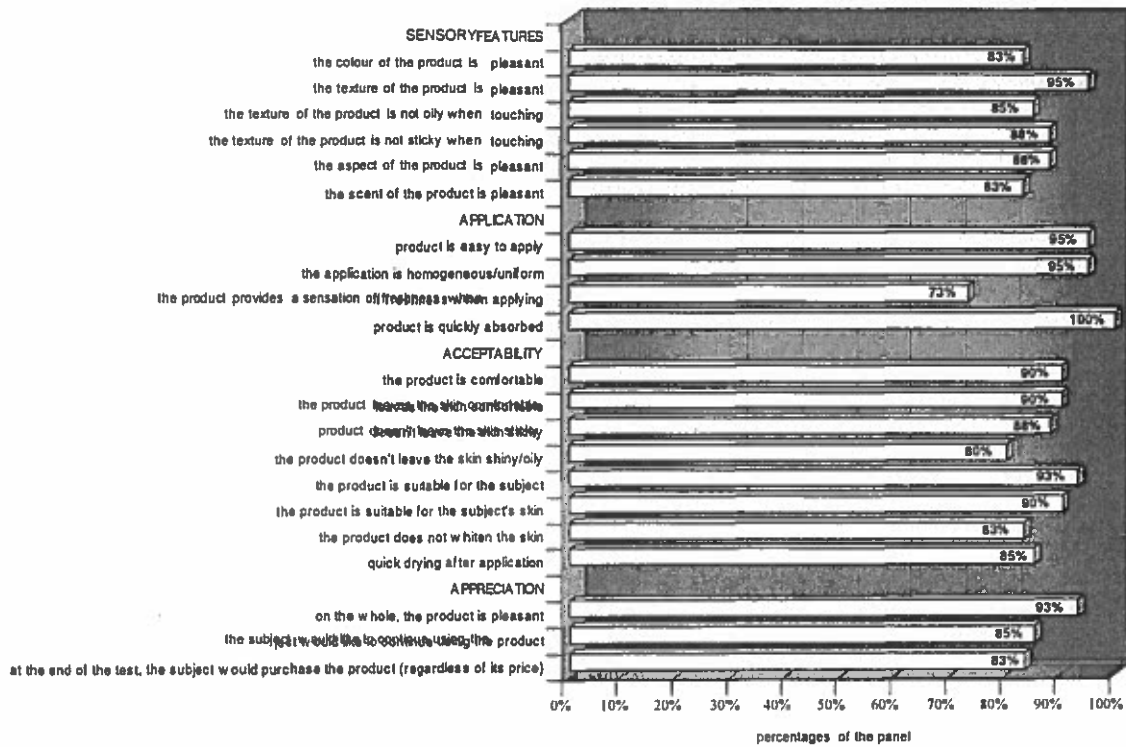
The synthesis of the reactions noted during the study is shown in the table below (in % of the subjects questioned):

	Frequency of reaction
Reactions noted during the whole study	22% (9/41)
Reactions observed by the Dermatologist Investigator	0% (0/41)
Reactions reported by the subjects	22% (9/41)
. <i>discomfort</i>	20% (8/41)
. <i>irritation</i>	0% (0/41)
. <i>"small pimples"</i>	2% (1/41)
Reactions that needed to modify significantly the applications modalities	0% (0/41)
Reactions which can be considered as "pertinent"*	0% (0/41)
Reactions considered as adverse events linked to the investigational product	0% (0/41)
Reactions considered as serious adverse events linked to the investigational product	0% (0/41)

\* conclusion based on the analysis of the nature, of the duration, of the intensity, of the frequency and of the appearing time of the reactions.



- As regards to its cosmetic qualities, a favourable appraisal of these subjects for, in particular, the following criteria (in% of the subjects questioned):

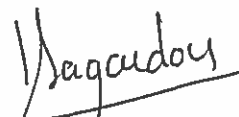


The CUTANEOUS ACCEPTABILITY of the investigational product designated as "CREME SPF 50 (formula n° BUTYROSPERMUM PARKII (SHEA) SEEDCAKE EXTRACT 0.006% - batch n° FPF1 du 05/02/09)" can be judged, on the whole, GOOD, after repeated applications in CHINA under normal conditions of use (without sun exposure), once a day for 4 consecutive weeks, to the face, neck and neckline skin, by 41 ASIAN female adult subjects, of all skin types, presenting with pigmented spots.

Lyon and Guangzhou,



Dr. S. XIE, M.D.  
Dermatologist Investigator



10106103

I. SAGARDOY  
Post Graduate in Molecular Biology  
Responsible for the Study

**Buty**

This study has been carried out by IEC China, which has research and cooperation agreements respectively signed with the Department of Dermatology of the Third Affiliated Hospital of Sun Yat Sen University - Department of Dr. LAI- as well as the Department of Ophthalmology of the Second Affiliated Hospital of Sun Yat Sen University - Department of Dr. LAN.



**IEC**

**BULGARIA**

INSTITUT  
d'EXPERTISE  
CLINIQUE

I.E.C. BULGARIE

**REPORT: SENSITISATION AND  
CUTANEOUS COMPATIBILITY STUDY**

DT032234

VERIFICATION OF THE ABSENCE OF SENSITISING POTENTIAL AND OF THE  
GOOD CUTANEOUS COMPATIBILITY OF A COSMETIC INVESTIGATIONAL  
PRODUCT, BY REPEATED EPICUTANEOUS APPLICATIONS UNDER OCCLUSIVE  
PATCH, IN 107 (OR 104, OR 103) HEALTHY ADULT SUBJECTS  
(modified Marzulli and Maibach method)

INVESTIGATIONAL  
PRODUCT

CREMESP50  
(fla n° BUTYROSPERMUM PARKII (SHEA) SEEDCAKE EXTRACT  
0.006% - batch n° PPF1 of05/02/09)

PROTOCOLS

Specific N° B090210PE of25 February 2009 and amendment n° 2  
of 23 March 2009 refers to Standard N°  
EN\_P\_STD\_CLITP\_5021\_01, of20 January 2005

REPORT

N° B09021ORD7 -version 1 of 19 June 2009

BEGINNING OF THE

OBSERVATIONS

10 March 2009

END OF OBSERVATIONS

18 April 2009

SAFETY ASSESSOR	TECHNICAL AND SCIENTIFIC MANAGER	DERMATOLOGISTS
	Mrs. M. VASSILEVA Post-Graduate in Life and Health Sciences I.E.C. Bulgarie Lozenetz - 16A, Kichinev Street 1407 SOFIA- BULGARIA	-Dr. M. KOSTOVA, M.D. (Investigator) -Dr. G. BOCHEVA, M.D., Investigating Laboratory: I.E.C. Bulgarie Lozenetz - 16A, Kichinev Street 1407 SOFIA- BULGARIA

Document of 61 pages

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## AUTHENTICATION

The study subject of the present report was conducted under my responsibility, in compliance with standard and specific study protocols, in accordance with I.E.C. Standard Operating Procedures and in the spirit of the general principles of the Good Clinical Practices (ICH topic E6-CPMP/ICH/135/95).

I assume the responsibility of the validity of all raw data obtained during this study and mentioned in the present report.



Dr. Miglena KOSTOVA, M.D.  
Dermatologist Investigator

I have read this report, I certify that these data are an accurate reflection of the results obtained and I agree with its content.



Margarita VASSILEVA  
Technical and Scientific Manager

## PERSONNEL INVOLVED IN THE REALISATION OF THE STUDY

(for I.E.C. France)

<p><u>President General Director</u>  Name: J.P. GUILLOT  Senior Toxicologist- Pharmacologist  (Eurotox Registered Toxicologist)  Address: Route de Bibost  69690 Bessenay - France  'ii': +33 (0) 4.74.70.93.39</p>	<p><u>Deputy General Director- Vice-President</u>  Name: E. CAMEL  Pharm. D., D.B.A. in Skin Biology and  Cosmetology, Senior Toxicologist  (Eurotox Registered Toxicologist)  Address: 88, boulevard des Belges  69006 Lyon- France  'ii': +33 (0) 4.72.69.89.61</p>
<p><u>Administration, Finance and Human Resources  Director</u>  Name: Y. POHLMANN  D.U.E.L. in English  Address: 88, boulevard des Belges  69006 Lyon- France  'ii': +33 (0) 4.72.69.70.91</p>	<p><u>Deputy General Director- Vice-President,  in charge of Operations Management</u>  Name: F. GUILLOT  Toxicologist, Masters in Management  and International Law  Address: 88, boulevard des Belges  69006 Lyon- France  'ii': +33 (0) 4.72.69.89.77</p>
<p><u>Head of Studies Management performed at  I.E.C. Bulgarie</u>  Name: J.R. CAMPOS  Graduate in Dermocosmetology  Doctor of Cellular Biology and Microbiology  Address: 88, boulevard des Belges  69006 Lyon - France  'ii': +33 (0) 4.72.69.89.66</p>	

(for I.E.C. Bulgarie)

<p><u>Executive Director</u>  Name: G. VELEY  Graduate of High School of Economy  Address: Lozenetz - 16A, Kichinev Street  1407 Sofia - Bulgaria  'li: + (359) 2.868.35.82</p>	<p><u>Administrative Manager</u>  Name: K. CHTEREVA  Master in French  Address: Lozenetz - 16A, Kichinev Street  1407 Sofia- Bulgaria  'li: + (359) 2.868.53.11</p>
<p><u>Dermatologists</u>  Names: Dr. M. KOSTOVA, M.D. (<i>Investigator</i>)  Dr. G. BOCHEVA, M.D.  Graduate in Dermatology &amp; Venerology  Address: Lozenetz - 16A, Kichinev Street  1407 Sofia- Bulgaria  'li: + (359) 2.868.53.11</p>	<p><u>Technical and Scientific Manager</u>  Name: M. VASSILEVA  Post-Graduate in Life and Health Sciences  Address: Lozenetz - 16A, Kichinev Street  1407 Sofia - Bulgaria  'li: + (359) 2.868.53.11</p>
<p><u>Technicians</u>  Names: M. KOLCHEVA, Master in Chemistry  and Physics  A. KRASTANOVA, Master in Biology  K. RANGELOVA, Bachelor in Chemistry  V. STOYANOVA, Bachelor in  Biotechnology  M. KAYTSANOVA, Secondary Degree in  Chemistry and Biology  Address: Lozenetz - 16A, Kichinev Street  1407 Sofia - Bulgaria  'li: + (359) 2.868.53.11</p>	<p><u>Technicians</u>  Names: M. GEORGIEVA, Master in Biology  E. ATANASSOVA, Master Higher in  Biotechnology  P. STOYKOVA, Master Higher in  Industrial Chemistry  I. GEORGIEVA, Master in Medical  Chemistry  Y. IVANOVA, Master in Biodiversity,  Ecology and Conservation  Address: Lozenetz- 16A, Kichinev Street  1407 Sofia - Bulgaria  'li: + (359) 2.868.53.11</p>
<p><u>Independent Ethical Committee</u>  Names:- Mr. G. VELEY, Executive Director I.E.C. Bulgarie  - Mrs. M. VASSILEVA, Post-Graduate in Life and Health Sciences, Technical and Scientific  Manager I.E.C. Bulgarie  - Dr. E. LICHEVA, Dermatologist, Clinical Investigator, Consultant I.E.C. Bulgarie  -Mr. G. STOIMENOV*, Law teacher in the "New Bulgarian University", European Law,  Protection of the Human rights  -Prof. R. YANKOVA*, M.D., Ph.D, Chief of Dermatology and Allergology Department,  University of Medicine "St. George" Plodiv, Bulgaria  - Dr. G. MINCHEYA*, M.D., Allergologist-Dermatologist (Allergology test with cosmetic  products and detergents), Dermatology &amp; Venerology Dispensary, Sofia, Bulgaria</p> <p><i>*Members independent from the Investigating Laboratory and from the Study Monitor (Sponsor), who  vote!/(ive their opinion about the study.</i></p>	

<b>INSTITUT D'EXPERTISE CLINIQUE BULGARIE</b>
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Head Office: Lozenetz- 16A, Kichinev Street- 1407 Sofia- Bulgaria  
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## ENGLISH SUMMARY OF THE REPORT

SPONSOR:

INVESTIGATIONAL PRODUCT: CREME SPF 50  
(fla n° BUTYROSPERMUM PARKII (SHEA)  
SEEDCAKE EXTRACT 0.006%- batch n° FPF1  
of05/02/09)

DT032234

### SENSITISATION AND CUTANEOUS COMPATIBILITY STUDY

**VERIFICATION OF THE ABSENCE OF SENSITISING POTENTIAL AND  
OF THE GOOD CUTANEOUS COMPATIBILITY OF A COSMETIC  
INVESTIGATIONAL PRODUCT, BY REPEATED EPICUTANEOUS  
APPLICATIONS UNDER OCCLUSIVE PATCH, IN 107 (OR 104, OR 103)  
HEALTHY ADULT SUBJECTS  
(modified Marzulli and Maibach method)**

<u>INTRODUCTION</u>	The study consists in the application of the investigational product under maximized application conditions according to the modified Marzulli and Maibach method. It is carried out on cosmetic product whose safety had been assured by a toxicologist, with the aim to further confirm safety of this product which will be used by a large number of consumers under normal and reasonably foreseeable use conditions.
<u>STUDY OBJECTIVE</u>	To confirm that the repeated application, under patch, of investigational product, on the subject's back, does not induce an allergic reaction and to evaluate its good cutaneous compatibility.
<u>STUDY RELEVANCE</u>	Cutaneous allergy is an individual phenomenon, of immune origin, of which setting off activating 3 phases (penetration of the foreign substance in the skin and forming of the allergen; development of the immune reaction; activating of the reaction, by a new application of the allergenic molecule to the skin). These 3 phases are thus required to check, in 50 or 100 subjects, the absence of sensitising potential of an investigational product, and are the basis of the method described by Marzulli and Maibach ( <i>protocol in conformity to note dated 4 August 1997 of the French "Repression des Fraudes" to the "Federation Francaise des Industries de la Parfumerie"</i> ).

<p><b>INCLUSION CRITERIA SPECIFIC TO THE STUDY</b> (in addition to the criteria given in the standard study protocol)</p>	<p>To be eligible, each subject must satisfy all the criteria written in the standard study protocol N°: EN_P_STD_CL1TP_5021_01, of 20 January 2005 and the specific following ones:</p> <ul style="list-style-type: none"> <li>. <i>Number of subjects:</i> 100 subjects divided in two panels of 50 subjects receiving each 12 investigational products (the product distribution being indicated in the application scheme of the Case Report Form).</li> <li>. <i>Selection of subjects:</i> exclusive selection of 100 valid cases (a valid case will be defined as a subject who has completed a full procedure (9 applications and 9 readings during the induction phase followed by a double application (induction and virgin sites) and 2 readings during the challenge phase [or more if this is necessary in order to fully evaluate observed reaction]).</li> </ul> <p>However, a subject who has presented with significant reactions (moderate erythema and/or infiltration and/or papules and/or vesicles) twice during the induction phase, inducing a stop of application, but who received the challenge phase application after decision of the Dermatologist Investigator and the Sponsor, will be considered as a valid case even though he had not followed the previous procedure.</p> <ul style="list-style-type: none"> <li>. <i>Sex:</i> female and male</li> <li>. <i>Age:</i> 18 to 70 years old (the 60-70 age bracket should not exceed 10% of the total number of subjects)</li> <li>. <i>Origin:</i> Caucasian</li> <li>. <i>Phototypes:</i> I, II or III</li> <li>. <i>Healthy subjects:</i> 100% without "atopic" background.</li> </ul>
<p><b>NON-INCLUSION CRITERIA SPECIFIC TO THE STUDY</b> (in addition to the criteria given in the standard study protocol)</p>	<p>To be eligible, each subject must not meet any criterion written in the standard protocol cited above.</p>
<p><b>METHODOLOGY</b></p>	<ul style="list-style-type: none"> <li>- Modes of application: <ul style="list-style-type: none"> <li>. <i>area:</i> back</li> <li>. <i>quantity:</i> 0.02 ml over a 50 mm<sup>2</sup> surface (occlusive patch: Small Finn Chambers on Scanpor).</li> <li>. <i>conditions of application:</i> the investigational product, being under a thick form and containing volatile components, was put about 15 min before application, in order to enable all or a part of these components to evaporate.</li> <li>. <i>frequency and duration:</i> <ul style="list-style-type: none"> <li>. induction phase: 9 applications spread out over 3 weeks as follows: <ul style="list-style-type: none"> <li>1st week: Day 0 (Tuesday: 1st application), Day 2 (Thursday), Day 4 (Saturday),</li> <li>2nd week: Day 7 (Tuesday), Day 9 (Thursday), Day 11 (Saturday),</li> <li>3rd week: Day 14 (Tuesday), Day 16 (Thursday), Day 18 (Saturday)</li> </ul> </li> <li>duration of exposure: 48 ± 4 hours for the 1<sup>st</sup>, 2nd, 4th, 5th, 11th and 18th applications or 72 ± 4 hours for the week-ends (3<sup>rd</sup>, 6th and 9th applications).</li> <li>. rest phase: the subjects are not submitted to any application from Day 22 (Wednesday) to Day 34 (Monday) inclusive, i.e. for a 13-day period.</li> <li>. challenge phase: single application on 2 sites (virgin and induced sites) on Day 35 (Tuesday) for 48 ± 4 hours.</li> </ul> </li> </ul> </li> </ul> <p>N.B.: the patches are removed by the Laboratory staff.</p>



	<p>- Modes of evaluation:</p> <p>- <i>Clinical observations</i>: readings performed, according to the Sponsor's specificities (D2, D35, D37 and D39), by the Dermatologist Investigator:</p> <ul style="list-style-type: none"> <li>. <i>Induction phase</i>: 15 to 30 minutes after removal of the patches</li> <li>. <i>"challenge" phase</i>: between 30 to 35 min and 48 ± 4 hours after removal of the patches or more if this is necessary in order to fully evaluate observed reactions.</li> </ul> <p>- <i>Grading</i>, according to a given numerical scale (irritation scale: 0 to 4 &amp; scale of the International Contact Dermatitis Research Group (I.C.D.R.G.): 0 to 3 [+++]).</p>												
<p><u>ANALYSIS OF THE RESULTS AND EVALUATION CRITERIA</u></p>	<p>- <i>Determination of the Mean Irritation Index (M.I.I.)</i>: equal to the sum of the quotations of the 9 readings of the induction phase divided by the number of subjects and of readings performed.</p> <p>- <i>Interpretation of the results obtained</i>, under the experimental conditions adopted:</p> <ul style="list-style-type: none"> <li>. for cumulative irritation: arbitrary classification ("non-irritating" to "severely irritating");</li> </ul> <table border="1" data-bbox="583 695 1349 926"> <thead> <tr> <th>M.I.I.</th> <th>Classification of the investigational product</th> </tr> </thead> <tbody> <tr> <td>lower than 0.25</td> <td>non-irritant</td> </tr> <tr> <td>0.25 to 1 not included</td> <td>slightly irritant</td> </tr> <tr> <td>1 to 2 not included</td> <td>moderately irritant</td> </tr> <tr> <td>2 to 3 not included</td> <td>very irritant</td> </tr> <tr> <td>3 to 4</td> <td>severely irritant</td> </tr> </tbody> </table> <ul style="list-style-type: none"> <li>. for sensitising potential: An erythema, of intensity higher than or equal to 2 during the "challenge" phase, with or without palpable lesions, must be evaluated in the following days to determine if the reaction decreases or increases in order to precise if the reaction observed is of allergic or irritative type. A quick decrease of the reaction indicates an irritation (decrecendo reaction). A reaction with presence of infiltration/oedema, which persists and/or which increases within time generally indicates a reaction of allergic type, and additional studies ("rechallenge" and/or R.O.A.T.: Repeated Open Application Test) could be performed 3 to 6 weeks after the first appearance of the challenge reaction and after all reactions have ceased.</li> <li>. also on the base of the type of investigational product and the I.E.C. statistics established on about 3,900 investigational products tested at I.E.C. Bulgarie between 2002 and 2007 (positionning of cumulative irritation and/or sensitisation in comparison of investigational products of the same type).</li> </ul>	M.I.I.	Classification of the investigational product	lower than 0.25	non-irritant	0.25 to 1 not included	slightly irritant	1 to 2 not included	moderately irritant	2 to 3 not included	very irritant	3 to 4	severely irritant
M.I.I.	Classification of the investigational product												
lower than 0.25	non-irritant												
0.25 to 1 not included	slightly irritant												
1 to 2 not included	moderately irritant												
2 to 3 not included	very irritant												
3 to 4	severely irritant												

## !RESULTS AND CONCLUSION

### STUDIED POPULATION

Number of subjects recruited	137*
Number of subjects who came to I.E.C.	121
Number of subjects included by the Dermatologist Investigator	110
Number of subjects discontinued from the study	7
Number of subjects for the analysis of the results	
. for the evaluation of Primary Cutaneous Irritation	107
. for the evaluation of Cumulative Irritation	104
. for the evaluation of Cutaneous Sensitisation	103

The physical characteristics of the subjects are summarized in the following table:

Subjects	Primary Cutaneous Irritation	Cumulative Irritation	Cutaneous Sensitisation
Number	107	104	103
Females	89	87	87
Males	18	17	16
Age minimum (y.o.)	18	18	18
Age maximum (y.o.)	69	69	69

\*Due to recruitment problems and in order to obtain results on at least 100 healthy adult subjects, one 2nd group of 7 subjects was recruited on Day 2 (12/03/2009).

### RESULTS

Percentage of subjects having presented with one or several well visible to severe irritation reactions (score2), during the induction	1%*
Mean Irritation Index (M.I.I.) of the induction Classification of the investigational product	0.16 <ul style="list-style-type: none"> <li>■ non-irritant: M.I.I. &lt; 0.25</li> <li>○ slightly irritant: M.I.I. [0.25 - 1[</li> <li>○ moderately irritant: M.I.I. [1 - 2[</li> <li>○ very irritant: M.I.I. [2 - 3[</li> <li>○ severely irritant: M.I.I. [3 - 4f</li> </ul>
Percentage of the sensitisation reactions observed	0%
Reactions considered as serious adverse events linked to the investigational product	0%

\* Among the 104 subjects who participated to the whole induction period:  
 - one subject (n° 104)\* presented with an erythema equal to 1 on D4, associated with papules and slight infiltration, leading to the application of the investigational product on a new area;  
 - 103 subjects did not present with any significant reaction.

CONCLUSION

In conclusion and given the results obtained under the experimental conditions adopted, the single and repeated epicutaneous applications of the investigational product designated as "CREME SPF 50 (fla n° BUTYROSPERMUM PARKII (SHEA) SEEDCAKE EXTRACT 0.006%- batch n° FPF1 ofOS/02/09)", under occlusive patch, in the healthy adult subject, did not provoke any primary or cumulative irritation reaction, nor any cutaneous sensitisation.

Lyon and Sofia,



A9 t/Dc:J

J.R. CAMPOS

Graduate in Dermocosmetology  
Doctor in Cellular Biology and  
Microbiology

Head of Studies Management  
performed at I.E.C. Bulgarie



M. VASSILEVA

Post-Graduate in Life and  
Health Sciences Technical  
and Scientific Manager



Dr. M. IvstOVA, M.D.  
Dermatologist Investigator

This study was conducted by INSTITUT D'EXPERTISE CLINIQUE- BULGARIE,  
registered by the Bulgarian Health Authorities:  
Professor Romyana YANKOVA, MD., Ph. D., Head of the Dermatology  
and Allergology Department of Plovdiv Medical University.



**Memorandum**

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Jonas, Ph.D.  
Industry Liaison to the CIR Expert Panel

**DATE:** January 11, 2017

**SUBJECT:** Butyrospermum Parkii (Shea) Seedcake Extract

Anonymous. 2017. Summary information Butyrospermum Parkii (Shea) Seedcake Extract.

January 2017

## Summary Information *Butyrospermum Parkii* (Shea) Seedcake Extract

### Method of manufacturing

The main steps of the manufacturing are :

- solubilization of seedcake of *Butyrospermum parkii* in a mix of water and butylene glycol (50%/50% - v/v),
- separation of soluble and insoluble phases,
- filtration and sterilizing filtration.

### Composition

INCI	Maximum Percentage	CAS No.
Butylene Glycol	50.0%	107-88-0
Water	47.2%	7732-18-5
<i>Butyrospermum Parkii</i> (Shea) Seedcake Extract	2.8%	91080-23-8

### Impurities

Assay of alkaloids was performed with the Dragendorff reagent. The quantity of alkaloid is less than the limit of sensitivity of the method (<0.05g/l).

Assay of heavy metals (Arsenic, Mercury, Nickel, Lead) indicated traces of Nickel (0.049 ppm) and Lead (0.478 ppm).

There is no trace of pesticides in this ingredient.

Assay of allergens was carried out to characterize and quantify 26 allergenic compounds in order to comply with the requirements of European Regulation 1223/2009. Allergens were not detected in this ingredient.

Assay on mycotoxins was carried out to characterize and quantify aflatoxins B1, B2, G1 or G2 in this ingredient. The sum of these aflatoxins is less than 1.0 µg/kg.

### Safety Studies

#### **1) Assessment of cutaneous tolerance after a single application under an occlusive patch for 48 hours.**

The product (mixture described above containing 2.8% *Butyrospermum Parkii* (Shea) Seedcake Extract), diluted to 5%, was applied under an occlusive patch in 23 volunteers during 48 hours. After 48 hours of application, one skin reaction was observed on the treated site and one on the control site. The mean irritation index was 0.04. According to the scoring table adopted to interpret the results, the product can be considered as non-irritating after 48 consecutive hours.

**2) Assessment of allergic contact eczema on the adult volunteer with all type of skin.**

The product (mixture described above containing 2.8% Butyrospermum Parkii (Shea) Seedcake Extract), diluted to 5%, was applied under an occlusive patch in 15 volunteers, selected in the cutaneous tolerance study (1). The cutaneous tolerance is considered as the induction phase application during 48 hours. Then, after a rest phase done during 6-8 weeks, a challenge phase was one application during 48 hours.

During the sensitization phase and the challenge, no skin tolerance reaction and no allergic reaction were noted.



**Memorandum**

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Jonas, Ph.D.  
Industry Liaison to the CIR Expert Panel

**DATE:** February 1, 2017


**SUBJECT:** Concentration of Use: shea oleine

Shea oleine was included in a concentration of use survey sent out in November 2016. No uses of shea oleine were reported.



**Memorandum**

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Jonas, Ph.D.  
Industry Liaison to the CIR Expert Panel 

**DATE:** September 20, 2016

**SUBJECT:** Draft Tentative Report: Safety Assessment of *Butyrospermum parkii*-Derived Ingredients As Used In Cosmetics (draft prepared for the September 26-27, 2016 CIR Expert Panel Meeting)

Key Issue

The information on *Butyrospermum Parkii* (Shea) Butter Unsaponifiables provided in Council memo 5 was provided before *Butyrospermum Parkii* (Shea) Butter was added to the report. Above the summaries of safety tests with memo 5 it states: "Studies completed on a material that contains up to 30% *Butyrospermum Parkii* (Shea) Butter Unsaponifiables in shea butter." This means that all the studies below this statement tested this mixture. When these studies are presented in the CIR report, they should be under a subheading of *Butyrospermum Parkii* (Shea) Butter and *Butyrospermum Parkii* (Shea) Butter Unsaponifiables.

Additional Considerations

**Introduction** - In the Introduction it should be stated that Triolein (defined as the triester of glycerin and oleic acid) has been reviewed and found "safe as used".

**Genotoxicity** - The material tested was about 70% *Butyrospermum Parkii* (Shea) Butter and 30% *Butyrospermum Parkii* (Shea) Butter Unsaponifiables.

**Irritation, Summary, Table 5** - It should be stated that the Episkin assay was completed following OECD Guideline 439. The material tested in both the Episkin assay and the human primary cutaneous tolerance test was about 70% *Butyrospermum Parkii* (Shea) Butter and 30% *Butyrospermum Parkii* (Shea) Butter Unsaponifiables. In the human study, a 30% dilution of the mixture was used resulting in test concentrations of 21% *Butyrospermum Parkii* (Shea) Butter and 9% *Butyrospermum Parkii* (Shea) Butter Unsaponifiables.

**Sensitization, Summary, Table 6** - The material tested in the Direct Peptide Reactivity Assay was the undiluted mixture containing about 70% *Butyrospermum Parkii* (Shea) Butter and 30% *Butyrospermum Parkii* (Shea) Butter Unsaponifiables.



Sensitization, Summary, Table 6 - It is not correct to call the studies in references 29, 30 and 31 HRIPTs. These three studies were maximization tests (as stated in the titles of the references).

Phototoxicity and Photosensitization - The material tested in the 3T3 NRU assay was about 70% Butyrospermum Parkii (Shea) Butter (0.0035-0.7 mg/mL) and 30% Butyrospermum Parkii (Shea) Butter Unsaponifiables (0.0015-0.3 mg/mL). It should be stated that this study was completed using OECD Guideline 432.

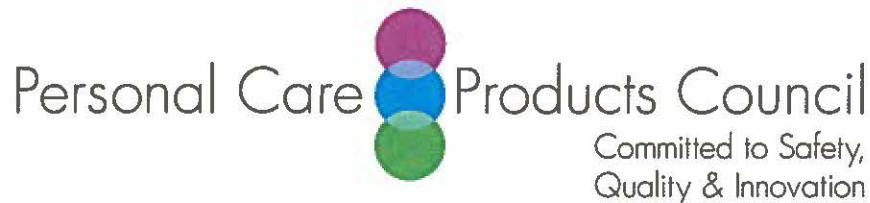
Ocular Irritation, *In Vitro*, Summary - The balm tested contained 1.5% of the mixture containing about 70% Butyrospermum Parkii (Shea) Butter and 30% Butyrospermum Parkii (Shea) Butter Unsaponifiables. The summary states that it contained 0.27-0.45% Butyrospermum Parkii (Shea) Butter Unsaponifiables, not "0.00405% to 0.00675% Butyrospermum Parkii (Shea) Butter Unsaponifiables" as stated in Ocular Irritation section.

Table 1 - The Dictionary includes the CAS numbers 91080-23-8 and 194043-92-0 with Butyrospermum Parkii (Shea) Butter. Is there a reason these numbers are not included in Table 1?

Table 4 - Shea oleine was not included in a Council concentration of use survey. Therefore, it is misleading to indicate "no reported use."

Table 5 - For reference 28, please add that the moisturizer was applied undiluted under occlusion (Blenderm patch). In addition to adding that Butyrospermum Parkii (Shea) Butter was tested with the unsaponifiables, and stating the concentrations tested, it should be stated that the treated skin sites were examined 30 minutes and 24 hours after patch removal.

Table 6 - More information about the maximization studies (references 29, 30, 31) should be added to this table. For example, the subjects were treated with 5 48-hour patches, followed 7-10 days later with challenge to a naive site.



**Memorandum**

**TO:** Lillian Gill, D.P.A.  
Director - COSMETIC INGREDIENT REVIEW (CIR)

**FROM:** Beth A. Jonas, Ph.D.  
Industry Liaison to the CIR Expert Panel

A handwritten signature in blue ink that reads "Beth A. Jonas".

**DATE:** November 2, 2016

**SUBJECT:** Tentative Report: Safety Assessment of *Butyrospermum parkii* (Shea)-Derived Ingredients As Used In Cosmetics (release date: October 7, 2016)

Physical and Chemical Properties - The properties of shea butter should be cited to the original reference rather than a CIR report. The following sentence is misleading. "No other relevant published physical and chemical properties data on *Butyrospermum parkii* (shea)-derived ingredients were identified in a literature search for these ingredients, and no unpublished data were submitted." Although additional information may not be needed to assess the safety of these ingredients as used in cosmetics, the report should not imply that additional information cannot be found. For example, the standard properties for fats and oils such as iodine value and saponification values for shea oil and butter can easily be found. These values are included in the *Food Chemical Codex* for shea oil. The following examples are references that may include additional information on the physical and chemical properties of shea butter and shea oleine.

Mital HC Dove FR. 1971. The study of shea butter. 1. Physico-chemical properties. *Planta Med* 20(3): 283-288.

Okullo JB. 2010. Physico-chemical characteristics of shea butter (*Vitellaria paradoxa* C.F. Gaertn.) Oil from the shea districts of Uganda. *African Journal of Food Agriculture Nutrition and Development* Online 10(1) (<http://www.bioline.org.br/pdf?nd10010>)

Natural Sourcing. 2012. Material safety data sheet shea olein. [https://naturalsourcing.com/downloads/msds/MSDS\\_Shea\\_Olein.pdf](https://naturalsourcing.com/downloads/msds/MSDS_Shea_Olein.pdf)

Dermal Irritation - It should be made clear that one study of the moisturizer containing 5% *Butyrospermum Parkii* (Shea) Butter Extract was a 4-week use test.

Phototoxicity and Photosensitization, In Vitro, Ocular Irritation, In Vitro - Shea butter needs to be added to the subheadings of these sections as a mixture containing shea butter and shea butter unsaponifiables was tested in the studies described.

Ocular Irritation - Please correct "reconstituted mucous model" to "reconstituted mucous membrane model"

Summary - At the beginning of the Summary, it would be helpful to state that studies included in the original report on shea butter and shea butter unsaponifiables are not included in the Summary.

Discussion - In the paragraph on dermal sensitization, it would be helpful to note that there are studies on products containing up to 60% shea butter summarized in the original report that also support the lack of sensitization potential of shea butter.