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

Status:	Revised Draft Final Report for Panel Review
Release Date:	August 18, 2017
Panel Meeting Date:	September 11-12, 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 Interim Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Christina L. Burnett, Senior Scientific Analyst/Writer.

1620 L St NW, Suite 1200◊ Washington, DC 20036-4702 ◊ ph 202.331.0651 ◊fax 202.331.0088
◊ cirinfo@cir-safety.org

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Memorandum

To: CIR Expert Panel Members and Liaisons
From: Christina Burnett, Senior Scientific Writer/Analyst
Date: August 18, 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 *shea092017rep* in the pdf document.)

At the April 2017 meeting, the Panel issued a revised tentative report for the 13 *Butyrospermum parkii* (shea)-derived ingredients with the conclusion that these are safe in cosmetics in the present practices of use and concentration described in this safety assessment when formulated to be non-sensitizing. Previously, the Panel had concluded that 9 of the ingredients were safe as used in the present practices of use and concentration and that the data were insufficient for Butyrospermum Parkii (Shea) Nut Extract, Butyrospermum Parkii (Shea) Nut Shell Powder, Butyrospermum Parkii (Shea) Seedcake Extract, and Hydrolyzed Shea Seedcake Extract: the data needs for these 4 ingredients were fulfilled. The Panel should review the minutes from the Full Panel meeting on April 11, 2017 to see if the discussion in the report adequately captures the rationale for the revised conclusion with the sensitization caveat.

Since the April meeting, a human repeat insult patch test on Butyrospermum Parkii (Shea) Seedcake Extract at 0.42% was received. This data has been incorporated into the report and highlighted with |brackets| in text and shaded in Table 6. Comments received from the Council prior to the April meeting and on the revised tentative report have been considered. The comments and the unpublished data can be found in this report package (*shea092017pcpc1*and *shea092017pcpc2* and *shea092017data).*

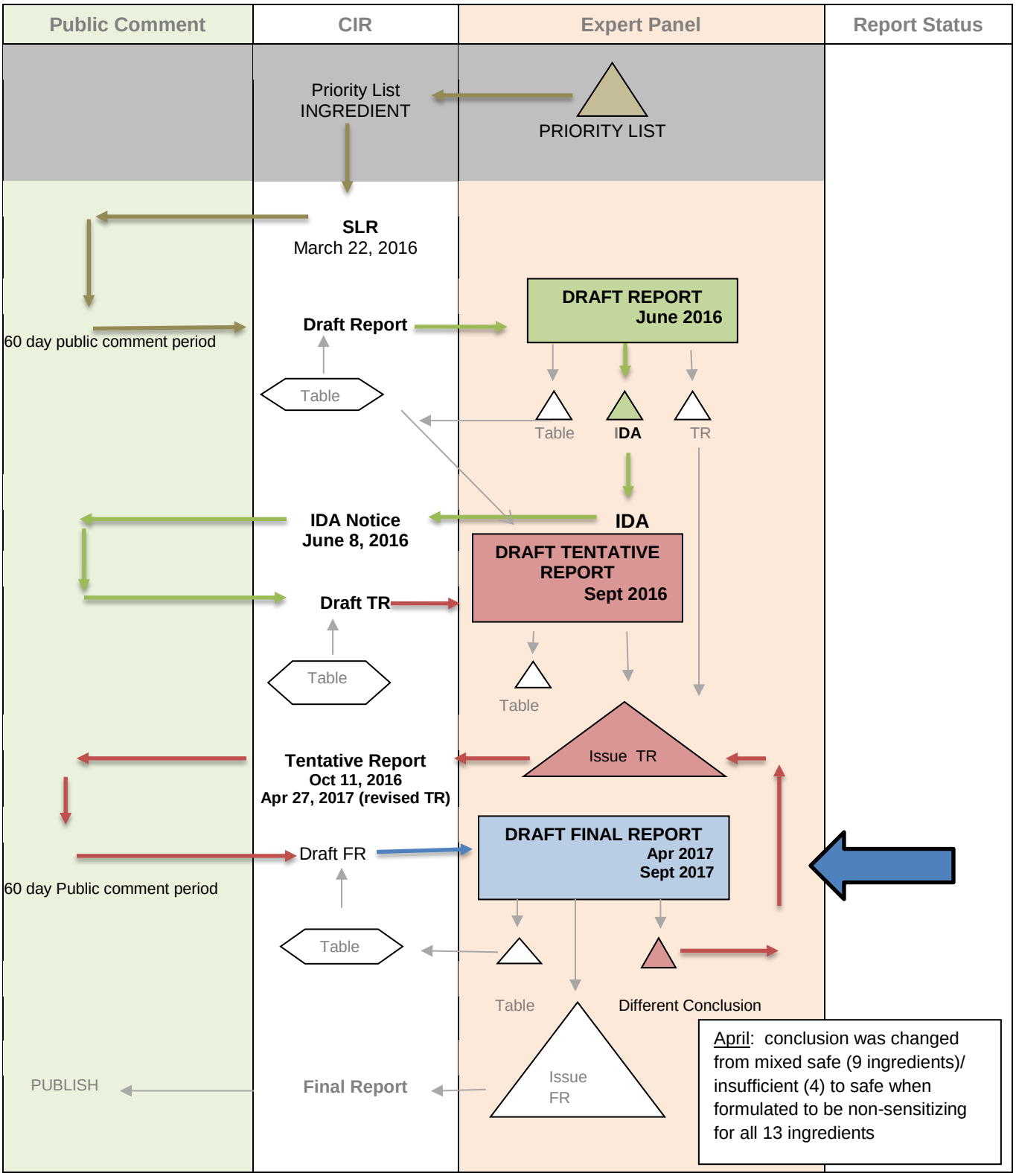
The Panel should carefully review the Abstract, Discussion, and Conclusion of this report. If these are satisfactory, the Panel should issue a final report.

1620 L Street NW, Suite 1200, Washington, DC 20036
(Main) 202-331-0651 (Fax) 202-331-0088
(Email) cirinfo@cir-safety.org (Website) www.cir-safety.org

SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY *Butyrospermum Parkii* (Shea)-Derived Ingredients

MEETING Sept 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
Buyrospemum Parkii (Shea) Oil
Butyrospermum Parkii (Shea) Butter Extract
Butyrospermum Parkii (Shea) Butter Unsaponifiables
Hydrogenated Shea Butter
Hydrogenated Shea Oil
Shea Butter Glyceride
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) Nut Shell Powder
Butyrospermum Parkii (Shea) Seedcake Extract
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

April 2017 - The Panel issued a revised tentative report with the amended conclusion that the 13 ingredients are safe in cosmetics in the present practices of use and concentration described in the safety assessment when formulated to be non-sensitizing.

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 shared constituent. Therefore, when formulating products, manufacturers should avoid reaching levels, in final formulations, of botanical constituents that may cause sensitization or other adverse effects.

There are no safety test data for Butyrospermum Parkii (Shea) Nut Extract and Butyrospermum Parkii (Shea) Nut Shell Powder, and no safety test data for Butyrospermum Parkii (Shea) Seedcake Extract and Butyrospermum Parkii (Shea) Butter at maximum use concentrations (5.5% and 100% in leave-on products, respectively). However, human repeated insult patch tests (HRIPT) for Butyrospermum Parkii (Shea) Seedcake Extract and Butyrospermum Parkii (Shea) Butter were negative when tested at lower concentrations. Moreover, based on the Panel's clinical experience, absence of adverse event reports, and the negative safety test data on other ingredients, the Panel was not concerned about dermal irritation or sensitization potential following exposure to these ingredients.

***Butyrospermum parkii* (Shea)-Derived Ingredients Data Profile – September 2017 – Writer, Christina Burnett**															
	In-Use	**Physical/Chemical Properties**	**Method of Manufacturing**	**Composition/Impurities**	**Toxicokinetics**	**Acute Toxicity**	**Repeated Dose Toxicity**	**Reproductive and Developmental Toxicity**	**Genotoxicity**	**Carcinogenicity**	**Irritation/Sensitization - Nonhuman**	**Irritation/Sensitization - Clinical**	**Ocular/Mucosal**	**Phototoxicity**	**Case Studies**
Butyrospermum Parkii (Shea) Butter	X	X	X	X					X		X	X	X	X	
Butyrospermum Parkii (Shea) Butter Extract	X										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.

Search updated July 2017 = 0 relevant references found.

Butyrospermum Parkii (Shea)-Derived Ingredients
April 10-11, 2017

Dr. Belsito's Team

DR. BELSITO: Okay. So then the next ingredient is shea. So if at the September meeting we issued a tentative report that nine butter, oil, and glyceride ingredients were safe in the present facts used in concentration, and that we included -- we concluded that the nut in seed cake ingredients were insufficient and wanted method of manufacture, composition, impurities, and sensitization. We have method of manufacture, composition, impurities for the nutshell powder and for the seed cake extract. And we've got irritation sensitization data on the seed cake extract, but not on the nutshell powder. And we got no other additional information on the nut extract or the nutshell powder. And so then the question becomes, can we use any of the new data that we got to complement our requests that weren't met

DR. SNYDER: What are those at and what concentration? How frequently used in the nutshell?

MS. BURNETT: The seed cake extract is used that up to 5.5%. The nutshell is used up to 1%. And there's only two uses. The seed cake extract three uses.

DR. BELSITO: What about the hydrolyzed?

MS. BURNETT: The hydrolyzed?

DR. BELSITO: Seed cake extract.

MS. BURNETT: Is that in your report? Hydrogenated, oh, hydrolyzed. There it is, sorry.

DR. BELSITO: Because I said, does the data in seed cake help with the hydrolyzed seed cake? I thought --

SPEAKER: (Inaudible.)

DR. BELSITO: -- it would, but I think when I

(inaudible) my nuts, I (inaudible).

MS. BURNETT: There's no uses reported for that one.

DR. BELSITO: Right.

MS. BURNETT: There's no uses reported for that.

DR. LIEBLER: And I'm okay with that. I think we can justify that, because we're not going to get anymore abuses.

DR. BELSITO: Okay. So we have data on nutshell powder, right?

MS. BURNETT: Just the method of manufacturing.

DR. BELSITO: Right. So, would we expect, and we got nothing on the nut extract.

MS. BURNETT: Right.

DR. BELSITO: So would we expect the shell powder to be significantly different from the extract?

DR. LIEBLER: No. I mean, except for having more materials in it, the extract would be simpler.

DR. BELSITO: And the extract is, if I recall, is this just like ground, bulky stuff, right?

DR. LIEBLER: I mean, I think we can reasonably expect the extract will be similar to, like, the seed cake extract, which is a water butylene glycol extract. I mean, these are pretty similar preps for these (inaudible) of extracts, plant extracts.

DR. BELSITO: I'm not a botanist. What's the difference between seed cake and the nutshell? So is it like that little skin you get around an almond or something?

SPEAKER: No idea.

MS. BURNETT: I was told to go find the definition of that, but we believe it's the material after the oil's been extracted, the leftover pulp, I guess.

DR. BELSITO: So they extract the oil from the shell.

MS. BURNETT: From the seed.

DR. BELSITO: From the seed, oh --

MS. BURNETT: The seed. The butter is made from the seed.

DR. BELSITO: Okay. So they --

MS. BURNETT: So it's --

DR. BELSITO: It's what's left after they take the oil out of the seed.

MS. BURNETT: Mm-hmm.

DR. BELSITO: That's called seed cake.

MS. BURNETT: That's what we believe.

DR. BELSITO: It makes sense.

SPEAKER: Cellulosic.

DR. LIEBLER: Yeah. There's not much --

SPEAKER: Resin.

DR. LIEBLER: -- left. Yeah, I really felt we had enough coverage on method of manufacture --

DR. BELSITO: So then --

DR. LIEBLER: -- composition, impurities, because we got more data on the nutshell powder and the seed cake extract. It's PDF 17, bottom.

DR. BELSITO: Mm-hmm.

DR. LIEBLER: And 18 at the top.

DR. BELSITO: So then in terms of sensitization --

SPEAKER: We received some of that.

DR. BELSITO: -- we've got --

DR. SNYDER: Seed cake.

DR. BELSITO: Right. But not nut, right?

DR. SNYDER: But the composition isn't any different, right? Or was it different? Nutshell powder or --

DR. BELSITO: Nutshell powder doesn't contain any of the seed. Woody tissues, that's all it says.

DR. ANSELL: Yeah, it's just the nutshells ground up and sterilized.

DR. BELSITO: Well, I don't think what's left --

DR. LIEBLER: It's like --

DR. BELSITO: -- of the nutshell --

DR. LIEBLER: -- depleted.

DR. BELSITO: -- is going to --

DR. LIEBLER: It's like depleted nut --

DR. BELSITO: -- sensitize --

DR. LIEBLER: -- extract --

DR. BELSITO: -- (inaudible).

DR. LIEBLER: -- essentially.

DR. BELSITO: But we don't have data on it. What is the concentration of the nut extract and the shell powder?

MS. BURNETT: Nutshell powder is used up to 1%.

SPEAKER: One percent, yeah.

MS. BURNETT: In the (inaudible). And the nut extract is also 1%.

DR. SNYDER: Two uses.

DR. BELSITO: So we have lots of sensitization studies on the butter. We have new ones on the seed cake extract that were clean, but nothing on the nut extract or the nutshell powder. So is that still insufficient for sensitization, or are we saying that it's basically going to be a whole bunch of fibers that aren't going to sensitize?

DR. LIEBLER: The latter, I think.

DR. SNYDER: We don't anticipate the composition of biological concern or something. I mean, it's two uses and one, up to 1% of nothing. I wonder why they put it in there.

DR. LIEBLER: Well, if you just think about this, the way this is made into the shea butter is the extract that's produced from the seed, right? And that should be the most enriched in possible substances of concern for

sensitization, the types that we think of. You know? Because we really don't have much in the way of (inaudible) there's nothing in the way of sensitization data right -- I mean, any problems for the shea butter.

DR. BELSITO: No.

DR. LIEBLER: And that is the one that should be the most enriched for possible constituency and concern for sensitization. Because the extract is shea oil.

DR. BELSITO: So we're saying that, although we didn't get it, we don't need sensitization on the hydrolyzed because we think it'll be similar to the seed cake, and we don't need sensitization on the nut extract, and the shell powder because we think it'll just be woody fibrous material and that the real concern would be the butter anyway.

SPEAKER: Right.

DR. BELSITO: And that was clean, so that we felt the new data we got satisfied our needs for the nutshell powder and the hydrolyzed seed cake extract even though we didn't get data for those. Is that correct? So we're --

SPEAKER: Correct.

DR. BELSITO: -- going safe as used for all of them?

SPEAKER: Correct.

DR. LIEBLER: Yeah, I felt that with those inferences you just summarized, I felt that our data needs

(inaudible).

DR. BELSITO: Okay, so that's our recommendation.

DR. SNYDER: Yeah, the powder is just simply ground up. It's not an extraction. There's no extraction. It's just ground up material, so there shouldn't be any impurities or anything associated with extraction.

SPEAKER: Right.

DR. SNYDER: So we can add that in, and then it's just a ground up material.

DR. BELSITO: Well, I'd say, it's already in there, basically. Okay. So everything is safe as used for the sheas.

SPEAKER: Yeah.

DR. BELSITO: Okay. Anything else on this report?

Dr. Marks' Team

DR. MARKS: Okay. Let's go ahead and start then. Our first ingredient will be the shea-derived ingredients, butyrospernum parkii. And, Christina has presented a draft final report at the September 2016 meeting, a tentative report for the 13 ingredients. Came to a conclusion that nine ingredients were safe. They are listed in the memo dated March 17th, from Christina. And, four were listed as insufficient because of method of manufacture, composition, impurities, and sensitization for these four ingredients, again, listed in the memo.

Since September we've received some new data. And, Ron's and Tom -- does the new data change the conclusion and what would that be?

DR. SHANK: We still need sensitization at use concentrations. We got sensitization data for the seed extract, but it was 50 times less than the use concentration, so that won't help.

DR. MARKS: Okay.

DR. HILL: I strongly suspect -- and maybe Carol has looked at this -- that at 5 percent use concentration, if that's what we're talking about, is an error, because at 5.5 percent it would be the ingredient, which is mostly butylene glycol and water. And, there's only 2.8 percent seedcake in there. I mean, it's just not 100 percent clear that that's what we're looking at.

DR. EISENMANN: I've asked for clarification, but I haven't gotten it on this one. You could set a limit at the concentration that you've received. So, you could say up to --

DR. HILL: Because, they did it on.14 which happens to be 5.5 times 2.8 percent.

DR. MARKS: Yeah. So, that was my potential alternative -- rather than keep the same conclusion was, I'd seedcake extract the previous nine so it'd make 10 but limit it to 0.006 percent based on the HRIPT we have on page 30. so, I think it's whether or not you set a limit and include that in the conclusion, that it's safe up to that concentration or you still say insufficient.

And, Ron Hill, I agree. It's 5.5 percent is what is reported is the use concentration. So, as you said, Ron Shank, much, much higher use concentration reported than what we have safety data on. We have safety data for sensitization up to, as I said, 0.006 percent.

The other three ingredients we don't still have method of manufacture, we don't have composition and impurities for the nut extract, the hydrolyzed seedcake extract. We don't have the sensitization irritation for the nut extract, the nutshell powder, and the hydrolyzed seedcake extracts. So, they would remain insufficient.

DR. EISENMANN: You do have method of manufacture for nutshell powder, and it is just ground --

DR. MARKS: Yes, I didn't --

DR. EISENMANN: -- shells. They're sterilized. And, I was wondering if, for an exfoliant use, just rinse off, if you might consider that use based on what it is.

DR. MARKS: Yeah, we're missing it for the nut extract, not the -- not shell powder, just the nut extract we're missing, method of manufacturing, composition, and impurities, along with the hydrolyzed seedcake extract. How do you want to proceed? Do you want to do a limit on the seedcake extract, or do you want to continue insufficient? We do have sensitization data. So, we could put a limit unless we hear something different.

DR. SHANK: We could put a limit. We have sensitization with 15 subjects at.14, and that was negative. So, we could set that as the limit.

DR. MARKS: .14.

DR. SHANK: That's in Table 4.

DR. MARKS: And, what page is that, Ron? I based it on the HRIPT, which was page 30. And, what is the.14? What page is that, again?

DR. SHANK: Let's see. Table 4 is what I have, so.

DR. MARKS: Table 4. Okay. Let me go back and see what page Table 4 is.

DR. HILL: I think they're on 27 and 28.

DR. SHANK: Page 28.

DR. MARKS: Twenty-eight. Extract. I see the.006. Where's the -- I missed the.0 -- what'd you say it was --.14?

DR. SHANK: Yes. Let me find the text.

DR. EISENMANN: It's in the text, but I'm not sure I see it in the table.

DR. SHANK: Okay. So, --

DR. MARKS: That's what I was concentrating on. What page is that? Should be somewhere around --

DR. HILL: Twenty-one.

DR. MARKS: Twenty-one. Sensitization. (Reads to himself.) Oh, okay. And, we don't have much data, do we, on that? We don't know how that sensitization was determined of 0.14. We don't know whether that was HRIPT or what.

DR. SHANK: I mean, go to Table 6.

DR. MARKS: (Inaudible), Christina?

MS. BURNETT: It's, I believe, on Table 6 it's possible -- I'm still waking up -- the 0.14 percent might be the 2.8 percent of seedcake extracted having diluted to 5 percent. That's possible I didn't do the math correctly.

DR. HILL: Yeah, 5 percent of 2.8 is.14 percent at dilution.

MS. BURNETT: That's that number.

DR. MARKS: So, which one? Okay. Product diluted to 23 -- 48-hour cutaneous tolerance -- single -- oh, yeah. I ignored that.

DR. SHANK: Okay.

DR. MARKS: Because, it's only one 48-hour tolerance test. It's not really a challenge. If I interpret that, it was a single patch test and that's it. It didn't produce a reaction, but.

MS. BURNETT: That should be under the irritation --

DR. MARKS: Yeah.

DR. SHANK: Okay. So, then we need --

DR. MARKS: The one right below on Table 5 is the -- that's where I got the 0.006 percent.

DR. SHANK: Okay.

DR. MARKS: And, that was a use. Again, not exactly an HRIPT. But, was there another HR -- there must have been another one. Yeah. If you go on to page 30, and it's the last row there, the 0.006 in 103 subjects. HRPIT was negative.

DR. HILL: So, I have a question, and this is your area of expertise. In that one that was just above it, they're talking about that the tolerance test was used as a sensitization phase. That was on the previous page. And, then they came back and they did this challenge here. It was after -- what was it -- 6 to 8 weeks with a single patch, 23 subjects. And, I guess 15 were chosen for the sensitization. That's a little weird. I don't know why we dropped from 23 to 15, except, I guess, people withdrew from the study.

DR. MARKS: Yeah, I see what you're saying in terms of that was considered an induction. But, I wouldn't really consider that a very stringent induction where you just get a single occlusive patch and then you go back. You know, basically, all the sensitization, they have multiple challenges. And, then you do multiple sensitizations over a period of time, usually a couple weeks, and then they do the last challenge to see whether or not sensitization has occurred.

DR. HILL: While we're on sensitization, I didn't see the need myself for the ground nut, but we don't have any data on that, --

DR. MARKS: Correct.

DR. HILL: -- the shell.

DR. MARKS: So, that's why I included it in. So, move with the limit, and then change the conclusion to --

DR. BERGFELD: I didn't understand your limit, though. Which one are you going with?

DR. MARKS: It would be the 0.006 percent, --

DR. BERGFELD: Okay.

DR. MARKS: -- because that's what we have in HRIPT. So, we can say at that concentration it's safe. We can't say higher than that it is.

DR. BERGFELD: And, it's only for that one ingredient?

DR. MARKS: Yeah. So, it would be safe for nine ingredients, and then the 10th ingredient would be -- limit the concentration to 0.006 percent. And, then three would remain insufficient still for method of manufacturing, composition, and impurity for the nut extract and the hydrolyzed seedcake, and then extract and then sensitization and the irritation for the nut extract for all three. Does that sound reasonable? I'll be seconding it tomorrow, so. Okay?

So, to review that, there will be a new draft final report. So, that'll go out as a -- still, for -- and who knows, we may get more data after it, then the next one. The ingredients are safe. We add the seedcake extract to the previous nine, but we limit it's concentration because of sensitization, where we can feel comfortable at 0.006 percent. And, the other three are insufficient for the reasons I mentioned. We'll see if the Belsito team comes up with the same conclusion. Yes. Go ahead, Ron Hill.

DR. HILL: I think I dropped it in here, but I wanted to make sure it was noted. There's something on page…about molecular distillation. I don't know that there is such a thing, unless we're doing ultracentrifugation of helium or something. So, I wanted to see if we could get clarification. Actually, I'm hoping somebody here can enlighten me. What exactly is seedcake? Because, I'm not getting that in method of manufacture. I assume it's after the oils that are extracted. It's the solids that are left.

DR. SHANK: Yes.

DR. HILL: But, somewhere in here it ought to clarify -- somewhere there ought to be clarification seedcake is this, because we're using components on this sort of thing, being that they're botanicals, and we sort of need to have some idea.

The only other thing -- this is for toxicologists -- there's a carcinogenicity studies of shea olein. I'm having Monday morning syndrome. It'll stop in a minute. There's one dose and the results are kind of squirrelly. I guess, somewhere down the line somebody needs to do a dose-dependent study of that effect. I mean, that's not for us to say, but I just wanted to put it in.

DR. SLAGA: One dose. That's all we have.

(inaudible).

DR. HILL: I know, you know. And, some of these botanicals, for no surprising reasons given the mixtures of materials we're seeing, sort of U-shaped dose-response curves. And, I think going forward --

DR. MARKS: Tom, are you still comfortable including it into the safe group?

DR. SLAGA: Yes.

DR. HILL: I am, too.

DR. MARKS: You are. Okay.

DR. HILL: I just wanted to ask a question.

DR. MARKS: Good. And, then, Christina, you'll have time to hopefully clarify what seedcake is.

MS. BURNETT: Okay.

DR. MARKS: Okay. Any other comments?

Full Panel Meeting

DR. BERGFELD: …Then moving on to the next ingredient, with is Shea. Dr. Belsia --. Belsito, excuse me. (Laughter)

DR. BELSITO: Okay. So, at the September meeting, we issued a tentative report for public comment, with the conclusion that the nine butter, oil and glyceride ingredients were safe in the present practice of use in concentration in cosmetics. But, we thought that four of the ingredients, the nut and the seed cake ingredients were insufficient. And we requested data on method of manufacture, composition and purities and sensitization. We did get some limited data, method of manufacture, composition and purities data for the nut shell powder. And for the seed to cake extract. We also got some irritation and sensitization data on the seed cake extract. However, we did not get the other data we requested. However, in looking at what nut shell extract really was, we didn't think that we needed sensitization data for that. And we felt that we had a good sense of, from the information we got on the powder and the seed cake extract, exactly what was in the other seed cake ingredient. And so we felt we could now vote safe as used for this entire group.

DR. BERGFELD: And that's a motion?

DR. BELSITO: That's a motion.

DR. BERGFELD: A comment or a second?

DR. LIEBLER: Second.

DR. BERGFELD: Second? Comment? Discussion?

DR. MARKS: Yeah. Our team, I figured we would have to discuss this, because our team came to the conclusion, Don, we largely agree, we got some more data. But we felt we could go safer. 10 ingredients. We would add seed cake extract to the previous 9, which is listed in the memo by Christina. And, we would limit the concentration of the seed extract to 0.006 percent, based on an HRIPT. The concentration as used is up to 5.5 percent. We still felt that there were the three insufficient method of manufacture, composition and impurities for the nut extract. The hydrolyzed seed cake. And we still felt we needed seed cake extract. And we needed sensitization and irritation for the nut extract. The nut shell powder and a hydrolyzed seed cake extract. So, we didn't think that we could read-across site for those. But, again Don, you can repeat your reasoning while your team felt all could be safe. And maybe we will be reassured, our team.

DR. BELSITO: Well we, I mean, when you look at what is in the nut shell, basically we felt it was a lot of fibers that were just going to be ground up. And, the seed cake extract, as we understand it from the definition in the dictionary, is basically after you extract all of the oil out of the seed, the rest of that pulpy stuff, which is going to be carbohydrate and fiber, is what is seed cake extract. We had some data on the seed cake extract, in terms of manufacturing and impurities. And looking at that and looking at the fact that, sort of following the same reasoning that we used with peppermint oil, which probably has even a sounder basis for these ingredients, that it would be the oil that would be more likely to be sensitizing than the fibers in the shell. Or the remaining parts of the seed that are the so called seed cake, so. We do not feel that we needed additional sensitization data on it. And then, when we looked and comment on anything further there since --.

DR. LIEBLER: Yeah. I think that Don's made the main point. We felt that, you know, if you look, if you refer to the flow scheme on PDF, page 16, under Method of Manufacture, you know, if you peel off the outside, that's the shell. And you work with the shell, then you get basically cellulose and, you know, mostly cellulose. But the likely constituents of concern, with respect to, you know, any possible sensitization, would be contained in the oil. The oil is, you know, if you take the entire seed and you use boiling extract to get the oil, what's left is the seed cake, evidently. And it's that seed cake, really contains mostly the nut shell, which would contain, logically mostly the nut

shell. And traces of the oil. And, in fact, the descriptions, I felt the descriptions gave, you know, sufficient explanation of what the pieces were. What the different parts were, that make me feel that the, you know, potential impurities and component constituents is of concern, you know, that we had from the others that were better documented, were satisfactory. Let me reach a conclusion on the safety of these from that standpoint.

DR. BERGFELD: Did you include this in your discussion? As to the lack of --?

DR. BELSITO: We had written a discussion, but that's what --

DR. BERGFELD: What the intention was?

DR. BELSITO: -- is what was pointed out. Yes.

DR. BERGFELD: Okay.

DR. MARKS: This would be a new draft final report, so it would have to go out again. Correct?

DR. BELSITO: Yes.

DR. MARKS: Yeah.

DR. BERGFELD: Final.

DR. MARK: Team.

MS. BECKER: This is a final report.

DR. BERGFELD: This is a final report?

DR. BELSITO: But we've changed the conclusion.

DR. MARK: Yeah.

DR. BELSITO: If we say all that are safe as used, it's a change of conclusion. No?

DR. BERGFELD: That's a positive change.

DR. GILL: But it's a less restrictive change. And the panel has traditionally said, that if it's less restrictive, then it can go through.

DR. BELSITO: Okay.

DR. MARK: Teams.

DR. SLAGA: My initial, in looking at it, I had some of the similar thoughts about the -- being mainly cellulose and my first time going through it, I -- with the new data, I felt that they were all okay. But, our discussion around the sensitivity, in setting a limit, I went with our team on that. But, I could go -- it's very marginal the differences that we're talking about.

DR. BERGFELD: Ron Shank?

DR. SHANK: Did the Belsito team put in the conclusion when formulated, not to be sensitizing?

DR. BELSITO: At this point we didn't, because this material doesn't have any other ingredients in it that would be of concern in terms of sensitization, when you look at the composition. You know, if you want to put that in because you're concerned that cellulose is going to sensitize, I wouldn't have an issue with that. But I didn't see any reason to put that in based upon the information we had.

DR. SHANK: Well, that's the problem. We don't have the information. The HRIPT test was ordered to magnitude below used concentrations.

DR. BELSITO: Mm-hmm.

DR. SHANK: And we usually don't dismiss that.

DR. MARKS: I think non-sensitizing, we've done it with a lot of botanicals. And even though I agree with you Don, and our clinical experience with Shea butter is lack of sensitivity, I still think from a safety point of view, putting that in doesn't hurt in that conclusion.

DR. BELSITO: I don't have a problem with it.

DR. BERGFELD: That --.

DR. HILL: Are we restricting all ingredients with the sensitization caveat? Or just selected ones?

DR. MARKS: No. I'd say it all. Then that way, particularly, for our team, that's --

DR. BERGFELD: As well.

DR. MARKS: -- that three that we had insufficient for irritation sensitization that takes care of that also. Although Don, your reasoning, I agree with why you weren't concerned.

DR. BELSITO: Right. I would just like to comment Ron, so that we're 100 percent consistent. If we were to follow your logic, we shouldn't say that the butters are safe, because they're used up to 100 percent. We have no data at 100 percent.

DR. HILL: But we know what --.

DR. BELSITO: I'm just trying to make sure that we understand that, you know, that their logic should flow uniformly across all ingredients.

DR. HILL: I guess I was a little fuzzy on the information provided, exactly how they captured the oil on the comment that was just made for the butter. We know what's in the butter. I mean, there was probably nothing captured that causes concern. I just think using the -- formulated to be non-sensitizing caveat for most of these ingredients is unnecessary. But, because we -- I still say we don't have a clear definition of exactly what the process is, and what's taken away before we end up with seed cake that's then toasted in butylene glycol 50 percent, which could, if it's only cellulose, if it's only fiber, then I agree with Don. Or excuse me, Dan. But I don't know.

DR. BERGFELD: You want to comment Jim?

DR. MARKS: No. I think if I understand my team correctly, we can move forward with a safe for all 10 -- for all the ingredients. All 13. And then add the caveat formulate to be non-sensitizing.

DR. BERGFELD: That would --.

DR. MARKS: And this can be discussed. Put in the discussion request. And it sounds like we can just move to a final report. We don't have to do a draft and have public comment.

DR. GILL: I think with the addition of the non- sensitizing caveat, we'll have to post it. Yeah.

DR. MARKS: Hmm.

DR. HILL: That being the case, can we get better clarification of exactly --? I mean, I know there's that flow chart. But it's still, to me, incomplete. Or unclear. If we had a little better information about that, because we don't have any characterization of -- like we do for some of the ingredients. Peppermint, for example. We don't have any detailed characterization of what's in these things, as in the seed cake in particular.

DR. BERGFELD: Well, we can make that request if the vote goes that way.

DR. HILL: Yes. Right.

DR. BERGFELD: We would have to have an amendment to Don's original conclusion.

DR. BELSITO: I'll make that amendment.

DR. BERGFELD: Makes that amendment --.

DR. LIEBLER: I'd like to just -- I think Don had a very important point about consistency. And, but then the suggestion was made, if we add non-sensitizing and we really are directing that at one or two ingredients here. Maybe just a seed cake extract, it sounds like. Then, if we clarify our thinking in the discussion, does that address the issue of being consistent? In other words, you're saying, well, this is not really directed at the Shea butter. This is not directed at the (inaudible) things. This is really directed at a specific ingredient. I guess the nut shell extract.

DR. BELSITO: That we're not concerned in sensitizing --

DR. LIEBLER: The seed cake extract.

DR. BELSITO: -- but we don't have the data.

DR. LIEBLER: But right. Exactly. And that, because I do agree with the kind of the, you know, is there sort of a little horse trading with respect to conclusion here? And I think that's reasonable on a Committee. But on the other hand, the consistency is important. With that, (inaudible) in a discussion, and that way, make you more comfortable Don?

DR. BELSITO: I think it's fine, if you want to put that in. But then I think we also should put in the fact that we don't have data on the Shea butter at 100 percent. We're allowing that to go forward. And therefore, we have concerns that that might sensitize, despite the fact there's never been a report in the world's literature of Shea butter sensitizing. I just think that we should be consistent. If we're saying we're not going to allow concentrations to go forward higher than an HRIPT, then we should go back and look at all the reports where we've done that. Because we've done it multiple times.

DR. BERGFELD: So, I hear that there's been an amendment. Put non-sensitizing into the conclusion, there is now in the discussion what you would like to include there. I see two areas that you're looking at.

DR. BELSITO: No. I mean, I think I'm fine. You can do --

DR. BERGFELD: You're fine?

DR. BELSITO: -- you can formulate it to be non- sensitizing.

DR. BERGFELD: Sensitizing.

DR. BELSITO: But we should point out also, that in addition to the nutshell, we don't have the data that would support 100 percent Shea butter.

DR. BERGFELD: Okay.

DR. BELSITO: We should be consistent. We shouldn't --

DR. BERGFELD: Is that agreeable?

DR. BELSITO: -- take the one that could be the most sensitizing and not say anything about it. And the one that's a bunch of woody fibers and say something about it.

DR. BERGFELD: Okay.

DR. MARKS: I agree. There were actually three ingredients we were concerned about sensitization and irritation. Not just the nutshell extract, but the nutshell powder. Again, the caveat that they're just cellulose fibers and this. And the other was the hydrolyzed seed cake extract. Just to be clear on the three, that we didn't have any data. And then we felt, okay, we --. In our team, we felt we wanted to see sensitization, irritation for those. But, if we have, say formulate to be non-sensitizing, then we have that covered.

DR. BELSITO: Right.

DR. BERGFELD: I think that we've discussed the discussion. And we -- I believe that you know what you're going to put in that. And now we have a conclusion that's been amended. Are there any other comments? Seeing none, I'll call the question. All those in favor of the amended conclusion. Unanimous. Thank you.

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

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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 Interim Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Christina L. Burnett, Senior Scientific Analyst/Writer.

1620 L St NW, Suite 1200◊ Washington, DC 20036-4702 ◊ ph 202.331.0651 ◊fax 202.331.0088
◊ cirinfo@cir-safety.org

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 these ingredients are safe in the present practices of use and concentration when formulated to be non-sensitizing.

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*).[1] This report assesses the safety of the following 13 *Butyrospermum parkii* (shea)-derived ingredients:

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

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.[2] 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 in this report 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.

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*.[1,3] 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.[4])

This safety assessment includes relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an exhaustive search of the world's literature. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that CIR typically evaluates, is provided on the CIR website (http://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites; http://www.cir-safety.org/supplementaldoc/cir-report-format-outline). Unpublished data are provided by the cosmetics industry, as well as by other interested parties.

CHEMISTRY

Definition and Plant Identification

The definitions and functions of the *Butyrospermum parkii* (shea)-derived ingredients included in this report are provided in Table 1. 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.[5-7]

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).[8-13] Butyrospermum Parkii (Shea) Oil is a pale yellow liquid.[14] Shea Oleine is a clear yellow liquid, with a characteristic fatty odor and a density of 0.922-0.928 at 20 ˚C.[15]

Method of Manufacture

The general description of the method of manufacturing of several *Butyrospermum parkii* (shea)-derived ingredients is described in the following schematic:[16]

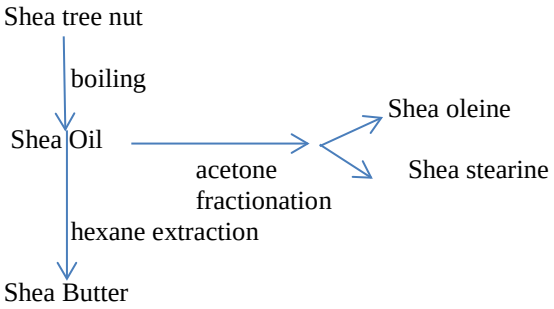

Figure 1. General description of the manufacturing of *Butyrospermum parkii* (shea)-derived ingredients

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.[17]

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.[18] 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, filtering, and sterilizing.[19]

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.[5,6]

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%).[20] Triterpene ester contents ranged from 0.5% to 6.5% and consisted of α-amyrin cinnamate (mean 29.3% of total triterpene esters), butyrospermol cinnamate (14.8%), α-amyrin acetate (14.1%), lupeol cinnamate (9.0%), β-amyrin cinnamate (7.6%), lupeol acetate (7.2%), butyrospermol acetate (5.8%), and β-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.[21] 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 α-amyrin, β-amyrin, lupeol, and butyrospermol with minor or trace amounts of ψ-taraxasterol, taraxasterol, parkeol, 24-methylene-24-dihydroparkeol, 24-methylenecycloartanol, 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.[7] 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.

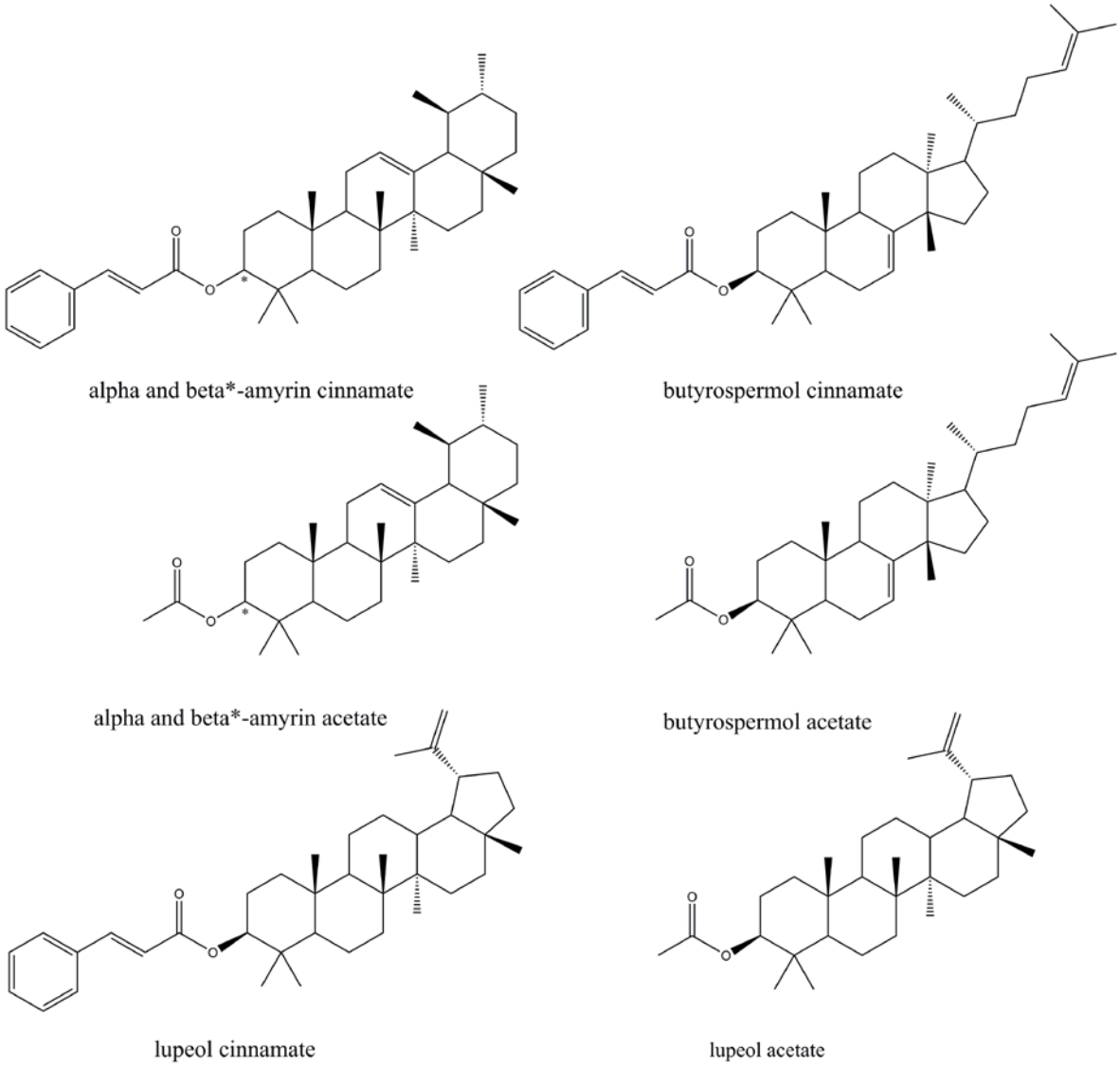

Figure 2. Triterpene esters.

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 α- and β-amyrin, lupeol, butyrospermol, and cycloartenol) and phytosterols including α-spinasterol, Δ7-stigmasterol, and stigmasterol).[17]

Butyrospermum Parkii (Shea) Nut Shell Powder

A supplier has reported that Butyrospermum Parkii (Shea) Nut Shell Powder does not contain any fragments or pieces of shea seed. [18] 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 seedcake extract, 50.0% butylene glycol, and 47.2% water.[19] 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).

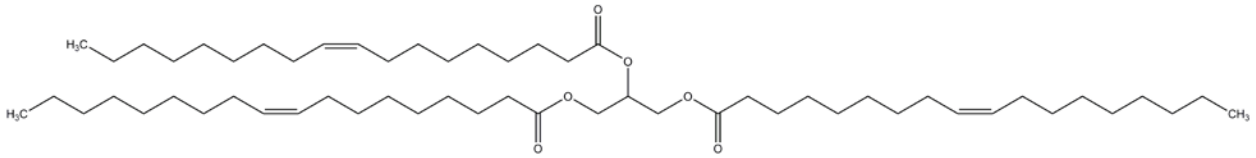

Figure 3. Oleate triglyceride.

However, the sterol component of shea oleine is approximately 8% (w/w), of which approximately 97% is 4,4-dimethyl sterols (mostly as esters of cinnamic acid), 2% is 4-demethylsterols and 0.5% is 4-α-methylsterols.[16]

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; more than three-fourths of the uses are in leave-on formulations (Table 4).[3,22] 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.[23] Butyrospermum Parkii (Shea) Oil has the second highest maximum concentrations of use, and is used at up to 11% in lipsticks.[24] 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 23 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%.[24] 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) Butter was reported to be used in a face powder at 3%.[23] 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.[25-27]

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.[28]

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.[14]

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

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.[34] 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 fraction (~ 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.[34] 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, groups of 15 male and 15 female Colworth-Wistar rats received a diet containing 20% (w/w; 10 to 15 g/kg/day) shea oleine or hydrogenated shea oleine.[35] Additional 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.[35]

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.[36] 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 or Butyrospermum Parkii (Shea) Oil 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 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 by 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_1 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_0 animals for lipogranulomata in Study 2.

Slightly decreased body weight gain, reduced cholesterol, and increased alkaline phosphatase activities 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, hydrogenated shea oleine, and Butyrospermum Parkii (Shea) Oil 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, hydrogenated shea oleine, and Butyrospermum Parkii (Shea) Oil in rats at concentrations equating to 15% (7.5 g/kg/day).[36]

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.[17] 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 and Butyrospermum Parkii (Shea) Oil were evaluated in a dietary study in Colworth-Wistar rats for 104 weeks.[16] The study also evaluated 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, feed 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. Decreased 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. Decreased heart weights 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 and Butyrospermum Parkii (Shea) Oil showed no tumorigenic potential in the rat at 15% in the diet (7.5 g/kg/day).[16]

DERMAL IRRITATION AND SENSITIZATION STUDIES

Irritation

Dermal irritation studies are summarized in Table 5. [17,19,37-39] 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 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.[2] 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. [17,19,40-45] A material containing Butyrospermum Parkii (Shea) Butter (70%) and Butyrospermum Parkii (Shea) Butter Unsaponifiables (30%) was negative in a direct peptide reactivity assay (DPRA) when tested undiluted, thereby indicating a lack of sensitizing potential. Butyrospermum Parkii (Shea) Butter Extract was non-sensitizing in human patch tests at up to 5% in formulation. Butyrospermum Parkii (Shea) Seedcake Extract at 0.14% did not produce sensitization reactions in 15 human subjects in a non-standard sensitization study where a 48 h cutaneous patch test was followed 6-8 weeks later with another 48 h patch test. Butyrospermum Parkii (Shea) Seedcake Extract was not irritating or sensitizing in human repeat insult patch tests (HRIPTs) at concentrations up to 0.42%.

Butyrospermum Parkii (Shea) Butter

Butyrospermum Parkii (Shea) Butter was not sensitizing in a guinea pig maximization study.[2] 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.[17] 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.[2] 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.[2]

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.[17] 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 this this summary. The original safety assessment found these ingredients to be safe as used in cosmetics.

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 reportedly 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 produced adverse effects. No reproductive effects were observed in rats fed shea oleine, hydrogenated shea oleine, or Butyrospermum Parkii (Shea) Oil (up to 15% w/w, equivalent to 7.5 g/kg/day, for all test materials) for up to 20 weeks. No tumorigenic potential or adverse effects to shea oleine or Butyrospermum Parkii (Shea) Oil (15% w/w, equivalent to 7.5 g/kg/day) were 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 DPRA 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 did not produce sensitization reaction in humans in a non-standard sensitization study (at 0.14%) or in HRIPTs (at up to 0.42%).

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 membrane 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

There are no safety test data for Butyrospermum Parkii (Shea) Nut Extract and Butyrospermum Parkii (Shea) Nut Shell Powder, and no safety test data for Butyrospermum Parkii (Shea) Seedcake Extract and Butyrospermum Parkii (Shea) Butter at maximum use concentrations (5.5% and 100% in leave-on products, respectively). However, human repeated patch tests for Butyrospermum Parkii (Shea) Seedcake Extract and Butyrospermum Parkii (Shea) Butter were negative at lower concentrations (0.42% and 70%, respectively). Based on the Panel's clinical experience, the lack of adverse event reports, and the negative safety test data (including negative results from DPRAs), the Panel was not concerned about dermal irritation or sensitization following exposure to these ingredients.

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. While there are no specific constituents of concern detailed for the *Butyrospermum parkii* (shea)-derived ingredients described in this safety assessment, not all constituents have been identified, especially for the nut shell and seedcake ingredients. Therefore, when formulating products, manufacturers should avoid reaching levels in final formulation of known 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.

CONCLUSION

The CIR Expert Panel concluded that the following 13 ingredients are safe in cosmetics in the present practices of use and concentration described in this safety assessment when formulated to be non-sensitizing.

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

*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.[1]

Ingredient/CAS No.	Definition	Function
Butyrospermum Parkii (Shea) Butter CAS No. 91080-23-8; 194043-92-0	Butyrospermum Parkii (Shea) Butter is a fat obtained from the fruit of *Butyrospermum parkii*. The accepted scientific name for *Butyrospermum parkii* is *Vitellaria paradoxa*.	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 *Butyrospermum parkii* is *Vitellaria paradoxa*.	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 *Butyrospermum parkii* is *Vitellaria paradoxa*.	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 Butyrospermum parkii*. The accepted name for *Butyrospermum parkii* is *Vitellaria paradoxa*.	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 *Butyrospermum parkii*. The accepted scientific name for *Butyrospermum parkii* is *Vitellaria paradoxa*.	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 *Butyrospermum parkii* is *Vitellaria paradoxa*.	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 *Butyrospermum parkii*. The accepted name for *Butyrospermum parkii is Vitellaria paradoxa*.	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 *Dictionary*.	Not in *Dictionary*.

Table 2. Mean concentrations of tocopherols in 102 Butyrospermum Parkii (Shea) Butter samples by HPLC analysis (μg/g)[5]

α-tocopherol	β-tocopherol	γ-tocopherol	δ-tocopherol	total tocopherol
112	16	38	34	208

Table 3. Total fatty acid composition of *Butyrospermum parkii* (Shea)-derived ingredients (%) [2,6,46]

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.[3,22-24,47]

	# of Uses	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*
	Butyrospermum Parkii (Shea) Butter		**Butyrospermum Parkii (Shea) Butter Extract**		**Butyrospermum Parkii (Shea) Butter Unsaponifiables**		**Butyrospermum Parkii (Shea) Nut Extract**	
Totals[†]	**5447***	**0.0001-100**	**560**	**0.0000095-5**	**75**	**0.01-4.5**	**NR**	**0.00028-1**
Duration of Use								
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	0.00028-0.51
Diluted for (Bath) Use	35	0.05-3	7	0.05	NR	NR	NR	NR
Exposure Type								
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	0.25-2.55	NR	NR
Incidental Inhalation -Sprays	23; 1751[a]; 1124[b]	0.1-0.33; 0.001-8[a]; 0.59[b]	14; 132[a]; 111[b]	0.001-0.025; 0.001-0.8[a]; 0.0001[b]	6[a]; 7[b]	0.5[a]	NR	NR
Incidental Inhalation - Powders	9; 36[c]; 1124[b]	3; 0.59[b]; 0.05-8[c]	2; 8[c]; 111[b]	0.015; 0.0000095-5[c]; 0.0001[b]	4; 1[c]; 7[b]	0.06	NR	NR
Dermal Contact	4625	0.0004-100	489	0.0001-5	67	0.051-4.5	NR	0.00028-1
Deodorant (underarm)	21[a]	NR	1[a]	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	0.051-2.55	NR	0.00028-0.51
Baby Products	46	0.005-7	10	0.1	1	4	NR	NR

	Butyrospermum Parkii (Shea) Nut Shell Powder		**Butyrospermum Parkii (Shea) Oil**		**Butyrospermum Parkii (Shea) Seedcake Extract**		**Hydrogenated Shea Butter**	
Totals[†]	**2**	**0.00028-1**	**82**	**0.001-11**	**3**	**0.0002-5.5**	**23**	**NR**
Duration of Use								
Leave-On	2	0.01-1	47	0.01-11	2	0.00023-5.5	12	NR
Rinse Off	NR	0.00028-0.5	32	0.001-2.5	1	0.00028-2	11	NR
Diluted for (Bath) Use	NR	NR	3	NR	NR	NR	NR	NR
Exposure Type								
Eye Area	NR	NR	2	0.5-8	NR	0.00023-5.5	NR	NR
Incidental Ingestion	NR	NR	1	0.5-11	NR	3	1	NR
Incidental Inhalation -Sprays	1[b]	NR	33[a]; 6[b]	1; 0.2[a]	2[a]	0.0095-4; 0.01[a]	1; 5[a]; 3[b]	NR
Incidental Inhalation - Powders	1[b]	NR	1; 1[c];6[b]	0.95-8[c]	NR	0.0012-5[c]	3[b]	NR
Dermal Contact	2	0.00028-1	75	0.005-8	2	0.00023-5.5	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	0.00028-3	4	NR
Baby Products	NR	NR	1	NR	NR	5	NR	NR

Table 4. Frequency and concentration of use according to duration and type of exposure for shea ingredients.[3,22-24,47]

	# of Uses	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*
	Shea Butter Glyceride		**Shea Butter Glycerides**		**Shea Oleine**			
Totals†	**NR**	**0.49**	**39**	**0.49-6.5**	**3**	**NR**		
Duration of Use								
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		
Exposure Type								
Eye Area	NR	NR	4	NR	NR	NR		
Incidental Ingestion	NR	NR	1	NR	NR	NR		
Incidental Inhalation -Sprays	NR	NR	13[a]; 5[b]	NR	1; 1[a]	NR		
Incidental Inhalation - Powders	NR	NR	5[b]	NR	NR	NR		
Dermal Contact	NR	0.49	31	0.49-6.5	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.

[a.] It is possible these products may be sprays, but it is not specified whether the reported uses are sprays.

[b.] Not specified whether a powder or a spray, so this information is captured for both categories of incidental inhalation.

[c.] 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
In Vitro					
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	[17]
Human					
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	[37]
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	[38]
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	[17]
Butyrospermum Parkii (Shea) Seedcake Extract (supplied as 2.8% in 47.2% water and 50.0% 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	[19]
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	[39]

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

Test Article	Concentration/Dose	Test Population	Procedure	Results	References
			In Vitro		
70% Butyrospermum Parkii (Shea) Butter and 30% Butyrospermum Parkii (Shea) Butter Unsaponifiables	undiluted	N/A	DPRA; 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	[17]
			Human		
Butyrospermum Parkii (Shea) Butter Extract	2% in a body lotion	28 healthy subjects	Maximization test; 0.05 ml 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	[40]
Butyrospermum Parkii (Shea) Butter Extract	2% in a body lotion	26 healthy subjects	Maximization test; 0.05 ml 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	[41]
Butyrospermum Parkii (Shea) Butter Extract	5% in a face cream	25 healthy subjects	Maximization test; 0.05 ml 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	[42]
Butyrospermum Parkii(Shea) Butter Extract	1.7975% in a lipstick	104 subjects	HRIPT; 0.2 g test material applied to area 1 in^2 on upper back ; semi-occluded	Not a dermal irritant or dermal sensitizer	[43]
Butyrospermum Parkii (Shea) Seedcake Extract (supplied as 2.8% in 47.2% water and 50.0% butylene glycol)	product diluted to 5%	15 subjects	Subjects were those of the cutaneous tolerance study described above, in which 48 h patch 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	[19]
Butyrospermum Parkii (Shea) Seedcake Extract (supplied as 2.8% in 47.2% water and 50.0% butylene glycol)	product diluted to 15%	104 subjects	HRIPT; occlusive patch; no further details provided	Not irritating or sensitizing; test score = 0.01	[45]
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^2 area via occlusive patch (Finn Chambers on Scanpor) on back	Not irritating or sensitizing	[44]

Data highlighted is new since the Panel's last review.

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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

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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: May 31, 2017

SUBJECT: Butyrospermum Parkii (Shea) Seedcake Extract

Anonymous. 2017. Safety assessment of Butyrospermum parkii (Shea)-derived ingredients as used in cosmetics (updated information on Butryrospermum Parkii (Shea) Seedcake Extract included with memo 14),.

1620 L Street, N.W., Suite 1200 | Washington, D.C. 20036 | 202.331.1770 | 202.331.1969 (fax) | www.personalcarecouncil.org

Safety assessment of Butyrospermum parkii (Shea)-derived Ingredients as Used in Cosmetics (Update of memo 14)

Date : 31th May 2017

Contexte : CIR Expert Panel needs clarification on the method of manufacture, types and concentrations of impureties, and additional toxicological data of products which contains Butyrospermum parkii (Shea)-derived Ingredients, that would help assess the safety of the use of cosmetics Butyrospermum parkii (Shea)-derived ingredients.

There is one product which contains Butyrospermum parkii (Shea) seedcake Extract.

Answer :

Our product is an hydroglycolic solution composed of :

I.N.C.I USA	Percentage maximum	CAS n°
Butylene glycol	50,00%	107 – 88 – 0
Water	47,20%	7732 – 18 – 5
Butyrospermum parkii (Shea) Seedcake Extract	2,80%	91 080 – 23 – 8

- Toxicology profile

Toxicology profile was evaluated with several tests.

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). These traces are safe for consumers if the ingredient is used in a rinsed-off face product.

There is no trace of pesticides in this ingredient.

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

- 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.

- Safety studies

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

The product, 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, 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.

These kinds of results affirm that the risks of inducing sensitization through skin contact with this product are minimal. The product can be considered as non-allergenic.

3) **Assessment of the sensitizing potential on volunteer. Final clinical security test under dermatological control.**

This study has been done In the spirit of the Good Clinical Practive defined by the ICH Topic E6, the Helsinki Declaration and its successive updates.

The product, diluted to 15%, was applied on occlusive patch in 104 volunteers healthy adults.The induction phase was 3 times a week during 48 hours, and the challenge phase, one during 48 hours after 2 weeks of rest phase.

Under these study conditions, the test item showed a score 0.01. It can thus be considered non irritating.

No reaction ++ (2) nor +++ (3) was observed, so the test item can be considered non-sensitizing.

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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: April 4, 2017

SUBJECT: Draft Final Report: Safety Assessment of *Butyrospermum parkii* (Shea)-Derived Ingredients as Used In Cosmetics (draft prepared for the April 10-11, 2017 CIR Expert Panel Meeting)

Introduction - The statement in the Introduction, "Except for specific constituents of concern..." gives the reader the expectation that there will be information about "constituents of concern" in this report. It is not clear what constituents in the shea ingredients are a concern.

Summary - In the Summary, it would be helpful to restate the conclusion of the 2011 CIR report.

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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: May 3, 2017

SUBJECT: Comments Amended on the Tentative Report: Safety Assessment of *Butyrospermum parkii* (Shea)-Derived Ingredients as Used in Cosmetics

Introduction - It is not clear what should be stated in the Introduction when the CIR Expert Panel has not specifically identified constituents of concern. Based on the CIR Expert Panel's concern about formulating with other plant-derived ingredients, the constituents of concern may vary depending on the other ingredients included in the formulation. Therefore, the formulator may be the one to identify constituents of concern for a specific formulation. When the CIR Expert Panel has not specifically identified constituents of concern, should the Introduction include the statement: "No specific constituents of concern have been identified"?

Developmental and Reproductive Toxicity Studies - In study 2, the rats were provided diets containing 15% of either shea oleine or shea oil. Therefore, it is not clear why the last sentence of the section states "at concentrations equating to greater than 15% (7.5 g/kg/day)."

Sensitization, Summary - At the April 2017 meeting, the CIR Expert Panel questioned the methodology of the non-standard "sensitization" study of the product containing 0.14% (as tested) Butyrospermum Parkii (Shea) Seedcake Extract. Because this was a 48-hour cutaneous patch test followed 6-8 weeks later with another 48-hour patch in 15 subjects, the method should be described in the text and the HRIPT of the product containing 0.006% Butyrospermum Parkii (Shea) Seedcake Extract should be mentioned in the text.

Summary - Please correct: "reconstituted mucous model"

Table 6, reference 19 - Please indicate that the cutaneous tolerance test was a 48 hour patch test.

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