
Safety Assessment of *Cocos nucifera* (Coconut)-Derived Ingredients as Used in Cosmetics

Status: Draft Tentative Report for Panel Review
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Panel Meeting Date: September 14-15, 2020

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D.; Lisa A. Peterson, Ph.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Alice Akinsulie, former Scientific Analyst/Writer, and Christina Burnett, Senior Scientific Analyst/Writer, CIR.



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Christina L. Burnett, Senior Scientific Writer/Analyst, CIR
Date: August 21, 2020
Subject: Safety Assessment of *Cocos nucifera* (Coconut)-Derived Ingredients as Used in Cosmetics

Enclosed is the Draft Tentative Report of the Safety Assessment of *Cocos nucifera* (Coconut)-Derived Ingredients as Used in Cosmetics. (It is identified as *cocosn092020rep* in the pdf document.) At the December 2019 meeting, the Panel issued an Insufficient Data Announcement (IDA) for these ingredients. The additional data needed to determine safety were:

- Method of manufacturing data for Cocos Nucifera (Coconut) Fruit Powder
- Composition and impurities data for Cocos Nucifera (Coconut) Flower Extract, Cocos Nucifera (Coconut) Fruit Powder, Cocos Nucifera (Coconut) Shell Powder, and Cocos Nucifera (Coconut) Fruit Extract or another *Cocos nucifera* (coconut) fruit-derived ingredient.
- Data on Cocos Nucifera (Coconut) Flower Extract and Cocos Nucifera (Coconut) Shell Powder on the following endpoints:
 - 28-day dermal toxicity, and if positive, DART may be needed
 - Genotoxicity
 - Dermal irritation and sensitization
- Clarification as to whether the data on the trade name mixture containing 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus* are actually for a *Lactobacillus* ferment of coconut fruit extract, or for a mixture of the fruit extract and *Lactobacillus*.

Since the issuance of the IDA, CIR has received unpublished data on the composition of Cocos Nucifera (Coconut) Fruit Extract (*cocosn092020data*). These data have been incorporated into the report and are highlighted to aid in the Panel's review. Per discussions from the December meeting, and because data clarifying the identity of the trade name mixture containing 20% Cocos Nucifera (Coconut) Fruit Extract and 80% *Lactobacillus* were not received, information pertaining to this mixture have been stricken from the safety assessment. Additionally, comments on the Draft Report from the Council have been addressed (*cocosn092020pcpc*).

CIR staff have also received unpublished data submissions for a coconut ingredient identified as Cocos Nucifera (Coconut) Fruit Juice; however, clarification has been requested by staff regarding this data. A memo and the data are included in this report package (*cocosn092020_Sabinsa_memo* and *cocosn092020_Sabinsa1* through *cocos092020_Sabinsa3*). The data will be incorporated into the report once our query has been satisfactorily addressed.

Also, since December, CIR staff has been made aware that Cocos Nucifera (Coconut) Flower Nectar Extract has been added to the *Dictionary*. This ingredient is defined as the extract of the nectar obtained from the flowers of *Cocos nucifera*, and it is reported to function as an antimicrobial agent, antioxidant, and pH adjuster in cosmetic products. Currently, there are no reported uses for this ingredient in the VCRP. The Council is performing a concentration of use survey. A search of PubMed and the Internet using both the INCI nomenclature and the generic term "coconut flower nectar extract" found no relevant chemical or toxicological data for this ingredient. Would the Panel consider adding this ingredient to this safety assessment at this review stage?

The Use Table (Table 3) was updated with 2020 VCRP data (*cocosn092020fda*). Use for most ingredients has increased slightly. The largest increase in uses reported is in Cocos Nucifera (Coconut) Fruit Extract: total uses increased from 429 to 469, with the majority of the uses reported in moisturizing skin care products.

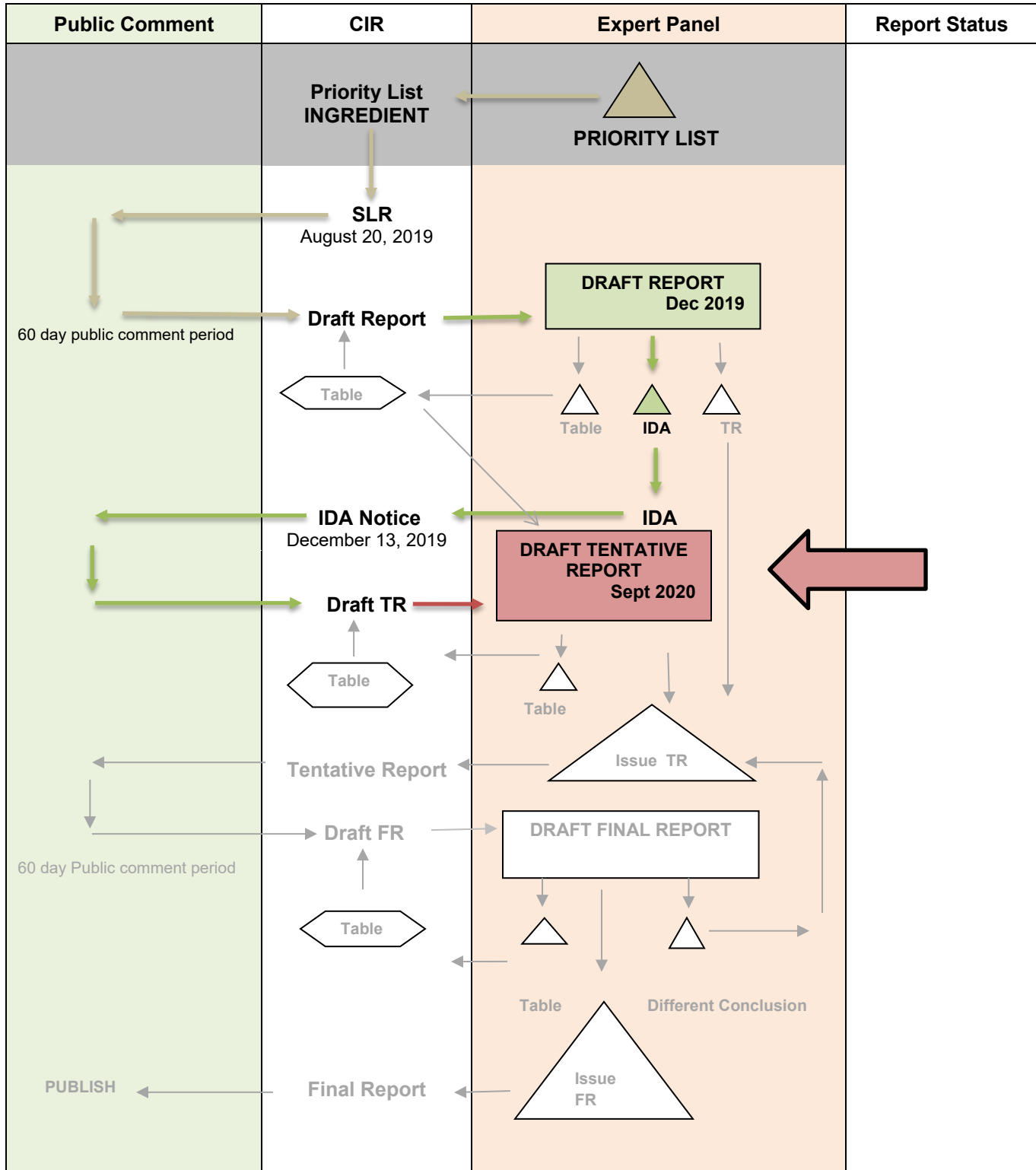
Other supporting documents for this report package include a flow chart (*cocosn092020flow*), report history (*cocosn092020hist*), transcripts from the previous meeting (*cocosn092020min*), a search strategy (*cocosn092020strat*), and a data profile (*cocosn092020prof*).

Based on the proceedings and comments from the December 2019 meeting, a draft Discussion has been included. The Panel should carefully consider and discuss the data (or lack thereof) and the draft Abstract and Discussion presented in this report, and issue a Tentative Report with a safe, safe with qualifications, unsafe, insufficient data, or split conclusion.

SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY Cocos nucifera (coconut)-derived ingredients

MEETING September 2020



Coconut-Derived Ingredients History

August 29, 2019 – Scientific Literature Review announced.

December 2019 - The Panel issued an IDA. The additional data needed for these cosmetic ingredients were:

- Method of manufacturing data for *Cocos Nucifera* (Coconut) Fruit Powder
- Composition and impurities data for *Cocos Nucifera* (Coconut) Flower Extract, *Cocos Nucifera* (Coconut) Fruit Powder, *Cocos Nucifera* (Coconut) Shell Powder, and *Cocos Nucifera* (Coconut) Fruit Extract or another *Cocos nucifera* (coconut) fruit-derived ingredient.
- Data on *Cocos Nucifera* (Coconut) Flower Extract and *Cocos Nucifera* (Coconut) Shell Powder on the following endpoints:
 - 28-day dermal toxicity, and if positive, DART may be needed
 - Genotoxicity
 - Dermal irritation and sensitization
- Clarification as to whether the data on the trade name mixture containing 20% *Cocos Nucifera* (Coconut) Fruit Extract and 80% *Lactobacillus* are actually for a *Lactobacillus* ferment of coconut fruit extract, or for a mixture of the fruit extract and *Lactobacillus*.

Coconut Derived Ingredients, September 2020 – Christina Burnett

	Coconut Derived Ingredients, September 2020 – Christina Burnett																													
	Reported Use	GRAS	Method of Mfg	Constituents	Impurities	Toxico-kinetics		Acute Tox			Repeated Dose Tox			DART		Genotox		Carci		Dermal Irr.			Dermal Sens.			Phototoxicity	Ocular Irr.		Clinical Studies	
						Dermal Penetration	ADME	Dermal	Oral	Inhalation	Dermal	Oral	Inhalation	Dermal	Oral	In Vitro	In Vivo	Dermal	Oral	In Vitro	Animal	Human	In Vitro/In Chemico	Animal	Human		In Vitro	Animal	Retrospective/ Multicenter	Case Reports
Cocos Nucifera (Coconut) Flower Extract	X		X	X																										
Cocos Nucifera (Coconut) Fruit	X																					X								
Cocos Nucifera (Coconut) Fruit Extract	X		X	X	X				X					X																
Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract																														
Cocos Nucifera (Coconut) Fruit Juice	X																				X									
Cocos Nucifera (Coconut) Fruit Powder	X																													
Cocos Nucifera (Coconut) Fruit Water	X		X																											
Cocos Nucifera (Coconut) Liquid Endosperm	X			X									X	X				X			X	X		X						
Cocos Nucifera (Coconut) Shell Powder	X		X	X																										
Cocos Nucifera (Coconut) Flower Nectar Extract *																														

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

*Pending approval by the Panel for addition.

Cocos Nucifera (Coconut)-Derived Ingredients

Ingredient	CAS #	InfoB	SciFin	PubMed	TOXNET	FDA	EU	ECHA	IUCLID	SIDS	ECETOC	HPVIS	NICNAS	NTIS	NTP	WHO	FAO	NIOSH	FEMA	Web
Cocos Nucifera (Coconut) Fruit Extract	999000685	1/1	✓	0/22	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Flower Extract		1/1	✓	0/10	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Fruit	999002544	1/1	✓	10/243	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract		1/1	✓	0/3	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Fruit Juice	999001659	1/1	✓	0/16	NR	✓	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Fruit Powder	999003837	1/1	✓	0/3	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Fruit Water	-	1/1	✓	0/90	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Oil	8001-31-8	1/1	✓	15/304	✓	✓	Listed; No Restriction	NR	NR	NR	NR	NR	No assessment	NR	NR	NR	NR	NR	✓	✓
Cocos Nucifera (Coconut) Seed Butter	999004789	1/1	✓	0/7	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Shell Powder	999001305	1/1	✓	0/19	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓
Cocos Nucifera (Coconut) Water/ Coconut Liquid Endosperm	977026257	1/1	✓	0/16	NR	NR	Listed; No Restriction	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	✓

*NR – No results were found; Check mark - Data available; 0/0 – relevant/hits

Botanical and/or Fragrance Websites (if applicable)

Ingredient	CAS #	Dr. Duke's	Taxonomy	GRIN	Sigma-Aldrich	IFRA	RIFM
Cocos Nucifera (coconut) (generic search)	8001-31-8	✓	✓	✓	✓	NR	NR

Search Strategy

Web search: Cocos Nucifera Fruit Extract; Copra oil; Cocos oil; Coconut butter; Coconut extract; Coconut kernel extract; Coconut palm oil; coconut palm oil; Copra oil; coconut water; Allergic Contact Dermatitis cocos nucifera, references were then narrowed by “adverse effects, including toxicity” or “dermal” or “sensitization” or “irritation”.

Coconut oil allergy: [21 hits in pubmed]

Cocos Nucifera (Coconut) Fruit Extract: 21 hits, 1 relevant

Cocos Nucifera (Coconut) Flower Extract :10 hits; 0 relevant

Cocos Nucifera (Coconut) Fruit; 243 hits; 0 relevant ; coconut nucifera (coconut) fruit toxicity; 8 hits; 0 relevant; coconut nucifera coconut fruit in vitro; 26 hits; 2 relevant

Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract; 21 hits; 0 relevant

Cocos Nucifera (Coconut) Fruit Juice; 6 hits; 0 relevant

Cocos Nucifera (Coconut) Fruit Powder; 25 hits; 0 relevant

Cocos Nucifera (Coconut) Oil; 303 hits;

Cocos Nucifera (Coconut) Seed Butter; 7 hits;

Cocos Nucifera (Coconut) Shell Powder

Cocos Nucifera (Coconut) Water**

SEARCH UPDATED JULY 2020 – no new relevant data.

Search of PubMed and the Internet for Cocos Nucifera (Coconut) Flower Nectar Extract and coconut flower nectar extract was performed and initially no relevant chemical or toxicological data for this ingredient were found. This ingredient is pending addition to the Cocos nucifera (Coconut)-derived ingredient safety assessment.

Typical Search Terms

- INCI names
- CAS numbers
- chemical/technical names
- additional terms will be used as appropriate

LINKS

Search Engines

- Pubmed (- <http://www.ncbi.nlm.nih.gov/pubmed>)
- Toxnet (<https://toxnet.nlm.nih.gov/>); (includes Toxline; HSDB; ChemIDPlus; DART; IRIS; CCRIS; CPDB; GENE-TOX)
- Scifinder (<https://scifinder.cas.org/scifinder>)

appropriate qualifiers are used as necessary

search results are reviewed to identify relevant documents

Pertinent Websites

- wINCI - <http://webdictionary.personalcarecouncil.org>
- FDA databases <http://www.ecfr.gov/cgi-bin/ECFR?page=browse>
- FDA search databases: <http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234631.htm>;
- EAFUS: <http://www.accessdata.fda.gov/scripts/fcn/fcnavigation.cfm?rpt=efuslisting&displayall=true>
- GRAS listing: <http://www.fda.gov/food/ingredientspackaginglabeling/gras/default.htm>
- SCOGS database: <http://www.fda.gov/food/ingredientspackaginglabeling/gras/scogs/ucm2006852.htm>
- Indirect Food Additives: <http://www.accessdata.fda.gov/scripts/fdcc/?set=IndirectAdditives>
- Drug Approvals and Database: <http://www.fda.gov/Drugs/InformationOnDrugs/default.htm>
- <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM135688.pdf>
- FDA Orange Book: <https://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm>
- OTC ingredient list: <https://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm135688.pdf>
- (inactive ingredients approved for drugs: <http://www.accessdata.fda.gov/scripts/cder/iig/>)
- HPVIS (EPA High-Production Volume Info Systems) - <https://ofmext.epa.gov/hpvis/HPVISlogon>
- NIOSH (National Institute for Occupational Safety and Health) - <http://www.cdc.gov/niosh/>
- NTIS (National Technical Information Service) - <http://www.ntis.gov/>
- NTP (National Toxicology Program) - <http://ntp.niehs.nih.gov/>
- Office of Dietary Supplements <https://ods.od.nih.gov/>
- FEMA (Flavor & Extract Manufacturers Association) - http://www.femaflavor.org/search/apachesolr_search/
- EU CosIng database: <http://ec.europa.eu/growth/tools-databases/cosing/>

- ECHA (European Chemicals Agency – REACH dossiers) – <http://echa.europa.eu/information-on-chemicals;jsessionid=A978100B4E4CC39C78C93A851EB3E3C7.live1>
- ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals) - <http://www.ecetoc.org>
- European Medicines Agency (EMA) - <http://www.ema.europa.eu/ema/>
- IUCLID (International Uniform Chemical Information Database) - <https://iuclid6.echa.europa.eu/search>
- OECD SIDS (Organisation for Economic Co-operation and Development Screening Info Data Sets)- <http://webnet.oecd.org/hpv/ui/Search.aspx>
- SCCS (Scientific Committee for Consumer Safety) opinions: http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm
- NICNAS (Australian National Industrial Chemical Notification and Assessment Scheme)- <https://www.nicnas.gov.au/>
- International Programme on Chemical Safety <http://www.inchem.org/>
- FAO (Food and Agriculture Organization of the United Nations) - <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/>
- WHO (World Health Organization) technical reports - http://www.who.int/biologicals/technical_report_series/en/
- www.google.com - a general Google search should be performed for additional background information, to identify references that are available, and for other general information

Botanical Websites, if applicable

- Dr. Duke's - <https://phytochem.nal.usda.gov/phytochem/search>
- Taxonomy database - <http://www.ncbi.nlm.nih.gov/taxonomy>
- GRIN (U.S. National Plant Germplasm System) - <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx>
- Sigma Aldrich plant profiler- <http://www.sigmaaldrich.com/life-science/nutrition-research/learning-center/plant-profiler.html>
- American Herbal Products Association Botanical Safety Handbook (database) - <http://www.ahpa.org/Resources/BotanicalSafetyHandbook.aspx>
- European Medicines Agency Herbal Medicines - http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal_search.jsp
- National Agricultural Library NAL Catalog (AGRICOLA) <https://agricola.nal.usda.gov/>
- The Seasoning and Spice Association List of Culinary Herbs and Spices
http://www.seasoningandspice.org.uk/ssa/background_culinary-herbs-spices.aspx

Fragrance Websites, if applicable

- IFRA (International Fragrance Association) – <http://www.ifraorg.org/>
- Research Institute for Fragrance Materials (RIFM) - <http://rifm.org/>

DECEMBER 2019 PANEL MEETING – INITIAL REVIEW/DRAFT REPORT

Belsito's Team Meeting – December 9, 2019

DR. BELSITO: Okay. Coconut. So, this is the first time we're looking at these nine ingredients, and so make it brief, let's see what we thought, huh?

Just a comment, on page 11, and I think Dan would agree, it says that the safety of these ingredients is evaluated by the Research Institute for Fragrance Material. That's not quite correct. They are evaluated by the Expert Panel for Fragrance Safety.

DR. LIEBLER: Correct. Key distinction.

DR. BELSITO: Yes. So, wherever you mention that, in limits are set by IFRA, RIFM just does any necessary research that the panel wants.

The next thing that I had is, looking at the concentrations of use for the liquid endosperm, are we sure that that is only a fragrance ingredient? I know what the dictionary says, but are we reviewing it as a non-fragrance ingredient? Because that, we have a significant amount of data. That's probably one of the easiest to get through. And it's repeatedly done throughout the paper. So, are we looking at liquid endosperm?

DR. EISENMANN: I think part of the problem is there was recently a name change with it. And so, I think, the dictionary water is always a distillation product and that was mistakenly called water, which is what it is called in the food industry.

But that must be the only function that we had listed. And I'm not sure that they have added any additional functions. But it doesn't matter to me if you want to look at it for skin conditioning agent miscellaneous.

DR. BELSITO: I figured it would make sense to do it, because it's like used at, what, percentages like 12 percent? I mean, that's not the way a fragrance is typically used.

DR. EISENMANN: (Inaudible).

DR. LIEBLER: We frequently run into this thing where it's in the dictionary, it's in our list, and then it apparently has a fragrance use and no other use listed. But it's in the dictionary and it's in our list, so I think we should default to reviewing them, even if -- in other words, a fragrance use shouldn't exclude it from our consideration.

DR. BELSITO: Right. I mean, if it's clearly a fragrance like geraniol, that's one thing.

DR. LIEBLER: Yeah. But in this case, that's not the case. And I think our default should be to do it as opposed to trying to file it off.

DR. BELSITO: Okay.

DR. BERGFELD: It says in the administrative regs, if it's a fragrance totally, we don't review it. So if it's iffy we review it, basically.

DR. LIEBLER: Then it could be in the dictionary, in our list, and then it's a fragrance, and then we sort of say because of administrative regs, we don't do it?

DR. SNYDER: Well, we can safe as used as a fragrance, could we not?

DR. BELSITO: Right.

DR. LIEBLER: That's the problem.

DR. BELSITO: Yeah.

DR. LIEBLER: So we are kind of -- I think if --

DR. BELSITO: Can we say in the discussion that, given the reported ranges of concentration, the panel questioned whether the liquid endosperm was solely a fragrance ingredient or was being used for other benefits -- or whatever word you want -- in cosmetic products. And in that regard, it would be safe as used up to the concentrations reported?

MS. FIUME: I don't know if we need to go that far.

DR. BELSITO: Okay.

MS. FIUME: We've discussed, and it has been on public record that the functions listed in the dictionary are not necessarily always all the functions. And when we refer to, "as used in cosmetics," we're talking about what's given in that use table, not necessarily what the specific function is.

Our procedures say we can defer review of ingredients that are fragrance only, so that it is not a duplication of effort. And that's why we do contact RIFM. It doesn't say we have to exclude them from our review. But when we do refer to, "as used in cosmetics," we are talking more about the use table than the given function.

DR. BELSITO: Okay. Paul, are you concerned about the DART and estrogenic effects?

DR. SNYDER: No. You know, I looked at that study with the estrogen effects; and that was kind of a weird study where they ovariectomized rats and then fed them 100 mL of coconut water every day. I think there is -- the sum total of the data are not of concern.

DR. BELSITO: What about the sperm effects?

DR. SNYDER: Well, that was all improvement though, wasn't it?

DR. BERGFELD: Improved, yeah.

DR. SNYDER: Yeah, improvements. Increased sperm concentration, so no.

DR. BELSITO: Okay. All right, genotox. We have no mammalian?

DR. LIEBLER: I didn't have a concern about that.

DR. KLAASSEN: No concern.

DR. BELSITO: Okay. So, we got some information in Wave 2 on HRIPTs for the fruit and the fruit juice. And in the original, we had information also on the liquid endosperm and the fruit extract.

So the question is -- I think we can easily go safe for the extract and the endosperm, and the fruit and the fruit juice. Do we need manufacturing and impurities for all of the others except flower extract, fruit water needs impurities, fruit shell needs manufacturing. And then sensitization and irritation would be needed for all except for the fruit, the fruit juice and the endosperm.

MS. FIUME: Don, can I ask a question?

DR. BELSITO: Yeah.

MS. FIUME: So, this is an example of a report where the sensitization data, the HRIPTs that are submitted, are those simple tables that have really no details, which is what we're getting more and more.

DR. BELSITO: Right.

MS. FIUME: So are those data acceptable if it says there are low level reactions in X number of patients, but it doesn't tell you any of the details?

Because it seems primarily what we've gotten over the last few submissions are these summary tables. So is it sufficient to decide whether or not it is a sensitizer or if the data are sufficient for that determination?

DR. BELSITO: So, I presume you are referring to the data in Wave 2 where they tested rinse-offs. And they were seeing low level irritation in the rinse-offs, and so, that didn't bother me. And then when they came back and they looked at the leave-ons, at the same concentration, there was nothing.

And in fact, in one they did the -- at least in one, the HRIPT, I can't remember, was semi-occlusive for the rinse-off. The other, it was actually occlusive for the rinse-off. And that's the one where you saw a lot of -- during the induction period, not the elicitation. So, it didn't really bother me.

MS. FIUME: I guess my question is, in general, are the submissions that are being sent acceptable?

DR. BELSITO: It would be nice to see a panel of all the patients that were done and what their responses were at different times. I think that, just like some of our boilerplates, it's case by case.

You know, if you're looking at something and you know that we are going to restrict it because under certain conditions it can be irritant, like a surfactant rinse-off, and you're seeing low level reactions during the induction. And then when you look at the same product in a leave-on, and you're not seeing it, I can dismiss that.

Whereas if it's a product that you -- or an ingredient material that you would not expect to be irritant, and you're beginning to see low-level reactions during the induction, then I think I would like to see that material. I don't think I could make a blanket rule, at least for myself, as to how comfortable or uncomfortable I am with a summary.

DR. BERGFELD: Could I ask a question, and that is, when the CIR or the PCP presents this information, this one did not document what lab it came out of. I think that's helpful. Am I to assume that whatever you send us is a good lab that has done the testing?

DR. EISENMANN: I send you what they provide me. I mean, they don't like to put things -- a lot of companies are uncomfortable having their studies put up on the CIR website. And that's why we're getting these summaries instead of the whole study for some companies.

DR. BERGFELD: But do they name the research lab doing the testing?

DR. EISENMANN: No. What I provided is what they gave. That's it. I didn't see any other information. They did not provide the RETHA (phonetic). But that is one thing I could ask for if that would be helpful, if you want to know the lab that did it.

DR. BERGFELD: I would think that would be an interesting point. Because instead of just a pass-through, we'd just have some kind of quality marker on the research lab, at least.

DR. LIEBLER: I agree. I think that's always a judgment call when we get these summaries, particularly when we get things like method of manufacture, impurities, that, you know, a lot of details on the analytical methods used for testing are not provided to us. But the data are reasonably plausible.

And, in this case -- this is not my area, obviously, skin sensitization studies, but I've seen enough of the big reports with the charts of the individual patients and the pages of GLP and all that stuff. And at least I know that that was done in a well-documented way. Here, I can't say that.

And in the worst case, it is possible for somebody to make this up, and send it to us, and then we just go, okay; and I'm not comfortable with that.

DR. BERGFELD: That's all I had.

DR. BELSITO: So, why is it, Carol, that companies don't want to produce the actual --

DR. EISENMANN: Because they don't want it on your -- on the CIR website.

MS. KOWCZ: They don't want it public.

DR. EISENMANN: It can be cited. I mean, I am not sure they would have a problem with you seeing it, but they don't want it -- I mean, I have data submitted to me all the time and then I go back to them and say, oh, can it be put on the CIR website? And they say no, so I can't give it to you. So, I sometimes see data that I can't give to you, because they don't want it on your website.

Because as soon as I ask if -- so sometimes they will come up with a summary, sometimes they will just say, no, we're not going to provide it. I mean, even that inhalation study that was done in 1984, they didn't want to provide the whole study. They provided you that summary on MCI/MI.

DR. SNYDER: I mean, the point of that is, is that sensitization data is not sufficient, because the maximum concentration of use is 1.5 percent, and that was 0.098 percent. So we're well below the maximum concentration use for leave-ons.

DR. BELSITO: Which one?

DR. SNYDER: The one we got, the second wave. The one we got was 0.09 percent, 110, 107, or was negative with the fruit juice. There was 0.003 percent for the rinse-off, where we had the 7 out of 110 had reaction in induction phase, 6 out of 110 had it on challenge phase.

DR. BELSITO: That was with the rinse-off product.

DR. SNYDER: Yes, but the leave-on was 0.098 percent. And we have a maximum leave-on at 1.5 percent. So we're still deficient there, right?

DR. BELSITO: For fruit juice? We have a maximum leave-on of one.

DR. SNYDER: I have 1.5 in my notes.

DR. BELSITO: It's one.

MS. BURNETT: The liquid endosperm is 1.5 as the maximum leave-on.

DR. KLAASSEN: Right.

DR. BELSITO: Fruit juice is one.

DR. SNYDER: Yeah, but that's 0.098, that's 0.01 -- or, I mean 0.1.

DR. BELSITO: I wasn't bothered by that, so let me just go back. I mean, I may have missed it, Paul. I have to go back to Wave 2, because I didn't move that over.

DR. SNYDER: It's 0.098 percent.

DR. BELSITO: Now I have to rotate the view. So this is with the fruit juice we're talking about.

DR. SNYDER: Correct.

DR. BELSITO: 0.098, leave-on, inclusive. Okay. There was one subject with a low-level reaction during challenge. Okay. And what data -- in the original report we had fruit extract at -- okay. So, then we have two percent with fruit extract was fine. So, you don't think the fruit juice, or the fruit extract can be used for the fruit juice?

DR. SNYDER: I'm just pointing it out --

DR. BELSITO: No, I know, I guess the print was so small I probably saw it at 0.98 when I was reviewing it and not 0.098.

DR. SNYDER: I mean, we're going to have other insufficiencies, right?

DR. BELSITO: Right.

DR. SNYDER: May be we could ask for it to fill in the data gap.

DR. BELSITO: So, are we safe for the fruit extract and the endosperm?

DR. BERGFELD: Irritation sensitivity.

DR. BELSITO: No, I mean, safe as used for the fruit extract and the fruit endosperm; are people okay with that?

MS. BURNETT: I do want to point out, the data we have on the liquid endosperm is actually a mixture product that we haven't gotten confirmation as to what it actually is, because it has --

DR. BERGFELD: On the fruit extract.

MS. BURNETT: Oh, I'm sorry, on the fruit extract. It's a ferment product -- it's fermented. And the manufacturer has not really given us a whole lot of data as to whether it is a standalone or if it's actually a ferment product.

DR. BELSITO: That's the data on which, Christina, I'm sorry.

MS. BURNETT: The fruit extract. The data, when you look at it presented throughout the report, it says 98 percent -- oh wait, no, there's two; I'm sorry.

There's fruit extract, which says 20 percent fruit extract, and 80 percent lactobacillus. But there is also a mixture ingredient of 98 percent liquid endosperm with two percent leuconostoc radish root ferment.

DR. BELSITO: Right.

MS. BURNETT: But we were trying, we have been trying to get a confirmation with the fruit extract as to what that actually is.

DR. SNYDER: I didn't think we received anything that we asked for, or that we were deficient in, right?

DR. BELSITO: This is new. We have never seen this report before.

DR. SNYDER: Oh, okay.

DR. LIEBLER: So that's why we didn't receive anything.

DR. SNYDER: Yeah, okay.

DR. BELSITO: So first of all, it's a food -- at least parts of it are a food. So, we have the pesticides in heavy metals and inhalation. Paul has dismissed the DART, so we don't need absorption, distribution, metabolism. Right, Paul?

DR. SNYDER: Let me see what the other tox data is. Yeah.

DR. BELSITO: Gene tox is fine.

DR. SNYDER: Yeah.

DR. BELSITO: So, what you're saying is that you're not sure that the data -- first of all the fruit is up to 1 percent and we only have sensitization at 0.01 -- or 0.1, 0.098. And there were some quirky things in the challenge, so you're not comfortable with increasing it ten-fold.

DR. SNYDER: Well, I mean, it's just -- I'm not an HRIPT expert, but I've read enough of these over the years to know that usually they're pretty clean. And that one had some --

DR. BELSITO: Right. Okay. And then the endosperm, the issue there, Christina?

MS. BURNETT: It's more of -- with the fruit extract is. The data is all on a mixture with lactobacillus.

DR. BELSITO: Okay. So, is the endosperm liquid okay?

MS. FIUME: The data were submitted by industry but, again, that's just simply a summary. It's on PDF Page 38; that just says we did this HRIPT in 104 subjects and it was negative. But no details are provided.

DR. BELSITO: This is in the Wave 2?

MS. FIUME: The original document. The original document, the liquid endosperm, with the 1.47 percent.

DR. BELSITO: Page 16.

MS. FIUME: Page 38, PDF page 38, is the actual data.

DR. BELSITO: And, do we at least get to, what do we get to cite from this? We don't know the company who submitted it?

MS. FIUME: The only information we can cite is the concentration tested, the number of subjects, that it was semi-occlusive, and the results are negative -- or that the researcher stated that there was no irritation or sensitization.

DR. BELSITO: So, we don't have a lab, we don't have a company, we have no one to point to, to say where this data came from?

MS. FIUME: And no table of individual results.

DR. BELSITO: Then I don't think we can use it.

DR. EISENMANN: We are going to end up not getting any data because of the policy to post things on your website.

DR. BELSITO: I understand. But then, you know, they're going to have to understand that we're going to --

DR. EISENMANN: They share the information with their customers because they get confidentiality. I get their requests of can I have a confidentiality agreement? And I can say, no, you can't. But I do say, you know, they will accept summaries.

But if that's not going to be the policy, then you're not going to get any data, period. Because they don't want the information -- they want to keep control of it. They don't want to have it on somebody else's website.

MS. FIUME: But Carol, I guess I'm confused. I don't understand the concern. If they're giving you the test -- we get information redacted that's proprietary all the time. But to not provide the individual results --

DR. EISENMANN: It's individual -- different companies have different policies. So, some companies, their policy is not to give a lot of information, just to provide a summary, as long as it's going to be on your website. They sometimes offer, can I sign a confidentiality agreement, and I have to say, no.

DR. BELSITO: I mean, we can't because our meetings are public, right?

MS. KOWCZ: Right. And as you get into these botanical type materials, you're going to have more and more problems like this because a CBI is very important for the companies. There are so many people that are making these ingredients, so any information they provide publicly is helping another company. And that company does not have to be in the US either.

We're coming across this in many, many categories. Just want to let you know.

MS. FIUME: But I guess, though, where my confusion still lies is we're not asking for the proprietary information on the product, just to see the actual results of the tests.

MS. KOWCZ: But then, Monice, we have to be very specific what we're asking for. Are we asking for -- you know, to Wilma's point, are we asking for them to describe the lab where they did it? Are we asking for a summary table? What are we asking for?

Because we always provide you with the summary tables and the summaries, and now it's, today especially -- and I have been here for, this is my fifth meeting -- now it seems to be a little bit more specific. So, I just want to understand what it is that we are asking for?

And I just want the panel to understand that the reason a lot of these companies -- Don, a lot of them don't give, you know, all of this information, is because they don't want to give a competitive advantage to anyone else.

DR. BELSITO: I understand that, but typically we would get a report, Harrison Labs --

MS. KOWCZ: Yeah.

DR. BELSITO: We would get -- the specific ingredient name would be crossed out, but it would say, contained 0.97 of Product X.

DR. SNYDER: And then we would have data for all 106 subjects, and what their reaction was on each of the days they were evaluated. Now we're getting a paragraph, we're not even told what laboratory is doing it.

MS. KOWCZ: We can always ask. You can always ask.

DR. EISENMANN: I can ask for the laboratory, that's reasonable.

MS. BURNETT: I mean, in the past, before we put things online, the data was publicly available if they requested it. So, the competitor could still get that data.

MS. KOWCZ: And how much data was really publicly requested, though, Christina?

DR. EISENMANN: But that was --

MS. KOWCZ: Not that much.

DR. EISENMANN: That was enough for somebody to not -- I mean, to have it in your files is a big difference than putting it on your website. It's a huge difference for that.

DR. LIEBLER: This is not proprietary data. We're not asking for descriptions of how these ingredients were made. I mean, we ask for general descriptions for method of manufacturing in our report. But for the test, we usually have a very generic description.

You know, skin lotion containing 0.02 percent of the ingredient we're studying, and that's all we have on it. And then we have the documentation from the laboratory of how the test was done and the test results.

And that, I think, should not violate any proprietary information of the supplier.

DR. SNYDER: I mean, before we would get it blacked out. I mean, it's blacked out, the trade name is redacted. All we want to know is what percent of coconut is in what was tested. That's all we care about. We don't care about anything else.

DR. BERGFELD: We care about what procedure was done too.

DR. SNYDER: We do, oh yeah, yeah, yeah. But I mean, as far as anything to do with the proprietary information. So, what we want there is very, very minimal.

MS. KOWCZ: But on this, we can ask, we can go back and ask.

DR. LIEBLER: I mean, this is a corporate brainstem reaction.

DR. BELSITO: Yeah, I don't understand that. Because actually by --

MS. KOWCZ: No, this is exactly what they told us.

DR. BELSITO: The effect that this has is to allow their competitors to use these ingredients at a certain percentage, right? So how does that change their competitive advantage if we say, 0.2, you know, coconut fruit in a product that is totally redacted -- we don't know if it was a face cream, an eye cream, a lipstick, da-da-da-dah -- was tested in 106 individuals by, you know, Harrison Labs, and here are the results. It doesn't change -- it doesn't give them any more of a competitive advantage.

DR. KLAASSEN: I don't see it either.

MS. KOWCZ: We can ask for the lab, for sure. Carol does her very best to get all the information.

DR. BELSITO: I understand.

MS. KOWCZ: And on this one, if you didn't have the right information, it would be helpful to tell us so that we're not wasting your time, even though this is the first time. I just want to make sure that we know what we want and what we're asking for them.

DR. KLAASSEN: I think we need to see the data.

MS. KOWCZ: Okay.

DR. KLAASSEN: The company is not sufficient.

DR. LIEBLER: You can show them a copy of other reports that we published where that's been appendix material and say, this is what they did. This is what the panel found to satisfactorily document the test and its results. And as you can see, the information -- the specific -- any proprietary information --

MS. KOWCZ: Is redacted.

DR. LIEBLER: -- including even the manufacturer, was redacted.

MS. KOWCZ: Um hmm. Perfect.

DR. LIEBLER: And then if they have a specific problem with that, we can have that discussion.

MS. KOWCZ: Yeah, we should. We will definitely ask.

DR. BELSITO: Okay, so then, in this case --

DR. BERGFELD: The question is, how do you ask? I mean, do you just verbally ask?

MS. KOWCZ: Directly. Say this is what the panel requested.

DR. BERGFELD: And do they understand exactly what you want?

MS. KOWCZ: And this is -- what you submitted is not --

DR. EISENMANN: I send emails.

MS. KOWCZ: -- yeah -- and it's not acceptable, that's all. We're just going to tell them it's not acceptable.

DR. SNYDER: Well, I mean, I think in this case the unacceptability has to deal with the validity of the testing, because there's some quirky results. So, we need to understand that before we make it -- we don't want to overinterpret it.

DR. BELSITO: Okay, so basically it's going to be insufficient for manufacturing and composition for fruit, for fruit juice extract, for fruit juice, for fruit powder, for --- we have composition for liquid endosperm but not impurities.

So, we need impurities for liquid endosperm. And we need composition for shell --- we have composition for shell powder, but we don't have method of manufacturing. Do we need method of manufacturing for that?

DR. LIEBLER: So, wait a second --- I'm sorry, but we kind of breezed over method of manufacturing and impurities. But I think this is kind of like the pomegranate discussion with regard to fruit and fruit extract and fruit. So, first of all with the method of manufacture for fruit extract, I think, will allow us to clear the fruit.

DR. BELSITO: Okay.

DR. LIEBLER: And the fruit water method of manufacture description is actually only a general statement of how extracts are produced, and it doesn't have anything specific to coconut. So the fruit water -- I mean, we know that that's probably how it's produced, but there is nothing on the fruit water. So I would actually like to see fruit extract -- I think fruit extract covers us for fruit and fruit extract.

The liquid endosperm, it essentially is defined and that's -- you know, nature made it. So, we don't have any real method of manufacture there. It's under composition.

The shell powder, the first two sentences of shell powder is actually the method of manufacture, top of PDF 13. So, that can be moved up. So now, we've got method of manufacture for shell powder.

DR. BELSITO: And composition.

DR. LIEBLER: And composition.

DR. BELSITO: Okay.

DR. LIEBLER: So I think, actually, our insufficiencies on method of manufacturing and impurities aren't that great. I think that the --

DR. BELSITO: So, the fruit juice extract you're okay with too?

DR. LIEBLER: Yeah.

DR. BELSITO: And that's covered by the fruit water?

DR. LIEBLER: The fruit extract.

DR. BELSITO: Fruit juice extract?

DR. LIEBLER: Right, I think the fruit extract --

DR. BELSITO: We have the fruit extract.

DR. LIEBLER: Right, I think the fruit extract also suffices for the fruit/fruit juice extract.

DR. BELSITO: So, both of those?

DR. LIEBLER: Yeah. So I think we're okay with those. And we've got flower extract, method of manufacture, and we've got composition for that.

DR. BELSITO: So, the fruit juice we're okay with too?

DR. SNYDER: But we don't have fruit extract composition. We have flower extract composition, liquid endosperm composition and shell powder. Nothing composition for the fruit extract.

DR. BELSITO: No, Dan is saying that's --

DR. LIEBLER: We don't have composition on any fruit stuff, you're right, and we should get that.

DR. BELSITO: We have manufacturing and impurities on fruit extract.

DR. LIEBLER: Right.

DR. BELSITO: And Dan is saying that covers the fruit, the fruit juice extract and the fruit -- we have manufacturing and composition on the fruit water. So, between the fruit water and the fruit extract, we can cover the other fruity ingredients, the fruit, the fruit juice.

DR. LIEBLER: Yeah, the one glaring hole in this, Don, is composition.

DR. BELSITO: Do we need the fruit powder?

DR. LIEBLER: We don't have any composition for fruit anything. But you got flower extract.

DR. BELSITO: I thought you just told me that was covered by the fruit extract. No?

DR. SNYDER: We don't have fruit extract composition.

DR. LIEBLER: We don't have composition for fruit extract either.

DR. SNYDER: No.

DR. BELSITO: But we have manufacturing and impurities?

DR. LIEBLER: That's true. But the impurities --

DR. BELSITO: It's a food.

DR. LIEBLER: Right. But the impurities is basically a heavy metal statement.

DR. SNYDER: Yeah.

DR. BELSITO: Okay.

DR. SNYDER: We need composition.

DR. LIEBLER: So let's get composition. If we can get composition on a fruit or fruit extract, I think we'd be okay.

DR. BELSITO: So we have composition on flower -- okay. Okay, so then I've got all of these wrong. So, let's go through it. The flower extract, we don't need anything.

DR. LIEBLER: Right.

DR. BELSITO: So let me get rid of that, I agree. The fruit, we need composition?

DR. LIEBLER: Correct.

DR. BELSITO: But it could be covered by any of the fruit ingredients.

DR. LIEBLER: Yeah, fruit or fruit extract would be best.

DR. BELSITO: Okay, fruit extract, we have manufacturing and impurities, but we need composition.

DR. LIEBLER: Correct.

DR. BELSITO: Composition for that or we could cover that by composition of the fruit.

DR. LIEBLER: Correct.

DR. BELSITO: Okay. Juice -- the juice extract?

DR. LIEBLER: That could be covered by fruit or fruit extract.

DR. BELSITO: Okay.

DR. BERGFELD: What about the shell powder? Where'd you put that?

DR. BELSITO: The fruit juice.

DR. LIEBLER: Same. And shell powder, we have composition.

DR. BELSITO: So, you don't care about -- and we have method of manufacturing.

DR. LIEBLER: Not for shell powder.

DR. SNYDER: No.

DR. BELSITO: So do we need that?

DR. LIEBLER: Sure.

DR. SNYDER: And impurities.

DR. LIEBLER: Yeah. That's a good one for impurities.

DR. BELSITO: The fruit powder?

DR. LIEBLER: Shell powder.

DR. BELSITO: No, you can --

DR. LIEBLER: Oh, fruit powder.

DR. BELSITO: Shell powder we need composition and manufacturing. And impurities?

DR. SNYDER: Yes.

DR. LIEBLER: Yeah, shell powder, we've got composition.

DR. BELSITO: So, we need manufacturing and impurities.

DR. LIEBLER: Actually, shell powder, we actually have manufacture. It's the first two sentences under composition. It just needs to be moved up under manufacture and we'll have shell powder covered.

DR. BELSITO: So, we need impurities?

DR. SNYDER: We'll need impurities.

DR. BELSITO: The fruit powder?

DR. SNYDER: We have nothing. So, we need -- fruit extract would cover that probably, right?

DR. LIEBLER: Yeah, I think fruit or -- with the fruit powder, we can say what it probably is. But for composition and impurities, I expect that fruit could cover fruit powder. We don't have method of manufacture on fruit powder. We should probably ask for that.

DR. BELSITO: Okay, so flower extract. We need --

DR. LIEBLER: We've got composition. We've got method of manufacture. We don't have impurities in terms of like heavy metals, but the composition description.

DR. BELSITO: For flower extract?

DR. LIEBLER: For flower extract.

DR. BELSITO: I didn't flag that for some reason.

DR. SNYDER: Yeah, we have method of manufacture and composition for flower extract.

DR. LIEBLER: Yeah.

DR. BELSITO: We have method of manufacture and composition?

DR. SNYDER: Yes, we have.

DR. BELSITO: So, do we need anything else?

DR. LIEBLER: I mean, the only thing we don't have for flower extract would be the usual heavy metals description, which we can cover in the boilerplate. Because the flower extract description is pretty chemically comprehensive.

DR. BELSITO: Okay. So for manufacturing -- composition, manufacturing and impurities, the only one on the list that is totally okay is the flower extract. Is that correct?

DR. LIEBLER: Yeah.

DR. BELSITO: So, for the fruit and the fruit extract, we need -- for the fruit, fruit extracts, we need manufacturing and impurities. And that's the same for the juice and for the powder, the fruit water. The liquid endosperm we just need composition, and the shell powder we need impurities.

DR. SNYDER: No. Nope, nope, nope, nope. Nope. For the fruit extract we only need composition.

DR. LIEBLER: Yep.

DR. SNYDER: For the liquid endosperm we have composition. So, for the fruit extract we need composition. For the shell powder we need impurities. We have method of manufacture, it's under composition, move to the materials and methods. For the fruit powder we need method of manufacture and impurities, and the flower extract or flower components, it's okay.

DR. BELSITO: I thought we just needed -- I thought for the fruit powder we just needed manufacture and the composition, and impurities were covered by the fruit or the fruit extract. I thought all the fruit ingredients we just were asking for manufacturing.

DR. SNYDER: No, I think the fruit powder, we were a little -- the fruit powder is a little different. I think Dan wanted method of manufacture and impurities for fruit powder.

DR. LIEBLER: Yeah. That's correct. I originally generalized all the fruit-derived ingredients, but the fruit powder is probably a little different.

DR. BELSITO: So, manufacturing and impurities for the powder?

DR. SNYDER: Yes. Fruit powder. Shell powder, we have method of manufacture, it's under composition, it will be moved. But we need impurities. And then for the fruit juice, fruit extract, we just need composition for one of those. The flower, we're okay.

DR. BELSITO: So, I had fruit, water -- okay. So, the liquid endosperm we need manufacturing and impurities. Is that correct?

DR. LIEBLER: I think maybe just impurities because it's defined in terms of --- we don't really need manufacturer. It's the juice basically; it's the liquid that comes out when you crack it open. And that's defined at the beginning, it's not to be manufactured.

DR. BELSITO: What impurities are you going to worry about beyond pesticides or heavy metals?

DR. LIEBLER: Impurities, yes, but not method of manufacturer.

DR. BELSITO: I understand. But what impurities are you going to worry about other than heavy metals and pesticides?

DR. LIEBLER: That's it.

DR. SNYDER: We have a lot of the --

DR. BELSITO: But we restrict those anyways.

DR. SNYDER: Right.

DR. BELSITO: So why do we need them?

DR. SNYDER: We have a lot of composition data on liquid endosperm.

DR. BELSITO: I understand. My point is, if we're going to turn around and restrict them, and the only ones you're concerned about is, why are we asking for them?

DR. LIEBLER: Sure, we don't need them. You know, we can use a heavy metals boilerplate.

DR. BELSITO: So, the endosperm is okay. We have everything we need?

DR. LIEBLER: Yes.

DR. BELSITO: Okay.

MS. BURNETT: Did you need anything on the fruit water?

DR. BELSITO: Yeah, we need something on all of the fruit. And it can be covered by any of them, and that's composition, right?

MS. BURNETT: Okay.

DR. BELSITO: So, anything that's just fruit, we need at least one of them to give us composition and we're saying we can use it for all of them. For the flower extract, we're saying we're okay, we're just going to limit the impurities.

And for the endosperm, we're going to say okay, we're just limiting impurities. And for the coconut shell powder, we just -- that should be okay, too. No, you said that's a different, a horse of a different color. We want impurities for that one. Okay.

DR. SNYDER: The only concern I have about the liquid endosperm, is that it's defined as young, young green and mature green. There are three different categories of -- so I'm not certain what this composition data we have is. Is it on the young, the young green or is on the mature green? And would there be a difference?

DR. LIEBLER: In mature fruit, the endosperm is called coconut meat, so that implies very strongly that it's not liquid. So if it say liquid endosperm, it really has to be the coconut water, the liquid from the young fruit.

DR. SNYDER: No -- oh yeah. It's not coconut milk, but it's specifically defined as that liquid endosperm that happens before they mature. But again, we list in there that there are three different levels of maturity, which I don't know what that means as far as the -- does the composition change? I don't know. It's just a lovely botanical.

DR. BELSITO: So, what are you saying, Paul.

MS. BURNETT: I think it has to be some level of green. Because once it turns to the mature brown, it's dry inside.

DR. SNYDER: Okay.

DR. BELSITO: Okay.

MS. DEWAN: Can I ask a question.

DR. BELSITO: Yes.

MS. DEWAN: So, one -- coconut fruit extract, they have submitted some irritation in vitro studies and they're saying -- one of the studies says, 20 percent mixture of CFE and 80 percent lactobacillus, and that's also done for dermal and sensitization.

So actually, what did they test? Like it's 80 percent lactobacillus. That's probiotics, right?

MS. BURNETT: That was our question back to the manufacture.

MS. DEWAN: Yeah, so basically what are they testing? It's just not very clear.

DR. SNYDER: Yeah.

MS. DEWAN: And this is in vitro, dermal, sensitization and all the studies there. Every time they --

DR. BELSITO: We're basically saying that all of them are insufficient for sensitization and irritation.

DR. LIEBLER: And concentration of use.

DR. BELSITO: At maximum concentration of use. I mean, so basically what we're trying to define is all of them are insufficient for sensitization and irritation. What we want with those studies is the lab that performed them, the concentration of use of the chemical and the actual individual data. We don't need the specific product information.

And then, in addition to sensitization and irritation, which we would probably -- Dan would you agree -- accept fruit for fruit extract, for fruit juice?

DR. LIEBLER: Yes.

DR. BELSITO: Okay. But for manufacturing and impurities, that information -- everything else is fine. So those are the only two pieces we need.

DR. LIEBLER: But that 80 percent lactobacillus, 20 percent coconut fruit extract mix is probably not going to be relevant due to the coconut fruit; don't you think?

DR. BELSITO: Well, I mean, it certainly sounds like it's a probiotic that had coconut flavoring.

DR. LIEBLER: Yeah, it's not a cosmetic ingredient. That was the question you had, right? Is this even relevant to our assessment? I think it's not.

DR. BELSITO: It was put on the skin.

DR. EISENMANN: The problem is that's how these materials are sold, is these complex mixtures. And if we got an HRIPT of a private-containing coc- -- I don't know how it got put into that. It was probably in some complex mixture like this.

So, I'm not sure why you would accept a product that contains 0.01 percent of coconut fruit juice, and not defray to a makeup.

DR. LIEBLER: The way it's described to us here makes it sound like it's a different ingredient, not just a component of a mixture. It's a complex mixture. I get that they are all complex mixture products, but this sounds like a special ingredient.

DR. EISENMANN: I do agree with you.

DR. LIEBLER: And that's why --

DR. EISENMANN: It would be helpful to get clarified whether or not this is a -- if they fermented it or if it -- Joanna (phonetic) is trying to work on that, and I don't think she has gotten a good answer from them.

MS. FIUME: We have been asking -- it looks as it's -- for all intents and purposes, she hasn't received confirmation. It's appearing that it is a ferment product and not a simple mixture.

DR. LIEBLER: Okay, as it is, we can't evaluate it.

MS. BURNETT: Should I strike all that data?

DR. LIEBLER: I think so, unless we can have some clarification that could save it. Right now, we just don't have enough information. So, if don't get any more information, I don't think we can use those data.

MS. BURNETT: On both the ferment with the fruit extract; and there's two different ferments in the data.

DR. BELSITO: There is the endosperm with the leuconostoc radish root ferment.

DR. LIEBLER: Yeah. I think that the way they are represented here, they're different ingredients than are on our list.

MS. BURNETT: Okay.

DR. LIEBLER: And so, I don't think we can use the data. But if we have sufficient clarification that -- I would certainly consider. I am the person saying no here, I don't know if everybody else agrees, but --

DR. SNYDER: No, I agree.

DR. BERGFELD: Could I ask a question? It's used in sprays, and I don't believe we have any inhalation data. Just cover that with the inhalation boilerplate?

And the other question I have is the fruit oil is a fruit extract, it's the solid portion remaining. And it's not in the total list, but it's in the documented fruit oil.

MS. BURNETT: I'm sorry.

DR. BERGFELD: Fruit oil is a -- after --

MS. BURNETTE: Coconut oil?

DR. BERGFELD: Yep, the coconut oil.

MS. BURNETT: We've reviewed that, like, three times.

DR. BERGFELD: Three times, so that's safe?

MS. BURNETT: Yeah.

DR. BERGFELD: Okay.

MS. BURNETT: I should have mentioned that in the introduction somewhere.

DR. BERGFELD: I did read that, I just forgot.

DR. BELSITO: Okay, anything else on coconuts? Okay. Christina, are you straight?

MS. BURNETT: I think so.

DR. BELSITO: Okay.

MS. FIUME: Can I clarify? There's still no concern on the genotox, even though it was all the ferment products.

DR. LIEBLER: It's the ferment? Oh, then we're insufficient on genotox, too. Because, again, I don't know what that stuff is.

MS. FIUME: Thank you for pointing that out.

DR. BELSITO: We also have no mammalian for the -- Dan, we have no mammalian for genotox; is that a problem?

DR. LIEBLER: Right. And genotox is back to square one; because it's the ferment mix, and who knows what that stuff is until somebody describes it clearly to us.

DR. KLAASSEN: I would like to note that coconut is a food.

UNIDENTIFIED FEMALE: Says who?

DR. BELSITO: I've said that before, so do we still want genotox? I mean, the shell is not a food. The flower, I don't know, do we eat coconut flower? We eat all sorts of crazy flowers though.

MS. BURNETT: I don't think so.

DR. BELSITO: So do we need genotox on the fruit -- the fruit juice -- the fruit elements, or just on the flower and the bark?

DR. KLAASSEN: Usually, we don't require it.

DR. BELSITO: Dan? Paul?

DR. LIEBLER: Yeah. Okay, so what Curt was trying to say, I think, is that since it's a food we don't usually require genotox on foods, correct Curt?

DR. KLAASSEN: Correct.

DR. LIEBLER: Okay. And I was thrown for a loop by this -- again, this fermented.

DR. BELSITO: You were just getting fermented.

DR. LIEBLER: I was fermented halfway through MCI. And so, I think genotox on the shell and the flower.

DR. SNYDER: We could ask for it.

DR. LIEBLER: Those aren't foods. And if we're clear on genotox, no carcinogenicity.

DR. BELSITO: Okay. And where were those crazy endocrine studies, were they fermented as well? No, that was fruit juice -- fruit extract.

DR. LIEBLER: It was a coconut juice powder? Oh, fruit juice, yes.

DR. SNYDER: And liquid endosperm.

DR. BELSITO: Okay. Okey-doke. Are we done with our macaroons? Amino acids.

DR. BERGFELD: So it's an IDA, or is it --

DR. BELSITO: Yes.

MS. FIUME: Can I take it back one step, just so we have -- building the information for the discussion? Once the discussion is written, anything need to be stated about the estrogen-like characteristics study? Or what would you like to say about it, if anything?

DR. SNYDER: That there's significant composition data on the liquid endosperm, doesn't indicate any phytoestrogens. And there are multiple DART studies which do not implicate any reproductive effects. So, therefore, that all negates the one study that had some questionable (inaudible) effect.

DR. BELSITO: It's a food.

DR. SNYDER: Yes.

DR. LIEBLER: And questionable relevance of the model itself.

DR. SNYDER: Yes.

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DR. MARKS: Okay. So, next ingredient group is *Cocos nucifera*, coconut-derived ingredients. This is the first review of these nine coconut-derived ingredients.

And I say nine now because it may be decreased to eight, depending on what we decide to do with the liquid endosperm. Which, at least, from, I think, the data Christina sent us up to this point, the question occurred as to whether it's only used as a fragrance. And then, if that were the case, we would delete it. So, I guess probably, you know, are the ingredients okay? And my question would be is --

DR. SLAGA: What about the shell?

DR. SHANKS: The shell? You don't want to include the shell? I actually -- we're going to get into what the shell is, because I lumped that -- or I questioned, is that part of the fruit, when I looked it up.

But, any rate, Christina, do you have any more -- in terms of, is the liquid endosperm only used as a fragrance? Should we include it at this point?

MS. BURNETT: We have included fragrance ingredients that are known in only making fragrances in the past.

DR. MARKS: Um-hm.

MS. BURNETT: And based on the use levels, the dictionary lists functions, but that doesn't necessarily mean that's what they were used for, as Bart will also argue. Based on the pattern of use, it kind of looks like it's more than just fragrance. The concentration's really high.

DR. HELDRETH: The rationale for excluding fragrance ingredients is because we don't want to be redundant.

DR. ANSELL: Right.

DR. HELDRETH: That's another safety assessment body, like the Research Institute of Fragrance Materials. So, usually our bar for, do we exclude this ingredient for being a fragrance-only ingredient, is two-fold. One, its only reported function is fragrance ingredient. And two, RIFM has reviewed it or has confirmed that they're going to review it in the near future.

That way, we're sure that some ingredient isn't falling through the cracks, and everybody is saying, not it, and it's getting lost.

So, I don't think we have confirmation of the liquid endosperm, seeing something on a different radar.

DR. ANSELL: What I have is not the fragrance, but that it's not a cosmetic ingredient. That coconut --

DR. HELDRETH: It has 44 reported uses in the VCRP.

DR. ANSELL: Well, yeah, but it's misnamed. But the liquid endosperm is coconut water, which has not been distilled, so it doesn't meet the -- all waters must be distillation products.

It's the coconut water not distilled. So it doesn't meet the definition of coconut fruit water. So, it's more an INCI issue than fundamentally a different --

DR. MARKS: But we have -- so, do you think then this water was -- we have toxicologic data on it which, to me, was reassuring.

DR. ANSELL: Yeah. Well, it's coconut water. But it can't be called coconut water because the water has to be distilled.

DR. MARKS: Yeah. So, there's not another --

DR. ANSELL: A product of distillation.

DR. MARKS: I see.

DR. HELDRETH: So there's some confusion out there as to what is being called what. And, therefore, they're probably not reported as liquid endosperm to the VCRP. That doesn't mean it's not being used; that just means nobody knew to report it as a liquid endosperm, because the name changed rather recently from water to liquid endosperm.

DR. ANSELL: Yeah, and that's mentioned in Christina's memo.

DR. MARKS: Yes, she refers in that second paragraph on -- the steam distillate plant parts are coconut water. Okay. And she talks about, just as you mentioned, that coconut water is a common term for endosperm liquid of the coconut fruit.

Any rate, it sounds like we're going to include that as an ingredient, and not be concerned about the potential fragrance use or when it'd be reviewed. So, the nine ingredients, I think, Ron, Tom, or Lisa, do you have any problems with any of the ingredients?

DR. SHANKS: The flower extract and shell powder.

DR. SLAGA: Yeah. I had shell. I didn't have flower.

DR. MARKS: And expand upon that. So, the flower -- you said the flower --

DR. SHANKS: The flower extract and shell powder, we need impurities.

DR. MARKS: Oh, this is needs now? You would include them as ingredients, obviously.

DR. SHANKS: Well, if we include them, we need data. Or we can exclude them and then the rest are safe.

DR. MARKS: Okay.

DR. SHANKS: Do we have the option --

DR. MARKS: We normally don't exclude things unless -- in this case, we're a biologic family. But unless they're not chemically in the same family or grouping, or whatever similar, we exclude ingredients chemically if they're dissimilar. We've done that in the past ketones and so on.

DR. SHANKS: And this is a plant.

DR. MARKS: Yeah, exactly. So, my feeling is, you keep everything in, and then you say, okay, here are our needs. Okay. So, let me get that in there because I -- your needs were for the flower --

DR. SHANKS: Extract.

DR. MARKS: Extract.

DR. SHANKS: And shell powder.

DR. MARKS: And you needed -- what'd you say?

MS. BURNETT: Impurities.

DR. MARKS: Impurities?

DR. SHANKS: Impurities.

DR. MARKS: Not method of manufacturer?

DR. SHANKS: 28-day dermal, genotoxicity, irritation.

DR. MARKS: Hold on a second. Dermal -- 28-day dermal --

DR. SHANKS: Toxicity.

DR. MARKS: Yeah.

DR. SHANKS: Genotoxicity.

DR. MARKS: Oh, that's it. Geno.

DR. SHANKS: Irritation, skin sensitization.

DR. MARKS: Yeah. Let me see. Read-across -- yeah, that was my question. On the flower, there's just five uses. We don't know the concentration, and can we read across? It'd be pretty hard to read across. And then, the shell powder, my question was, is that part of the fruit?

MS. BURNETT: It's the outer husk.

DR. MARKS: Outer husk. Yeah, that's what I would --

MS. BURNETT: The little brown part.

DR. MARKS: So, I wouldn't think it would be part of the fruit?

MS. BURNETT: Um-um.

DR. MARKS: No? Okay.

DR. SHANKS: Well, we need to talk about the definition of fruit.

DR. MARKS: Yes. Go ahead. You want it defined more?

DR. SHANKS: Okay. Yeah. On Page 12, under Chemistry, it says a coconut fruit is a fibrous drupe with a smooth outer skin (exocarp), et cetera.

DR. MARKS: I had to look up fruit. And that's why I asked was the shell part of the fruit? Because that definition -- read it again. It's that fibrous outer --

DR. SHANKS: Fibrous drupe with a smooth outside skin, which is the exocarp, which is -- this is covered up. Let me --

DR. MARKS: Thank you, Ron.

DR. SHANKS: -- which may vary from green to red brown, or even ivory in color. The exocarp and the mesocarp make up the husk. But in Table 1, it says the fruit is the hardened endosperm.

MS. BURNETT: So, the definitions in Table 2 were provided to us by the council, through their botanical expert. And this is a table that we've been creating for the botanicals whenever. So, this is based on their definitions of what it is.

DR. SHANK: Okay.

MS. BURNETT: And then, what I have in text is based on what I found in my research.

DR. SHANK: Okay. So, which do we use since they're not the same?

MS. BURNETT: This is the continuing saga of botanicals --

DR. SHANK: Dr. Jay?

MS. BURNETT: -- how definitions change with the plant. And I can't always give you what it is, because when I look it up I'll have five different pictures pointing to different plant parts, and of course none of them will be consistent for the same plant.

DR. SHANK: Okay.

MS. BURNETT: So, fun stuff.

DR. ANSELL: So your question relates to --

DR. SHANK: When we say the fruit is okay, what do we mean?

DR. ANSELL: How much of the shell is included in the fruit?

DR. SHANK: What is the fruit?

DR. MARKS: Well, see, that's what my issue is when I looked at that other definition. Exactly what she's saying, that, presumably, all that little fibrous part on the outside of a coconut is not part of the fruit. But then, how much of the shell is part of the fruit is --

DR. ANSELL: Because I thought the definition of the fruit was ripe ovary. And I don't know how much of the --

DR. HELDRETH: For some plants --

MS. BURNETT: The definitions in Table 2 are generic, as far as I understand, that were given to us by industry.

DR. ANSELL: Right.

MS. BURNETT: The definition that I have in the text is specific to coconut.

DR. ANSELL: Mature, ripened ovary of the flowering plant, including seeds -- containing seeds, not including seeds, but containing seeds.

DR. HELDRETH: Yeah, that works for a blueberry.

DR. ANSELL: Yeah.

DR. HELDRETH: But that doesn't apply to a coconut.

DR. ANSELL: Well, yeah.

DR. HELDRETH: No, it's not. It's a drupe. It's not an ovary. Blueberry is an ovary.

MS. BURNETT: Well, what I have written on Page 12 is specific to coconut, and what we're looking at today.

DR. SHANK: Okay. So, maybe we should have both. What you have on Page 12, and then add one more sentence. The dictionary defines a fruit as hardened endosperm.

DR. ANSELL: Well, I think -- I mean, first of all, this is the first time. But putting Table 2 in without referencing it to any part of the report, is just confusing. I mean, if at somewhere you say, this is the definition we're using for fruit, or drupe, that would be okay. But this just floats out there.

So, I think that would be a good question to ask in terms of going forward with this.

DR. MARKS: I like your approach, Jay, in terms of, this is the definition we're going to use. And so, we're basing our safety analysis on this definition. This definition is based on such and such.

And in the future, if it changes, or the definition is refined and, perhaps, we didn't interpret it right, and as you said, Jay, this is going to go out as an insufficient data announcement, there's time to clarify that. But Ron, yeah, I was wondering what the fruit was too.

MS. BURNETT: So, should I strike Table 2 if it's too confusing, since it is only generic and not specific to this ingredient?

DR. SLAGA: Can it just be put in the text somewhere?

DR. MARKS: Yeah, it is in the text on Page 12, right?

MS. BURNETT: On Page 12 --

DR. SLAGA: Yeah, maybe expand that and take the table out.

MS. BURNETT: But if it's conflicting, I'm not sure how it's going to help.

DR. ANSELL: Yeah, it can't be conflicting. I mean, either it explains what the term means, or it doesn't, but it just can't -- so, if you use fruit somewhere in the report, you can reference, this is the definition we're using for fruit, and reference it back to INCI or whoever provided it.

DR. MARKS: Yeah.

DR. SHANK: And leave out the generic definition.

DR. MARKS: Yeah.

DR. HELDRETH: So, you have to pick one, because there's so many different definitions under that one.

DR. MARKS: No, I think as long -- you know, and again, I don't know how much we want to wordsmith it; but you could say the panel realizes that there are multiple definitions, and this is the one we are going to use for this report.

DR. SHANK: Okay.

DR. MARKS: And then it allows one to change in the future if that definition is no longer applicable or, like, a re-review of changes.

DR. ANSELL: Which, presumably, is Table 1, which includes the definition that's going to be used for purposes of coconut fruit juice, coconut fruit powder.

DR. MARKS: Yeah. What page is that, Jay?

DR. ANSELL: 18.

DR. MARKS: 18. Is that where I was wondering what the hell -- where is the shell powder? From the dried ground shells.

DR. ANSELL: Shell powder is the powder obtained from dried ground shells.

DR. MARKS: Makes sense.

DR. ANSELL: Which --

DR. MARKS: Abrasive -- okay. Yeah, I agree. I kind of like the -- yeah, I kind of like Table 1. Table 2, I don't think we need. Do we? Then that'll reduce the potential of confusion.

MS. BURNETT: Okay.

DR. MARKS: Okay? Let me see. Let me go back. One of the things -- so I agree with you, the irritation, sensitization of the fruit extract and the liquid endosperm were fine. We talked about the read across.

We got Wave 2 data, but they were pretty dilute. That wasn't very helpful for the fruit, it was very dilute -- 0.003 percent fruit juice, with 0.098 percent HRPTs. Yeah.

I had a question. It was, is there any concern about estrogenic effect? And on Page 15, endocrine disruptors or whatever. And then the last portion of that first under the fruit juice is, the young coconut juice has estrogen-like characteristics. Should we be recommending only use old coconuts that are post-menopausal? Is that politically incorrect?

MS. BURNETT: Yeah.

DR. SHANK: Yeah.

DR. ANSELL: Not as long as you're talking about coconut.

DR. MARKS: Coconut, that's what I am. So, is this study valid?

DR. SLAGA: I had this as a no concern, but I'm trying to find it.

MS. BURNETT: Page 15. It's the middle of the page. It's under, "Other Relevant Studies."

DR. MARKS: So, Tom, you didn't feel this -- does there need --

DR. SLAGA: Well, most of the components, or ingredients, that do have estrogenic effect, it's extremely weak if you compare it to, you know, estrogen or an estradiol and certainly the typical estrogens, and they come up very weak.

DR. MARKS: Okay.

DR. SLAGA: And the level that you're going to have of any ingredient like that, it would be very small. So, you would have to eat a lot of coconut or -- okay, eating it could be different. But putting it on the skin, the concentration would be very, very small.

DR. MARKS: Yeah, okay.

DR. SLAGA: I do always have a concern that, when you're eating something and you're putting something on your skin, different routes of exposure, and you could potentially -- may get up to a level. But, I mean, we're dealing with the skin.

So, I have to look at the level of an ingredient that would have estrogenic activity would be extremely low. And besides, when you look at the compounds, they're extremely weak.

DR. MARKS: Yeah, sort of the parabens, same sort of thing.

DR. SLAGA: Yeah. Yeah. Yeah, we went through that many times with the parabens.

DR. MARKS: Concentration of the ingredient, and very weak effects.

DR. SLAGA: Yeah.

DR. MARKS: So, should that -- as a heads up for Christina, do you think that should be in the discussion?

DR. PETERSON: If you're looking at data and the data's really --

DR. SLAGA: No.

DR. MARKS: No. So, you'd just leave it as is. Do you like that last sentence? "The authors concluded that young coconut juice has estrogen-like characteristics." And just leave it as is, and don't even comment in the discussion or any place?

DR. SLAGA: They're going to do be --

DR. MARKS: I mean, I'm fine. That's why I'm asking your guidance on it. Lisa, you were going to say something, and I think I spoke.

DR. PETERSON: The data.

DR. MARKS: And Ron Shank, you said you're fine not even mentioning it in the discussion.

DR. SHANK: Correct.

DR. MARKS: And Tom, I assume that's the case with you too, when you look --

DR. SLAGA: Yeah, it's the same here.

DR. MARKS: Okay.

DR. SLAGA: Maybe we ought to scratch that one last sentence.

DR. MARKS: Well, that's -- but then, here in your conclusion, I guess -- we still cite the study. Do we need to cite the author's conclusion?

DR. SLAGA: It's a very weak statement.

DR. MARKS: Well, we can always -- we're right in the beginning of evaluating these.

DR. SLAGA: Just leave it in right now.

DR. MARKS: Just leave it in and then see where it takes us. Lisa, did you have a --

DR. PETERSON: I don't have anything different than what's been brought up already.

MS. BURNETT: I did want to point out to the team, that the data that we have on the fruit extract is mostly on this mixture that we haven't confirmed what it is exactly. If it is a ferment product, or if it is truly coconut fruit extract and *Lactobacillus*.

The manufacturer has been contacted. Council's trying to clear it up, but they're kind of being unresponsive about it.

So, based on the concentration, it's 20 percent coconut fruit, but 80 percent *Lactobacillus*. We don't know what the actual ingredient is that they're testing -- or compound I should say. So, it could be just a ferment, which is not one of these ingredients.

DR. SHANK: Sounds like it's the ferment.

DR. PETERSON: That's what it sounds like to me.

MS. BURNETT: And if that's the case, do you want that data in here? Because if we strike it, that takes out a good portion of the data in the report.

DR. SHANK: I guess they have to clarify that.

MS. BURNETT: Okay.

DR. MARKS: Okay. So, at this point, I'll be seconding a motion tomorrow. I assume it's going to be a call for an insufficient data announcement. The needs our team wants are for the flower extract and the shell powder, impurities, 28-day dermal tox, genotox, irritation and sensitization.

The other seven ingredients, we feel they're safe as long as they're formulated to be non-sensitizing. But that obviously -- that's just the preview of what's to come.

MS. BURNETT: Let me get the flower extract and shell powder.

DR. MARKS: Right.

MS. BURNETT: So, it's impurities, 28-day dermal --

DR. MARKS: 28-day dermal tox.

MS. BURNETT: Okay. Genotox.

DR. SLAGA: Genotox.

DR. MARKS: Irritation and sensation.

DR. SLAGA: Irritation and sensitization.

MS. BURNETT: Irritation and sensitization. Okay. Got it.

DR. MARKS: Yep. Any other comments? If not, we'll see what happens tomorrow. Let's see.

Full Team Meeting – December 10, 2019

DR. BELSITO: Well, hopefully I'll get this right; we made so many changes and spent so much time on this.

So, this is the first time we're reviewing the safety of these nine coconut-derived ingredients. They function in cosmetics as skin conditioning agents and some are reported to have other functions; I won't go through those.

And, we felt, after reviewing these, that the extracts, the flower extracts, the fruit, the fruit extract, the fruit juice extract -- Dan, help me if I'm getting this right. The fruit juice and the fruit powder, and fruit water, and the liquid endosperm were safe. And the coconut shell powder was insufficient for composition, manufacturing and impurities.

DR. LIEBLER: Actually, the shell powder does have a composition description; and the first two sentences of that composition description, on PDF 13, actually describes the manufacture.

DR. BELSITO: Okay.

DR. LIEBLER: So, we're okay on method of manufacture and impurities. And, in fact, the description of what's in it in composition, we don't strictly have impurities on that. So, but I felt that we had enough information that I was okay with the shell powder.

DR. BELSITO: So, we're going safe as used for all of them?

DR. SNYDER: No.

DR. BELSITO: No? Then I got it wrong.

DR. SNYDER: We wanted composition data on any fruit, either the fruit extract or the fruit juice extract. Any one of them we said would suffice for all of them, is what I have in my notes that we --

DR. LIEBLER: Yeah, that's a glaring omission, is the composition of the fruit. If you look under composition, PDF 12 to 13, we've got shell powder, liquid endosperm, and flower extract. So we just weren't sure if we could use liquid endosperm to infer enough about the fruit.

DR. BELSITO: I see. So, we're going safe for flower extract, liquid endosperm, and shell powder?

DR. SNYDER: Yes.

DR. BELSITO: And the others, we could use any composition on any of those fruit ingredients to read across?

DR. SNYDER: Well -- yeah, I mean, the fruit powder we felt that we needed -- we couldn't use the shell powder unless we understood more about the relationship of the shell and the fruit powder. But, we said we needed composition for any fruit, fruit extract to clear the fruit extract, the fruit juice extract.

And for the fruit powder we still needed method of manufacture and impurities. We said the flower extract was okay, and the liquid endosperm was okay. And the shell powder was okay because we actually had materials and methods that were listed under compositions.

DR. BELSITO: Okay. So then, we're going safe as used for the flower extract, the liquid endosperm, and the shell powder. And all of the others would need manufacturing and impurities?

DR. SNYDER: Method of manufacture and impurities for the fruit powder, only composition for the fruit extract.

DR. BELSITO: Okay, so manufacture and impurities for the powder, and only composition for any fruit.

DR. SNYDER: For any fruit, clear all the fruits.

DR. HELDRETH: So, since this is a draft report --

DR. BELSITO: It changed so much; I apologize. I couldn't keep up with the notes.

DR. MARKS: And we have some other comments.

DR. BELSITO: Okay.

DR. MARKS: So, obviously this is going to be an insufficient data announcement, since this is the first time we reviewed these. We thought that seven of the ingredients we could move forward with a safe conclusion. And we had two, the flower extract and the shell powder, so we'll be reconciling those.

And actually we had not picked up on the shell powder that the impurities were hidden in there. So, for those two ingredients, the flower extract and the shell powder, we got impurities, 28-day dermal tox, genotox, irritation and sensitization.

So, I think we can sort of mend our two teams. Christina, you can put it together and it's an insufficient data announcement and we'll go from there. Obviously, things you wanted like composition --

DR. LIEBLER: Just to be clear, the shell powder manufacture method was -- not the impurities -- was imbedded in there with the composition.

DR. MARKS: Oh, okay.

DR. LIEBLER: So, we don't strictly have impurities, depending on how you want to define it, they give you composition. They give you carbohydrates, crude fiber, moisture, fat, you know. They don't give you individual flavonoids or terpenes or anything like that. They do give you some mineral data, but nothing like heavy metals or pesticides or anything like that.

So, you know, if we're to have our want list -- because there's a fair reasonable number of uses on the shell powder and we could probably ask for impurities. And then decide how comfortable we are, or whether or not, you know, based on what we get.

But, I want to underscore Paul's point that the fruit extract is by far the most uses in this whole family. That's what we're most likely to get data on. I think that would probably be sufficient for fruit, which has far fewer uses, but is probably quite similar.

DR. MARKS: Yeah, I agree with that. I think the flower's going to be problematic; the flower extract, because it's only five uses. We don't know the concentration. And how much are we going to get from the flower extract.

DR. LIEBLER: We do have composition and method of manufacture on the flower extract.

DR. MARKS: Yep.

DR. BERGFELD: Go ahead, Christina.

MS. BURNETT: All right, I just want to remind the panel that yesterday I brought up that the data that we have on the fruit extract is a mixture with lactobacillus, that we are trying to get clarification on, as to whether that is an actual fruit extract or if that is something else. So, I can add that clarification to the IDA.

DR. LIEBLER: Yeah, I forgot about that. Thanks for reminding me because that is really ambiguous, so.

DR. BERGFELD: Any other comments regarding what the needs will be?

DR. BELSITO: So, wait a minute. At this point, we're going insufficient again for all of them, it sounds like? Because we were saying flower extract and shell, and you're saying those are insufficient.

DR. SHANK: Right.

DR. BELSITO: So --

DR. SNYDER: Well, we had cleared it because we had the composition and the method of manufacture and --

DR. LIEBLER: For the shell.

DR. SNYDER: For the shell powder, yes.

DR. SHANK: Where is the flower extract composition?

DR. BELSITO: It's someplace, I have to see.

DR. LIEBLER: Bottom of PDF 12, the first one under composition.

DR. SHANK: That's tricky.

DR. LIEBLER: It's fairly general. I was wondering, though, you got a citation; could that be excerpted into a table?

MS. BURNETT: Possibly, yes.

DR. SHANK: But there's nothing specific there. It contains chemicals that you would find in a plant.

DR. LIEBLER: Microphone, Ron, sorry.

DR. SHANK: What it's saying is you'll find the composition is typical of a plant.

DR. LIEBLER: Um-hm.

DR. SHANK: That's not very helpful to me.

DR. LIEBLER: So that's why I asked if we could excerpt the data from that citation into a table.

MS. BURNETT: I'll have to go back to look. Because usually if it has percentages, I try to incorporate them. It could have been they just said this contains x-y-z without any breakdowns. So, I'll go back and look at the --

DR. LIEBLER: I mean, at this stage I think you've got a point -- well, you've got a point regardless of the stage of the report, Ron. At this stage, we should probably ask for it.

DR. BELSITO: So, basically we're insufficient for all of them, primarily, one or the other of manufacturing, composition or impurities, based upon what's absent in this report.

DR. BERGFELD: Is there a general agreement that it's insufficient? Because we're not going to need to vote on this, we just need the list.

DR. BELSITO: Right, so, what I have here is we have manufacturing and composition for the flower extract. But we now feel we don't have adequate composition. So, we need composition and impurities for that. We have composition -- the fruit we're looking for composition from any of them. We're thinking it'll probably be the fruit extract, which is most used.

The fruit powder we need manufacturing and impurities. Is everyone satisfied with the composition there? The fruit water, again, would be covered by the fruit. The liquid endosperm, we have manufacturing and impurities, and composition for this or the fruit. Is that right; we want composition for the endosperm? No?

DR. LIEBLER: Sorry, that's the same -- sort of the same --

DR. BELSITO: Because you said you thought it would be covered by the fruit.

DR. LIEBLER: I thought it was fine, but I -- I mean, it is -- literally, it's just a listing of chemicals. So, if the citation does not provide more quantitative information -- for the liquid endosperm, Ron, are you in the same place with that? Bottom of PDF 12 to the top of PDF 13?

DR. SHANK: So that's better.

DR. LIEBLER: It's better? It's a longer list.

DR. SHANK: Well, there're actually individual chemicals rather than classes of chemicals.

DR. LIEBLER: Okay. All right.

DR. BELSITO: Okay.

DR. LIEBLER: I'm just getting recalibrated -- different season.

DR. BELSITO: Okay, so, and then the shell powder, we've got composition, manufacturing. We need impurities. So, those are our needs at this point.

DR. MARKS: And then our team was for the flower extract and the shell powder, 28-day dermal tox, genotox, irritation and sensitization.

DR. BELSITO: We can throw that in, that's fine.

DR. MARKS: Yeah.

DR. BERGFELD: Do you believe that you have the list?

MS. BURNETT: I believe so.

DR. BERGFELD: All right, we can move on then. We have now declared that this is going out as an insufficient data announcement on coconut. We have a long list of needs. And, hopefully next meeting we'll see some of that returned to us. The next one that --

DR. BELSITO: Vote?

DR. BERGFELD: Yes?

DR. BELSITO: We need a vote?

DR. BERGFELD: Not on this, I don't believe; not when you have a list. Would you like to vote? We can vote.

DR. BELSITO: Yeah, we need to vote.

DR. BERGFELD: Okay, all those in favor?

DR. BELSITO: And then, a little discussion.

DR. BERGFELD: Okay, a little discussion.

DR. BELSITO: Okay, so we were told that the liquid endosperm was a fragrance-only ingredient. However, in reviewing this, even though that may be the definition in the dictionary, looking at the concentration of use, I think it has other uses other than as a fragrance.

So, our team had decided that this should be included in our review of the materials, and not just dismissed for the expert panel for fragrance safety to review.

DR. MARKS: We had the same discussion and concur.

DR. BERGFELD: Any other discussion points?

DR. BELSITO: No.

DR. BERGFELD: Now I believe there was a unanimous, very quick vote on that, is that correct, everybody?

DR. MARKS: Yes.

DR. BELSITO: Yes.

SEPTEMBER 2020 PANEL MEETING – SECOND REVIEW/DRAFT TENTATIVE REPORT

Safety Assessment of *Cocos nucifera* (Coconut)-Derived Ingredients as Used in Cosmetics

Status: Draft Tentative Report for Panel Review
Release Date: August 21, 2020
Panel Meeting Date: September 14-15, 2020

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D.; Lisa A. Peterson, Ph.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Alice Akinsulie, former Scientific Analyst/Writer, and Christina Burnett, Senior Scientific Analyst/Writer, CIR.

DRAFT ABSTRACT

The Expert Panel for Cosmetic Ingredient Safety (Panel) assessed the safety of 9 *Cocos nucifera* (coconut)-derived ingredients, most of which are reported to function as skin-conditioning agents in cosmetic products. The Panel reviewed the available data to determine the safety of these ingredients. The Panel concluded that...TBD.

INTRODUCTION

Most of the *Cocos nucifera* (coconut)-derived ingredients detailed in this safety assessment are reported to function in cosmetics as skin-conditioning agents, while some are reported to have other functions, such as humectants, abrasives, and hair conditioning agents, according to the web-based *International Cosmetic Ingredient Dictionary and Handbook* (WINCI; *Dictionary*; Table 1).¹ This assessment of the safety of the following 9 coconut-derived ingredients is based on the data contained in this report:

Cocos Nucifera (Coconut) Flower Extract	Cocos Nucifera (Coconut) Fruit Powder
Cocos Nucifera (Coconut) Fruit	Cocos Nucifera (Coconut) Fruit Water
Cocos Nucifera (Coconut) Fruit Extract	Cocos Nucifera (Coconut) Liquid Endosperm
Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract	Cocos Nucifera (Coconut) Shell Powder
Cocos Nucifera (Coconut) Fruit Juice	

The Expert Panel for Cosmetic Ingredient Safety (Panel) has previously reviewed the safety of some related *Cocos nucifera* (coconut)-derived ingredients. In 1986, the Panel first issued a final report on the safety of Cocos Nucifera (Coconut) Oil, Coconut Acid, Hydrogenated Coconut Acid, and Hydrogenated Coconut Oil; the Panel concluded that the ingredients are safe for use as cosmetic ingredients.² In 2011, the Panel published a report on the safety of Cocos Nucifera (Coconut) Oil and related ingredients with a conclusion that the ingredients are safe for use as cosmetic ingredients.³ Finally, in a report published in 2017, the Panel reviewed the safety of plant-derived fatty acid oils and concluded that the 244 plant-derived fatty acid oils, including Cocos Nucifera (Coconut) Oil and Cocos Nucifera (Coconut) Seed Butter, are safe in present practices of use and concentration.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. Due to the paucity of published safety and toxicity data on these ingredients, this report includes summary information included in technical dossiers, when appropriate.⁵ A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that the Panel typically evaluates, are provided on the Cosmetic Ingredient Review (CIR) website (<https://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites>; <https://www.cir-safety.org/supplementaldoc/cir-report-format-outline>). Unpublished data are provided by the cosmetics industry, as well as by other interested parties.

These ingredients are all derived from the same species, *Cocos nucifera*. As such, there is likely some overlap of constituents and/or potential impurities. Botanicals, such as *Cocos nucifera*-derived ingredients, may contain hundreds of constituents, some of which may have the potential to cause toxic effects. In this assessment, the Panel is reviewing the potential toxicity of each of the botanical ingredients as a whole, complex mixture. The Panel is not reviewing the potential toxicity of the individual constituents. Additionally, some of the ingredients reviewed in this safety assessment are consumed as food, and daily exposure from food use would result in much larger systemic exposures than possible from use in cosmetic products. Therefore, the primary focus of the safety assessment of these ingredients as used in cosmetics is on the potential for local effects (i.e. from topical exposure).

Note: In many of the published studies, it is not known how the substance being tested compares to the cosmetic ingredient. Therefore, if it is not known whether the substance being discussed is a cosmetic ingredient, the test substance will be identified as “coconut...” or “*Cocos nucifera*...” (e.g. “coconut extract” or “*Cocos nucifera* shell”); if it is known that the substance is a cosmetic ingredient, the *Dictionary* nomenclature “Cocos Nucifera (Coconut) ...” (e.g. “Cocos Nucifera (Coconut) Fruit Extract”) will be used. Also, often in the published literature, the specific identities of the ingredients were not discerned (specifically, Cocos Nucifera (Coconut) Liquid Endosperm or coconut water). If it is not known how the substances being tested in these studies compare to the cosmetic ingredients being reviewed in this assessment, the terminology used in the study (e.g., “coconut water”) will be used. However, if it can be discerned that the data are on coconut liquid endosperm, the *Dictionary* nomenclature (Cocos Nucifera (Coconut) Liquid Endosperm) will be used in place of coconut water. In botanical cosmetic ingredients, the term “water” refers to the aqueous solution of the steam distillate of plant parts; however, in the food industry, “coconut water” is the common term for the endosperm liquid of the coconut fruit.

CHEMISTRY

Definition and Plant Identification

The definitions of the *Cocos nucifera*-derived ingredients included in this review are provided in Table 1.¹ *Cocos nucifera* L. is native to Indonesia, Papua New Guinea, Philippines, Australia, and Vanuatu.⁶ *Cocos nucifera* is an important member of the family Arecaceae (palm family), and is more commonly known as coconut.⁷ The plant is an arborescent

monocotyledonous tree of approximately 25 m in height (giant coconut) with a dense canopy.⁷ The giant adult coconut produces 12 – 14 groups of flowers that emit from the main stem (inflorescence spikes) yearly, while the adult dwarf coconut can emit 18 spikes in the same period.

While the *Dictionary* definition states *Cocos Nucifera* (Coconut) Fruit is the fruit (or hardened endosperm) of *Cocos nucifera*, botanical resources define the coconut fruit as a fibrous drupe with a smooth outside skin (exocarp), which may vary from green to red brown, or even ivory in color.⁸⁻¹⁰ The exocarp and mesocarp make up the "husk" of the coconut. The mesocarp is the hard, fibrous reddish-brown husk from which coir or fiber is obtained. Between the shell and the kernel is a thin brown seed coat or testa, which adheres to the hard endosperm or kernel (also called meat or jelly), about 12 mm thick in a mature nut. The edible part of the coconut fruit is the endosperm tissue. In young fruit, the endosperm is a liquid called "coconut water," while in mature fruit, the endosperm is called coconut meat. The kernel (called copra when dried to 60% moisture) constitutes 40% – 70% of the weight of the husked nut and contains about 50% water and 30% - 40% oil. "Coconut water" is not the same as "coconut milk;" the latter is obtained by grating coconut meat, with or without the addition of water.⁹

Chemical Properties

Cocos Nucifera (Coconut) Fruit Extract

A supplier reported that *Cocos Nucifera* (Coconut) Fruit Extract prepared in water is a colorless to light yellow liquid with a characteristic odor.¹¹ At 25°C, the pH is 6.7 and the specific gravity is 0.99 - 1.00. This ingredient is soluble in any proportion in water.

No chemical properties on these cosmetic ingredients were discovered in the published literature, and no other unpublished data were submitted.

Method of Manufacture

Cocos Nucifera (Coconut) Flower Extract

The method described herein is general to the processing of a coconut flower extract, and it is unknown if it applies to cosmetic ingredient manufacture. The shade-dried flowers of *Cocos nucifera* were extracted with various solvents.¹² Chloroform, methanol, ethanol, hydroalcohol (80% aqueous ethanol), and aqueous batches of extracts of flowers of *Cocos nucifera* were prepared at ~10% solute. The excess solvent in the extracts was removed by distillation and concentrated using a water batch. The extracts were then collected in a Petri dish and stored in desiccators at room temperature.

Cocos Nucifera (Coconut) Fruit Extract

A supplier reported that *Cocos Nucifera* (Coconut) Fruit Extract is produced by extracting the fruit with specified eluent(s) under appropriate temperature conditions to yield a concentrate.¹¹ Typical eluents include water, butylene glycol, glycerin, *Carthamus tinctorius* (safflower) seed oil, and propylene glycol. The concentrate containing phytochemical constituents is then blended with the desired diluent(s) and preservation system to produce the final ingredient.

Cocos Nucifera (Coconut) Fruit Water

In general, botanical waters are prepared from the leaves, stems, flowers, bark, roots, or other parts of a plant or the whole plant.¹ The condensate from steam distillation produces two distinct fractions that contain the volatile ingredients from the plant. The water insoluble fraction contains the "oil." The water-soluble fraction contains ingredients from the plant that are water soluble, and is identified by the term "Water" in the INCI name.

Cocos Nucifera (Coconut) Shell Powder

In a study of the composition of coconut shell, the outer pericarp of the *Cocos nucifera* shell was collected, air-dried, ground into a fine powder, and then sieved with 2 mm mesh pore size.¹³

Composition

Cocos Nucifera (Coconut) Flower Extract

Cocos nucifera flower extracts that were prepared as described above, were used in phytochemical analysis.¹² The chloroform extract showed the presence of alkaloids, flavonoids, tannins and carbohydrates. The methanol extract showed the presence of alkaloids, flavonoids, phenols, carbohydrates, and amino acids. The ethanol extract contains phytosterols and tannins. The hydroalcoholic extract showed the presence of flavonoids, phenols, tannins, and carbohydrates. The aqueous extract contains alkaloids, flavonoids, phenols, tannins, and carbohydrates. The various extracts of *Cocos nucifera* flowers showed the absence of saponins and anthraquinones.

Cocos Nucifera (Coconut) Fruit Extract

A supplier reported that an extract of coconut fruit is prepared with 90% water and 10% butylene glycol.¹⁴ The composition of the dry matter is 73% sugars (disaccharides), 22% mineral ashes (calcium, magnesium, sodium, potassium, phosphorus, sulfur, and chloride), and 5% protein.

Cocos Nucifera (Coconut) Liquid Endosperm

The aqueous part of the coconut endosperm contains mainly water (~94 - 95 g/100 g).⁹ Components found in liquid endosperm are dependent on coconut type (young, young green, mature green), and the average weight, age, and source of the coconut. Components that may be present include sugars (sucrose, glucose, fructose), sugar alcohols (mannitol, sorbitol, myo-inositol, scyllo-inositol), lipids, fatty acids, amino acids (alanine, β -alanine, γ -aminobutyric acid, arginine, asparagine and glutamine, aspartic acid, asparagine, cystine, glutamic acid, glutamine, glycine, homoserine, histidine, isoleucine, leucine, lysine, methionine, ornithine, phenylalanine, pipercolic acid, proline, serine, tyrosine, tryptophan, threonine, valine, dihydroxyphenylalanine, hydroxyproline and pipercolic acid), nitrogenous compounds (ethanolamine and ammonia), organic acids (malic acid and pyridinolone), and enzymes. Furthermore, naturally-occurring phytohormones were identified in the liquid endosperm from young green and mature coconuts, including indole-3-acetic acid, various cytokinins, gibberellins and abscisic acid, and salicylic acid. The liquid endosperm of tender coconut water contains vitamin B, especially nicotinic acid (vitamin B3), pantothenic acid (vitamin B5), biotin, riboflavin (vitamin B2), folic acid, trace amounts of thiamine (vitamin B1), and pyridoxine (vitamin B6).¹⁵

Cocos Nucifera (Coconut) Shell Powder

The proximate analysis of the composition of coconut shell pericarp indicated that it is composed of carbohydrates (52.63%), crude fiber (32.39%), moisture (10.10%), ash (2.28%), crude fat/oil (2.14%), and protein (0.46%).¹³ The mineral composition of the coconut shell was reported to be 11.64 mg/100 g phosphorus, 16.02 mg/100 g calcium, 1.22 mg/100 g magnesium, 0.76 mg/100 g sodium, 3.30 mg/100 g potassium, 618.00 mg/100 g iron, 1.20 mg/100 g zinc, and of 6.00 mg/100 g manganese.

Impurities*Cocos Nucifera (Coconut) Fruit Extract*

A supplier reported that Cocos Nucifera (Coconut) Fruit Extract in butylene glycol had the following heavy metals profile via inductively coupled plasma-optical emission spectrometry: antimony 0.363 ppm, arsenic 0.091 ppm, nickel 0.046 ppm, and vanadium 0.054 ppm.¹⁴ Cadmium, chromium, cobalt, mercury, and lead were not quantifiable. No phytosanitary (pesticide) substances or aflatoxins were detected via high performance liquid chromatography and or gas chromatography.

Another supplier reported that Cocos Nucifera (Coconut) Fruit Extract concentrate in a glycerin and water base had 0.115 mg/l arsenic and 0.083 mg/l nickel.¹¹ Antimony, cadmium, chromium, iron, lead, and mercury were below levels of detection. No residual pesticides were detected. The 26 allergens defined by the European Union Cosmetic Regulations were below threshold levels in a concentrate of Cocos Nucifera (Coconut) Fruit Extract concentrate in an alcohol base.

USE**Cosmetic**

The safety of the cosmetic ingredients addressed in this assessment is evaluated based on data received from the US Food and Drug Administration (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 the FDA Voluntary Cosmetic Registration Program (VCRP) database. Use concentration data are submitted by the cosmetic industry in response to a survey, conducted by the Personal Care Products Council (Council), of maximum reported use concentrations by product category.

According to 2020 VCRP data, Cocos Nucifera (Coconut) Fruit Extract is reported to be used in 469 formulations, 242 of which are leave-on formulations (Table 2).¹⁶ All other in-use ingredients are reported to be used in 79 formulations or less. The results of the concentration of use survey conducted by the Council in 2019 indicate that Cocos Nucifera (Coconut) Liquid Endosperm has the highest maximum concentration of use; it is used at up to 6.5% in shampoos (non-coloring).¹⁷⁻¹⁹ Cocos Nucifera (Coconut) Liquid Endosperm also has the highest maximum concentration of use in dermal leave-on formulations; it is used at up to 1.5% in face and neck products. Cocos Nucifera (Coconut) Fruit Extract is reported to be used at up to 0.02% in leave-on hair products. No uses were reported in the VCRP or by the Council for Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract.

Cocos nucifera (coconut)-derived ingredients may be used in products that can be incidentally ingested or come into contact with mucous membranes; for example, Cocos Nucifera (Coconut) Liquid Endosperm is reported to be used in a lipstick at up to 0.32%.¹⁸ Additionally, *Cocos nucifera* (coconut)-derived ingredients are reported to be used in products that could possibly be inhaled; e.g. Cocos Nucifera (Coconut) Liquid Endosperm is used in spray face and neck products at 1.5% and Cocos Nucifera (Coconut) Fruit Juice is used in a face powder formulation (concentration of use not reported).^{16,18,19} In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters > 10 μ m, with propellant sprays yielding a greater fraction of droplets/particles < 10 μ m compared with pump sprays.^{20,21} Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and thoracic regions of the respiratory tract and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount.^{22,23} 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.²⁴⁻²⁶

The coconut-derived ingredients described in this report are not restricted from use in any way under the rules governing cosmetic products in the European Union.²⁷

Non-Cosmetic

Coconut fruit can be made into a variety of foods and beverages.⁹ Coconut water is served directly as a beverage, while coconut milk is usually used as a food ingredient in various traditional cooking recipes.

The FDA requires allergen labeling when major allergens, such as tree nuts like coconut, are included in food.²⁸ A major food allergen is an ingredient from a food or food group, such as coconut, that contains protein derived from the food.

The juice and shell of *Cocos nucifera* have been researched for use as antifungal and antibacterial treatments.^{15,29-31} Various parts of the coconut including (coconut liquid endosperm, husk fiber, and coconut juice) have also been researched for use as alternative or therapeutic treatments (as herbal medicines or dietary supplements) for dermal wounds, health promotion, and cardiovascular protection.³²⁻³⁶ The electrolyte composition of coconut water (e.g., potassium) can cause vasodilation in blood vessels; therefore, coconut water has been used as intravenous fluid for hydration and as a resuscitation fluid.³⁷ Coconut flower clusters (also called inflorescence) and coconut juice are reportedly used in traditional folk medicine in Southeast Asia to treat menstrual cycle disorders.^{38,39}

TOXICOKINETIC STUDIES

No relevant toxicokinetics studies on coconut-derived ingredients were found in the public literature, and unpublished data were not submitted. In general, toxicokinetics data are not expected to be found on botanical ingredients because each botanical ingredient is a complex mixture of constituents.

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Oral

Cocos Nucifera (Coconut) Fruit Extract

An alcoholic extract of *Cocos nucifera* fruit was administered orally to male albino mice (6/group).⁴⁰ Mice received a single dose of *Cocos nucifera* fruit extract at doses of 0.25, 0.5, 1, 1.5, 2, 2.5, or 3 g/kg body weight via gavage. The control group received 1 ml of saline. Mice were observed for toxicity, morbidity, or mortality for 24 h. No deaths, significant decreases in body weight, or gross pathological abnormalities were observed.

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY (DART) STUDIES

Cocos Nucifera (Coconut) Fruit Extract

The potential reproductive toxicity of an alcoholic extract of *Cocos nucifera* fruit was tested in two groups of male albino mice (8/group).⁴⁰ A negative control group was administered saline, and test groups 1 and 2 were given 125 mg/kg and 200 mg/kg of the alcoholic extract, respectively, of coconut fruit for 15 days. The left and right testis with epididymides were removed and weighed after removing the fat and surrounding tissues. Sperm counts were made from a homogenized solution of saline and caudal epididymides. There was a significant ($p < 0.01$) increase in relative testicular weight/body weight in test group 1 compared to the control group. However, test group 2 showed a significant decrease in testis weight/body weight compared to the control group and test group 1. Also, an increase in sperm concentration was noted in male mice administered 125 mg/kg of coconut fruit extract.

Cocos Nucifera (Coconut) Liquid Endosperm

The conceptive and anti-abortion effects of coconut water was studied using groups of 5 gravid female albino rats.⁴¹ The rats received coconut water starting the day after the rats were mated. The animals were dosed for 21 days (gestation period) as follows: group 1 (control group) was given 1.0 ml/100 g of distilled water; group 2 was given 0.5 ml/100 g of coconut water; group 3 received 1.0 ml/100 g coconut water; and group 4 was administered 2.0 ml/100 g coconut water. The rats were weighed on days 1, 7, 14, and 21. Rats in groups 1, 2, and 3 underwent laparotomy on day 10 of pregnancy, while group 4 delivered on day 21. (No additional details were readily available.) Upon delivery, the number of offspring from each female was counted. An increase in body weight was noted in pregnant female rats of all dose groups compared to the control. No significant differences in the implantation site and number of litters between treated groups and the control group were observed. The authors determined that low doses of coconut water protracted the gestation period, but not significantly.

The reproductive effects of coconut water were studied in male Wistar rats (5/group).⁴² The first group was given 20 ml/kg of distilled water and served as the control. Group 2 was orally administered 20 ml/kg of corn oil, group 3 was given 20 ml/kg of coconut water, group 4 was administered 200 mg/kg of danazol (a synthetic androgen), and group 5 was given 200 mg/kg of danazol and 20 ml/kg coconut water. The rats received the test materials daily for 6 weeks. The rats showed a

significant ($p < 0.05$) increase in sperm count, sperm motility, and sperm viability in groups 3 and 5 while a significant reduction in these variables was observed in group 4. A significant increase in luteinizing hormone (LH), follicle-stimulating hormone (FSH) and testosterone levels were observed in groups 3 and 5 when compared with group 4. All test groups showed a significant increase in reduced glutathione, total protein, and a significant reduction in malondialdehyde in testicular homogenates, when compared with the control and corn oil groups.

GENOTOXICITY

In Vitro

Cocos Nucifera (Coconut) Liquid Endosperm

The genotoxicity potential of a trade name mixture containing 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate was evaluated in a bacterial reverse mutation assay using *S. typhimurium* strains: TA98, TA100, TA1537, and TA1535, and *E. coli* strain WP2uvrA.⁴³ The test article dissolved in sterile distilled water was administered at concentrations of 1.5, 5.0, 15, 50, 150, 500, 1500, and 5000 µg/plate, with and without metabolic activation. Appropriate positive and negative controls were used. The trade name mixture containing Cocos Nucifera (Coconut) Liquid Endosperm was non-genotoxic.

In Vivo

No in vivo genotoxicity studies were discovered in the published literature, and no unpublished data were submitted.

CARCINOGENICITY

No carcinogenicity studies were discovered in the published literature, and no unpublished data were submitted.

OTHER RELEVANT STUDIES

Estrogenic Effects

Cocos Nucifera (Coconut) Fruit Juice

A study was performed to analyze the estrogenic effects of young coconut fruit juice using 4 groups of female Wistar rats (10/group).³⁶ The test material was prepared from reconstituted young coconut juice powder daily for oral administration. The first group consisted of ovariectomized rats, the second group consisted of sham-operated rats (placebo surgery), the third group consisted of ovariectomized rats injected intraperitoneally with exogenous estrogen (2.5 g/kg of estradiol benzoate) twice a week for 4 wk, and the fourth group consisted of ovariectomized rats that were orally administered young coconut fruit juice (100 ml/kg/d) for 4 wk. The rats were killed on the first day of the sixth week of the study, and their serum estradiol (E2) level was measured by chemiluminescent immunoassay. The ovariectomized rat group administered young coconut juice had significantly higher serum E2 levels ($p < 0.05$) than the control ovariectomized group. A significant increase ($p < 0.05$) was also observed when compared with the sham-operated group. A significant reduction ($p < 0.05$) in neuronal cell death was observed in ovariectomized rats administered young coconut fruit juice compared to the control ovariectomized group. The authors concluded that young coconut juice has estrogen-like characteristics.

Cytotoxicity

Cocos Nucifera (Coconut) Shell Powder

The cytotoxic properties of coconut shell crude extract (concentrations of crude ranging from 0.1 mg/ml to 5 mg/ml) was evaluated in a DNA fragmentation analysis involving immortalized human epithelioid (HeLa) cells.⁴⁴ After a 48-h incubation period, cell viability was measured using a 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) assay. At concentrations ranging from 0.1 mg/ml to 5 mg/ml, the percentage of inhibition gradually increased from 60% to 85%. The median inhibitory concentration (IC₅₀) was 1.77 mg/ml. The authors concluded that the cytotoxic activity was found due to the apoptosis induced in HeLa cells, which was demonstrated by DNA fragmentation analysis.

DERMAL IRRITATION AND SENSITIZATION

Dermal irritation and sensitization studies are summarized in Table 3. The results of an in vitro dermal irritation study of a trade name mixture containing 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate found this substance non-irritating.⁴³ A trade name mixture containing 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate was predicted to be non-sensitizing in a direct peptide reactivity assay (DPRA). A rinse-off product containing 0.3% Cocos Nucifera (Coconut) Fruit (diluted 1% in tap water), a leave-on product containing 0.098% Cocos Nucifera (Coconut) Fruit Juice (undiluted), and a leave-on product containing 1.47% Cocos Nucifera (Coconut) Liquid Endosperm were not irritating and not sensitizing in human repeat insult patch tests (HRIPTs).⁴⁵⁻⁴⁷

OCULAR IRRITATION STUDIES

In Vitro

Cocos Nucifera (Coconut) Liquid Endosperm

The EpiOcular™ model (human corneal epithelial model) assay was used to evaluate the irritation potential of a trade name material containing 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate.⁴³ Each tissue was dosed with 20 µL Dulbecco's phosphate buffered saline (DPBS) prior to administering the test article. Fifty µL of the undiluted test article were then applied to 2 tissue inserts which were incubated for 30 minutes for liquid substances and 90 minutes for solid substances. Sterile DPBS and sterile deionized water were used as negative controls and 5% sodium dodecyl sulfate solution and methyl acetate were used as positive controls. The test substance was considered to be non-irritating.

SUMMARY

According to the *Dictionary*, most of the 9 *Cocos nucifera* (coconut)-derived ingredients detailed in this safety assessment are reported to function in cosmetics as skin-conditioning agents, while some are reported to have other functions, such as humectants, abrasives, and hair conditioning agents. Botanicals, such as *Cocos nucifera*-derived ingredients, may contain hundreds of constituents, some of which may have the potential to cause toxic effects. In this assessment, the Panel is reviewing the potential toxicity of each of the botanical ingredients as a whole, complex mixture. The Panel is not reviewing the potential toxicity of the individual constituents. Additionally, some of the ingredients reviewed in this safety assessment may be consumed in food, and daily exposure from food use would result in much larger systemic exposures than those from use in cosmetic products. Therefore, the primary focus of the safety assessment of these ingredients as used in cosmetics is on the potential for local effects (i.e. from topical exposure).

According to 2020 VCRP data, Cocos Nucifera (Coconut) Fruit Extract is reported to be used in 469 formulations, 242 of which are leave-on formulations. All other in-use ingredients are reported to be used in 79 formulations or less. The results of the concentration of use survey conducted by the Council in 2019 indicate that Cocos Nucifera (Coconut) Liquid Endosperm has the highest maximum concentration of use; it is used at up to 6.5% in shampoos (non-coloring). Cocos Nucifera (Coconut) Liquid Endosperm also has the highest maximum concentration of use in dermal leave-on formulations; it is used at up to 1.5% in face and neck products. Cocos Nucifera (Coconut) Fruit Extract is reported to be used at up to 0.12% in leave-on hair products. No uses were reported in the VCRP or by the Council for Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract.

Coconut fruit and coconut water (i.e. coconut liquid endosperm) can be made into a variety of foods and beverages. The juice and shell have been researched for use in alternative or therapeutic treatments.

In an acute oral toxicity study, an alcoholic extract of *Cocos nucifera* fruit was administered orally to male mice extract at doses up to 3 g/kg body weight via gavage. No deaths, significant decreases in body weight, or gross pathological abnormalities were observed.

An alcoholic extract of *Cocos nucifera* fruit increased relative testicular weight/body weight at 125 mg/kg, but significant decreased testis weight/body weight at 200 mg/kg in male mice. An increase in sperm concentration was noted in male mice that received 125 mg/kg of the test material. In a study of female rats, coconut water at up to 2.0 ml/100 g caused an increase in body weight pregnant rats when compared to the control. No significant differences in the implantation site or number of litters between treated groups and the control group were observed. In a study of coconut water in male rats, significant increases in sperm count, sperm motility, and sperm viability in groups that received coconut water were observed. A significant increase in LH, FSH, and testosterone levels were also observed in these groups.

A trade name mixture containing Cocos Nucifera (Coconut) Liquid Endosperm (98%) and 2% *Leuconostoc*/radish root ferment filtrate was not genotoxic in an Ames assay, with or without metabolic activation.

A study performed to analyze the estrogenic effects of coconut fruit juice in rats found that ovariectomized rats that received young coconut juice had significantly higher serum E2 levels than the control ovariectomized rats and sham-operated rats. A significant reduction in neuronal cell death was observed ovariectomized rats administered young coconut fruit juice when compared to the control ovariectomized group.

The cytotoxic properties of coconut shell crude extract (concentrations of crude ranging from 0.1 mg/ml to 5 mg/ml) was evaluated in a DNA fragmentation analysis involving immortalized HeLa cells. The percentage of inhibition gradually increased from 60% to 85%. The median IC₅₀ was 1.77 mg/ml.

The results of an in vitro dermal irritation study of a trade name mixture of 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate found these substances non-irritating. A trade name mixture containing 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate was predicted to be non-sensitizing by DPRA. A rinse-off product containing 0.3% Cocos Nucifera (Coconut) Fruit (diluted 1% in tap water), a leave-on product containing 0.098% Cocos Nucifera (Coconut) Fruit Juice (undiluted), and a leave-on product containing 1.47% Cocos Nucifera (Coconut) Liquid Endosperm were not irritating and not sensitizing in HRIPTs.

The results of an in vitro ocular irritation study of a trade name mixture containing 98% *Cocos Nucifera* (Coconut) Liquid Endosperm and 2% *Leuconostoc*/radish root ferment filtrate found this substance non-irritating.

No relevant in vivo genotoxicity studies or carcinogenicity studies were discovered in the published literature, and no unpublished data were submitted. No relevant toxicokinetics studies were found in the published literature; however, in general, toxicokinetics data are not expected to be found on botanical ingredients because each botanical ingredient is a complex mixture of constituents.

DRAFT DISCUSSION

[Please note, this discussion is in draft form and will be modified following the meeting.]

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

Panel noted the study of estrogenic effects in young coconut juice; however, composition data of coconut liquid endosperm does not indicate any phytoestrogens. Additionally, the DART studies on coconut liquid endosperm do not implicate any reproductive effects. These facts, coupled with the very weak estrogenic effects noted in the study that used a concentration greater than that used in cosmetic products, helped mitigate concern.

Some *Cocos nucifera*-derived ingredients were reported to be used in spray and powder products that could possibly be inhaled. For example, *Cocos Nucifera* (Coconut) Liquid Endosperm is used in a face and neck spray at 1.5% and *Cocos Nucifera* (Coconut) Fruit Juice is used in a face powder at an unreported concentration. There were no inhalation toxicity data available. The Panel noted that in aerosol products, 95% – 99% of droplets/particles would not be respirable to any appreciable amount. Furthermore, droplets/particles deposited in the nasopharyngeal or bronchial regions of the respiratory tract present no toxicological concerns. 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 <https://www.cir-safety.org/cir-findings>.

Remaining discussion to be determined...

CONCLUSION

To be determined...

TABLES**Table 1.** Definitions and reported functions of the ingredients in this safety assessment.¹

Ingredient	Definition	Function(s)
Cocos Nucifera (Coconut) Flower Extract	Cocos Nucifera (Coconut) Flower Extract is the extract from the flowers of <i>Cocos nucifera</i> .	Humectants; Skin-Conditioning Agents - Humectant; Skin-Conditioning Agents-Miscellaneous
Cocos Nucifera (Coconut) Fruit	Cocos Nucifera (Coconut) Fruit is the fruit (or hardened endosperm) of <i>Cocos nucifera</i> .	Abrasives; Skin-Conditioning Agents- Miscellaneous
Cocos Nucifera (Coconut) Fruit Extract	Cocos Nucifera (Coconut) Fruit Extract is the extract of Cocos Nucifera (Coconut) Fruit	Skin-Conditioning Agents-Miscellaneous
Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract	Cocos Nucifera (Coconut) Fruit/Fruit Juice Extract is the extract of Cocos Nucifera (Coconut) Fruit and Cocos Nucifera (Coconut) Fruit Juice.	Skin-Conditioning Agents-Miscellaneous
Cocos Nucifera (Coconut) Fruit Juice	Cocos Nucifera (Coconut) Fruit Juice is the liquid expressed from Cocos Nucifera (Coconut) Fruit.	Hair Conditioning Agents; Skin-Conditioning Agents-Humectant
Cocos Nucifera (Coconut) Fruit Powder	Cocos Nucifera (Coconut) Fruit Powder is the powder obtained from the dried, ground Cocos Nucifera (Coconut) Fruit.	Skin-Conditioning Agents-Miscellaneous
Cocos Nucifera (Coconut) Fruit Water	Cocos Nucifera (Coconut) Fruit Water is an aqueous solution of the steam distillate obtained from the fruit of <i>Cocos nucifera</i> .	Hair Conditioning Agents; Skin-Conditioning Agents – Miscellaneous
Cocos Nucifera (Coconut) Liquid Endosperm	Cocos Nucifera (Coconut) Liquid Endosperm is the watery liquid obtained from the young fruit, <i>Cocos nucifera</i> .	Fragrance Ingredients
Cocos Nucifera (Coconut) Shell Powder	Cocos Nucifera (Coconut) Shell Powder is the powder obtained from the dried, ground shells of <i>Cocos nucifera</i> .	Abrasives; Bulking Agents

Table 2. Frequency (2020) and concentration of use (2019) for coconut-derived ingredients.^{16,18,19}

	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)	# of Uses	Max Conc of Use (%)
	Coconut Flower Extract**		Cocos Nucifera (Coconut) Fruit		Cocos Nucifera (Coconut) Fruit Extract	
Totals*	5	NR	25	0.001- 1	469	0.0000016 – 0.02
Duration of Use						
Leave-On	1	NR	16	0.001	242	0.00001 – 0.02
Rinse-Off	3	NR	8	0.001 - 1	222	0.0000016 – 0.04
Diluted for (Bath) Use	1	NR	1	NR	5	NR
Exposure Type						
Eye Area	NR	NR	NR	NR	4	NR
Incidental Ingestion	NR	NR	1	NR	1	NR
Incidental Inhalation-Spray	NR	NR	5 ^a ; 2 ^b	0.001 ^b	26; 36 ^a ; 148 ^b	0.0000016-0.011; 0.02 ^b
Incidental Inhalation-Powder	NR	NR	5 ^a	NR	36 ^a	0.0007 – 0.02 ^c
Dermal Contact	3	NR	20	0.001 - 1	382	0.00005 – 0.04
Deodorant (underarm)	NR	NR	NR	NR	2 ^b	NR
Hair - Non-Coloring	2	NR	3	0.001	85	0.0000016 – 0.04
Hair-Coloring	NR	NR	NR	NR	NR	0.003
Nail	NR	NR	1	NR	NR	NR
Mucous Membrane	3	NR	9	0.001	137	0.0025 – 0.04
Baby Products	NR	NR	NR	NR	1	NR

	Cocos Nucifera (Coconut) Fruit Juice		Cocos Nucifera (Coconut) Fruit Powder***		Cocos Nucifera (Coconut) Fruit Water	
Totals*	31	0.006 – 1	20	NR	NR	0.0012-0.0098
Duration of Use						
Leave-On	23	0.006 - 1	7	NR	NR	NR
Rinse Off	8	0.41	10	NR	NR	0.0012-0.0098
Diluted for (Bath) Use	NR	NR	3	NR	NR	NR
Exposure Type						
Eye Area	2	NR	NR	NR	NR	NR
Incidental Ingestion	NR	0.006	1	NR	NR	NR
Incidental Inhalation-Spray	3 ^a ; 1 ^b	NR	5 ^a ; 1 ^b	NR	NR	NR
Incidental Inhalation-Powder	1; 3 ^a	0.015 - 1 ^c	5 ^a	NR	NR	NR
Dermal Contact	28	0.015 - 1	18	NR	NR	0.0012-0.0098
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	3	NR	1	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	6	0.006	9	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR

	Cocos Nucifera (Coconut) Liquid Endosperm****		Cocos Nucifera (Coconut) Shell Powder		
Totals*	79	0.0021 – 6.5	35	NR	
Duration of Use					
Leave-On	57	0.0065 - 1.5	13	NR	
Rinse-Off	22	0.0021 - 6.5	22	NR	
Diluted for (Bath) Use	NR	NR	NR	NR	
Exposure Type					
Eye Area	NR	NR	NR	NR	
Incidental Ingestion	NR	0.32	1	NR	
Incidental Inhalation-Spray	5; 9 ^a ; 31 ^b	0.0065-1.5; 0.1 ^b	4 ^a	NR	
Incidental Inhalation-Powder	9 ^a	0.008 ^c	4 ^a	NR	
Dermal Contact	63	0.0021-1.5	34	NR	
Deodorant (underarm)	1 ^b	NR	NR	NR	
Hair - Non-Coloring	12	0.0021-6.5	NR	NR	
Hair-Coloring	4	NR	NR	NR	
Nail	NR	NR	NR	NR	
Mucous Membrane	3	0.32	19	NR	
Baby Products	NR	NR	NR	NR	

NR = Not reported.

*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.

**Coconut Flower Extract is reported in the VCRP; it was assumed it refers to Cocos Nucifera (Coconut) Flower Extract

***Includes 1 entry for Cocos Nucifera (Coconut) Milk Powder, which is not an ingredient in the *Dictionary*

****Most entries are referred to as Cocos Nucifera (Coconut) Water in the VCRP

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

Table 3. Dermal irritation and sensitization

Ingredient/Concentration/ Dose/Vehicle	Test System	Method	Results	Reference
<i>Irritation – In Vitro</i>				
Trade name mixture of 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% <i>Leuconostoc</i> /radish root ferment filtrate; 30 µl	Reconstructed human epidermal tissue	EpiDerm™ model	Non-irritating	43
<i>Sensitization – In Chemico</i>				
Trade name mixture of 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% <i>Leuconostoc</i> /radish root ferment filtrate	Cysteine and lysine peptides	DPRA in accordance with OECD 442C	Not sensitizing; mean depletion rate was 2.37%	43
<i>Sensitization – In Vitro</i>				
Trade name mixture of 98% Cocos Nucifera (Coconut) Liquid Endosperm and 2% <i>Leuconostoc</i> /radish root ferment filtrate; 0.98 to 2000 µM in DMSO	KeratinoSens™ cell line	ARE-Nrf2 luciferase test method in accordance with Organization for Economic Co-operation and Development Test Guideline (OECD TG) 422D; 12 test concentrations tested in triplicate and incubated for 48 h; positive control was cinnamic aldehyde in DMSO and negative control was a 1% DMSO	Not sensitizing; IC ₅₀ was > 1000 µM	43
<i>Sensitization- Human</i>				
0.3% Cocos Nucifera (Coconut) Fruit in a rinse-off product; material concentration/dilution was 1% in tap water; 0.2 g tested	110 subjects	HR IPT; test sites occluded; 2-wk rest period; challenge patches on virgin site; reactions scored 24, 48, 72, and 96 h post application	7 subjects had low level reactions during induction and 6 subjects had low level reactions during challenge; study concluded material did not induce dermal sensitization	46
0.098% Cocos Nucifera (Coconut) Fruit Juice in a leave-on product; material was tested neat at 0.2 g	107 subjects	HR IPT; test sites occluded; 2-wk rest period; challenge patches on virgin site; reactions scored 24, 48, 72, and 96 h post application	1 subject had low level reaction during challenge; study concluded material did not induce dermal sensitization	47
1.47% Cocos Nucifera (Coconut) Liquid Endosperm in a leave-on facial spray; 0.2 g tested	104 subjects	HR IPT; test sites semi-occluded; approximate 2-wk rest period prior to challenge patch; reactions score 24 and 72 h post application	Not irritating and not sensitizing	45

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2020 FDA VCRP Raw Data

COCOS NUCIFERA (COCONUT) FRUIT	02A	Bath Oils, Tablets, and Salts	1
COCOS NUCIFERA (COCONUT) FRUIT	05I	Other Hair Preparations	3
COCOS NUCIFERA (COCONUT) FRUIT	07E	Lipstick	1
COCOS NUCIFERA (COCONUT) FRUIT	08C	Nail Creams and Lotions	1
COCOS NUCIFERA (COCONUT) FRUIT	10A	Bath Soaps and Detergents	4
COCOS NUCIFERA (COCONUT) FRUIT	10E	Other Personal Cleanliness Products	3
COCOS NUCIFERA (COCONUT) FRUIT	11B	Beard Softeners	3
COCOS NUCIFERA (COCONUT) FRUIT	12A	Cleansing	1
COCOS NUCIFERA (COCONUT) FRUIT	12C	Face and Neck (exc shave)	3
COCOS NUCIFERA (COCONUT) FRUIT	12D	Body and Hand (exc shave)	2
COCOS NUCIFERA (COCONUT) FRUIT	12F	Moisturizing	2
COCOS NUCIFERA (COCONUT) FRUIT	12J	Other Skin Care Preps	1
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	01C	Other Baby Products	1
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	02A	Bath Oils, Tablets, and Salts	2
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	02B	Bubble Baths	2
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	02D	Other Bath Preparations	1
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	03D	Eye Lotion	3
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	03F	Mascara	1
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	04A	Cologne and Toilet waters	6
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	04E	Other Fragrance Preparation	18
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	05A	Hair Conditioner	30
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	05B	Hair Spray (aerosol fixatives)	2
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	05C	Hair Straighteners	1
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	05E	Rinses (non-coloring)	3
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	05F	Shampoos (non-coloring)	26
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	05G	Tonics, Dressings, and Other Hair Grooming Aids	19
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	05H	Wave Sets	2
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	05I	Other Hair Preparations	2
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	09A	Dentifrices	1
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	10A	Bath Soaps and Detergents	102
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	10B	Deodorants (underarm)	2
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	10E	Other Personal Cleanliness Products	29
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	12A	Cleansing	27
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	12C	Face and Neck (exc shave)	11
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	12D	Body and Hand (exc shave)	25
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	12F	Moisturizing	127
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	12G	Night	1
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	12H	Paste Masks (mud packs)	1
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	12I	Skin Fresheners	1
COCOS NUCIFERA (COCONUT) FRUIT EXTRACT	12J	Other Skin Care Preps	23

COCOS NUCIFERA (COCONUT) FRUIT JUICE	03D	Eye Lotion	2
COCOS NUCIFERA (COCONUT) FRUIT JUICE	05I	Other Hair Preparations	3
COCOS NUCIFERA (COCONUT) FRUIT JUICE	07B	Face Powders	1
COCOS NUCIFERA (COCONUT) FRUIT JUICE	07C	Foundations	8
COCOS NUCIFERA (COCONUT) FRUIT JUICE	07F	Makeup Bases	5
COCOS NUCIFERA (COCONUT) FRUIT JUICE	10A	Bath Soaps and Detergents	6
COCOS NUCIFERA (COCONUT) FRUIT JUICE	12A	Cleansing	2
COCOS NUCIFERA (COCONUT) FRUIT JUICE	12C	Face and Neck (exc shave)	3
COCOS NUCIFERA (COCONUT) FRUIT JUICE	12F	Moisturizing	1
COCOS NUCIFERA (COCONUT) FRUIT POWDER	02A	Bath Oils, Tablets, and Salts	1
COCOS NUCIFERA (COCONUT) FRUIT POWDER	02D	Other Bath Preparations	2
COCOS NUCIFERA (COCONUT) FRUIT POWDER	05I	Other Hair Preparations	1
COCOS NUCIFERA (COCONUT) FRUIT POWDER	09A	Dentifrices	1
COCOS NUCIFERA (COCONUT) FRUIT POWDER	10A	Bath Soaps and Detergents	5
COCOS NUCIFERA (COCONUT) FRUIT POWDER	11E	Shaving Cream	1
COCOS NUCIFERA (COCONUT) FRUIT POWDER	12A	Cleansing	3
COCOS NUCIFERA (COCONUT) FRUIT POWDER	12C	Face and Neck (exc shave)	2
COCOS NUCIFERA (COCONUT) FRUIT POWDER	12D	Body and Hand (exc shave)	2
COCOS NUCIFERA (COCONUT) FRUIT POWDER	12F	Moisturizing	1
COCOS NUCIFERA (COCONUT) LIQUID ENDOSPERM	12A	Cleansing	1
COCOS NUCIFERA (COCONUT) MILK POWDER	12C	Face and Neck (exc shave)	1
COCOS NUCIFERA (COCONUT) SHELL POWDER	09C	Other Oral Hygiene Products	1
COCOS NUCIFERA (COCONUT) SHELL POWDER	10A	Bath Soaps and Detergents	8
COCOS NUCIFERA (COCONUT) SHELL POWDER	10E	Other Personal Cleanliness Products	10
COCOS NUCIFERA (COCONUT) SHELL POWDER	12A	Cleansing	2
COCOS NUCIFERA (COCONUT) SHELL POWDER	12C	Face and Neck (exc shave)	3
COCOS NUCIFERA (COCONUT) SHELL POWDER	12D	Body and Hand (exc shave)	1
COCOS NUCIFERA (COCONUT) SHELL POWDER	12H	Paste Masks (mud packs)	1
COCOS NUCIFERA (COCONUT) SHELL POWDER	12J	Other Skin Care Preps	9
COCOS NUCIFERA (COCONUT) WATER	04E	Other Fragrance Preparation	5
COCOS NUCIFERA (COCONUT) WATER	05A	Hair Conditioner	2
COCOS NUCIFERA (COCONUT) WATER	05F	Shampoos (non-coloring)	5
COCOS NUCIFERA (COCONUT) WATER	05G	Tonics, Dressings, and Other Hair Grooming Aids	2
COCOS NUCIFERA (COCONUT) WATER	05I	Other Hair Preparations	3
COCOS NUCIFERA (COCONUT) WATER	06D	Hair Shampoos (coloring)	4
COCOS NUCIFERA (COCONUT) WATER	07C	Foundations	1
COCOS NUCIFERA (COCONUT) WATER	07F	Makeup Bases	1
COCOS NUCIFERA (COCONUT) WATER	10A	Bath Soaps and Detergents	3

COCOS NUCIFERA (COCONUT) WATER	10B	Deodorants (underarm)	1
COCOS NUCIFERA (COCONUT) WATER	12A	Cleansing	7
COCOS NUCIFERA (COCONUT) WATER	12C	Face and Neck (exc shave)	7
COCOS NUCIFERA (COCONUT) WATER	12D	Body and Hand (exc shave)	2
COCOS NUCIFERA (COCONUT) WATER	12F	Moisturizing	23
COCOS NUCIFERA (COCONUT) WATER	12I	Skin Fresheners	2
COCOS NUCIFERA (COCONUT) WATER	12J	Other Skin Care Preps	6
COCOS NUCIFERA (COCONUT) WATER	13B	Indoor Tanning Preparations	4
COCONUT FLOWER EXTRACT	02D	Other Bath Preparations	1
COCONUT FLOWER EXTRACT	05F	Shampoos (non-coloring)	1
COCONUT FLOWER EXTRACT	05I	Other Hair Preparations	1
COCONUT FLOWER EXTRACT	10A	Bath Soaps and Detergents	2



Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review (CIR)

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council

DATE: January 13, 2020

SUBJECT: Cocos Nucifera (Coconut) Fruit Extract

Anonymous. 2020. Cocos Nucifera (Coconut) Fruit Extract - Composition.

January 2020

Coconut Nucifera (Coconut) Fruit Extract - Composition

Extract of coconut fruit prepared with 90% water and 10% Butylene Glycol

The composition of the dry matter is:

- Sugars (disaccharides): 73%
- Mineral ashes (Calcium, Magnesium, Sodium, Potassium, Phosphorus, Sulfur, Chloride): 22%
- Protein: 5%

Impurities:

Heavy metals:

Identification of heavy metals is carried out by inductively coupled plasma-optical emission spectrometer (ICP-OES). Quantification is performed thanks to a calibration curve of standards.

Heavy metals	Quantity (ppm)	LQ (ppm)	Acceptability threshold (ppm)
Antimony	0.363	0.020	0.5
Arsenic	0.091	0.020	0.5
Cadmium	NQ	0.030	0.5
Chromium	NQ	0.020	0.5
Cobalt	NQ	0.020	0.5
Mercury	NQ	0.020	0.5
Nickel	0.046	0.020	0.5
Lead	NQ	0.020	0.5
Vanadium	0.054	0.020	0.5
Sum	0.228	/	/

NQ : not quantifiable

The sum of heavy metal quantified in the product is lower than 5 ppm

- **Phytosanitary substances assay:**

Identification and quantification of phytosanitary substances are carried out by high performance liquid chromatography (HPLC) or gas chromatography (GC) (depending on the compounds nature), coupled to mass spectrometry (MS).

NAME	Results	LQ (ppm)
Acetamiprid	ND	< 0.01
Carbaryl	ND	< 0.01
Carbendazim (+benomyl)	ND	< 0.01
Chlordane (cis+trans)	ND	< 0.01
Chlorothalonil	ND	< 0.01
Chlorpyrifos-ethyl	ND	< 0.01
Chlorpyrifos-methyl	ND	< 0.01
Cyhalothrin (Lambda)	ND	< 0.01
Cypermethrin (a+b+q+z)	ND	< 0.01
DDT (sum of isomers)	ND	< 0.01
Dichlorvos	ND	< 0.01
Dieldrin (+Aldrin)	ND	< 0.01
Dimethoate (+Omethoate)	ND	< 0.01

Dithiocarbamates	ND	< 0.05
Endosulfan	ND	< 0.01
Endrin	ND	< 0.01
Epoxiconazole	ND	< 0.01
Fenpropimorphe	ND	< 0.01
Fenthion (+sulfone + sulfoxide)	ND	< 0.01
Fenthion-oxon (+sulfone + sulfoxide)	ND	< 0.01
HCH gamma	ND	< 0.01
HCH ((a + b+ g+ d)	ND	< 0.01
Heptachlor (+epoxyde)	ND	< 0.01
Imidachloprid	ND	< 0.01
Iprodione	ND	< 0.01
Malathion (+Malaoxon)	ND	< 0.01
Monocrotophos	ND	< 0.01
Parathion-ethyl	ND	< 0.01
Parathion-methyl	ND	< 0.01
Pirimicarb	ND	< 0.01
Pirimicarb (+desmethyl)	ND	< 0.01
Pirimiphos methyl	ND	< 0.01
Thiachlopride	ND	< 0.01
Thiophanate-methyl	ND	< 0.01
Vinclozoline (+3.5-dichloroaniline)	ND	< 0.01

(ND: not detected; LQ: limit of quantification)

- **Aflatoxins**

The determination and quantification of 4 aflatoxins (B1, B2, G1 and G2) are performed by high performance liquid chromatography (HPLC).

NAME	Results	LQ (ppb)
Aflatoxin B1	ND	< 0.1
Aflatoxin B2	ND	< 0.1
Aflatoxin G1	ND	< 0.1
Aflatoxin G2	ND	< 0.1

- **Assay of methanol**

Quantification of traces of methanol was carried out by gas chromatography coupled with flame ionization detection (GC-FID). Quantity of methanol is lower than the limit of detection of the method.

- **Assay of formaldehyde**

Quantification of traces of formaldehyde was carried out by ionic chromatography with amperometric detection. Quantity of formaldehyde are lower than the limit of detection of the method (0.3 ppm)



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Christina L. Burnett, Senior Scientific Writer/Analyst, CIR
Date: August 21, 2020
Subject: Unpublished Data Submission for the Safety Assessment of *Cocos nucifera* (Coconut)-Derived Ingredients as Used in Cosmetics

CIR staff received unpublished data submissions for a coconut ingredient that is identified as *Cocos Nucifera* (Coconut) Fruit Juice. The data include a certificate of composition, a declaration of impurities content, and a manufacturing process flow chart (*cocosn092020_Sabinsa1*, *cocosn092020_Sabinsa2*, *cocosn092020_Sabinsa3*). Upon closer review of the data, it appears that the name of the ingredient does not comport with the method of manufacturing because 1) the collection of the liquid endosperm is the first step, 2) freeze drying is the last step (i.e. the final product is a solid), and 3) referral of the generic term “tender coconut water” in the identification of the plant part used. CIR staff has reached out to the Council and the International Nomenclature Committee for clarification as to what ingredient this data actually addresses.



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CERTIFICATE OF COMPOSITION COCOCIN™

Issue No. 4.0

Effective date: February 16, 2018

Plant/ Part used	<i>Cocos nucifera</i> /Tender coconut water
Freeze dried tender coconut water (Organic and Inorganic materials) INCI: Cocos Nucifera (Coconut) Fruit Juice	85 to 100%
Water:	0 to 15%
Excipients/Carriers	None
Extract Ratio	50: 1



August 11, 2020

TO WHOM IT MAY CONCERN

This is to certify that the raw material used for the manufacture of Cococin™ is *Cocus nucifera* water (Tender coconut water).

It is free from GMO, Gluten, BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy).

The elemental impurities (Lead, Arsenic, Cadmium and Mercury) are complying with USP<2232>.

We are neither adding nor handling any prohibited substances in cosmetics listed in Annex II and III, substances of Very High Concern (SVHC) and volatile organic compounds in our products and in our manufacturing facilities

It is suitable for vegan and vegetarians as Cococin™ does not contain any animal ingredients or animal-derived ingredients.

It is not tested on animals after March 11, 2013 for its cosmetic application.

The country of origin is India.

For Sami Labs Limited,

Dr. Mahadeva Nayak

Manager – Technical Marketing

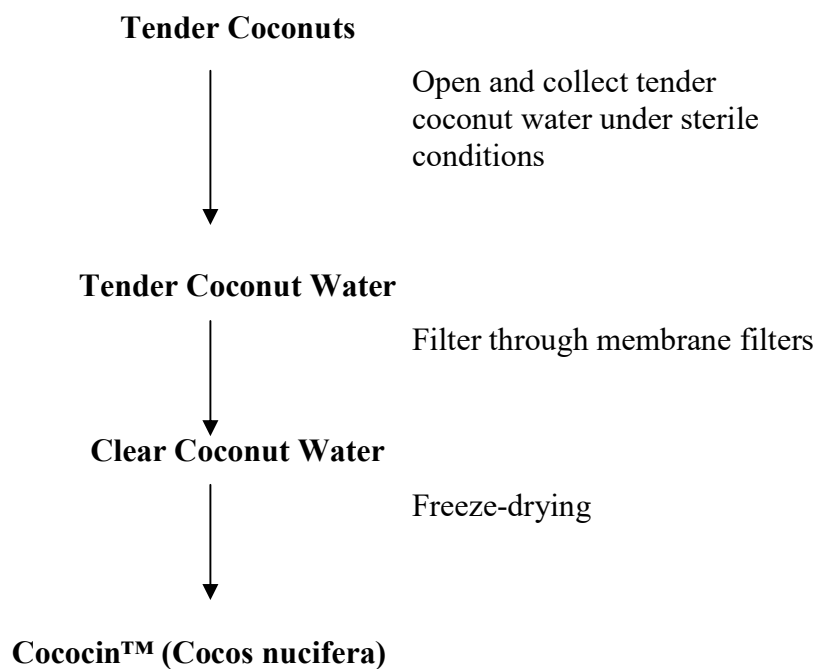


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MANUFACTURING PROCESS FLOW CHART COCOCIN™ (COCOS NUCIFERA)

Issue No. 4.0

Effective date: February 16, 2018





Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review (CIR)

FROM: Alexandra Kowcz, MS, MBA
Industry Liaison to the CIR Expert Panel

DATE: December 3, 2019

SUBJECT: Draft Report: Safety Assessment of *Cocos nucifera* (Coconut)-Derived Ingredients as Used in Cosmetics (draft prepared for the December 2019 CIR Expert Panel meeting)

The Personal Care Products Council respectfully submits the following comments on the draft report, Safety Assessment of *Cocos nucifera* (Coconut)-Derived Ingredients as Used in Cosmetics .

Introduction - Perhaps *Cocos Nucifera* (Coconut) Oil, Coconut Acid, Hydrogenated Coconut Acid and Hydrogenated Coconut Oil should be called related ingredients rather than “components”. The Composition section identifies many other components of these ingredients such as amino acids and sugars that have also been reviewed by CIR.

Composition, *Cocos Nucifera* (Coconut) Shell Powder - As reference 14 looked at more than just mineral composition, it is not clear why the first sentence just mentions mineral composition.

Acute, Oral - Only one study in male mice is described in this section. Therefore, “in either species” at the end of the paragraph needs to be deleted.

DART, *Cocos Nucifera* (Coconut) Liquid Endosperm - In the description of the developmental toxicity study in rats (reference 39) the following needs to be corrected: “the number of litter from each female” as each female only had one litter. It is likely that the investigators counted both the number of litters per dose group and the number of offspring from each dam.

Summary - The acute study of *Cocos Nucifera* (Coconut) Fruit Extract should be mentioned in the Summary.

Table 4 - As the KeratinoSens™ assay uses cells, it should not be under a In Chemico subheading. This is an *in vitro* assay. The DPRA, which does not use cells is an In Chemico method.