
Safety Assessment of Polysilicone-11 as Used in Cosmetics

Status: Draft Final Report for Panel Review
Release Date: November 13, 2020
Panel Meeting Date: December 7-8, 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.; David E. Cohen, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.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. Previous Panel member involved in this assessment: James G. Marks, Jr., M.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Priya Cherian, Scientific Analyst/Writer, CIR.



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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Priya Cherian, Scientific Analyst/Writer, CIR
Date: November 13, 2020
Subject: Safety Assessment of Polysilicone-11 as Used in Cosmetics

Enclosed is the Draft Final Report on the Safety Assessment of Polysilicone-11 as Used in Cosmetics (*polysi122020rep*). At the September 2020 meeting, the Expert Panel for Cosmetic Ingredient Safety (Panel) issued a Tentative Report with the conclusion that Polysilicone-11 is safe in cosmetics in the present practices of use and concentration as described in the safety assessment.

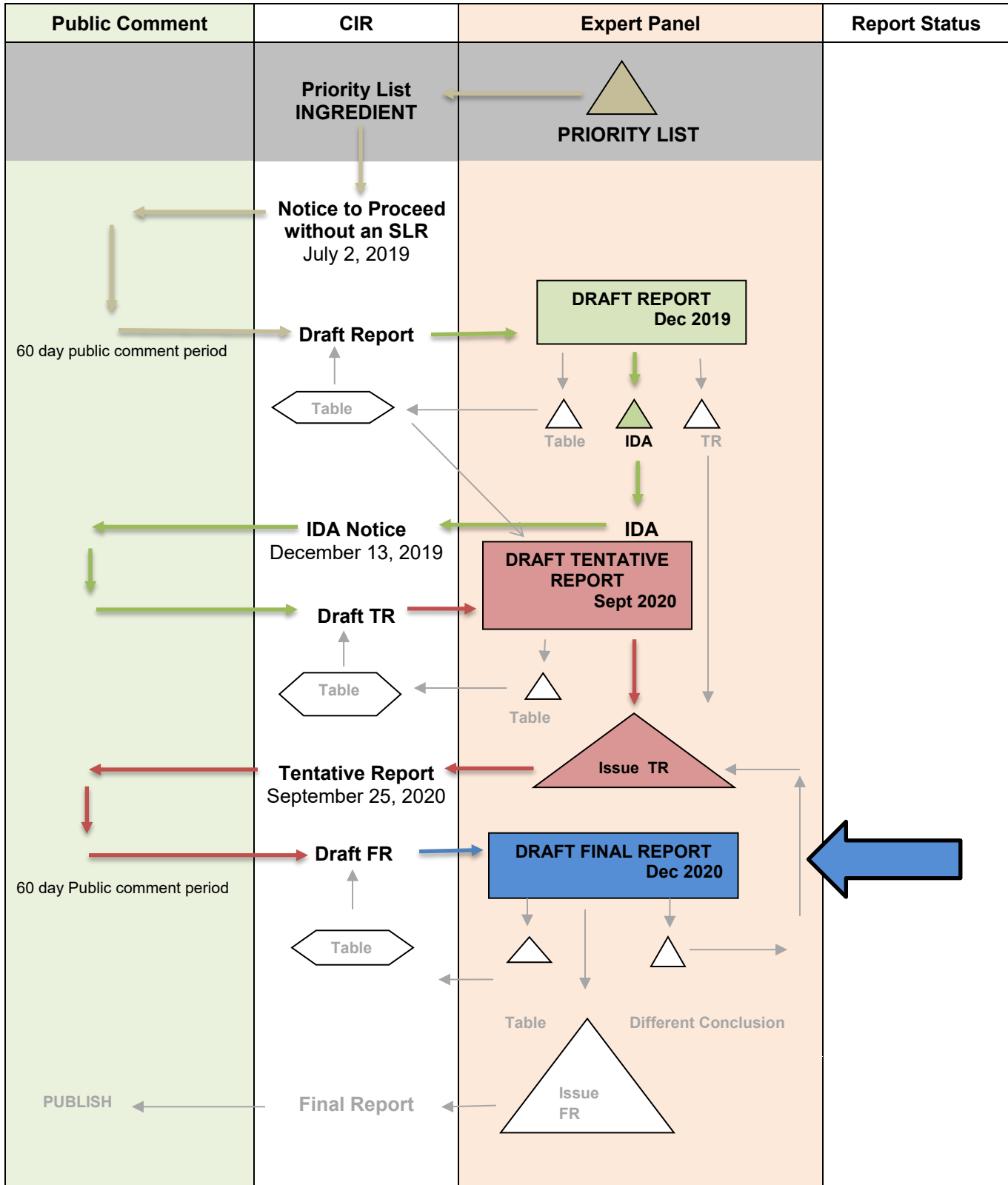
Comments on the Tentative Report were received and addressed (*polysi122020pcpc*). Also included in this package for your review are the report history (*polysi122020hist*), flow chart (*polysi122020flow*), minutes (*polysi122020min*), literature search strategy (*polysi122020strat*), data profile (*polysi122020prof*), and 2020 VCRP data (*polysi122020FDA*).

The Panel should carefully consider the Abstract, Discussion, and Conclusion presented in this report. If these are satisfactory, the Panel should issue a Final Report.

SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY Polysilicone-11

MEETING December 2020



Polysilicone-11 History

July 2019

-A notice to proceed (NTP) was issued and the following data was requested:

- Chemistry information, including composition and structure, method of manufacture, and impurity data
- Toxicokinetics data relevant to routes of exposure expected with cosmetic use
- General toxicity data
- Developmental and reproductive toxicity data
- Genotoxicity data
- Carcinogenicity data
- Dermal irritation and sensitization data
- Inhalation toxicity data
- Any other relevant safety information that may be available

-The following unpublished data was received:

- HRIPTs on a leave-on product containing 9.675% Polysilicone-11 and a rinse-off product containing 19.830% Polysilicone-11 was received
- Summary toxicity information received on various mixtures containing Polysilicone-11
- An in vitro tissue equivalent assay to evaluate the ocular irritation potential of a face cream containing 1.6% Polysilicone-11
- A human cumulative irritation patch test on a face cream containing 1.6% Polysilicone-11

August 2019

-The following unpublished data was received:

- General method of manufacturing information
- A 48-hour patch test performed using a lipstick containing 1.8% Polysilicone-11
- A MatTek EpiOcular™ methyl thiazole tetrazolium (MTT) Viability Assay on a test substance containing 98.5% Polysilicone-11
- A human dermal maximization assay performed to evaluate the contact-sensitization potential of a liquid blend containing 24.625% Polysilicone-11
- An HRIPT on a product containing 1.45% Polysilicone-11

December 2019

-Panel reviews the draft report and issues an IDA

-Insufficiencies include:

- residual monomers and other reactants (e.g., polymerization initiators, chain propagators, terminators solvents),
- molecular weight distribution
- composition
- impurities
- 28-day dermal toxicity
- mammalian genotoxicity
- sensitization/irritation data at maximum use concentration.

Data received from Council:

- impurities/method of manufacturing data received

- data on a cytotoxicity assay on a trade name mixture containing 12 – 16% Polysilicone-11, 43 – 50% dimethicone, and 36 – 42% cyclopentasiloxane

-Council Comments on the Draft Report received

-corrected information on concentration of use received (maximum concentration decreased to 19.9%)

March 2020

- HRIPT on a trade name mixture containing 98% Polysilicone-11 and 2% laureth-12 received

September 2020

-Draft Tentative Report reviewed by Expert Panel

-Expert Panel concluded that Polysilicone-11 is safe in the present practices of use and concentration

-Tentative Report posted

October 2020

-comments on Tentative Report received from Council

December 2020

-Expert Panel reviews the Draft Final report

Polysilicone-11 Data Profile – December 2020 – Priya Cherian, Scientific Analyst/Writer

				Toxicokinetics			Acute Tox			Repeated Dose Tox			DART		Genotox		Carci		Dermal Irritation			Dermal Sensitization					Ocular Irritation		Clinical Studies	
	Reported Use	Method of Mfg	Impurities	log P/log K _{ow}	Dermal Penetration	ADME	Dermal	Oral	Inhalation	Dermal	Oral	Inhalation	Dermal	Oral	In Vitro	In Vivo	Dermal	Oral	In Vitro	Animal	Human	In Vitro	Animal	Human	Phototoxicity	In Vitro	Animal	Retrospective/Multicenter	Case Reports	
Polysilicone-11	X	X	X						X						X				X	X			X		X	X				

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

[Polysilicone-11]

Ingredient	CAS #	InfoB	PubMed	TOXNET	FDA	EU	ECHA	IUCLID	SIDS	ECETOC	HPVIS	NICNAS	NTIS	NTP	WHO	FAO	NIOSH	FEMA	Web
Polysilicone-11	63394-02-1 156065-02	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No

Search Strategy**Typical Search Terms**

- INCI name
- CAS numbers
- chemical/technical names
-

Key Words: dermal, irritation, sensitization, inhalation, metabolism, toxicity

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)

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=eafuslisting&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

DECEMBER 2019 PANEL MEETING – INITIAL REVIEW/DRAFT REPORT

Belsito Team – December 9, 2019

DR. BELSITO: So, Polysilicone-11. Just looking at the points, it's the first time we're looking at it. Is everyone happy with the method of manufacture and impurities? That's page 11.

It says, "According to a supplier, Polysilicone-11 is manufactured in cosmetic grade cyclopentasiloxane solvent, preferably from low cyclotrisiloxane, D4 feed stock using a hydrosilylation catalyst." Whatever that catalyst is.

And then the impurities, less than 20 parts per million platinum catalyst, which I guess is the catalyst for hydrosilylation. Are you happy with those?

DR. LIEBLER: I'd like to see whether there are residual monomers.

DR. BELSITO: Okay.

DR. LIEBLER: And I think that the material from industry on page 58, indicates molecular weight greater than one megadalton, very big molecules.

So, that information should be cited in the physical chemical properties section, because that makes all the difference. These are not going to be absorbed because they're huge.

DR. BELSITO: Okay. So then, that was my next question. Given size, are they insufficient for dermal absorption, and you're saying we don't need dermal absorption?

MR. LIEBLER: Don't need it.

DR. BELSITO: So, you want to add in what, from where, Dan, to show their size?

DR. LIEBLER: On Page 58, I think, there is a table or something. Let me look real quick. There is just a summary of data provided by industry, molecular weight greater than one million Dalton, i.e. one megadalton.

DR. BELSITO: And bring that into physical properties?

DR. LIEBLER: Correct. So once that's there, that pretty much nails it that these molecules are not going to be absorbed. So, we're really down to irritation and sensitization at that point. I don't know if you felt that the sensitization data were adequate?

DR. BELSITO: Yes. Because they were pretreated with SLS.

DR. LIEBLER: So, if you did then I felt like they were safe as used.

DR. BELSITO: But you just said you want to know residual monomer.

DR. SNYDER: Impurities, yeah.

DR. LIEBLER: Yeah, once the impurities. Can be addressed. I just meant that's where I see this heading.

DR. BELSITO: Okay. Well, I was going even beyond that. Okay. So basically, we need insufficient for residual monomer.

DR. LIEBLER: You know what, if these are clean, with safety data in skin tests, then we don't need to ask about residual monomers.

DR. SNYDER: Well, we do have lipstick use at 8.8 percent and sprays at 0.04 percent, so maybe we probably should have it, I think.

DR. LIEBLER: Well, if -- and if the sensitization data --

DR. BELSITO: This is the first time we're looking at it. We can ask for the data and decide later. So, insufficient for residual monomer.

DR. LIEBLER: Okay.

DR. BELSITO: Okay, now you can go to lunch. That's one way of moving through a chemical fast is to threaten holding lunch, right? Yeah, we have honey for lunch.

Marks Team – December 9, 2019

DR. MARKS: Priya, you're up again, huh? So this is a draft report of polysilicone-11. This is the first review of the single agent. It's a reaction -- chemical reaction between vinyl dimethicone and hydrogen methicone, which the panel previously evaluated and found both of them to be safe. So, Ron, Tom, needs? What should we move for?

DR. SHANK: I have insufficient for more chemical properties. It says the test agent was a molecular weight of greater than the million, if that's typical of the cosmetic ingredient. And I had a question -- I'm not sure what was tested -- what was mentioned was the cosmetic ingredient.

But if it isn't molecular weight of over a million, then I don't think it's likely it would cross the skin. So, systemic toxicity data are not needed. But the skin sensitization data were below a maximum concentration of use. So, I thought perhaps we needed more skin sensitization data done at the maximum use concentration.

DR. MARKS: Yeah. So, the human maximization assay was at 25 percent, and the maximum use concentration's up to 35 percent. So for sure, get a sensitization, preferably HRIPT at 35 percent. Yeah, even though, as you say, the molecular weight, if it is -- was that under the chemistry section of molecular weight over a million?

DR. SHANK: Page 58.

DR. MARKS: Page 58. Okay. Now, if that's accurate, which is hard to believe, probably it's not going to sensitize either, it's not going to get through. But we'll ask for that. We'll be seconding. Tom, your input?

DR. SLAGA: Well, I agree with Ron, insufficient in terms of, I had that there was bacterial genotox, but there wasn't any mammalian. I'm not sure we really need it because of the size. But it's the first time, I wouldn't mind seeing it.

I always love to see a 28-day dermal, just because it gives a lot of data to help support potential or give you an idea if there may be some alert for carcinogenic activity.

But once again, I don't have any concerns. It's nice data to have, so therefore, I'd like to see it.

DR. MARKS: Okay.

DR. SHANK: I agree, if the molecular weight's over a million --

DR. SLAGA: We probably don't need it.

DR. SHANK: I don't think we need genotox or developmental, reproductive, 28-day.

DR. ANSELL: Or sensitization. I could see an irritation, a direct effect. But if, in fact, it's over a million, any type of systemic driven endpoints are, I think, off the table. So, I would question whether we really do need to go up from 25 to 32 percent.

DR. HELDRETH: Yeah. In addition to -- if we have confidence that this is the molecular weight to expect when this ingredient was used, remember also that this ingredient is cross-linked. So, we're not talking about a thin, linear change. We're talking about probably a very large lattice network. So not only is there high molecular weight, there's probably very large molecular volume.

DR. ANSELL: In essence, a single molecule.

DR. SLAGA: I don't have any concern it'd get through to skin, but things still can have effect on the skin, right?

DR. MARKS: Oh, absolutely. So, the two building blocks in this were both felt to be safe. Is that reassuring? Do we need to molecular weight? Because the question would be, is the question are there smaller -- is it smaller than a molecular weight over a million? That's what you found in your -- Priya, when you did the research, the molecular weight was defined as over a million?

MS. CHERIAN: It came in a data supplement.

DR. HELDRETH: Yeah. It was in unpublished data that was submitted to us anonymously. I mean, theoretically, you could make these polymers practically any size. They could vary from being a liquid to being a very hard rubbery material.

But the only information we have that directly points to use as an ingredient demonstrates a molecular weight this high.

DR. MARKS: So really, we get back to -- I guess, and then how much of the monomer would be present, and would it get through.

DR. PETERSON: That was my question. Whenever you have a polymer, there might be some leftovers at the beginning part.

DR. MARKS: So, it could be as you said, Ron Shank, to begin with, define the chemical. I guess one could also put in there as a molecular weight of a million and how much of a monomer is left. Of course, are we really worried about the monomer? I guess we really don't know that unless we have the data.

DR. ANSELL: Just as a point of reference, it's not a million, it's in excess of a million. It's actually not measurable.

DR. PETERSON: Polymers are hard to measure. Yeah. Molecular weight on it.

DR. HELDRETH: Particularly cross-linked.

DR. PETERSON: Yup.

DR. SHANK: So, what are you saying?

DR. ANSELL: It's infinite. But that is a very unsatisfying answer for many people.

DR. SHANK: Yes.

DR. ANSELL: So typically, it's just recorded as greater than a million. But it isn't actually a million. It's --

DR. SHANK: Really big.

DR. ANSELL: It's really big. It's a bounding estimate. Whatever it is, it's certainly greater than a million.

DR. SHANK: Okay.

DR. MARKS: So tomorrow, it looks like for our team I'll be seconding a motion. Hopefully that motion is insufficient data announcement. Lisa, the sense there is whenever we see the group of ingredients, or in this case, a single ingredient the first time, if we feel like we can't come to a conclusion, either it's safe or safe with whatever caveat, we'll send out an insufficient data announcement. And then, so by the next time we review it, industry has time -- and the CIR scientific staff have time to get that data and then give us it.

So, it looks like we're still back on the molecular weight and define the chemical is the real concern.

DR. SLAGA: Yeah.

DR. MARKS: And then perhaps mammalian toxicity, 28 dermal tox, and sensitization/irritation, but, Jay, I hear you loud and clear. I agree with you. If it's a large polymer, sensitization would be highly unlikely. Probably, it's not going to be irritation.

DR. SLAGA: As well as genotoxicity. It's highly unlikely. And we do have bacteria, which is --

DR. MARKS: So, shall we put it out tomorrow the way I stated all of this, and then see where it goes?

DR. SLAGA: See where it goes. Yeah.

DR. MARKS: And we'll see what the Belsito team has to say.

DR. SHANK: Yes.

DR. MARKS: And oftentimes, you'll see tomorrow, Lisa, the nice thing is, even though the two teams have the same dataset, we oftentimes will arrive at different conclusions.

DR. SHANK: Yep.

DR. MARKS: And it's a very amiable resolution, and it's done usually relatively quickly; with, obviously, the bottom line is what's safest for the public. So, we tend to be conservative. Okay. Any other comments?

DR. SHANK: On Page 11, under method of manufacture, it refers to cosmetic grade solvent. Is there such a thing as cosmetic grade? I used to use it, and I got stepped on every time. So, I'd like to ask, is there such a thing as cosmetic grade?

DR. ANSELL: No.

DR. SHANK: No. Okay.

DR. MARKS: So Priya, you'll delete that. That's editorial.

DR. HELDRETH: Yeah. That came directly from the anonymous submission, their verbiage.

DR. MARKS: It sounds like the evening news, the anonymous submission. I'm not so sure we can -- okay. Any other comments?

So tomorrow, presumably, I'll be seconding an insufficient data announcement. We really want to clarify, or define, the chemical nature of this polysilicone-11. Monomers, is the -- not is. The molecular weight is somewhere over a million it appears. And if it's that large a molecular weight, then we probably don't need much more to move forward. But we discuss the mammalian tox, the 28-day dermal tox, and sensitization and irritation. Sound good, team?

DR. SHANK: Yes.

DR. PETERSON: Yup.

DR. MARKS: Okay.

Full Panel – December 10, 2019

DR. BELSITO: Yes, so this is the first time we're reviewing this ingredient. We thought that everything was fairly good except we were concerned about residual monomer. And we're going, I believe, Dan, insufficient for residual monomer.

DR. LIEBLER: Yeah, the chemistry description didn't explicitly state how big these were, but there was a bit of data from industry on Page 58 that said that these are in excess of a million Daltons.

So, I think that is going to take care of a lot of concerns for us in terms of absorption. But we typically ask for some monomer information and that's usually available, so that's what I think we should get here.

DR. MARKS: Yeah, our team concurs with the insufficient data announcement. Besides the molecular weight, which Priya really includes the defining the chemical monomers, we thought that we needed mammalian tox data, 28-day dermal tox, and sensitization and irritation.

We had a human maximization assay at 25 percent, but the use in a leave-on is up to 35 percent. So, we'd like to see if we could get something closer to 35 percent in that -- in this insufficient data announcement.

DR. BELSITO: Right. I mean, I'm fine with that. I just point out that the sensitization study was with pretreatment with SLS, so it was really maximizing the test. But that's fine; as long as we're going insufficient, we can add to the wish list.

DR. BERGFELD: So, we have a list of data needs. And, you have that list?

MS. CHERIAN: Can I get a repeat?

DR. MARKS: Yeah, the molecular weight issue and then the mammalian toxicity, 28-day dermal toxicity, and then the sensitization at use concentration at 35 percent.

DR. BELSITO: And residual monomer.

DR. MARKS: Yeah, residual -- yes, I'm sorry. Should have clarified the molecular weight.

DR. BERGFELD: Any other discussion points here or needs that the panel members think they should put in? Seeing none --

DR. GREMILLION: Can I ask?

DR. BERGFELD: Sure, Tom.

DR. GREMILLION: So, there are a couple of reports here that has this language, the inhalation language. It's on Page 12 in this one that in practice 95 to 99 percent of the droplet particles released from cosmetic sprays have these diameters above 10 micrometers.

Is that language being refined? I couldn't remember from our -- I know we had discussed that and there was the assertion that that was inaccurate. Was the decision made that this is sufficiently nuanced and it's going to be in the reports here on out, or is that process ongoing to decide if this boilerplate needs to be refined?

DR. BERGFELD: Any response?

DR. HELDRETH: Yeah, we do have that finalized inhalation resource document now complete. Our plan is to start incorporating it into new reports as we move forward. But if the panel feels that we should bring that language into this report now, we certainly can do so.

DR. GREMILLION: Does it contradict this? Or is it inconsistent with this? I mean, I just remember all this conversation about -- like actually the diameter size of these sprays sometimes they're much smaller, you know, and is this accurate?

DR. BERGFELD: Depend on the monomer. Dan?

DR. LIEBLER: I think that we considered that issue, and the problem is -- I mentioned we were talking about this yesterday. Is that even though we had additional information that we included in our inhalation tox document, that the biggest problem remains accurate assessment of particle sizes under exact conditions of use.

Even though we have a lot of new data on ways to measure particle sizes, the distributions varies quite a bit, depending on what else is in the formulation. So we felt that our existing language really didn't change, as I recall. Gents is that -- yeah.

So, in other words it's not in conflict with what we've got here. But we do have a lot of additional information on the report, but it doesn't change that part of our assessment.

DR. GREMILLION: Because this sounds like -- yeah, I mean, what you just said sounds like maybe 99 percent of the particles don't have a diameter above this number. And these reports just keep saying, you know, the statement in practice they have these large particle sizes. It kind of, you know, throws me through a loop every time I see it. And, I'll leave it at that.

DR. BERGFELD: Dan?

DR. LIEBLER: It's still true.

DR. GREMILLION: Okay. Yeah. Okay. Well, that's what I wanted to clarify.

DR. LIEBLER: I mean, it's still true. Even though we looked at a lot more data, we ended up in the same place.

DR. GREMILLION: Okay, yeah.

DR. LIEBLER: Sorry if I wasn't clear enough.

DR. BERGFELD: I don't believe we called for the question on this one. I'd like to do that now. All those in favor of this conclusion of an IDA, please indicate by raising your hand. Thank you, unanimous.

Then moving on, unless there's more discussion, here? Moving on to Honey, Dr. Marks.

SEPTEMBER 2020 PANEL MEETING – SECOND REVIEW/DRAFT TENTATIVE REPORT

Belsito Team – September 14, 2020

DR. BELSITO: So, at the December 2019 meeting, we issued an insufficient data announcement, residual monomers and other reactants, molecular weight, composition, impurities, 28-day dermal tox, mammalian genotox, sensitization. We've got updates on manufacturing and impurities, cytotoxicity assay, and the HRIPT, and a published retrospective study -- wait a minute. No, wrong page. Hold on. Too many pages. We got updated VCRP and corrected concentrations of use.

So we got a lot of the data that we asked for, and the question is whether this was significant to allow us to go with a safety. Again, I apologize, my computer is very slow here.

DR. SNYDER: My comment was based on molecular weight size, absence of monomers, HRIPT, no other data needs, safe as used.

DR. LIEBLER: I agree completely. High molecular weight precludes absorption to the skin available acute tox data indicates low potential for toxicity, safe as used.

DR. KLAASSEN: Safe as used.

DR. BELSITO: Yeah. I did too. So lack of clinical reports in terms of sensitization, limited data on sensitization. There were no studies with an N of a hundred, but there was a human max and HRIPT at 98 percent in 51 patients.

DR. SNYDER: Yeah.

DR. BELSITO: So I think the bulk of data mitigates concern about sensitization and irritation and concentration of use, so, yeah, safe as used.

And the discussion, you know, I think, all the points we pointed out -- high molecular weight, not likely to be absorbed, sensitization -- is fine. Any other points for the discussion? Respiratory boilerplate, is this in there? I can't remember if it's in hairsprays. I didn't mark them for any sprayer (audio skip).

MS. FIUME: It's in suntan pump sprays. So there is inhalation possibility.

DR. BELSITO: Okay.

MS. FIUME: And face powders, up to 3.5 percent.

DR. BELSITO: Okay. Okay. So, in the discussion, basically, the respiratory boilerplate then goes in. Yeah, it's already there. Okay. Okie-doke. Any other points for Priya? Okay. If not, Diacetone Alcohol.

Marks Team – September 14, 2020

DR. MARKS: The next one is polysilicone-11. And at the December 2019 meeting the Panel issued an insufficient data announcement. That's the IDA. The needs are listed in Priya's memo, and you can see those, like residual monomers, molecular weight, composition, impurities, 28-day tox, mammalian genome, sensitization and irritation. We have received data. And Lisa, Ron, Tom, your comments? Is it enough now we can move -- well, we'll move on to a tentative report. The question is, is it safe or do we still need data? Is it insufficient?

DR. SHANK: Well, I feel if Lisa and Dan feel the information of residual monomers and reactants in the molecular weight range -- if that's sufficient, then it's unlikely these will cross the epidermis. And therefore, we have enough information. If the chemistry information's not enough, then we will need some systemic toxicity testing.

DR. MARKS: Yeah. On page 16, Ron, I agree. The molecular weight was greater than a million Daltons. There was no residual monomer stated. Sensitization and irritation were good. So Lisa, Tom, your comments?

DR. PETERSON: Well, I felt that --

DR. SLAGA: Well -- go ahead.

DR. PETERSON: Go ahead.

DR. SLAGA: I still had insufficient based on what Ron said. We didn't really get everything we asked for. I personally agree with you, Jim, that it's safe, but there's no impurities. The first data need is very important, and I think Dan Liebler really pushed that. So I don't know. Insufficient.

DR. MARKS: Insufficient because of?

DR. SLAGA: The monomers in that.

DR. MARKS: Now, on page 16 it said no residual monomers is how I read it.

DR. SLAGA: No residual?

DR. MARKS: Is that what you read, Lisa?

DR. PETERSON: Yeah. That's what I read.

DR. SLAGA: Okay.

DR. MARKS: So that to me took --

DR. SLAGA: So with that, I would go safe because that's the most important of the ones.

DR. PETERSON: Yeah. I thought that they provided enough information to be able to judge the impurities.

DR. MARKS: Good. Okay. So tomorrow then I'll move that our team recommends issuing a tentative report with a safe conclusion. And David, just for the entire way this is usually stated as safe in the present practices in use and concentration in cosmetics. I just abbreviate it by a safe conclusion, and then we can add modifiers on that safe sometimes, like not irritating. You'll see as we go through. So does that sound good Ron, Tom, and Lisa?

DR. SHANK: Yes.

DR. SLAGA: Yes.

DR. PETERSON: Yeah.

DR. MARKS: Tentative report safe. Okay.

DR. COHEN: So Jim, will this come back around again at all, or once --

DR. MARKS: Yes.

DR. COHEN: It will.

DR. MARKS: There's -- Bart can comment on that, but there's like a 60-day waiting period in which outside individuals can comment on it. So you'll see it again, and then it will be as a draft final report with that safe conclusion. And it gives the public opportunity to comment. That's assuming that tomorrow the Belsito team agree with us that it's safe, and that's not always predictable.

DR. COHEN: You mean with Don it's not predictable?

DR. MARKS: No, no, with their team. As Tom brought up, Dan was concerned about the molecular weight and residual monomer, appropriately so. And if he sees something that we have not taken in consideration, then the Belsito team it may be different. And just as this -- when I move tomorrow, I'll be actually -- I'm moving for our entire team.

DR. COHEN: Got it. Thank you.

DR. MARKS: You're welcome. Okay.

DR. HELDRETH: Yes, that's correct as you were mentioning, Dr. Marks. If the Belsito team agrees and this goes out safe as used in the present practices of use and concentration, Priya will incorporate any of the edits that the Panel provides to her and will issue a tentative report. It'll be publicized on our website and give anyone that's interested 60 days to comment.

After that comment period is over, any comments that we received, any information that we received that are relevant will be either incorporated or be brought alongside as a memo to the draft final version that would come to the Panel either at the December meeting or at the spring 2021 meeting. And then at that point, if the Panel agrees and there's no major changes, that would be the last time the Panel would see this report.

DR. MARKS: And David, there's a flow sheet in the beginning of every ingredient info, so it can show you actually how it goes through these different steps, which is actually quite nice.

DR. COHEN: Yeah. With all the arrows and the --

DR. MARKS: Yup.

DR. COHEN: I've been reviewing some of those already.

DR. MARKS: Yeah. You'll get used to that. Don't feel like you may not understand everything now. It takes a while to get in the swing of things. Okay.

Full Panel – September 15, 2020

DR. MARKS: So at the December 2019 meeting the Panel issued an insufficient data announcement. Priya's memo lists the needs. Of particular was whether there were residual monomers, what the molecular weight was, composition, impurities, 28-day dermal, mammalian, tox, sensitization, irritation.

I think the most important data we received, there is no residual monomer, molecular weight was greater than a million Daltons, sensitization and irritation was okay. Our team felt we could move on and issue a tentative report with a safe conclusion. That's a motion; this ingredient is safe.

DR. BERGFELD: Second?

DR. BELSITO: Second.

DR. BERGFELD: Any further discussion?

DR. BERGFELD: Again, the sensitization, while we had no studies with n's of 100 that we usually look at there were a number of different studies and including an HIRPT at 98 percent with 51 patients with no evidence of sensitization. And the lack of mammalian genotox was mitigated by the composition, impurities and molecular weight.

DR. BERGFELD: Okay. Do you want to hear anything in the discussion?

DR. BELSITO: That's what I just said.

DR. BERGFELD: Oh, that's what you just said; sorry about that.

DR. BELSITO: Yeah.

DR. BERGFELD: Okay. Any other discussion points before we call the question as safe? Any of those voting against this safety conclusion? Hearing none, unanimous approval of the Polysilicone-11, safe. Moving on to the next ingredient, Diacetone Alcohol, Dr. Belsito.

Safety Assessment of Polysilicone-11 as Used in Cosmetics

Status: Draft Final Report for Panel Review
Release Date: November 13, 2020
Panel Meeting Date: December 7-8, 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.; David E. Cohen, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.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. Previous Panel member involved in this assessment: James G. Marks, Jr., M.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Priya Cherian, Scientific Analyst/Writer, CIR.

ABSTRACT

The Expert Panel for Cosmetic Ingredient Safety (Panel) assessed the safety of Polysilicone-11 as used in cosmetic formulations. This ingredient is reported to function as a film former. The Panel considered the available data and concluded that Polysilicone-11 is safe in cosmetics in the present practices of use and concentration described in this safety assessment.

INTRODUCTION

This is a safety assessment of Polysilicone-11 as used in cosmetic formulations. According to the web-based *International Cosmetic Ingredient Dictionary and Handbook* (wINCI; *Dictionary*), Polysilicone-11 functions as a film former in cosmetics.¹ Polysilicone-11 is the product of a reaction between bis-vinyldimethicone and hydrogen methicone.

This safety assessment includes relevant unpublished data that are available for each endpoint that is evaluated. An exhaustive search of the world's literature was performed, and very little published data were found regarding this ingredient. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints the Panel typically evaluates, is provided on the 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.

CHEMISTRY

Definition and Structure

According to the *Dictionary*, Polysilicone-11 (CAS No: 63394-02-5, 156065-02-0) is a crosslinked dimethyl siloxane formed by the reaction of bis-vinyldimethicone and hydrogen dimethicone.¹

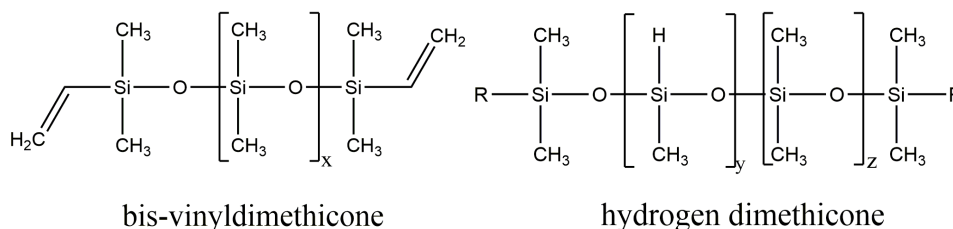


Figure 1. Polysilicone-11 reactants (wherein each instance of R may be hydrogen or methyl; x, y, and z not defined)

For use in cosmetics, copolymers, such as Polysilicone-11, are typically supplied to finishing houses as swollen gels (i.e. trade name mixtures) that contain 1 or more solvents (e.g., cyclopentasiloxane).² The addition of the comonomer (i.e. the vinyl-substituted dimethicone) affects both the chemical and the rheological properties of the resultant ingredient. Furthermore, the degree of crosslinking could also significantly affect these properties. Accordingly, this 1 copolymer ingredient theoretically represents a wide variety of materials ranging from liquids to elastomeric solids.

Chemical Properties

The molecular weight of Polysilicone-11 has been reported to be greater than 1 million Da, in the form of an elastomer rubber, amorphous polymer.³ For 3 different tradename mixtures, Polysilicone-11 was stated to comprise 10 – 20% of the mixture composition.⁴⁻⁶ The composition remainder of these mixtures (i.e. the other 80 – 90%) was reported to be isododecane, cyclopentasiloxane, or dimethicone. Each of these tradename mixtures is a clear liquid, with a viscosity ranging from 300 to 500 pascal second (Pa·s).

Method of Manufacture

According to a supplier, Polysilicone-11 is manufactured in cyclopentasiloxane (D5) solvent, preferable from low cyclotetrasiloxane (D4) feedstock using a hydrosilation catalyst.³ This is reported to be a pure addition reaction in which no impurities are formed during the reaction and no residual monomers remain after completion.

Impurities

According to a manufacturer, Polysilicone-11 generally contains less than 20 ppm platinum catalyst from hydrosilation.³ The same manufacturer also reported that heavy metal testing results for Polysilicone-11 typically include: below limits of detection for mercury, and less than 1 ppm for lead and arsenic.

USE

Cosmetic

The safety of the cosmetic ingredient 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 this ingredient 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 the 2020 VCRP survey data, Polysilicone-11 is reported to be used in 440 total formulations (432 of which are leave-on formulations; Table 1).⁷ The majority of these uses are in face and neck (excluding shave) products, moisturizing products, eye lotions, and foundations. The results of the concentration of use survey conducted by the Council in 2018, and updated in 2019, indicate Polysilicone-11 is used at up to 19.9% in products that have dermal exposure (i.e., other skin care preparations).⁸ This ingredient may result in incidental ingestion and mucous membrane exposure, as it is reported to be used in 8 lipstick formulations at up to 8.8%. In addition, Polysilicone-11 may also be used near the eyes, as it is reported to be used in eyeliner (1 formulation; concentration of use not reported), eye shadows (30 formulations; up to 9.4%), eye lotions (46 formulations; up to 12.2%), mascaras (3 formulations; up to 0.59%), and other eye makeup preparations (19 formulations; up to 0.24%).

Additionally, Polysilicone-11 is used in cosmetic sprays and could possibly be inhaled; for example, it is reported to be used in suntan pump sprays at up to 0.04%. In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters > 10 µm, with propellant sprays yielding a greater fraction of droplets/particles < 10 µm compared with pump sprays.^{9,10} 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.^{11,12} Polysilicone-11 was reportedly used in face powders at concentrations up to 3.5%, and could possibly be inhaled. 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 air.¹³⁻¹⁵

Polysilicone-11 is not restricted from use in any way under the rules governing cosmetic products in the European Union.¹⁶

TOXICOKINETIC STUDIES

Toxicokinetics studies on Polysilicone-11 were not found in the published literature, and unpublished data were not submitted.

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Oral

An acute oral toxicity study was performed on Sprague Dawley rats (5/sex) using a test substance consisting of 6% Polysilicone-11 and 94% cyclotetrasiloxane.¹⁷ The test substance was administered undiluted. The LD₅₀ was reported to be > 5 g/kg. No other details regarding this study were provided.

Short-Term, Subchronic, and Chronic Toxicity Studies

Short-term, subchronic, and chronic toxicity studies on Polysilicone-11 were not found in the published literature, and unpublished data were not submitted.

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY (DART) STUDIES

DART studies on Polysilicone-11 were not found in the published literature, and unpublished data were not submitted.

GENOTOXICITY STUDIES

The genotoxic potential of a mixture consisting of 14% Polysilicone-11, 47% dimethicone, and 39% cyclopentasiloxane, was evaluated in an Ames assay.¹⁷ Bacterial cell lines (*Salmonella typhimurium* strains TA98 and TA100) were tested with and without metabolic activation. The test substance was tested at concentrations of 50, 100, 500, 1000, and 5000 µg/plate, and was considered to be non-mutagenic.

CARCINOGENICITY STUDIES

Carcinogenicity studies on Polysilicone-11 were not found in the published literature, and unpublished data were not submitted.

OTHER RELEVANT STUDIES

Cytotoxicity

An agar diffusion test was performed in vitro to determine the biological reactivity of a mammalian cell culture (not specified) following indirect contact with the test substance (a trade name mixture containing 12 - 16% Polysilicone-11, 43 - 50% dimethicone, and 36 - 42% cyclopentasiloxane). The test substance exhibited no reactivity after the 24-h observation period, and did not induce cytotoxicity.

DERMAL IRRITATION AND SENSITIZATION STUDIES

Details of the dermal irritation and sensitization studies summarized below are provided in Table 2.

A skin irritation study was performed on 6 New Zealand white albino rabbits.¹⁷ The test substance (6% Polysilicone-11 and 94% cyclotetrasiloxane) was applied, undiluted, under a patch (type of patch not specified), on intact and abraded skin. The test substance was not considered to be a primary irritant. A 48-h patch test was performed on 50 subjects using a lipstick containing 1.8% Polysilicone-11 under semi-occlusive conditions.¹⁸ No dermal irritation was observed. Similarly, a 7-d dermal irritation study was performed on 38 subjects using a face cream containing 1.6% Polysilicone-11 under semi-occlusive conditions.¹⁹ On day 1, patches were applied for 24 h and removed. After evaluation of the site, identical patches were applied to the same site, and the process was repeated for 7 d. The subjects showed no evidence of irritation to the test substance.

A human repeated insult patch test (HRIPT) was performed to evaluate the sensitization potential of a product containing 1.45% Polysilicone-11.²⁰ The test article was placed on the skin of 54 subjects, under an occlusive patch. No evidence of irritation or sensitization was observed. Another HRIPT was performed on 110 subjects using a facial product containing 19.83% Polysilicone-11.²¹ Applications were made using a 10% dilution of the test substance (2% Polysilicone-11) under a semi-occlusive patch. No sensitization or irritation was observed. The amount of test substance used was not stated in either study. No sensitization or irritation was observed in an HRIPT performed on 51 subjects using a facial product containing 9.68% Polysilicone-11.²¹ The product was applied neat, under semi-occlusive conditions. An HRIPT was performed on 50 subjects using a test substance consisting of 11% Polysilicone-11 and 89% cyclopentasiloxane.¹⁷ All applications were performed neat (type of patch used not specified). The test substance was considered to be non-irritating and non-sensitizing. A maximization assay was performed on 17 subjects to evaluate the sensitization potential of a test substance containing 24.625% Polysilicone-11 (applied undiluted).²² No instances of contact allergy were recorded at either 48 or 72 h after the application of the challenge patch. The test substance was not considered to possess a detectable contact-sensitizing potential. No signs of sensitization or irritation were observed when an HRIPT was performed on 51 subjects using a trade name mixture consisting of 98% Polysilicone-11 and 2% laureth-12.²³

OCULAR IRRITATION STUDIES

In Vitro

A tissue equivalent assay was performed with EpiOcular™ cultures to evaluate the ocular irritation potential of a face cream containing 1.6% Polysilicone-11.²⁴ The face cream was tested neat (100 µl), the test samples were treated in duplicate, and the exposure periods were 8, 16, 20, and 24 h. Appropriate negative and positive controls were used. The ET_{50s} (i.e., the time at which the tissue viability was reduced 50% compared to negative control tissues) for Polysilicone-11 and the positive control were 18.2 h and 30.3 min, respectively.

A MatTek EpiOcular™ methyl thiazole tetrazolium (MTT) viability assay was also performed to evaluate the ocular irritation potential of a test substance containing 98.5% Polysilicone-11.²⁵ The chemical was tested neat (100 µl), the test samples were treated in duplicate, and the exposure periods were 64, 256, and 1200 min. Appropriate negative and positive controls were used. The ET₅₀ was 12 h, and the ocular irritancy classification for this test substance was “non-irritating, minimal.”

Animal

An acute eye irritation study was performed on 6 New Zealand albino rabbits using a test substance consisting of 6% Polysilicone-11 and 94% cyclotetrasiloxane.¹⁷ Approximately 0.1 ml of the test substance was applied to the eye, undiluted. No other details regarding this study were provided. The test substance was reported to be minimally irritating.

SUMMARY

This is a safety assessment of Polysilicone-11 as used in cosmetics. According to the *Dictionary*, Polysilicone-11 is a crosslinked dimethyl siloxane formed by the reaction of bis-vinyldimethicone and hydrogen dimethicone, and is reported to function as a film former in cosmetics.

According to 2020 VCRP data, Polysilicone-11 is reported to be used in 440 formulations, 432 of which are leave-on formulations. The majority of these uses are in face and neck (excluding shave) products, moisturizing products, eye lotions, and foundations. Results of the concentration of use survey conducted by Council in 2018, and updated in 2019, indicate Polysilicone-11 is used at a maximum concentration of up to 19.9% in other skin care preparations.

An LD₅₀ of > 5 g/kg was established in an acute oral toxicity study performed on Sprague-Dawley rats given a test substance consisting of 6% Polysilicone-11 and 94% cyclotetrasiloxane.

No mutagenicity was reported in an Ames assay performed using a mixture consisting of 14% Polysilicone-11, 47% dimethicone, and 39% cyclopentasiloxane. The test substance was tested on *S. typhimurium* (TA98 and TA100) at concentrations of up to 5000 µg/plate.

No cytotoxicity was observed in an agar diffusion test using a test substance consisting of 12 - 16% Polysilicone-11, 43 - 50% dimethicone, and 36 - 42% cyclopentasiloxane.

No irritation was observed in a skin irritation study performed on New Zealand white albino rabbits using a test substance consisting of 6% Polysilicone-11 and 94% cyclotetrasiloxane. A 48-h patch test was performed on 50 subjects using a lipstick containing 1.8% Polysilicone-11. No irritation was observed. In addition, no dermal irritation was observed in a 7-d dermal irritation study (24-h patches) performed on 38 subjects using a face cream containing 1.6% Polysilicone-11.

No sensitization was observed in multiple HRIPTs using the following test materials: product containing 1.45% Polysilicone-11 (54 subjects), a 10% dilution of a facial product containing 19.83% Polysilicone-11 (2% Polysilicone-11 as actual test concentration; 110 subjects), a facial product containing 9.68% Polysilicone-11 (51 subjects), a mixture of 11% Polysilicone-11 and 89% cyclopentasiloxane (50 subjects), or a trade name mixture containing 98% Polysilicone-11 and 2% e laureth-12 (51 subjects). In a maximization assay performed on 17 subjects using a pre-treatment with SLS, the test substance (containing 24.625% Polysilicone-11) was considered to be non-sensitizing.

An in vitro tissue equivalent assay was performed in order to evaluate the ocular irritation potential of a face cream containing 1.6% Polysilicone-11. The ET_{50} s for Polysilicone-11 and the positive control were 18.2 h and 30.3 min, respectively. A MatTek EpiOcular™ MTT viability assay was also performed to evaluate the ocular irritation potential of a test substance containing 98.5% Polysilicone-11. The ET_{50} was 12 h, and the ocular irritancy classification for this test substance was “non-irritating, minimal.” In an ocular irritation study in New Zealand white rabbits, a test substance consisting of 6% Polysilicone-11 and 94% cyclotetrasiloxane applied to the eyes was considered to be minimally irritating.

DISCUSSION

The Panel determined that the available acute toxicity, genotoxicity, irritation, and sensitization data were adequate for assessing the safety of Polysilicone-11 as used in cosmetics. There was a lack of chronic toxicity and mammalian genotoxicity data in this safety assessment; however, the Panel was not concerned about these gaps because Polysilicone-11 is reported to have a large molecular weight, and therefore it is unlikely that skin penetration would occur. According to a supplier, this ingredient is reported to be the product of a pure addition reaction, forming no impurities and resulting in no residual monomers. Therefore, data regarding residual monomers and impurities were considered sufficient. In addition, safety of this ingredient was supported by the lack of adverse clinical reports.

The Panel discussed the issue of incidental inhalation exposure from powders and suntan pump sprays. The Council survey results indicate that Polysilicone-11 is being used in face powders at concentrations up to 3.5%. In addition, Polysilicone-11 is used in spray suntan products at up to 0.04%. 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 based on the chemical and biological properties of these ingredients. 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>.

CONCLUSION

The Expert Panel for Cosmetic Ingredient Safety concluded that Polysilicone-11 is safe in cosmetics in the present practices of use and concentration described in this safety assessment.

TABLES**Table 1. Frequency and concentration of use of Polysilicone-11^{7,8}**

	<i># of Uses</i>	<i>Max Conc. of Use (%)</i>
Totals*	440	0.025 – 19.9
Duration of Use		
<i>Leave-On</i>	412	0.025 – 19.9
<i>Rinse-Off</i>	8	0.061 – 5.8
<i>Diluted for (Bath) Use</i>	NR	NR
Exposure Type		
Eye Area	94	0.24 – 12.2
Incidental Ingestion	8	7.2 – 8.8
Incidental Inhalation-Spray	100 ^a ; 90 ^b	0.04; 0.47 – 0.48 ^b
Incidental Inhalation-Powder	8; 100 ^a	0.025 – 3.5; 0.08 – 14.6 ^c
Dermal Contact	407	0.025 – 19.9
Deodorant (underarm)	NR	NR
Hair - Non-Coloring	1	0.48
Hair-Coloring	NR	NR
Nail	1	NR
Mucous Membrane	8	7.2 – 8.8
Baby Products	NR	NR

*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.

^a Not specified that this is used in spray or powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories

^b It is possible these products are sprays, but it is not specified whether the reported uses are sprays.

^c It is possible these products are powders, but it is not specified whether the reported uses are powders

NR – no reported use

Table 2. Dermal irritation and sensitization studies

Test Article	Concentration/Dose	Test Population	Procedure	Results	Reference
ANIMAL					
IRRITATION					
6% Polysilicone-11 and 94% cyclotetrasiloxane	100%; 0.5 g	6 New Zealand White Rabbits	The test substance was applied under a 2.5 cm ² patch on intact and abraded skin (type of patch and duration of administration not specified)	Non-irritating	17
HUMAN					
IRRITATION					
Lipstick containing 1.8% Polysilicone-11	100%; 0.2 ml	50	The test material was applied to a 1" x 1" absorbent pad portion of a clear adhesive dressing, and placed on the back. This dressing formed a semi-occlusive patch. The material remained on the skin for 2 d.	Non-irritating	18
Face cream containing 1.6% Polysilicone-11	100%; 0.2 g	38	On day 1, the undiluted test substance (0.2 g) was applied to the back, under semi-occlusive conditions. After approximately 24 h, patches were removed. Twenty to 40 minutes after patch removal, sites were evaluated, and identical patches were applied to the same site. This process was repeated daily for a total of 7 d. Distilled water and 0.75% sodium lauryl sulfate (SLS) served as the negative and positive controls, respectively.	Non-irritating	19
SENSITIZATION					
Product containing 1.45 % Polysilicone-11	100%; 0.1 – 0.15 g	54	HR IPT; The test substance was applied neat, under an occlusive patch, 3 times per week during the induction period. Patches were removed 24 h after each application. After a 2-wk rest period, a challenge patch was applied to a previously untreated test site. Patches were removed and the site was scored 24 and 72 h post-application.	Non-irritating; Non-sensitizing	20
Facial product containing 19.83% Polysilicone-11	10% dilution (actual test concentration 2% Polysilicone-11); amount of test substance not reported	110	HR IPT (same procedure as above); semi-occlusive patch	Non-irritating; Non-sensitizing	21
Facial product containing 9.68% Polysilicone-11	100%; amount of test substance not reported	51	HR IPT (same procedure as above); semi-occlusive patch	Non-irritating; Non-sensitizing	21
11% Polysilicone-11 and 89% cyclopentasiloxane	100%; amount of test substance not reported	50	HR IPT (same procedure as above); patch type not specified	Non-irritating; Non-sensitizing	17
Liquid blend containing 24.625% Polysilicone-11	100%; 0.05 ml	17	Maximization assay. Approximately 0.05 ml of aqueous SLS was applied to the skin of each subject under occlusive conditions for 24 h. After 24 h, patches were removed and 0.05 ml of the test material was applied to the same site, and covered with occlusive tape. This induction patch was left in place for 48 or 72 h. After removal of the induction patches, if no irritation was present, a 0.25% SLS aqueous patch was again reapplied to the same site for 24 h, followed by reapplication of a fresh induction patch with the test material. This sequence of SLS pre-treatment followed by 48 h of test material application continued for a total of 5 induction exposures. The induction phase was followed by a 10-d rest period. After the rest period, subjects were challenged with a single, 48-h application of the test material to a previously untreated site. Pre-treatment with SLS was performed prior to challenge. Evaluations were performed 48 and 72 h after application of challenge patch.	Non-sensitizing	22
Trade name mixture containing 98% Polysilicone-11 and 2% laureth-12	100%; 0.2 g	51	HR IPT (same procedure as above); occlusive patch	Non-irritating; Non-sensitizing	23

HR IPT = human repeated insult patch test; SLS = sodium lauryl sulfate

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24. Institute for In Vitro Sciences I. 2013. Tissue equivalent assay with Epiocular™ cultures (face cream containing 1.6% Polysilicone-11).
25. MB Research Laboratories. 2009. MatTek EpiOcular MTT Viability Assay (98.5% Polysilicone-11).

2020 VCRP Data – Polysilicone-11

POLYSILICONE-11	Eyeliners	1
POLYSILICONE-11	Eye Shadow	30
POLYSILICONE-11	Eye Lotion	46
POLYSILICONE-11	Mascara	3
POLYSILICONE-11	Other Eye Makeup Preparations	19
POLYSILICONE-11	Powders (dusting and talcum, excluding aftershave talc)	2
POLYSILICONE-11	Tonics, Dressings, and Other Hair Grooming Aids	1
POLYSILICONE-11	Blushers (all types)	3
POLYSILICONE-11	Face Powders	6
POLYSILICONE-11	Foundations	43
POLYSILICONE-11	Leg and Body Paints	1
POLYSILICONE-11	Lipstick	11
POLYSILICONE-11	Makeup Bases	12
POLYSILICONE-11	Rouges	2
POLYSILICONE-11	Other Makeup Preparations	20
POLYSILICONE-11	Other Manicuring Preparations	1
POLYSILICONE-11	Aftershave Lotion	1
POLYSILICONE-11	Cleansing	4
POLYSILICONE-11	Face and Neck (exc shave)	78
POLYSILICONE-11	Body and Hand (exc shave)	23
POLYSILICONE-11	Foot Powders and Sprays	1
POLYSILICONE-11	Moisturizing	63
POLYSILICONE-11	Night	23
POLYSILICONE-11	Paste Masks (mud packs)	4
POLYSILICONE-11	Skin Fresheners	1
POLYSILICONE-11	Other Skin Care Preps	35
POLYSILICONE-11	Indoor Tanning Preparations	6



Memorandum

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

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

DATE: October 5, 2020

SUBJECT: Tentative Report: Safety Assessment of Polysilicone-11 as Used in Cosmetics
(release date: September 25, 2020)

The Personal Care Products Council respectfully submits the following comments on the tentative report, Safety Assessment of Polysilicone-11 as Used in Cosmetics.

Cosmetic Use – As there is only one ingredient in this report, “these ingredients” in the second line of the Cosmetic Use section needs to be changed to “this ingredient”.

Discussion – It is misleading to suggest that there was a “lack of impurities and residual monomer data”. The supplier indicated that because this ingredient is manufactured from two polymers there are no residual monomers. The supplier provided the level of residual catalyst (<20 ppm platinum) and heavy metal concentrations.

Table 2 – Please put the single patch tests before the sensitization tests. In the HRIPT described in reference 22, the Dose column states 0.1-0.15 g, while the Procedure column states: “The amount of test substance used was not reported.” - which is not correct and should be deleted.