Dimethiconol

CIR EXPERT PANEL MEETING
DECEMBER 13-14, 2010
November 18, 2010

Memorandum

To: CIR Expert Panel

From: Wilbur Johnson, Jr.
      Senior Scientific Analyst

Subject: Dimethiconol and its Esters and Reaction Products

At the August 30-31, 2010 CIR Expert Panel meeting, the Panel issued a tentative report with a safe as used conclusion on these ingredients. All of the unpublished data received prior to that meeting have now been incorporated into the report. Technical comments were received from the Council and addressed.

A copy of the draft final report on these ingredients is included along with the following: CIR report history, minutes from the April, June, and August 2010 Panel meetings, and literature search strategy. A data profile is not included because almost all of the available data relate to dimethiconol. The absence of absorption, distribution, metabolism, and excretion (ADME) data is explained in the discussion. The Teams need to review the discussion carefully to make certain that they capture why it is acceptable to “read-across” the available data to the other ingredients.

With any needed editorial changes, a final report with a safe as used conclusion on dimethiconol and its esters and reaction products should be issued.
SAFETY ASSESSMENT FLOW CHART

Public Comment
60 day public comment period
ANNOUNCE

CIR
Draft Priority List
Draft Priority List

Expert Panel
Priority List INGREDIENT

Re-Reviews
15 years; or
New Data; or

Report Color
Buff Cover

December 16
SLR

Statement

2009
Decision not to reopen the report*

Draft Report

Table
ISD

Draft Amended Report
Green Cover 1st time;
Pink Cover 2nd time.

ISD Notice

Draft TR ISD

Draft Tentative Report

Tentative Report

Sept 2 2010

Draft Final Report

Final Report

PUBLISH

*The CIR Staff notifies the public of the decision not to re-open the report and prepares a draft statement for review by the Panel. After Panel review, the statement is issued to the Public.

**If Draft Amended Report (DAR) is available, the Panel may choose to review; if not, CIR staff prepares DAR for Panel Review.

Expert Panel Decision
Document for Panel Review
Option for Re-review

CIR Panel Book Page 1
CIR History of:

Dimethiconol and its Esters and Reaction Products

The availability of a scientific literature review (SLR) on this group of ingredients was announced on December 16, 2009.

Data and comments from the Personal Care Products Council and Silicones Environmental, Health Safety Council (SEHSC) were subsequently received.

1st Review, Belsito and Marks Teams/Panel: April 5-6, 2010

Unpublished data received from the Personal Care Products Council and SEHSC have been added to the safety assessment.

The Panel issued an insufficient data announcement with the following data requests: (1) Method of manufacture and impurities; (2) UV absorption; if there is absorption in the UVB/UVA band, then phototirritation and photosensitization data may be needed; and (3) Molecular weights or information about dermal absorption that can predict if dermal absorption can occur. If absorption occurs, then reproductive and developmental toxicity data may be needed. The Panel noted that, in order for dimethiconol/silsesquioxane copolymer to remain in this safety assessment, additional information on its composition is needed. The need for data on the composition of Dow Corning mixtures and FD80 and FD80/II polymers included in the safety assessment was also expressed.

2nd Review, Belsito and Marks Teams/Panel: June 28-29, 2010

The draft tentative report has been revised to include use concentration data from industry and studies on polymers FD 80 and FD 80/II from the SEHSC that were reviewed at the April 2010 Panel meeting. Data from the SEHSC are identified by a vertical line in the right margin of the report text. Additionally, the report now contains a table (table 2) on the composition of oil/butter sources of dimethiconol fatty acid moieties and excerpts from the summary and discussion of the published CIR final report on dimethicone and related compounds. At the Panel’s request, the following ingredients have been deleted from the report text because of specific components that may raise different safety issues: dimethiconol fluoroalcohol dinoleneic acid, dimethiconol/IPDI copolymer, and trifluoropropyl dimethiconol.

The draft safety assessment was tabled at the June 28-29, 2010 Panel meeting pending receipt of data promised by the Silicones Environmental, Health and Safety Council of North America/Dow Corning Corporation, which included most of the data requested in the insufficient data announcement.

3rd Review, Belsito and Marks Teams/Panel: August 30-31, 2010

To date, the following data have been received: (1) spreadsheet with data on physical properties, composition, impurities, and methods of manufacture for materials that are registered under the dimethiconol INCI name; (2) spreadsheet with data on the composition of tested materials containing dimethyl siloxane, hydroxy-terminated (CAS No. 70131-67-8) - UV absorption data on 4 of these materials provided; (3) justification for removal of certain studies from the safety assessment; (4) definition of dimethiconol/silsesquioxane copolymer; and (5) Complete Dow Corning reports for 9 study summaries previously submitted. Composition data on the FD80/II polymer included in the safety assessment were not received. The safety assessment has been updated to include industry data.

4th Review, Belsito and Marks Teams/Panel: December 13-14, 2010

Comments from the Personal Care Products were received on September 14, 2010.
Ingredients

DM – Dimethiconol OR dyhydroxyplydmethylsiloxane OR 31692-79-2 OR 70131-67-8
DA – Dimethiconol arginine
DB – Dimethiconol beeswax OR 227200-35-3
DBE – Dimethiconol behenate OR 227200-34-2
DBO – Dimethiconol borageate OR 226994-45-2
DCA – Dimethiconol candelillate
DCN – Dimethiconol carnauba
DCY – Dimethiconol cysteine
DDB – Dimethiconol dhupa butterate OR 243981-39-7
DFD – Dimethiconol fluoroalcohol dilinoleic acid
DH – Dimethiconol hydroxystearate OR 133448-13-2
DIB – Dimethiconol illipe butterate
DIP – Dimethiconol/IPDI copolymer OR 193281-67-3 OR 193281-67-3
DI – Dimethiconol isostearate OR 133448-14-3
DK – Dimethiconol kokum butterate OR 226994-48-5

*Data in Table: Publications used (Total no. in search); Multidatabase = HSDB, CCRIS, ITER, IRIS, Gene-Tox, and LacMed;

InitialSearch: 2-25-2010
Search Updated (PubMed+Toxline) on 5-19-2010. No useful information was found.
Search Updated (PubMed+Toxline) on 10-15-2010. No useful information was found.
DL – Dimethiconol lactate OR 227200-33-1
DMF – Dimethiconol meadowfoamate
DM – Dimethiconol methionine
DMS – Dimethiconol/methylsilanol/silicate cross polymer OR 68956-02-6
DMB – Dimethiconol mohwa butterate OR 225233-88-5
DP – Dimethiconol panthenol
DSB – Dimethiconol sal butterate
DSC – Dimethiconol/silica cross polymer
DSQ – Dimethiconol/silsesquioxane copolymer OR 68554-67-6
DS – Dimethiconol stearate OR 130169-63-0
DSM – Dimethiconol/stearyl methicone/phenyl trimethicone copolymer
HC – Hydrolyzed collagen PG-propyl dimethiconol
ID – Isopolyglyceryl-3 dimethiconol
TD – Trifluoropropyl dimethiconol
TDC – Trimethylsiloxydimethicone crosspolymer OR 68440-70-0
ADA – Acrylates/dimethiconol acrylate copolymer

Dimethiconol OR 227200-35-3 OR 227200-34-2 OR 226994-45-2 OR 243981-39-7 OR 133448-13-2 OR 193281-67-3 OR 193281-67-3 OR 133448-14-3 OR 226994-48-5 OR 227200-33-1 OR 68956-02-6 OR 225233-88-5 OR 68554-67-6 OR 130169-63-0 OR 68440-70-0
Dimethiconol Group

DR. BELSITO: Dimethiconol. This is the first time that we're looking at this ingredient. We got quite a bit of data, but unfortunately not all of the data that we needed to make a safety assessment. We felt that we needed manufacturing and impurities and UV absorption data, and if UV absorption, photosensitization and photoirritation data may be needed. Dermal absorption data are needed, and if we have dermal absorption, then reproductive toxicity data may be needed. We also received some data on a polymer that was labeled FD80 and FD80/2 and we wanted clarification as to what exactly was the composition of that polymer. It wasn't clear to our group. Those were the data needs. Then there were other compounds to consider along with dimethiconol. Of that list, some of them were plant-derived fatty acids and seed oils, and we look forward to Christina's report to tell us exactly what those were, things like the borageate and dhupa butterate, et cetera. Some were amino acids and we felt that those could stay in the report as well as the fatty acids, pending a decision as to the composition of those. There were a couple specifically, the isophorone diisocyanate copolymer. It had no uses and I think it would be an issue in terms of isocyanate, both IGE-mediated sensitization respiratory-wise and also delayed-type hypersensitivity skin-wise, so that we would recommend that that dimethiconol IPDI copolymer be removed. Also there were two fluorinated compounds that we felt should be removed from the list, the dimethiconol fluoroalcohol dilinoleic acid and the trifluoropropyl dimethiconol. One compound that we didn't want to delete at this point, but we did feel we needed more information on the dimethiconol silsesquioxane copolymer. So moving ahead with an insufficient and deleting three ingredients, the two fluoros and the diisocyanate, and requesting if we're going to keep the silsesquioxane copolymer in, more information on exactly what that was. DR. BERGFELD: Dr. Liebler?

DR. LIEBLER: My point is very similar to the one Jim just said, that a lot of the safety data that's cited in the report just refers to a Dow proprietary designation and doesn't tell us what part of this dimethiconol chemical space is represented by those compounds so that it would be better describe what the materials are. DR. BERGFELD: Is there any other discussion? Dr. Slaga? Dr. Hill, anything? Dr. Klaassen, Dr. Snyder, nothing? I'll call for the vote then. It's been seconded. All those in favor of going for an insufficient? Approved. We'll go insufficient with those data needs.
Minutes from the June 28-29, 2010 (115th) CIR Expert Panel Meeting – Dr. Belsito’s Team

Dimethiconol Group

DR. BELSITO: Okay. Dimethiconol.

DR. ANSELL: We have one comment on the table 1.

DR. BELSITO: Sure.

DR. ANSELL: It includes a lot of trade names, I think.

DR. BELSITO: Back on the --

DR. ANSELL: Table 1, page 34, chemical names, definitions, functions.

DR. BELSITO: Right.

DR. ANSELL: Does include trade names.

We don't necessarily think that's particularly useful or appropriate within the document.

DR. BELSITO: Well, I guess -- so you want the trade names deleted from that table?

DR. ANSELL: Yeah.

DR. BELSITO: We've traditionally included trade names, including when we looked at studies.

DR. ANSELL: I think to the extent that it's associated with a study, it may help inform structure -- when --

DR. BELSITO: But, I mean, all of our former documents for under synonyms have been the associated trade names. I don't have a problem eliminating them, but it's a -- you know,

particularly when we report a study that would say, you know, whatever trade name and then in parentheses what the drug actually -- or what the chemical actually was.

Why did you want them deleted?

DR. ANSELL: I -- when they're associated with identity, I think it's fine. When it's in a table that's talking about chemical structures, you know, the trade names come and go.

And, you know, I don't know that I feel strongly about it as I did when we had formulation trade names, which are often, you know, gone within a year. But that was one of the comments that came through. So I will advance this argument no farther.

DR. BELSITO: I mean, I -- again, I'm totally neutral. Curt, Paul, Dan?

DR. KLAASSEN: I personally would like to have the trade names removed.

DR. BELSITO: One remove. Paul?

DR. SNYDER: I'm indifferent.

DR. BELSITO: Two indifferents, one remove. Dan?

DR. LIEBLER: Remove.

DR. BELSITO: Two removes, two indifferents. Madame Chair, what do you feel like?

DR. BERGFELD: (inaudible) I like the trade names in.

DR. BELSITO: Alan?

DR. ANDERSEN: I guess I'm in the...
indifferent category. It seems like it would be useful information for a reader in the off chance that that reader is a formulator who is going to go rush out and now buy some of this stuff. But you don't buy it with the INCI name, you buy it with the trade name. And now I've got the trade names here, that's neat. Yes, I could go to the dictionary and get them, but it's nice that it's all here. This is an informative source.

So that -- it just seems like it -- you know, a very narrow window. Those pieces of information might be actually useful to somebody.

DR. SNYDER: I mean, historically --

DR. ANDERSEN: But I'm still indifferent.

DR. SNYDER: Historically, we look at studies that are with a trade name product that contains X percentage --

DR. ANDERSEN: No question. And those trade -- and they're often identified by the trade name. But in those circumstances, there's no reason we can't when we're talking about that study identify that this is a trade name for hexamethyl chicken fat. I mean, it's not difficult to do. And still be responsive to what Jay is saying here of having them out of this section of the report. We're not constrained to not say that it's a trade name. Just, there's a -- if there's a study that has a trade name, you say so. It's not hard.

I just -- it's just a -- sometimes it can be a huge amount of work to put them in. And if we didn't have to do that, to some small degree, it's easier to write these things.

DR. BERGFELD: Looking at it from a different perspective and widening your reader base to the non-chemist, it's nice to have the trade names in because that's what we see.

DR. KLAASSEN: Well, there's -- to me, there's a number of problems with the trade names. One, it's a little bit of an advertisement.

Number two, a trade name does -- I mean, you don't always have the same ingredient even though in the same trade name. For example, Tide soap is different in California than it is in Ohio.

Another problem is, how many trade names are we going to put in? Is there only one trade name?

DR. ANSELL: Well, no, and I think that's it exactly. To the extent that it's associated with a study, it helps inform the material identity. To the extent where we're turning it upside down now, now the trade name is defining the chemistry as opposed to -- or the chemistry is defining the trade name as opposed to the other way around. So I think it's entirely appropriate in the study. I just don't think it's necessarily appropriate here where we're trying to tie a specific chemistry in. And the right place is in the supplier guides, where you can call them up and find out the details. But again, this was not intended to precipitate --

DR. BELSITO: Okay. Well, I mean, you got two to remove it and two who don't care, so that goes -- our panel will go with you to remove it. We'll have the discussion with the other panel tomorrow.

Any other points on the pelargonic acid?

If not --
DR. SNYDER: I just want to make one comment to Wilbur. I thought that the intro was very well written, and I liked the scope and extent section that you had in the use. Because I thought that put things in correct perspective of what we were viewing, what had been previously reviewed. And so, I thought that was very nicely done.

DR. BELSITO: Okay. Dimethiconol, Pink 1. What? And we've got handouts here. We got something from the silicone industry, and then we have responses -- who are these responses to the SEH -- SE from? It just says, "Responses to SEH comments on dimethiconol."

DR. ANDERSEN: Wilbur.

MR. JOHNSON: They're from the Silicones Environmental Health and Safety Council, SEHSC.

DR. BELSITO: No, this here.

MR. JOHNSON: Okay.

DR. BELSITO: Is titled, "Responses to SE --"

MR. JOHNSON: Oh, yeah, that's my document. I produced that.

DR. BELSITO: Oh, this is what -- how we handle their comments.

MR. JOHNSON: Yes.

DR. BELSITO: Based upon our last meeting?

MR. JOHNSON: Yes.

DR. BELSITO: So this is our response -- the panel's responses to their comment?

DR. ANDERSEN: I don't know. I think it's the --

DR. BELSITO: More Wilbur's.

DR. ANSELL: Yeah. It's Wilbur's suggestions as to what the panel may say in response to the comments we did submit.

DR. BELSITO: Now, we reviewed those comments at our last meeting, no? We had the SEHSC's comments to look at at our last meeting.

MR. JOHNSON: Right, that's correct.

DR. BELSITO: And so I'm assuming this is a summary of our responses to their comments?

Or, I mean, is this --

MR. JOHNSON: In red -- well, no. You came from our team and the other team or?

MR. JOHNSON: No, no, I just purely, initially -- I had looked at the comments that were received from SEHSC, you know, based upon the recommendations that they were making and I had certain questions, you know, relating to those.

DR. BELSITO: Okay.

MR. JOHNSON: And they responded and the responses to those are included in this document.

DR. BELSITO: Okay. And then can you tell me what this document is supposed to be telling us?

DR. ANSELL: It was a -- one of the data requests went to manufacturing.

DR. BELSITO: So this is going to help us understand the manufacturing. So it's a hydrolysis reaction to polysiloxanes. Is that
what I'm to understand?

MS. ANDROIT: Yes. So, you've got some
different pieces of information that have come in.
One is there's an Excel spreadsheet, which
actually has molecular weight information and it
has project names. It's the one that it was
(inaudible) proprietary, but actually --
REPORTER: I'm sorry, (inaudible) can
you turn on your microphone?
MS. ANDROIT: And so what this is is
actually a (inaudible) that we collected on the
number of companies. We sent out surveys, we
gathered information based on the insufficient
data request that you guys had put together. So
we supplied molecular weight information,
manufacturing information, and impurity
information.
The other piece of information that I do
have but unfortunately it's Dow Corning data right
now and we have to get legal to sign off on it.
In mid-June we did do some UV absorption work on
several -- four products. And based on that data
there was no UV absorption seen with those
materials. But I do have that data and I do have
approval to give it to you once legal signs off on
it. So I will be supplying those study reports,
also.
And I did supply Wilbur with a CD today
of -- we had supplied some robust summaries of
additional information on dimethyconol, which is
the CAS number -- they were all done on CAS Number
70131-678, and they were greater than 95 percent
that CAS number, primary impurities being the
starting products, the linears and the cyclics.
We only supply robust summaries, we were
requested to provide the full study reports. And
I just provided a CD with all of those full study
reports to Wilbur today.
REPORTER: Ma'am, you are?
MS. ANDRIOT: Michelle Andriot, I
actually -- I work for Dow Corning, but I'm here
representing the silicone industry.
DR. LIEBLER: So I think our issue last
time was that a lot of the toxicology that was
described in our report draft was on this
proprietary material. And we didn't know where
this material fit in the chemical space that this
class of compounds is supposed to represent. We
didn't know how representative it is. And I'm
still trying to figure that out from the
spreadsheet.
DR. BELSITO: Well, what we had asked
for in April was, we came with an insufficient
data announcement for method of manufacture and
impurities. So, we now have method of manufacture
and, I presume, impurities for the polysiloxanes.
So, assuming you're comfortable with this
document, it's page 21/22. And the -- what we're
handed today, we have that.
We asked for UV absorption and if there
was absorption, then photosensitization and
phototoxirritation or phototoxicity. And we do not
have that present in front of us, but we're told
that it's available and will be given to us
forthwith. And then the last was dermal
absorption and if absorbed, yadda, yadda, yadda.
But if you look at the molecular weights of these
compounds, I guess that would be your argument.
There's no way in god's green earth that a
compound of 530,000 is going to get across the stratum corneum. So that -- do we really need any more data other than the molecular weight to make us happy that there's no absorption?

MR. JOHNSON: Excuse me, Dr. Belsito.

Michelle agreed to provide a data on the content of dimethiconol in each one of these materials. Because right now we don't even know, you know, what the content is of these materials and the table.

MS. ANDROIT: What the materials are is, they're basically dimethiconol at different percentages in things like D-5, hydrocarbon solvents. So they're basically emulsions of the dimethiconol to get it to the right viscosity for whatever they're going to be used for.

So what I did is, I told Wilbur we could get some more detailed information so you could see that the different concentrations of the dimethiconol that are in there.

But the study reports that Wilbur has, those are actually on pretty much 95 percent pure dimethiconol. It's not in a solvent.

DR. BERGFELD: So you are promising to fulfill all these needs, then to come up with the information as Wilbur described?

MS. ANDROIT: Right. I mean --

DR. BERGFELD: So --

MS. ANDROIT: You know --

DR. BERGFELD: So things to come yet.

MR. JOHNSON: And in addition to that, Michelle agreed to provide data -- if you look at table 4 on page 18? A number of material are included in studies summarizing this report. And we don't know the composition of the materials that were actually tested. So those materials are included in table 4 on page 18. So, Michelle agreed to provide that information as well.

MS. ANDROIT: For the Dow Corning materials, which are the predominant amount of the materials on that table.

DR. BERGFELD: And that could be provided by the -- before the next meeting?

MS. ANDROIT: Yes.

DR. LIEBLER: So the stuff on the spreadsheet, the long page, is not an attempt to address that issue? Is that right?

DR. BELSITO: It is an attempt.

DR. LIEBLER: Then it's not -- I -- we just got it this morning and I haven't been able to compare this to the stuff in the tables and try and match every ingredient for ingredient. I'm trying to do that now. I'm not getting very far.

So you're saying that there's more information that could be provided to assist us in determining what is the chemical composition of materials that were tested?

MS. ANDROIT: Right. So what -- because what I provided -- what was provided in this table was, we did not provide the actual composition information. But what I can say is, on all the products -- except for the last two, they do all contain the CAS number -- you know, the dimethiconol CAS number of 70131-678 at various percentages.

But what I agreed to do was to identify what those percentages are. So that you would have an understanding of what's in the materials -- and then I also agreed to look at the table 4.
And for the materials that are Dow Corning, I can provide that information, which, again, is most of the materials in the table.

DR. BELSITO: Okay. And in my notes -- and I'm having trouble locating, going back to why I asked this -- I said we still need composition of FD80 and FD80/something that I cannot read now.

So, FD80/II.

DR. SNYDER: Two Roman numerals.

DR. BELSITO: Yeah. Roman numeral II, good. So, why did we need that?

DR. SNYDER: Because the study we got -- parenthetically said composition not stated. So, you know, we didn't know what was comprised of.

DR. BELSITO: And are we getting that?

We still don't have that, right? And what study was that on?

DR. SNYDER: Page 5, on ocular irritation --

DR. BELSITO: Oh, right, okay.

DR. SNYDER: -- potential of the polymer FD80/II composition not stated.

MR. JOHNSON: No, we have not received that information.

DR. BELSITO: Okay. And then, I have a note that we need more information on the dimethiconol silsesquioxane mixture? And that came from -- where did we look at the mixture?

MR. JOHNSON: Is that -- what was it?

DR. BELSITO: It's just a note from the last meeting that for whatever reason we needed information on dimethiconol silsesquioxane.

MR. JOHNSON: Because what happened in looking at the data in table 1, you determined that certain ingredients should have been deleted from the safety assessment. And at that time you said that if you received, you know, certain data on that particular chemical then, you know, possibly that ingredient could remain in the safety assessment.

DR. ANSELL: And we have -- through the INFRO database have a chemical description of the dimethiconol silsesquio --

DR. BELSITO: Ah, so it was whether it would stay in table 1 as one of the ingredients --

DR. ANSELL: Right --

DR. BELSITO: -- that we're reviewing, and we haven't received that yet.

MS. ANDROIT: What kind of information are you looking for on it?

DR. BELSITO: What the heck it is.

DR. ANSELL: It's a copolymer of siloxane consisting of the trimethyl --
trimethoxysilane and dimethylsiloxane terminated
with hydroxyl groups.

MS. ANDROIT: Yeah, you’re -- basically,
your silsesquioxane starts to create a -- if you
think of a straight chain siloxane polymer, your
silsesquioxane starts to create your 3-D structure
to it. So you start to get branches and it's
actually -- your silsesquioxanes are even bigger
than your siloxane polymer. So it becomes even
larger. And then when you start to have your
dimethiconol, which has the OHN groups, you start
to get -- you know, things can start attaching and
it starts growing. So you get something very
large.

Your silsesquioxanes can actually start
going more towards your resinous materials.

DR. BELSITO: Dan?

to -- I appreciate the verbal description you
gave, particularly with the hand motions. But if
you could include that in your look-up list of
things so that we can have a little bit more
chemical composition information, that would be
good.

I think you're going to research the
things in table 4?

MS. ANDROIT: Mm-hmm.

DR. LIEBLER: And this item was not in
table 4. So, probably you should maybe include
things that are in table 1 and table 4.

DR. BELSITO: Okay. So we're satisfied
with the definition? We still don't have the
composition of what we got information -- safety
information -- on FD80 and FD80/II so we need
that.
with the understanding that the -- either Dow
Corning or the Silicon Council or whoever is going
to allow this data to come forward to us -- will
doing this by the September meeting, and it'll
be back on the table and we'll dispense with it?

DR. ANDERSEN: Would probably be a good
idea to table it, because that's what Jim's going
to move.

DR. BELSITO: Well, he must have read my
mind. Okay.

DR. ANDERSEN: And we will pull together
all of the new information -- knock on wood -- get
it incorporated into the report for your review at
the August meeting.

DR. BELSITO: So really it -- and I
guess just to give industry a heads up, it looks
like we have promises for everything we want,
except we still don't know what FD80 and FD80/II
are. And since we have safety information on
those, it should be fairly easy for someone to
tell us what those products are. And that would
be the missing piece of information.

MS. ANDROIT: Yeah, I'll go back to the
silicone industry on that, because those aren't
Dow Corning materials. So I'll have to find out
who they belong to and see if they'll provide
that.

DR. BELSITO: Thank you.

MS. ANDROIT: They get worried because
doctor and they like to keep things -- but Dow
Corning is kind of like, we need to get this out
there so we can get this one done and finished.
So, we'll go back.

DR. BELSITO: Good.

DR. LIEBLER: And I don't think we're
going to need UV on these. I can't see any reason
why they should absorb above.

DR. BELSITO: Well, we already have it
now. We asked for it, so we're getting it.
(Laughter)

DR. LIEBLER: You've got a bunch of
blank spectra, basically.

DR. ANSELL: That was our problem, since
there is no chromophore, no absorption -- there
weren't a lot of spectra available. But someone
did promise to run a blank one for us.

DR. BELSITO: Okay. Anything else?
We're going to table this with the understanding
that hopefully we can squeeze out of whoever makes
-- okay.
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Dimethiconol Group

DR. MARKS: Okay. If there's no more comments, we'll do the dimethiconol and its esters and reaction products. And that's in the Pink 1 book.

MS. EISENMANN: Dr. Marks? Michelle from Dow Corning. So if you have additional questions, she should be able to help you.

DR. MARKS: Good. Thank you. So, after my introduction, if, Michelle, you want to make any comments to clarify some of the insufficient data needs, that would be helpful.

So at the April 5th meeting of this year, we issued an Insufficient Data Announcement, with the following data request: Method of manufacture and purity, UV absorption. And if there's absorption, then photo irritation and photosensitization. Molecular weights, for information about the dermal absorption, that can predict dermal absorption. And then if there were absorption, obviously we need reproductive and developmental toxicity.

And then the last -- although it's not in the memo, the fourth really was additional information on the composition on the dimethiconol silsesquioxane, and also the Dow Corning mixtures and the FD80, FD80/II.

And as of the antedated data, we hadn't received anything. But it looks like we received something this morning. So Michelle, maybe you can talk to that.

MS. ANDRIOT: Yes, and actually this information -- I know it says "Dow Corning Proprietary" on it, but Tracy Guerrero from SEHSC actually liked my table that I sent her, and she forgot to take that indication off. Because that's actually SEHSC data, dimethiconol.

Granted, in Georgia, the products are primarily California materials. And so in that spreadsheet, what you'll see is the product name. There's molecular weight. There is information on manufacturing, and then also impurities.

Dimethiconol is primarily produced using our linears or our cyclics, the D4, the D5 and D6, with -- you use a hydroxide in there, and then that's stripped out.

Basically -- you're familiar with dimethicone, which is our polydimethylsiloxane.

And what this is, it's the same material with O-H end groups. So we end-block it with O-H. And it's a polymer. And if you look at the spreadsheets, you'll see for the most part these are fairly large polymers that are utilized.

And I should point out the tox data that was supplied -- and actually, I just gave Wilbur a disk, because it does take time to get tox reports actually released. And these were Dow Corning study reports. So we do have to go through a process. But I did provide him with all the tox study reports that I think we provided summaries of last time, and we were asked to actually provide the full study reports. Those are now on a CD that Wilbur has. And that was actually on dimethiconol, itself. It's an approximate 95 percent purity -- with your impurities being some of your starting products, being the cyclics and the linears.
And then the other thing -- and this, I can't give to you today because we just got it out. We did do some UV absorption data on four for the materials. And, basically, what the results say -- and I will, once I have approval from Legal to get the results -- this data was just done in June, mid-June. So the dimethiconol does not absorb within the UV spectrum. And the scans are roughly equivalent to the scan of a (inaudible).

And then we've got the official approval to release, but Legal has to sign off. And I'll send those reports to Wilbur.

DR. MARKS: So that would appear -- we have two, we have the method of manufacture, and impurities. UV absorption sounds like that's going to be good -- report pending.

Molecular weights, or information about the dermal absorption, we had that. And we have the -- we have information on the composition. So it sounds like we'll have all the information. It's just we're awaiting the UV absorption.

Does that sound correct, Rons and Tom?

On the UV absorption, we didn't expect these compounds to absorb, anyway. And the question was were there impurities in there.

DR. SHANK: (inaudible)

DR. MARKS: -- we could, could move forward. But to be safe, we need to have that data for inclusion (inaudible).

DR. SHANK: So I would suggest then, with that in mind -- and we always err to be on the safe side -- that I would propose that we table this, awaiting that data on UV absorption.

DR. MARKS: Is that -- right.

DR. SHANK: Well, the data on UV absorption and molecular weight, and the three needs specified -- method of manufacture, impurities --

DR. MARKS: Is that -- right.

DR. SHANK: So, you can put that -- all of that is coming, so.

DR. MARKS: It's right here.

MS. ANDRIOT: The table has the molecular weight.

DR. SHANK: But it's not in the report.

DR. SHANK: (inaudible)

DR. SHANK: -- we could move forward. But to be safe, we need to have that data for inclusion (inaudible).

DR. MARKS: So I would suggest then, with that in mind -- and we always err to be on the safe side -- that I would propose that we table this, awaiting that data on UV absorption.

DR. MARKS: Is that -- right.

DR. SHANK: Well, the data on UV absorption and molecular weight, and the three needs specified -- method of manufacture, impurities --

DR. MARKS: Is that -- right.

DR. SHANK: So, you can put that -- all of that is coming, so.

DR. MARKS: It's right here.

MS. ANDRIOT: The table has the molecular weight.

DR. SHANK: But it's not in the report.
DR. MARKS: No. I mean, we have the data, it's just not in the report. At this point, I think the only data need is the UV absorption, which is coming.

MS. ANDRIOT: Which I have in my hands, and you guys can look at them. I just can't leave them. (Laughter)

DR. SHANK: Well, the UV absorption, you wouldn't expect these compounds to absorb.

DR. MARKS: No.

DR. SHANK: So if the only -- if there were impurities that will absorb. So if that's the only thing outstanding, I would say let's just finish the report -- on the expectation that that's coming.

MR. ANDERSEN: I think the caution, though, is we have a disk full of all studies now, based on what were only summaries before. And on the usual circumstance is that the full study provides a lot more description for the document. I think caution is still the right approach here. If it's tabled, that gives an opportunity to look through those data. It gives the opportunity for the new data to come in. And then, come August, which is not that far away, we could wrap this up with a much improved document.

DR. MARKS: Wilbur?

MR. JOHNSON: I just have a question. Dimethiconol and a number of its reaction products are being reviewed in this safety assessment. I guess my problem is associated with matching these data with a specific chemical name included in this table?

MS. ANDRIOT: Okay, all those products there actually contain the dimethiconol, not dimethiconol plus the reaction product. And I can provide you more specific information on the levels of dimethiconol. Because those would be products that we would -- so it's, for example, some of them are dimethiconol in D5, so that you can get the right viscosity. But the primary ingredient is dimethiconol, which is the CAS number -- I think it's 70131-67-8.

So they're not any of the other reaction products that are listed under this review. Those are for dimethiconol itself.

MR. JOHNSON: So we will receive that on a percent composition of dimethiconol and each one of these materials.

MS. ANDRIOT: I can give you the general composition of those, yes.

MR. JOHNSON: And one other concern that I have relates to Table 4, on page 18. Yes -- there are number of studies in which Dow Corning materials for which we do not have a description are included in the safety assessment. So we really don't know the composition of a number of those materials. And is there any possibility that that information would be provided?

MS. ANDRIOT: Mm-hmm. So you're looking for additional information on the chemical composition in this table.

DR. MARKS: Yes, I think -- I'm not sure how helpful this would be, but in this document that you gave us, some of the compounds -- like the 1870 HV, as you mention in here, are mixtures
containing other ingredients which are known sensitizers, like methyl chloroanisol, methyl isothiazalone. So one would have to interpret the study on those compounds rather cautiously, if we got a positive result, because it may be due to the preservative in that mixture.

MS. ANDRIOT: (inaudible).

DR. MARKS: So I don't -- Wilbur, you can -- and then we're back to the IBT data issue here, which -- I forget how we handled that before, but we had the issue before of IBT data not being valid.

And -- what did we do? Did we delete that from that report? I'm trying to remember.

MR. JOHNSON: Yes.

DR. MARKS: We did delete it. So I think we need to do that where we have concern about whether or not the actual data has been fabricated.

Okay. So --

DR. HILL: One more quick comment --

DR. MARKS: Sure.

DR. HILL: -- is that given that D4, D5 and D6 are listed as impurities, in aggregate could be up to 5 percent from what I think I heard her just say, we need to make sure that when those are noted in the report, that it references our previous review, where we looked at those specifically.

DR. MARKS: Good. Good point, Ron.

MR. JOHNSON: Dr. Marks, could I just ask one more question?

DR. MARKS: Sure. Of course.

MR. JOHNSON: I know that the IBT study is going to be deleted, but with respect to the other studies that SCSA should be deleted, should they be deleted?

MS. ANDRIOT: And I can talk a little bit about that.

Those are Dow Corning studies, and Dow Corning goes through -- before we actually use any data in health and safety assessments, because some of our data is older data and we don't have all the raw material in our files, and we may not have all the information. And so Dow Corning does make a decision not to utilize that information, and we'll give it a (inaudible) code of "3" on some of them, or a "4" if it's insufficient data.

We have provided information like that before, but one of the things is that it needs to be -- some of these studies, I think, were actually feeding studies. So stability wasn't looked at. So we can't actually say what the dose was that was given to those animals. And that does raise a concern, because if you indicate, oh, these were the doses, they may have been dosed at something significantly less than that.

If you choose not to -- or if you choose
to keep the information in there, we would highly recommend that you know that there are limitations on those studies and the interpretation of the data. And I think I've listed them in that document what Dow Corning said those limitations are.

DR. HILL: Okay. We'll make sure that gets captured into wherever that's discussed in the report?

DR. MARKS: Yes. Thank you. Any other comments? So, since I'm the one who's going to be presenting this tomorrow, I'm going to move that we table this final conclusion -- or, I should say, issuing a tentative report. But we expect there will be a tentative report with a "safe" conclusion. That the preliminary data we've received appear fine; that the full studies, with the caveats we discussed will be incorporated in the report, and we'll have time to be sure that the full studies support our preliminary data. Does that capture it well? Ron, Ron, Tom?

Dimethiconol Group

DR. MARKS: In April of this year the CIR Expert Panel issued an insufficient data announcement for dimethiconol. There were four data requirements. We actually yesterday saw a summary of those data and they look like we will be able to issue a safe report. However, particularly data need number 2, the UV absorption, we had a verbal report that was okay but we didn't see anything in writing. We didn't see the full studies. So our team felt that we would prefer to table this, receive the full studies, confirm the preliminary reports that we have that all these four data needs, the method of manufacturing, impurities, UV absorption and molecular weights and the composition of the copolymer and also the Dow Corning mixtures that we have, the full studies and full information and then proceed with an expected safe. So I move that we table this report.

DR. BERGFELD: Is there a second?

DR. BELSITO: Second.

DR. BERGFELD: There is no discussion on the tabling. All those in favor of tabling please...
Minutes from the August 30-31, 2010 (116th) CIR Expert Panel Meeting – Dr. Belsito’s Team

DR. BELSITO: Okay. Isoparaffins we did, so we're to dimethiconal, Pink 1. Okay. So back in June we talked it so that further data could be provided by industry. We wanted some information on dimethiconal silesesquioxane co-polymer composition, if that was going to continue in the report. And we thought the remaining components of the report allowed us to go with a safe after all the expected data was received. And for the most part that data has been given except we still haven't gotten the composition of the FD80/II polymer. Having said all that, looking at this report, it's used in hairsprays, Wilbur, so we need the respiratory boilerplate from the cosmetics section. I didn't know if my colleagues would think that the information we got on manufacturing impurities was sufficient for this large group and whether additional data were needed.

DR. LIEBLER: I was happy with the additional data we got on composition. And I actually have noted the same thing you did, the FD80. So in Table 4, the second page of Table 4, which is Panel Book 58, it does indicate that the alpha-omega-dihydroxy-polydimethylsiloxane and is listed as aliases including polymer FD80. So it's right there.

DR. BELSITO: But not FD80/II.

DR. LIEBLER: So the question I would have for SCHC colleagues is what's the difference between FD80 and FD80/II? I wasn't sure if FD80 was just a short way of listing FD80/II. Are there two different ones? We don't know, so.

MS. GUERRERO: (Off mic) the information for both and that was provided on /II.

REPORTER: Can you introduce yourselves, please?

MS. GUERRERO: Yes, Tracy Guerrero from Silicones Environmental Health and Safety Council.

DR. BELSITO: So I guess we're not going to know the answer to that. And the basic reason we're asking for composition is that the data looked fine. We just wanted to know what we were looking at with the FD80/II. So I guess the question is if we don't know the composition or what back it is, does it stay included in the report or do we delete it? Otherwise, I thought the UV looked good.

We didn't actually get dermal penetration data, but we got octanol water coefficients and molecular weights that made it extremely unlikely that any of these materials would be absorbed through the skin. So, you know, I think everything was sufficient and, you know, safe as used with the respiratory boilerplate, but

what do we do with the FD80/II? Do we drop all the studies that refer to that? Do we say that it's dimethiconol, but we don't know what it is? That's sort of hard to do.

DR. SNYDER: So let me go back, what were our original data needs? I mean, we tabled this in June.

DR. BELSITO: Our original data needs were impurities. Manufacturing impurities, UV absorption and if it absorbs, phototoxicity, photosensitization, dermal absorption and if it absorbs the reproductive toxicity, and the impurities and FD80, FD80/II. So that's what we originally asked for.

We got some manufacturing impurities. Dan felt that was good. We got UV data. That's good. We got octanol -- we didn't get dermal absorption, but we got octanol water and molecular weight data that would suggest it's not absorbed.

So we got three of the four. The fourth one that we didn't get is what's the composition of FD80/II.

DR. BREISLAWEC: I just might point out that this wasn't the first time you asked for it. You had asked for it before as well so we've been asking for the composition of this since April, if not sooner, when the first report was issued, the SLR was issued in December. I'm just not sure. Is there a reasonable chance that we'll get the information or not? Because if there's not then I can (unintelligible) assume that we're not getting it.

DR. BELSITO: I would just drop the FD80/II data from the report. It's not like it's the only piece of information we have. Get rid of it, safe as used, let's move on.

DR. LIEBLER: I agree.

DR. SNYDER: On page 48, second paragraph, Chronic Feeding Study, do we know the composition of the Dow Corning special polymer? Page 48, under Chronic Toxicity Tumorgenicity, there was this chronic feeding study and chronic implantation studies using this.


MR. JOHNSON: You're welcome.

DR. LIEBLER: So this occurred to me while I was reading this. I finally realized that some of the tested materials that we have data on are not the same materials that are used in cosmetic products, but they represent the same types of chemical substances and therefore the data were relevant. And that includes things in Table 5.

Is that how -- am I getting that correct, Wilbur?

MR. JOHNSON: Yes.

DR. LIEBLER: Things in Table 5 are not cosmetic ingredients, but they're dimethicone and related compounds that were tested for which tox data or other relevant data are available.

MR. JOHNSON: Because actually when a literature search was performed initially there were certain studies that came up as a result of searching certain CAS numbers. And basically you had mixtures that were being tested and we didn't, you know, know the composition, the identity of...
some of the composition of some of the components of those mixtures. So that's why this information was included.

DR. LIEBLER: So with that in mind it could be a little confusing to a reader who comes across Table 5 and sees what looks like Dow Corning 22 emulsion that's got toluene and perchloroethylene in it, you know, which would be bad news. Perhaps the title of the table could be changed to indicate that these things in this table are not cosmetic ingredients.

MR. JOHNSON: Okay. But we have test data already on materials containing them already.

DR. LIEBLER: I mean, it's relevant because it just gives the wrong impression about those particular ingredients.

DR. BELSITO: And Wilbur?

MR. JOHNSON: Yes.

DR. BELSITO: On page 43, under Subchronic Oral Toxicity --

MR. JOHNSON: Which page, please?

DR. BELSITO: Page CIR Panel Book 43.

MR. JOHNSON: Thirty-three.

DR. BELSITO: Forty-three.

MR. JOHNSON: Okay.

DR. BELSITO: The last go-round there was also a one-year study. And one of the comments from the group was that unless we knew the doses, the eight month and the one year should be dropped. Obviously, it looks like you got the dose for the eight month. The one year was dropped because when you went back and looked you still couldn't calculate the dose that these animals received?

MR. JOHNSON: Which study are you referring to?

DR. BELSITO: It's not in the current document. It was in the prior version and one of the comments that we received, if you go to page 76, CIR Panel Book 76.

MR. JOHNSON: Yes.

DR. BELSITO: Point number 3. It was being requested that we delete the Food and Drug Research Lab's chronic one-year feeding study and that's the reference and their eight-month feeding study and the rationale was that we couldn't determine the actual dose level. In this current version you did delete the one-year study, however, you did not delete the eight-year study.

MR. JOHNSON: Eight-month.

DR. BELSITO: Eight-month study. In the eight-month study you -- the dose suddenly appears. And I'm assuming that the one-year study was deleted because you could not find that dose.

Is that, in fact, correct?

MR. JOHNSON: I assume that, but let me check just to make sure --

DR. BELSITO: Okay.

MR. JOHNSON: -- that I have.

DR. BELSITO: So basically what you need to check is not this document, but to go back at the Food and Drug Research Laboratory's one-year study. It's listed on page 76. And see if the dose was actually given.

MR. JOHNSON: Dr. Belsito, just reading this very carefully, and this was received from SEHSC, that was their basically decision which is the basis for deleting it because there was no ability to determine the actual dose.

DR. BELSITO: I understand. But in the prior report that was because you didn't tell them that in the eight-month study it was .05 percent.

MR. JOHNSON: Okay.

DR. BELSITO: We had no concentration of use. Miraculously, that concentration appears in this report. I'm wondering if we could make another miracle and find the concentration in the one-year study.

MR. JOHNSON: Okay.

DR. BELSITO: If we cannot, then fine, don't include it.

MR. JOHNSON: Okay.

DR. BELSITO: But please go back and check the document.

DR. SNYDER: So when we get those kinds of comments it's very useful that we just address whether or not you were able to find the data or not.

MR. JOHNSON: Sure.

DR. SNYDER: Because I kept flipping back and forth trying to figure out whether or not we were deleting it or keeping it or whether you found the information that they needed to support keeping it in the report.

MR. JOHNSON: Okay.

DR. BELSITO: On page 48, under skin irritation and sensitization, the first paragraph that's not in italics, that was an IBT study and I thought we were going to delete that. Okay. I had no other comments. Delete FD80/II from any of the data, safe as used.

DR. SNYDER: Agreed.

DR. BELSITO: And respiratory boilplate.

DR. SNYDER: And a whole new discussion.
inhaled adverse effects that would just blow away by particle size, we need to say that the panel noted the lack of reproductive toxicity and carcinogenicity data for --

DR. SNYDER: We have pretty limited absorption distribution --
DR. BELSITO: Right.
DR. SNYDER: -- and penetration as a whole.
DR. BELSITO: Right.
DR. SNYDER: We have very little, so.
DR. BELSITO: Well, I don't need -- I don't know that we need to go into that because the real issues would be repro and carcinogenicity. Right?
DR. SNYDER: Right.
DR. BELSITO: Regardless of the fact that we don't have metabolism. So we noted that there was relative lack of reproductive carcinogenicity. However, given the octenyl water partition coefficients and the molecular weight of these products, we do not feel that they would be absorbed and therefore these aren't issues. Then you can go on to potential adverse respiratory effects and the plant caveats.

Minutes from the August 30-31, 2010 (116th) CIR Expert Panel Meeting – Dr. Marks’ Team

DR. MARKS: The dimethiconol group. That's Pink 1. As you recall at the April meeting, we tabled these ingredients because we had verbal confirmation that we presume would be supported by written confirmation that these ingredients are safe. Are there any comments?

Did we get the written confirmation on this like physical properties, the compositions, et cetera? If anything, the main thing was the dimethiconol/silsesquioxane copolymer data? Are there any concerns with moving on with a tentative report as safe?

DR. SLAGA: I would agree with that.
DR. BERGFELD: We were concerned about something called FD80/11 and I searched and searched to see if we had gotten any information on that particular ingredient, whereas we did something on FD80 polymer. Can any of you make a comment on that?

DR. SLAGA: That was in our minutes from last time?
DR. BERGFELD: Yes. It's on page 25 of the Panel Book, line 20 through 2.
DR. HILL: What page did you just say?
DR. BERGFELD: Page 25.

DR. SHANK: My understanding that the materials submitted by Dow Corning explained FD80 and FD80/II polymers, including a safety assessment, was also expressed. I guess the question is do we keep that or do we just delete in this tentative report, meaning that single ingredient? That was really the only question. I guess if it remains an issue, we can just delete that one copolymer and that will settle this Dow FD80, FD80/II issue. Carol, you're shaking your head.

DR. EISENMANN: FD80 is a trade name for dimethiconol whereas the other one is completely different. The dimethiconol/silsesquioxane copolymer is something different.

DR. MARKS: I assume somewhere in that June meeting there must have been an association with that copolymer in the Dow product. I don't know. I'm not sure why that copolymer was particularly chosen to be considered.

DR. EISENMANN: The description of that copolymer is on CIR Panel Book page 83 if you want to look at that so that you do have a description of that copolymer now.

DR. HILL: Since you're here maybe you can answer a question about Attachment 1, although noted that in order for dimethiconol/silsesquioxane copolymer to remain in the safety assessment, additional information on its composition is needed. The need for data of the composition of the Dow Corning mixture is FD80 and FD80/II polymers, including a safety assessment, was also expressed. I guess the question is do we keep that or do we just delete in this tentative report, meaning that single ingredient? That was really the only question. I guess if it remains an issue, we can just delete that one copolymer and that will settle this Dow FD80, FD80/II issue.
I'm taking us on a short rabbit trail. I noticed that the composition of this Dow Corning CB1556 fluid is 60 percent phenyl siloxane. That appeared to be something new from what we'd seen before and I wondered if this is actually being used in cosmetic products if that's the case. But I'm taking us on a rabbit trail a bit away from the sesquioxane.

DR. MARKS: Is there any reason now with the clarification of that that we can't now proceed with issuing a tentative report of safe for these ingredients?

DR. SHANK: Safe.

DR. MARKS: Safe. Is there any other editorial discussion? I have rewrite.

DR. HILL: Dr. Marks, the question that I just asked Michelle is on Attachment 1 and this is Panel Book page 77. It's the seventh entry down. It's Dow Corning CB1556 fluid. It lists the composition as having 60 percent phenyl siloxane, which would seem to be unlike anything.

DR. MARKS: But, Ron, are we approving a branded composition or are we doing ingredients for cosmetics?

DR. HILL: Apparently this is being used as an ingredient in cosmetics. The only question in my mind is does that have anything to do with dimethiconol and if it's registered under a dimethiconol INCI name, which apparently it is, we suddenly have a substance in there I'm not sure I know exactly what that is and how it relates to the other substances that are here.

DR. EISENMANN: I don't know for sure, but it's probably a mixture. It's got two INCI names and at this point you're just reviewing the this point now that we have the data needs in here.

DR. BERGFELD: What was Dr. Shank's comment?

DR. MARKS: His comment was that the discussion could be limited to that almost. I'm sure it can be embellished slightly. It would be one of the shorter discussions with only those two paragraphs.

DR. EISENMANN: I have one question. On page 46 of the CIR Panel Book there is the sensitization study that I thought you decided to remove because it contains other components, including Kathon CG. I thought you agreed to remove that at the last meeting. If you're not going to remove it, you at least need to add to the list of other ingredients.

DR. MARKS: Correct.

DR. EISENMANN: Are you going to remove it? The sensitization is likely from the other components.

DR. MARKS: Yes, I'm fine with removing it because it doesn't add anything to this actually, but I'll defer to my colleagues to either leave it and have a qualifier that it's the other components of this that are likely the sensitizer or removing it. Which does the team prefer?

DR. SHANK: Remove it.

DR. HILL: I vote for leave it, but qualified.

DR. MARKS: Ron? This gets back to what do we leave in and what do we not or what studies do we include?

DR. SHANK: Specifically which paragraph are you talking about on Panel Book, 46?

DR. EISENMANN: It's the study on Dow Corning 2-1870. It's the third paragraph, the one that comes out to be a strong sensitizer. I think it's this whole maximization study. Yes, it's the maximization study that came out to be a strong sensitizer and that's likely because of the other components that are not listed here, they're listed in the memo from SCHSC.

DR. BAILEY: The question would be leaving this in might be confusing when I think taking it out was what we talked about before and seems like a good decision.

DR. EISENMANN: If you look, page 75 is where they describe what's in it. It's number 1.

DR. HILL: I change my vote. Taking it out would be good.

DR. MARKS: Wilbur will remove that study from this report.

MR. JOHNSON: Just to make sure, which paragraph is that, please, Carol? It's on page 46?

DR. MARKS: It's the max study.

MR. JOHNSON: The maximization?

DR. EISENMANN: Yes, it's the maximization study.

MR. JOHNSON: Thank you.

DR. EISENMANN: If you look at their comment number 1.

DR. HILL: One more question. This is editorial again. At the bottom of Panel Book page 39, we have this issue of multiple CAS registry numbers. It ends by saying: As both CAS registry files describe hydroxy-terminated dimethylsiloxane, the discrepancy is likely an one.

DR. HILL: So the INCI name doesn't refer to CB1556, it refers to the 10 to 10 percent CAS?

DR. EISENMANN: If you use that ingredient, you'd have to put on two names on the table so, no, it wouldn't be hidden. You've have to have the other name on the label too.

DR. HILL: Thank you.

DR. MARKS: On Panel Book page 52 in the draft inclusion will be safe. All those ingredients listed will be included, including silsesquioxane. Are there any comments about the discussion? It needs to be rewritten, doesn't it?

DR. SHANK: Rewritten, yes.

DR. MARKS: Are there any other comments?

MR. JOHNSON: Regarding rewriting of the discussion, are there any specific comments?

DR. SHANK: I was afraid you would ask that.

DR. BERGFELD: I think you need to keep the last two paragraphs at least, which is page 52.

DR. MARKS: Absolutely the boilerplate on inhalation.

DR. SHANK: That's all.

DR. MARKS: That's all. Wilbur, obviously we want to keep the boilerplate on inhaled aerosols. That's on page 52. And the plant-derived moiety is other boilerplate that we don't get contaminates in the final cosmetic ingredient. And Dr. Shank's comment, that's about all we need, although I'm sure you can elaborate. There is not much controversy I don't think at
error. And I wondered if someone associated with SCHSC or Dow could comment on that. I'm not sure that we have to have that comment right at the moment, but before this report gets finalized.

DR. MARKS: So you characterize that as an editorial comment?

DR. HILL: Yes, sir.

DR. MARKS: If you'd take that and note it, Wilbur, and clarify that.

Minutes from the August 30-31, 2010 (116th) CIR Expert Panel Meeting – Day 2

Then moving to the dimethiconol group, Dr. Belsito.

DR. BELSITO: Yeah, back in June, we tabled the discussion on this report pending further data that was promised from industry. We did receive data on -- some data on manufacturing and impurities that we thought were sufficient. We received some ultraviolet absorption data that we felt was sufficient. We did not get dermal absorption data directly, but we did get Kow and we got molecular weight, which would strongly suggest that these would not be absorbed.

The one bit of data that we didn't get -- we asked for the composition of FD80 and FD80/II. While we got information about FD80, we did not get the information about FD80/II, but felt that the data and the report on that specific product was not critical to the report. And so we're going out with a safe as used and a recommendation that the data on FD80/II be deleted.

DR. BERGFELD: Second? Is there a second?

DR. MARKS: Second.

DR. BERGFELD: Any further discussion?

None! Okay. Call for the vote. All those in favor of safe as a conclusion? Thank you, unanimous.
Dimethiconol and its Esters
and Reaction Products

November 18, 2010
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ABSTRACT

The safety of dimethiconol and its esters in cosmetic products is reviewed in this safety assessment. Most of these ingredients have the skin conditioning agent/hair conditioning agent function in common. The CIR Expert Panel has reviewed relevant data and concluded that these ingredients are safe in the present practices of use and concentration described in this safety assessment. The Expert Panel noted the absence of data on reproductive and developmental toxicity and limited tumorigenicity and metabolism data; however, after reviewing molecular weights, the Panel agreed that these ingredients would not be absorbed through the skin, thereby obviating further concern over potential reproductive and developmental toxicity or carcinogenicity.

INTRODUCTION

This safety assessment includes dimethiconol and its esters and reaction products. These reaction products can be categorized into two types:

1) end-capped homopolymers: dimethiconol arginine, dimethiconol beeswax, dimethiconol behenate, dimethiconol boraginate, dimethiconol candelillate, dimethiconol carnaubate, dimethiconol cysteine, dimethiconol dhupa butterate, dimethiconol hydroxyxstearate, dimethiconol illipe butterate, dimethiconol isostearate, dimethiconol kokum butterate, dimethiconol lactate, dimethiconol meadowfoamate, dimethiconol methionine, dimethiconol mohwa butterate, dimethiconol panthenol, dimethiconol sal butterate, and dimethiconol stearate; and


The end-capped homopolymers consist of polymers chains made from dimethyl siloxyl monomers, wherein each end of the polymer chain is capped with an ester side chain (e.g., dimethiconol behenate, a dimethyl siloxyl polymer which terminates on each end with the behenate ester). The copolymers consist of at least two monomers polymerized together. The skin conditioning agent/hair conditioning agent function in personal care products is associated with most of these ingredients.

Of the 28 ingredients that are being reviewed in this safety assessment, the following 10 are reported to the Food and Drug Administration as being used in personal care products: dimethiconol, dimethiconol arginine, dimethiconol beeswax, dimethiconol cysteine, dimethiconol meadowfoamate, dimethiconol methionine, dimethiconol panthenol, dimethiconol stearate, dimethiconol/silsesquioxane copolymer, and trimethylsiloxy-silicate/dimethiconol crosspolymer. Current use concentration data from the Personal Care Products Council also indicate that, while not reported to the VCRP, dimethiconol behenate and acrylates/dimethiconol acrylate copolymer are also being used in cosmetic products.

The CIR Expert Panel has reviewed the safety of similar chemicals, dimethicone and amodimethicone, in cosmetics and concluded that both are safe as used in cosmetic products. Excerpts from the summary and discussion in this safety assessment are included. Cyclotetrasiloxane (D₄) is listed as an impurity of dimethicone and dimethiconol/silsesquioxane copolymer emulsions and D₄ and cyclopentasiloxane (D₅) are listed as impurities of materials containing dimethyl siloxane, hydroxy-terminated (CAS No. 70131-67-8) that were tested in studies included in this safety assessment. The CIR Expert Panel has reviewed the safety of cyclomethicone, cyclotetrasiloxane, cyclopentasiloxane, cyclohexasiloxane, and cycloheptasiloxane in personal care products and concluded that these ingredients are safe in the present practices of use and concentration.

Most of the toxicity data included in this safety assessment are related to α,ω-dihydroxydimethylpolysiloxanes associated with CAS No. 70131-67-8, from Dow Corning. These hydroxy-terminated dimethyl siloxane (silicone) polymers are often listed in the CAS Registry and various literature references as siloxanes and silicones, dimethyl, hydroxy-terminated; or dimethoxy silicone/silane, hydroxy-terminated. The data herein refers
specifically to Dow Corning chemicals associated with the CAS No. 70131-67-8 at concentrations of ≥ 95%.
Siloxanes and silicones, dimethyl, hydroxy-terminated and CAS No. 70131-67-8 are listed among the other
chemical names/identification numbers for dimethiconol in the *International Cosmetic Ingredient Dictionary and
Handbook*; however, the name dimethiconol is not mentioned in any of the toxicity studies. Additionally, in the
Chemical Abstracts Service (CAS) Registry, the name dimethiconol is associated with 2 CAS numbers, 70131-67-8
and 31692-79-2; both CAS Registry files describe hydroxy-terminated dimethyl siloxane.

**CHEMISTRY**

**DEFINITION AND STRUCTURE**

Chemical definitions, other chemical names, and cosmetic ingredient functions for the ingredients reviewed
in this safety assessment are included in Table 1.3 The ingredient moieties that have been reviewed by the CIR
Expert Panel are also identified. Because the dimethiconol fatty acid (FA) moieties are of botanical origin by
definition, information on the composition of oil/butter sources of these FAs is included in Table 2. Chemical
structures for dimethiconol4 and its representative siloxanes are included in Figure 1A. The chemical structures for
3 dimethiconol polymers are included in Figure 1B.

Data provided by the Personal Care Products Council5 indicate that dimethiconol stearate and
dimethiconol beeswax are supplied at approximately 100% active. Similar information on the remaining ingredients
included in this review were not provided.

**CHEMICAL AND PHYSICAL PROPERTIES**

Dimethiconol and the copolymers have a reactive hydroxyl group on the terminal portion of the molecule.
The hydroxyl group is bonded directly to the silicon atom in a silicon-oxygen bond. These compounds condense,
under acid or alkaline catalysis, and also undergo ethoxylation. When these compounds undergo condensation
reactions in the presence of an acid or base, the molecular weight is increased (i.e., an increase in the n value) and
water is released.6

In addition to definition of dimethiconol/silsesquioxane copolymer provided in Table 1, the Silicones
Environmental, Health and Safety Council of North America (SEHSC) defines dimethiconol/silsesquioxane as the
product of a condensation reaction between dimethiconol and methyl trimethoxysilane and defines silsesquioxanes
as siloxane polymers that contain silicon atoms bonded to 3 other silicon atoms via siloxane bonds.7 According to
the SEHSC, the SiOH groups that terminate the siloxane polymer chains in dimethiconol are reactive under certain
circumstances. One common reaction is a condensation reaction with alkoxy-terminated siloxanes and alkoxy
silanes. In this reaction the SiOH groups react with the alkoxy groups to form a new siloxane bond (SiOSi) with the
release of the corresponding alcohol. So, for dimethiconol/silsesquioxane, the dimethiconol polymer reacts with the
m ethoxy groups on methyl trimethoxysilane, releasing methanol and forming new siloxane bonds. Since there are
three methoxy groups on this silane, the reaction produces a three-dimensional siloxane polymer network in which
dimethyl siloxane polymers link together silsesquioxane units.

The limited available data on the properties of dimethiconol, dimethiconol beeswax, dimethiconol
behenate, and dimethiconol/silsesquioxane copolymer (5%) and dimethiconol (20%) in anionic surfactant emulsion,
are included Table 3; octanol-water partition coefficients on these compounds are not included. Data on the
remaining compounds reviewed in this safety assessment were not found. However, properties/composition data on
Dow Corning materials and other materials that are considered by the silicones industry to represent dimethiconol
are included in Table 4.8 Table 5 contains data on the composition of materials that contain dimethyl siloxane,
hydroxy-terminated (CAS No. 70131-67-8).9 These data (Table 5) were provided by the SEHSC because the
materials included are components of test materials evaluated in various toxicity tests included in this safety
assessment.

**ANALYTICAL METHODS**

Dimethiconol has been analyzed via infrared spectroscopy.10 The same method has been used to analyze
dimethiconol (60%) in anionic surfactant emulsions11 and dimethiconol/silsesquioxane copolymer (5%) and
dimethiconol (20%) in anionic surfactant emulsions.12
UV ABSORPTION

UV absorption data (spectra not provided) on the following Dow silicone products were provided by the Silicones Environmental Health and Safety Council of North America (SEHSC): Dow Corning® 9564 Silicone Elstomer Blend, Dow Corning® 1501 Fluid, Dow Corning® 1503 Fluid, and Dow Corning® Q1-3563. Of these 4 materials, only Dow Corning® 9564 Silicone Elstomer Blend and Dow Corning® 1501 Fluid are registered under the INCI name Dimethiconol. Composition data on each of the 4 materials are included in Table 5. UV absorbance was determined by spreading the silicone products onto a quartz plate and then testing each using a UV analyzer (LabSphere model UV 1000S). The samples were applied to the quartz plate to give an average of 2 mg of sample per square centimeter. The UV analyzer illuminated the sample on the quartz plate and measured absorbance after the UV radiation passed through the sample. A total of fourteen measurements were made for each product and the results were averaged. UV absorbance curves were produced and an attenuation factor (SPF) was calculated for the UVB portion of the UV radiation. An SPF of 1.0 was defined as no significant absorption of UVB radiation. Results are included below.

An SPF average of 1.07 was calculated for Dow Corning® 9564 Silicone Elstomer Blend, and this result indicated that between 6 and 7% of the UVB radiation was absorbed by this sample. However, based on the small amount of dimethiconol in this blend and the results obtained for the other samples, it was determined that there was no basis for concluding that dimethiconol was absorbing significant amounts of UVB or UVA radiation. A lower SPF average of 1.01 was calculated for Dow Corning® 1501 Fluid, indicating that ~ 1% of the UVB radiation was absorbed by the sample. Detector noise was thought to have contributed to this finding. Absorbance in the UVA region of the spectrum was very close to zero.

The SPF average of 0.99 reported for Dow Corning® 1503 Fluid was considered due to detector noise, and, similarly, absorbance in the UVA region was very close to zero. The lowest SPF average (0.98), also considered due to detector noise, was reported for Dow Corning® Q1-3563. This result indicated that the blank (quartz plate only) absorbed more UVB than the plate with the sample, which was not considered possible. It was concluded that Dow Corning® Q1-3563 was essentially transparent to UVB radiation. Absorbance in the UVA region was very close to zero.

USE

PURPOSE IN COSMETICS

Most of the ingredients reviewed in this safety assessment function either as a skin conditioning agent or hair conditioning agent in personal care products (Table 1).

SCOPE AND EXTENT OF USE IN COSMETICS

According to information supplied to the Food and Drug Administration (FDA) by industry as part of the Voluntary Cosmetic Registration Program (VCRP) in 2010, the following ingredients are being used in personal care products: dimethiconol (935 products), dimethiconol arginine (4 products), dimethiconol beeswax (13 products), dimethiconol cysteine (6 products), dimethiconol meadowfoamate (9 products), dimethiconol methionine (4 products), dimethiconol panthenol (6 products), dimethiconol stearate (9 products), dimethiconol/silsesquioxane copolymer (2 products), and trimethylsiloxy-silicate/dimethiconol crosspolymer (6 products). These data are summarized in Table 6. Independent of these data, the results of a survey of current ingredient use concentrations that was conducted by the Personal Care Products Council in 2010 are also summarized in Table 6. For example, dimethiconol is used in 55 of the 1,744 body and hand creams, lotions, and powders reported to the VCRP, and results from the separate industry survey indicate use of this ingredient at concentrations ranging from 0.004% to 36% in these products. In other cases, e.g. dimethiconol arginine, uses are reported to the VCRP, but use concentration data are not available.

Current use concentration data from the Personal Care Products Council also indicate that, while not reported to the VCRP, the following ingredients are also being used in cosmetic products: dimethiconol behenate and acrylates/dimethiconol acrylate copolymer.
The use of amodimethiconol in 21 personal care products is also being reported to the FDA; however, amodimethiconol is not listed in the *International Cosmetic Ingredient Dictionary and Handbook* and data on this ingredient were not found in the published literature. Amodimethiconol is not included in this assessment.

Personal care products containing these ingredients may be applied to the skin, nails, or hair, or, incidentally, may come in contact with the eyes and mucous membranes. Products containing these ingredients may be applied as frequently as several times per day and may come in contact with the skin, nails, or hair for variable periods following application. Daily or occasional use may extend over many years.

Dimethiconol cysteine, dimethiconol methionine, and dimethiconol panthenol are used in hair sprays, and effects on the lungs that may be induced by aerosolized products containing this ingredient are of concern.

The aerosol properties that determine deposition in the respiratory system are particle size and density. The parameter most closely associated with deposition is the aerodynamic diameter, $d_a$, defined as the diameter of a sphere of unit density possessing the same terminal settling velocity as the particle in question. In humans, particles with an aerodynamic diameter of $\leq 10\mu m$ are respirable. Particles with a $d_a$ from 0.1 - 10µm settle in the upper respiratory tract and particles with a $d_a < 0.1 \mu m$ settle in the lower respiratory tract.

Particle diameters of 60-80 µm and $\geq 80 \mu m$ have been reported for anhydrous hair sprays and pump hairsprays, respectively. In practice, aerosols should have at least 99% of their particle diameters in the 10 – 110 µm range and the mean particle diameter in a typical aerosol spray has been reported as ~38 µm. Therefore, most aerosol particles are deposited in the nasopharyngeal region and are not respirable.

**NONCOSMETIC USE**

The insecticidal activity of dimethoxy silicone/silane, hydroxy-terminated has been reported.

**ABSORPTION, DISTRIBUTION, METABOLISM AND EXCRETION**

Information on absorption, distribution, metabolism and excretion of the ingredients reviewed in this safety assessment was not found.

**ANIMAL TOXICOLOGY**

The following data are included in this section: acute inhalation toxicity, acute oral toxicity, acute dermal toxicity, ocular irritation, skin and mucous membrane irritation, skin sensitization, and chronic toxicity/tumorigenicity. Some of the studies (unpublished data summaries) were provided by the Silicones Environmental, Health and Safety Council of North America (SEHSC), and all of the SEHSC studies are on chemicals that contain $\geq 95\%$ CAS No. 70131-67-8 (polysiloxanes, di-Me, hydroxy-terminated). However, in the Chemical Abstract Service’s Registry database, CAS No. 31692-79-2, but not CAS No. 70131-67-8, is listed as the CAS No. for dimethiconol (dihydroxy polydimethylsiloxane).

The published literature was not found to contain short-term toxicity, subchronic toxicity, reproductive toxicity, or phototoxicity/photosensitization data on the ingredients reviewed in this safety assessment.

**ACUTE INHALATION TOXICITY**

The acute inhalation toxicity of a mixture containing dimethoxy silicone/silane, hydroxy-terminated (80%) and 1-propamine, 3-((trimethoxysilyl)-N-(3-trimethoxysilyl)propyl (20%) was evaluated using groups of 10 Hilltop-Wistar rats (5 males, 5 females/group). The animals were exposed to vapor substantially saturated with the test material for 6 hours. None of the animals died, and neither signs of toxicity nor remarkable necropsy findings were observed.
**ACUTE ORAL TOXICITY**

The following LD50s were reported in acute oral toxicity studies involving rats: mixture containing 80% dimethoxy silicone/silane, hydroxy-terminated (LD50 > 16.0 ml/kg, suspension containing ≥ 95% polysiloxanes, di-Me, hydroxy-terminated [20% in corn oil] (LD50 > 2 g/kg), and polymer FD80 (LD50 > 2009 mg/kg).

The acute oral toxicity of a mixture containing dimethoxy silicone/silane, hydroxy-terminated (80%) and 1-propamine, 3-(trimethoxysilyl)-N-(3-trimethoxysilyl propyl (20%) was evaluated using groups of 10 Hilltop-Wistar albino rats (5 males, 5 females/group). The test substance was administered by stomach tube up to a dose of 16.0 ml/kg. None of the animals died and there were no signs of toxicity. Mottled lungs (red or pink and dark red) were noted at necropsy. The LD50 was > 16.0 ml/kg.

An acute oral toxicity study summary on a suspension containing Dow Corning® 60,000CSt, NO CO-SOLVENT in corn oil (20% w/v) (containing ≥ 95% polysiloxanes, di-Me, hydroxy-terminated) was provided by Dow Corning Corporation. A single dose of the test substance (2 g/kg body weight) was administered to 10 fasted Sprague-Dawley rats (6 weeks old) by gavage. None of the animals died and there were no overt signs of toxicity during the 14-day observation period. Lesions were not observed at gross necropsy. The LD50 was > 2 g/kg body weight.

The acute oral toxicity of polymer FD 80 was evaluated using Sprague-Dawley rats (5 males, 5 females). The test substance was administered by gavage at a dose of 2009 mg/kg, and necropsy was performed after day 14. None of the animals died and there was no evidence of pathological clinical signs. The LD50 was > 2009 mg/kg.

Dimethiconol Stearate

The acute oral toxicity of dimethiconol stearate was evaluated using 10 fasted, Wistar-derived albino rats (5 males, 5 females). Following dosing by gavage (dose = 5 g/kg body weight), feed and water were provided ad libitum. Dosing was followed by a 14-day observation period. Dimethiconol stearate was classified as non-toxic (LD50 > 5 g/kg).

**ACUTE DERMAL TOXICITY**

While acute dermal toxicity studies have either local irritation reactions or not, in all cases the LD50 values were >2g/kg, indicating low acute dermal toxicity. The LD50 values were for mixtures containing up to 95% dimethiconol.

The acute dermal toxicity of a mixture containing dimethoxy silicone/silane, hydroxy-terminated (80%) and 1-propamine, 3-(trimethoxysilyl)-N-(3-trimethoxysilyl propyl (20%) was evaluated using groups of 8 New Zealand White rabbits (4 males, 4 females/group). The test substance was applied (doses up to 16.0 ml/kg; 24 h period) under impervious plastic sheeting to clipped, intact skin of the trunk. Skin irritation was not observed. One male rabbit and 2 female rabbits died (all at 16 ml/kg dose). Mottled lungs (males) and mottled livers/lungs (females) were noted at necropsy. There were no remarkable necropsy findings in surviving animals. LD50s were > 16.0 ml/kg for males and females.

In another study, the acute dermal toxicity of siloxanes and silicones, dimethyl, hydroxy-terminated (22 wt. %) in Dow Corning® 2-1845 microemulsion was evaluated using 12 (6 males, 6 females) New Zealand White rabbits of the Hra:(NZW)SPF strain. The undiluted test substance was applied (under an occlusive wrap) to clipped dorsal skin at a dose of 2,000 mg/kg (dose volume = 1.9741 ml/kg) for approximately 24 hours. The following reactions (all test substance-related) were observed at the application site: erythema and desquamation (6 rabbits), erythema and edema (1 rabbit), and desquamation (1 rabbit). None of the animals died during the 14-day study, and there were no test substance-related effects on body weight gain. Macroscopic findings were not observed at necropsy. It was concluded that the Dow Corning® 2-1845 microemulsion was non-toxic (LD50 > 2,000 mg/kg).

An acute dermal toxicity study summary on Dow Corning® 60,000CSt, NO CO-SOLVENT was provided by Dow Corning Corporation. The test substance was applied to the skin of each of 10 (5 males, 5 females) New Zealand white rabbits for 24 h. Erythema was observed at application sites, having cleared by day 7. None of the animals died and there were no signs of systemic toxicity during the 14-day observation period. An acute dermal LD50 of > 2 g/kg body weight was reported.
The acute dermal toxicity of polymer FD 80 was evaluated using Sprague-Dawley rats (5 males, 5 females). The test substance was applied to the skin at a dose of 2009 mg/kg, and necropsy was performed after day 14. None of the animals died and there was no evidence of pathological clinical signs. The LD50 was > 2009 mg/kg.31

SUBCHRONIC ORAL TOXICITY

Neither mortalities nor test substance-related findings were reported in a subchronic oral study in which rabbits were fed a basal diet containing 0.05% Dow Corning special polymer (polymerized siloxane) for 8 months.

In an 8-month feeding study,32 6 of 18 rabbits were fed 0.05% Dow Corning special polymer 5-26-64, a polymerized siloxane containing siloxanes and silicones, dimethyl, hydroxy-terminated, in a basal diet. The remaining 12 rabbits comprised the control group (basal diet only). Both groups had equal numbers of males and females. None of the animals died during the feeding period, and all animals were killed after 8 months.

In both groups, signs of nasal/ocular irritation included nasal exudates, sneezing, and iridial inflammation for 1 to 2 h after feeding. There were no significant changes in weight (increases or decreases) in either group, and hematologic determinations revealed no abnormalities. Elevated serum cholesterol values were not test substance-related, and biochemical determinations indicated no effects on liver or biliary function. Additionally, urinalyses revealed no significant findings. At necropsy, there was no evidence of treatment-related effects in the abdominal viscera. However, all treated males had gross changes that were associated with the testis, including one with a prostate described as soft and practically gelatinous. Microscopic findings in the liver and kidneys of treated and untreated rabbits did not differ significantly. Incomplete testicular development was noted in 2 treated males. This finding is frequently observed in laboratory rabbits, although it was not observed in the study’s concurrent control males. It was concluded that there was no evidence that test substance administration caused any adverse effects in rabbits.32

It should be noted that Dow Corning has determined that the preceding study is scientifically invalid based on the following rationale: “No ability to determine the actual dose level that the rabbits received. No discussion on test article concentration, stability, homogeneity. We do not feel that this study should be used in health and safety assessments and do not want the general public using it because of limitations.”7

OCULAR IRRITATION

Some studies report an absence of ocular toxicity, but others demonstrate ocular irritation and/or corneal injury. In the latter studies, reactions had cleared by 72 h or 21 days-post-instillation. Dimethiconol stearate was classified as non-irritating to the eyes of rabbits.

The ocular irritation potential of an emulsion (Dow Corning® 35 emulsion) containing siloxanes and silicones, dimethyl, hydroxy-terminated at a concentration of 13% and another emulsion (Dow Corning® 22 emulsion) containing siloxanes and silicones, dimethyl, hydroxy-terminated at a concentration of 38% was evaluated using 2 groups of 10 albino rabbits (1 per test substance).33 Two drops of either emulsion were instilled into the right conjunctival sac, followed by rinsing. Two drops were also instilled into the left eye (not rinsed). Following instillation, the eyes were observed for conjunctival and corneal responses for up to 48 h, or as long as 9 days post-instillation, if warranted. The Dow Corning® 35 emulsion did not induce a significant ocular response in rinsed or unrinsed eyes. The Dow Corning® 22 emulsion elicited slight, transient conjunctivitis only in the unrinsed eye and appeared to elicit appreciable pain.

Dow Corning has determined that the preceding study is scientifically invalid based on the following rationale: “There was no control eye for comparison. Both eyes were treated. Grading scale not detailed. This testing was screening low level assessment for industrial hazard potential. The method is not robust enough to satisfy current health safety testing standards.”

The ocular irritation potential of a mixture35 containing dimethoxy silicone/silane, hydroxy-terminated (80%) and 1-propanamine, 3-(trimethoxysilyl)-N-(3-trimethoxysilyl propyl) (20%) was evaluated using groups of 6 New Zealand White rabbits (3 males, 3 females). The test substance was instilled into the lower conjunctival sac of one eye per animal per group at volumes up to 0.1 ml. Six eyes were dosed per test volume. Dose volumes of
0.005, 0.01, and 0.1 ml induced moderate, persistent corneal and conjunctival injury (in all rabbits per group). Moderate iritis was also observed at a dose volume of 0.1 ml. All reactions had cleared by day 21 post-instillation.

An ocular irritation study summary on Dow Corning® 60,000CSt, NO CO-SOLVENT was provided by Dow Corning Corporation. The undiluted test substance was instilled (0.1 ml) into the right eye of each of 3 female New Zealand white rabbits (3 to 4 months old). Conjunctival erythema, chemosis, and discharge were observed in all rabbits, having cleared by 72 h post-instillation. Lesions of the cornea or iris were not observed. The test substance was classified as a non-irritant.

The SEHSC also provided an ocular irritation study summary on Dow Corning® PA Fluid. Direct contact with the test substance resulted in very slight redness in the unrinsed rabbit eye through 48h. The rinsed eye was clear at 24 h post-exposure.

**Dimethiconol Stearate**

The ocular irritation potential of dimethiconol stearate was evaluated using 6 healthy, young adult New Zealand albino rabbits. The test substance (0.1ml) was instilled into the one eye of each animal; contralateral eyes served as controls. Ocular lesions were evaluated according to the Draize scale (0 to 110). An ocular irritation score of 0 was reported for each rabbit, and dimethiconol stearate was classified as nonirritating to the eyes of rabbits.

**MUCOUS MEMBRANE IRRITATION**

The following materials were non-irritating to mucosal membranes: Dow Corning® 4-2797 and 3 Dow Corning materials containing 82.1% siloxanes and silicones, dimethyl, hydroxy-terminated.

The mucous membrane irritation potential of 3 Dow Corning materials (TX-102A, TX-102B, and TX-102C) containing 82.1% siloxanes and silicones, dimethyl, hydroxy-terminated was evaluated using 6 dogs (2 dogs per test material). Each material (amounts ranging from 8 to 18 g) was maintained in contact with the hard palate for 7 h, using an aluminum mold previously shaped to the contour of the roof of the mouth. At the end of the contact period, the oral cavity was examined for evidence of irritation or lesions. The animals were killed on day 8, and punch biopsy specimens of the hard palate were obtained and examined microscopically. Test materials TX-102A and TX-102B did not induce irritation of the hard palate. Test material TX-102-C induced slight edema of the hard palate in both dogs; the edema had cleared by the end of the 8-day observation period. Results of microscopic examinations were not reported. However, according to the SEHSC, microscopic examinations were considered normal for all samples in this study.

A mucous membrane irritation study on Dow Corning® 4-2797 (X7-9192), dimethylsiloxane hydroxy-terminated fluid was provided by Dow Corning Corporation. Following application of the test substance (0.5 g) to the vaginal mucosa of each of 6 New Zealand white rabbits (10 to 12 weeks old), there were no signs of irritation, weight loss, or clinical signs of toxicity during the 72-h observation period.

**SKIN IRRITATION AND SENSITIZATION**

The following tested ingredients were non-irritating in studies involving rabbits: a mixture containing dimethoxy silicone/silane, hydroxy-terminated (80%) and 1-propanamine, 3-(trimethoxysilyl)-N-(3-trimethoxysilyl propyl) (20%); Dow Corning® 60,000CSt, NO CO-SOLVENT; and dimethiconol stearate. The following materials were not irritants or sensitizers: Dow Corning® X7-9192, dimethyl siloxane, hydroxy-terminated (non-irritant at concentrations up to 100%; non-sensitizer at 5%); Dow Corning® 60,000CSt, NO CO-SOLVENT in Dow Corning® 360 Medical Fluid (non-sensitizer at 5% w/v), and polymer FD 80 (non-irritant at concentrations up to 50%; non-sensitizer undiluted).

The skin irritation potential of a mixture containing dimethoxy silicone/silane, hydroxy-terminated (80%) and 1-propanamine, 3-(trimethoxysilyl)-N-(3-trimethoxysilyl propyl) (20%) was evaluated using 6 New Zealand White rabbits (3 males, 3 females). The test substance was applied (0.5 ml, 4-h application) under a gauze patch to clipped, intact skin. The patch was covered with impervious sheeting. Reactions were scored according to the
following Draize scale: 0 (no erythema) to 4 (severe erythema). Skin irritation was not observed in any of the rabbits.

A skin irritation study on Dow Corning® 60,000CSt, NO CO-SOLVENT was provided by Dow Corning Corporation. The undiluted test substance (0.5 g) was applied to clipped/shaved skin of the back of each of 3 female New Zealand white rabbits (3 to 4 months old). The application site was covered with a cotton gauze patch secured with porous tape for 4 h. Reactions were scored for up to 72 h post-removal. None of the rabbits had signs of dermal irritation or corrosivity, and the test substance was classified as a non-irritant.

A skin irritation and sensitization study on Dow Corning® X7-9192, dimethyl siloxane, hydroxy-terminated was provided by Dow Corning Corporation. In the primary irritation test, the test substance (0.1 ml in H2O, under Finn chamber) was applied to the skin of each of 4 young adult guinea pigs. Concentrations ranging from 25% to 100% were applied and reactions were scored for up to 72 h post-application. Skin irritation was not observed over the range of test concentrations. Skin sensitization test results are included below.

The sensitization potential of the test substance (5% in water emulsion) was evaluated in the maximization test using groups of 10 (5 males, 5 females) guinea pigs. Intradermal injections (0.1 ml) of the test substance were administered on day 0. On day 7 of induction, the test substance was applied under an occlusive patch for 48 h. During the challenge phase, initiated on day 21, the test substance was applied under an occlusive patch for 24 h. Reactions were scored on days 23 and 24. Sodium chloride (0.9%) and DNCB (0.1%) served as vehicle and positive controls, respectively. The test substance did not induce sensitization.

Skin sensitization data on Dow Corning® 60,000CSt, NO CO-SOLVENT in Dow Corning® 360 Medical Fluid (5% w/v) were provided by Dow Corning Corporation. The maximization test involved the following groups of male Hartley guinea pigs (4 weeks old): 20 test, 10 vehicle controls (Dow Corning® 360 Medical Fluid), and 10 positive controls (DNCB in propylene glycol, 1% w/v). The first induction involved intradermal injections (0.1 ml per injection) of the undiluted test substance, vehicle control, and positive control in the respective groups. The second induction involved the 48 h application of a 2 x 4 cm pad saturated with each substance per group. At 2 weeks after the last induction, test animals were challenged with the undiluted test substance (0.3 ml), and both control groups were also challenged with respective materials. Positive responses were not observed in test or vehicle control animals, and the test substance was not considered a skin sensitizer.

Prior to the following maximization test, 3 preliminary studies (4 guinea pigs per study) were conducted to evaluate the skin irritation potential of polymer FD 80. In study #1 (for induction), moderate irritation was observed in 4 guinea pigs at 24 h and 48 h after intradermal injection with 50% polymer FD 80 in liquid paraffin, and weak to moderate irritation was observed in these animals after injection at a concentration of 10%. In another study (study #2, for induction), undiluted polymer FD 80 (0.5 ml) and at a concentration of 50% in liquid paraffin were each applied to an 8 cm² area of skin for 48 h using occlusive patches. A weak irritant response was observed in one guinea pig patch tested with 50% FD 80 in study #2. In the final preliminary study (study #3, for challenge), skin irritation was not observed following a 24 h or 48 h occlusive patch application of undiluted or 50% FD 80 in liquid paraffin to a 4 cm² area of skin. It was concluded that polymer FD 80, as supplied, was a non-irritant.

The skin sensitization potential of polymer FD 80 was evaluated in the maximization test using 2 groups of 20 Dunkin-Hartley albino guinea pigs, one of which was the control group. The induction phase consisted of 0.1 ml intradermal injections of 10% or 20% polymer FD 80 in liquid paraffin and 48 h occlusive patch applications of undiluted polymer FD 80 (0.5 ml) to an 8 cm² area of skin. The challenge phase involved a 24 h occlusive patch application of undiluted polymer FD 80 (0.5 ml) to a 4 cm² area of skin. It was concluded that polymer FD 80 did not induce sensitization. Sensitization reactions also were not observed in control guinea pigs treated with liquid paraffin.

Dimethiconol Stearate

The skin irritation potential of dimethiconol stearate was evaluated using 6 healthy, New Zealand albino rabbits. The test substance (0.5 g under a 2.5 cm² patch) was applied to intact and abraded skin sites on the trunk, clipped free of hair. The entire trunk was wrapped with a rubberized elastic cloth during the 24 h application period. Reactions were scored at 24 h and 72 h according to the following scales: 0 (no erythema) to 4 (severe erythema to
slight eschar formation) and 0 (no edema) to 4 (extreme edema). Skin irritation was not observed in any of the
animals tested (primary irritation index [PII] = 0).

GENOTOXICITY

The following tested ingredients were not genotoxic in bacterial assays: uncured and cured Dow Corning®
X3-5040 sealant containing approximately 75% siloxanes and silicones, dimethyl, hydroxy-terminated; a mixture
containing siloxanes and silicones, dimethyl, hydroxy-terminated; Dow Corning® Q4-2797, dimethylsiloxane,
hydroxy-terminated fluid; and Dow Corning® 60,000CST NO Co-Solvent.

In the Ames spot plate test and overlay plate test,44 the mutagenicity of uncured and cured Dow Corning®
X3-5040 sealant containing approximately 75% siloxanes and silicones, dimethyl, hydroxy-terminated was
evaluated using the following Salmonella typhimurium strains with and without metabolic activation: TA98, TA100,
TA1535, TA1537, and TA1538. The test substance was extracted with dimethylsulfoxide and doses up to 500
μl/plate were tested. The positive control for activation assays was 2-anthramine, and the nonactivation assay
positive controls were sodium azide, 9-amino acridine, and 2-nitrofluorene. Dimethylsulfoxide was used as the
solvent control. In both the spot and overlay plate tests, results for the test substance and solvent control were
negative in all strains, both with and without metabolic activation, and the positive controls were mutagenic. The
test material was considered nonmutagenic.

In another Ames plate test,45 the mutagenicity of a mixture containing siloxanes and silicones, dimethyl,
hydroxy-terminated (concentration not stated; solvent, acetone) was evaluated using the following Salmonella
typhimurium strains with and without metabolic activation: TA98, TA100, TA1535, TA1537, and TA1538.
Concentrations up to 150 μl/plate were tested. The positive control for activation assays was 2-anthramine in
dimethylsulfoxide, and the nonactivation assay positive controls were: sodium azide, 2-nitrofluorene, and
quinacrine mustard. Results for the test substance were negative in all strains, both with and without metabolic
activation, and the positive controls were mutagenic. The test substance was considered nonmutagenic.

A mutagenicity study on Dow Corning® Q4-2797, dimethylsiloxane, hydroxy-terminated fluid was
provided by the Dow Corning Corporation.46 In the Ames test, the mutagenicity of this fluid (in DMSO, doses up
to 5,000 μg/plate) was evaluated using the following Salmonella typhimurium strains with and without metabolic activation:
Salmonella typhimurium strains TA97, TA98, TA100, and TA 1535, and Escherichia coli strain WP2. The
following positive controls were used: sodium azide, 4-nitroquinoline-N-oxide, daunomycin, and N-methyl-N-nitro-
nitrosoguanidine (with metabolic activation) and 2-anthramine and 2-aminofluorene (without metabolic
activation). The test substance was not mutagenic to any of the strains tested. All positive controls were mutagenic.

A mutagenicity study on Dow Corning® 60,000CST NO Co-Solvent was also provided by Dow Corning
Corporation.47 Test substance doses up to 5,000 μg/plate were evaluated in the Ames test using the following
bacterial strains with and without metabolic activation: Salmonella typhimurium strains TA98, TA100, TA1535,
TA1537 and E. coli strains WP2uvrA and WP2uvrA (pKM101). The following positive controls were used: 2-
aminonaphthacene (with metabolic activation), and sodium azide, 2-nitrofluorene, 9-aminoacridine, and methyl
methanesulfonate (without metabolic activation). The test substance was not mutagenic to any of the strains tested.
All positive controls were mutagenic.

CHRONIC TOXICITY/TUMORIGENICITY

The following materials were neither toxic or tumorigenic up to 36 months post-implantation in pure-bred
Beagle dogs: siloxanes and silicones, dimethyl, hydroxy-terminated (68%) in uncured DC 386; siloxanes and
silicones, dimethyl, hydroxy-terminated (72%) in uncured DC 382; siloxanes and silicones, dimethyl, hydroxy-
terminated (96%) in uncured DC 5392; and siloxanes and silicones, dimethyl, hydroxy-terminated (80%) in
uncured Medical Adhesive Type A. Negative results were reported for Dow Corning special polymer (contains
siloxanes and silicones, dimethyl, hydroxy-terminated (0.05% in diet) in a 1-year oral feeding study involving albino
weanling rats.

Chronic implantation studies of polysiloxanes were conducted using 38 pure-bred Beagle dogs (~ 5 to 7
months old).48 The 4 implanted materials (implant mass not stated) were defined as follows: siloxanes and
silicones, dimethyl, hydroxy-terminated (68%) in uncured DC 386; siloxanes and silicones, dimethyl, hydroxy-terminated (72%) in uncured DC 382; siloxanes and silicones, dimethyl, hydroxy-terminated (96%) in uncured DC 5392; and siloxanes and silicones, dimethyl, hydroxy-terminated (80%) in uncured Medical Adhesive Type A. Except for uncured Medical Adhesive Type A, the remaining compositions of materials tested (i.e., uncured DC 382 and DC 386) are unknown. The implants (intramuscular, intraperitoneal, and subcutaneous) were removed at intervals of 3, 9, 24, and 36 months. Neither gross nor microscopic findings revealed a pattern of polymer-induced systemic toxicity. The materials tested also did not induce any untoward chronic tissue reactions, and there was no evidence of tumorigenesis over a 3-year testing period.

A chronic feeding study on Dow Corning special polymer was conducted using 30 albino weanling rats. Regarding the composition of the polymer tested, the only chemical substance listed was siloxanes and silicones, dimethyl, hydroxy-terminated. The test group consisted of 10 rats (5 males, 5 females), and these animals were fed a basal diet consisting of 0.05% Dow Corning special polymer for 1 year. The control group (10 males, 10 females) was fed basal diet only. The only reported deaths were 2 rats in the control group. There were no test substance-related effects on hematological or clinical chemistry values. Gross evidence of severe pulmonary disease was noted at necropsy. Inflammatory changes in the lungs or tubular degenerative changes in the kidneys were fairly common in test and control groups, and were not considered test substance-related. It was concluded that administration of the test substance did not induce adverse effects in rats.

Dow Corning has determined that the preceding study is scientifically invalid based on the following rationale: “No ability to determine the actual dose level that the rabbits [rats] received. No discussion on test article concentration, stability, homogeneity. We do not feel that this study should be used in health and safety assessments and do not want the general public using it because of limitations.”

CLINICAL ASSESSMENT OF SAFETY

SKIN IRRITATION AND SENSITIZATION

Neither skin irritation nor sensitization was reported in patch tests or RIPTs involving the following ingredients/products: body lotion containing 1.125% dimethiconol; lip product containing 0.5% dimethiconol behenate; and undiluted dimethiconol beeswax.

Dimethiconol

In an RIPT, the skin irritation and sensitization potential of a body lotion containing 1.125% dimethiconol (0.2 g per 1” x 1” patch) was evaluated using 104 subjects ranging in age from 17 to 74 years. The test substance was applied to the upper back of each subject for 24 h, using a semicocclusive patch, for a total of 9 induction patch applications. A 24-h challenge patch was applied at the end of a 2-week non-treatment period. Induction and challenge reactions were scored according to the following scale: 0 (no visible skin reaction) to 4 (severe erythema, possible edema, vesiculation, bullae and/or ulceration). There were no visible skin reactions in any of the subjects, and it was concluded that the body lotion did not indicate a potential for dermal irritation or allergic contact sensitization.

Dimethiconol Behenate

In another RIPT (occlusive patches, similar procedure), the skin irritation and sensitization potential of lip product containing 0.5% dimethiconol behenate was evaluated using 50 subjects ranging in age from 18 to 70 years. The dose per cm² was not stated. There were no visible skin reactions in any of the subjects, and it was concluded that the lip product did not demonstrate a potential for eliciting dermal irritation or sensitization.

Dimethiconol Beeswax

The skin sensitization potential of a test product identified as undiluted dimethiconol beeswax was evaluated in an RIPT using 102 subjects (29 males, 73 females; > 18 years old) with no significant active skin pathology. During induction, the test material was applied to the back (0.025 g/cm² skin, 8 mm Finn chambers) of each subject, for a total of 10 occlusive patch applications. Each chamber remained in place for 48 h. Following a 12-day non-treatment period, an occlusive challenge patch was applied for 48 h to a new site on the back of each
subject. Reactions were scored at 48 h and 96 h post-application according to the following scale: 0 (no reaction) to 4 (erythema, edema, and bullae). Dimethiconol beeswax did not induce skin irritation or sensitization in this study.

**SUMMARY OF INFORMATION FROM EARLIER CIR SAFETY ASSESSMENT**

Most of the data reviewed in the CIR safety assessment on dimethicone, amodimethicone, and related compounds are studies on dimethicone. These ingredients were found to be safe as used in cosmetics, with a noted concern in the discussion regarding inhalation exposure. The following text is summarized from the previous CIR safety assessment:

Clinical and animal absorption studies generally reported that dimethicone was not absorbed following oral or dermal exposure. Dimethicone was not acutely toxic following oral exposure (mice, rats, and guinea pigs), and adverse effects were not observed in rats that received up to 10% dimethicone in the diet for 90 days.

The dermal LD50 for dimethicone was > 2 g/kg in rats and rabbits, and no adverse effects were found in rabbits, following short-term dermal dosing with 6% to 79% dimethicone. Most dermal irritation studies classified dimethicone as a minimal irritant. Studies that scored reactions according to the Draize scale reported PIIIs of < 2.8 (with test samples containing 5% to 100% dimethicone). Most ocular irritation studies using rabbits classified dimethicone as a mild to minimal irritant. Dimethicone (tested undiluted and at 79%) was not a sensitizer in 4 assays using mice and guinea pigs. It also was not a sensitizer at a concentration of 5% (in cyclomethicone) in a clinical RIPT using 83 panelists.

Dimethicone was tested in numerous oral-dose (using rats) and dermal-dose (using rats, rabbits, and monkeys) reproductive and developmental toxicity studies. In a few studies, treated males had significantly decreased body weight and/or decreased testes or seminal vesicle weights. Specifically, a significant reduction in the average seminal vesicle to body weight ratio was noted in male rats dosed orally with a dimethicone sample (3.3 ml/kg/day). Absolute testis weight was significantly reduced in male rats dosed dermally with undiluted motor oil (1.5 ml/kg/day) containing an unspecified amount of dimethicone. No treatment-related adverse findings were noted in dosed pregnant females or fetuses. Results for dimethicone were negative in all mutagenicity assays and in both oral (tested at 91%) and dermal (tested at unknown concentration) carcinogenicity assays using mice.

In the discussion of the safety assessment, the CIR Expert Panel did note a concern about inhalation exposure, which was addressed. Specifically, the Panel expects that the manufacturing process for cosmetic formulations in which dimethicone, amodimethicone, and related compounds are found and which may be inhaled would continue to produce particle size distributions that are not significantly respirable.

**SUMMARY**

The following ingredients are reviewed in this safety assessment: dimethiconol, dimethiconol arginine, dimethiconol beeswax, dimethiconol behenate, dimethiconol boraginate, dimethiconol candellilinate, dimethiconol carnauba, dimethiconol cysteine, dimethiconol dhupa butterate, dimethiconol hydroxyxystearate, dimethiconol ililipe butterate, dimethiconol isostearate, dimethiconol kokum butterate, dimethiconol lactate, dimethiconol meadowfoamate, dimethiconol methionine, dimethiconol/methylsilanol/silicate crosspolymer, dimethiconol mohwa butterate, dimethiconol panthenol, dimethiconol sal butterate, dimethiconol/silica crosspolymer, dimethiconol/silsequioxane copolymer, dimethiconol stearate, dimethiconol/stearyl methicone/phenyl trimethicone copolymer, hydrolyzed collagen PG-propyl dimethiconol, isopolyglyceryl-3 dimethiconol, trimethylsiloxyisilicate/dimethiconol crosspolymer, and acrylates/dimethiconol acrylate copolymer. The skin conditioning agent/hair conditioning agent function in personal care products is associated with most of these ingredients.
Of the 28 ingredients that are being reviewed in this safety assessment, the following 10 are reported to the Food and Drug Administration as being used in personal care products: dimethiconol, dimethiconol arginine, dimethiconol beeswax, dimethiconol cysteine, dimethiconol meadowfoamate, dimethiconol methionine, dimethiconol panthenol, dimethiconol stearate, dimethiconol/silsesquioxane copolymer, and trimethylsiloxy silicone/dimethiconol crosspolymer. Based on the results of an industry use concentration survey, the following 2 additional ingredients are also being used: dimethiconol behenate and acrylates/dimethiconol acrylate copolymer.

Dimethiconol is being used in cosmetic products at concentrations ranging from 0.004% to 36%.

Most of the toxicity data included in this safety assessment are on siloxanes and silicones, dimethyl, hydroxy-terminated; dimethoxy silicone/silane, hydroxy-terminated; and Dow Corning materials containing 95% or greater CAS No. 70131-67-8 (polysiloxanes, di-Me, hydroxy-terminated). The CAS number for these chemical names is identified as 70131-67-8 in these studies. Siloxanes and silicones, dimethyl, hydroxy-terminated and CAS No. 70131-67-8 are listed among the other chemical names/identification numbers for dimethiconol in the International Cosmetic Ingredient Dictionary and Handbook.

In an acute inhalation toxicity study, neither deaths nor toxic signs were reported for rats exposed to vapor substantially saturated with a mixture containing dimethoxy silicone/silane, hydroxy-terminated (80%) and 1-propamine, 3-(trimethoxysilyl)-N-(3-trimethoxysiloyl propyl (20%) for 6 h. Similar results were reported for the same mixture in an acute oral toxicity study involving rats (LD50 > 16 ml/kg), for polymer FD 80 (LD50 > 2 g/kg, rats), and for a suspension containing Dow Corning® 60,000CSt, NO CO-SOLVENT in corn oil (20% w/v) (LD50 > 2 g/kg, rats). The latter test substance contains 95% or greater CAS No. 70131-67-8 (polysiloxanes, di-Me, hydroxy-terminated). Dimethiconol Stearate was also classified as non-toxic in an acute oral toxicity study involving rats (LD50 > 5 g/kg).

Following dermal application of a mixture containing dimethoxy silicone/silane, hydroxy-terminated (80%) and 1-propamine, 3-(trimethoxysilyl)-N-(3-trimethoxysiloyl propyl (20%), irritation was not observed at application sites and 3 of 8 rabbits died (LD50 > 16 ml/kg). Both siloxanes and silicones, dimethyl, hydroxy-terminated (22 wt. %) in Dow Corning® 2-1845 microemulsion and Dow Corning® 60,000CSt, NO CO-SOLVENT (contains ≥ 95% polysiloxanes, di-Me, hydroxy-terminated) were non-toxic (LD50 > 2 g/kg) in acute dermal toxicity studies involving rabbits; skin irritation was observed at application sites. Polymer FD 80 was also classified as non-toxic (LD50 > 2 g/kg) in a dermal toxicity study.

Neither mortalities nor test substance-related findings were reported in a subchronic oral study in which rabbits were fed a basal diet containing 0.05% Dow Corning special polymer (polymerized siloxane) for 8 months. It should be noted that Dow Corning has determined that this study is scientifically invalid.

Dow Corning emulsions containing siloxanes and silicones, dimethyl, hydroxy-terminated at concentrations of 13% (Dow Corning® 35 emulsion) and 38% (Dow Corning® 22 emulsion) did not induce a significant ocular response in rabbits. It should be noted that Dow Corning has determined that the study on these 2 emulsions is not scientifically invalid. Transient ocular irritation, not classified as moderate or severe, was observed following the instillation of Dow Corning® 60,000CSt, NO CO-SOLVENT or Dow Corning® PA Fluid (≥ 95% polysiloxanes, di-Me, hydroxy-terminated in both) into the eyes of rabbits. Dimethiconol stearate was classified as nonirritating to the eyes of rabbits. However, a mixture containing dimethoxy silicone/silane, hydroxy-terminated (80%) and 1-propamine, 3-(trimethoxysilyl)-N-(3-trimethoxysiloyl propyl) (20%) induced moderate, persistent conjunctival and corneal injury and iritis in rabbits. This mixture did not induce skin irritation in rabbits.

Both a mixture containing dimethoxy silicone/silane, hydroxy-terminated (80%) and 1-propamine, 3-(trimethoxysilyl)-N-(3-trimethoxysiloyl propyl) (20%) and undiluted Dow Corning®, No Co-Solvent (contains ≥ 95% polysiloxanes, di-Me, hydroxy-terminated) were not irritating to the skin of rabbits. The same was true for dimethiconol stearate (0.5 g applied to skin) in rabbits.
Of the 3 Dow Corning materials (TX-102A, TX-102B, and TX-102C) containing 82.1% siloxanes and silicones, dimethyl, hydroxy-terminated that were maintained in contact with the hard palate of dogs, only one (TX-102) induced irritation (slight edema). Neither signs of vaginal mucosal irritation, weight loss, nor clinical signs of toxicity were observed in rats receiving an application of Dow Corning® 4-2797 (X7-9129), dimethylsiloxane hydroxy-terminated fluid (contains ≥ 95% polysiloxanes, di-Me, hydroxy-terminated) to the vaginal mucosa.

Dow Corning® X7-9129, dimethyl siloxane, hydroxy-terminated (contains ≥ 95% polysiloxanes, di-Me, hydroxy-terminated) was not a skin irritant in guinea pigs patch tested with concentrations up to 100% and, at a concentration of 5% in a water emulsion, also did not induce sensitization in the maximization test. Maximization test results for undiluted polymer FD 80 and Dow Corning® 60,000CSt, NO CO-SOLVENT in Dow Corning® 360 Medical Fluid (5% w/v) were also negative in guinea pigs. This Dow Corning material contains ≥ 95% polysiloxanes, di-Me, hydroxy-terminated.

Negative Ames test results were reported for the following chemicals: uncured and cured Dow Corning® X3-5040 sealant containing ~ 75% siloxanes and silicones, dimethyl, hydroxy-terminated (doses up to 500 µl/plate); a mixture containing siloxanes and silicones, dimethyl, hydroxy-terminated (up to 150 µl/plate); Dow Corning® 4-2797, dimethylsiloxane, hydroxy-terminated fluid (contains ≥ 95% polysiloxanes, di-Me, hydroxy-terminated) (up to 5,000 µg/plate); and Dow Corning® 60,000CST NO Co-Solvent (contains ≥ 95% polysiloxanes, di-Me, hydroxy-terminated) (up to 5,000 µg/plate).

In chronic implantation studies (38 pure-bred Beagle dogs), 4 materials containing siloxanes and silicones, dimethyl, hydroxy-terminated at concentrations of 68%, 72%, 80%, and 96%, respectively, were tested. The materials were removed at various intervals up to 36 months post-implantation, and neither gross nor microscopic findings were indicative of polymer-induced toxicity or tumorigenesis. Neither mortalities nor test-substance-related findings were reported for weanling rats fed a basal diet containing 0.05% Dow Corning special polymer (polymerized siloxane) for 1 year. It should be noted that Dow Corning has determined that this oral feeding study is scientifically invalid.

Negative results were reported in the following RIPTs evaluating skin irritation and sensitization potential: body lotion containing 1.125% dimethiconol (104 subjects), lip product containing 0.5% dimethiconol behenate (50 subjects), and undiluted dimethiconol beeswax (102 subjects).

**DISCUSSION**

The Expert Panel noted the absence of data on reproductive and developmental toxicity and limited tumorigenicity and metabolism data; however, after reviewing molecular weights, the Panel agreed that these ingredients would not be absorbed through the skin, thereby obviating further concern over potential reproductive and developmental toxicity or carcinogenicity.

The potential adverse effects of inhaled aerosols depend on the specific chemical species, the concentration and the duration of the exposure and their site of deposition within the respiratory system. In practice, aerosols should have at least 99% of their particle diameters in the 10 – 110 µm range and the mean particle diameter in a typical aerosol spray has been reported as ~38 µm. Particles with an aerodynamic diameter of ≤ 10µm are respirable. In addition to the negative acute inhalation toxicity data considered in this safety assessment, the Expert Panel determined that dimethiconol cysteine, dimethiconol methionine, and dimethiconol panthenol can be used safely in hair sprays, because the product particle size is not respirable.

Because some of the dimethiconol reaction products reviewed in this safety assessment contain a plant-derived moiety, the Expert Panel expressed concern regarding pesticide residues and heavy metals that may be present in these cosmetic ingredients. They stressed that the cosmetics industry should continue to use the necessary procedures to limit these impurities in the ingredient before blending into cosmetic formulation.
CONCLUSION

The Expert Panel concluded that the following ingredients are safe as cosmetic ingredients in the present practices of use and concentration described in this safety assessment: dimethiconol, dimethiconol arginine, dimethiconol beeswax, dimethiconol behenate, dimethiconol borageate, dimethiconol candelillate, dimethiconol carnaubate, dimethiconol cysteine, dimethiconol dhupa butterate, dimethiconol hydroxystearate, dimethiconol illipe butterate, dimethiconol isostearate, dimethiconol kokum butterate, dimethiconol lactate, dimethiconol meadowfoamate, dimethiconol methionine, dimethiconol mohwa butterate, dimethiconol panthenol, dimethiconol sal butterate, dimethiconol stearate, hydrolyzed collagen PG-propyl dimethiconol, dimethiconol/methylsilanol/silicate crosspolymer, dimethiconol/silica crosspolymer, dimethiconol/silsesquioxane copolymer, dimethiconol/stearyl methicone/phenyl trimethicone copolymer, isopolyglyceryl-3 dimethiconol, trimethylsiloxysilicate/dimethiconol crosspolymer, and acrylates/dimethiconol acrylate copolymer. Were ingredients in this group not in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in the group.
<table>
<thead>
<tr>
<th>Chemical Names</th>
<th>Definition/Other Data</th>
<th>Functions in Cosmetics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimethiconol; dihydroxpolydimethylsiloxane; dimethylsilanediol homopolymer, silanol-terminated; poly[oxy(dimethylsilylene)], α-hydroxy-ω-hydroxy-; siloxanes and silicones, dimethyl. 18hydroxy-terminated; CAS Nos. 31692-79-2 and 70131-67-8</td>
<td>A dimethyl siloxane terminated with hydroxyl groups</td>
<td>Antifoaming agents; skin-conditioning agents – emollient</td>
</tr>
<tr>
<td>Dimethiconol arginine</td>
<td>Reaction product of dimethiconol and arginine</td>
<td>Hair conditioning agents</td>
</tr>
<tr>
<td>Dimethiconol beeswax; CAS No. 227200-35-3*</td>
<td>Reaction product of dimethiconol and beeswax (reviewed by CIR – safe as used conclusion53,54)</td>
<td>Skin-conditioning agents-occlusive</td>
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<tr>
<td>Dimethiconol behenate; CAS No. 227200-34-2*</td>
<td>Ester of dimethiconol and behenic acid. Behenyl alcohol (reviewed by CIR – safe as used55)</td>
<td>Skin-conditioning agents-occlusive</td>
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<tr>
<td>Dimethiconol boragoate; CAS No. 226994-45-2*</td>
<td>Reaction product of dimethiconol and fatty acids derived from Borago Officinalis seed oil</td>
<td>Skin-conditioning agents-emollient</td>
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<tr>
<td>Dimethiconol candelillate</td>
<td>Reaction product of dimethiconol and candelilla wax (reviewed by CIR – safe as used53,54)</td>
<td>Skin-conditioning agents – occlusive</td>
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<tr>
<td>Dimethiconol carnaubate</td>
<td>Reaction product of dimethiconol and carnauba wax (reviewed by CIR – safe as used53,54)</td>
<td>Skin-conditioning agents-occlusive</td>
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<tr>
<td>Dimethiconol cysteine</td>
<td>Reaction product of dimethiconol and cysteine</td>
<td>Hair conditioning agents</td>
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<tr>
<td>Dimethiconol dhupa butterate; CAS No. 243981-39-7*</td>
<td>Reaction product of dimethiconol and fatty acids derived from dhupa butter</td>
<td>Skin conditioning agents-emollient</td>
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<td>Dimethiconol hydroxystearate; siloxanes and silicones, dimethyl, [(12-hydroxy-1-oxo octadecyl)oxy]-terminated; CAS No. 133448-13-2</td>
<td>Ester of dimethiconol and hydroxystearic acid (reviewed by CIR – safe as used56)</td>
<td>Skin-conditioning agents-occlusive</td>
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<td>Dimethiconol ilipe butterate</td>
<td>Reaction product of dimethiconol and the fatty acids derived from ilipe butter</td>
<td>Skin conditioning agents-emollient</td>
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<td>Dimethiconol isostearate; siloxanes and silicones, dimethyl, [(oxoisooctadecyl)oxy]-terminated; CAS No. 133448-14-3</td>
<td>Ester of dimethiconol and isostearic acid (reviewed by CIR – safe as used57,54)</td>
<td>Skin-conditioning agents-occlusive</td>
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<td>Dimethiconol kokum butterate; CAS No. 226994-48-5*</td>
<td>Reaction product of dimethiconol and the fatty acids derived from kokum butter</td>
<td>Skin-conditioning agents-emollient</td>
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<tr>
<td>Dimethiconol lactate; CAS No. 227200-33-1*</td>
<td>Ester of dimethiconol and lactic acid (reviewed by CIR – safe with qualifications58,59)</td>
<td>Hair conditioning agent; skin conditioning agents-emollient</td>
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<td>Dimethiconol meadowfoamate</td>
<td>Reaction product of dimethiconol and the fatty acids derived from meadowfoam seed oil</td>
<td>Skin-conditioning agents-emollient</td>
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<tr>
<td>Dimethiconol methionine</td>
<td>Reaction product of dimethiconol and methionine</td>
<td>Hair conditioning agents</td>
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<tr>
<td>Dimethiconol/methylsilanol/silicate crosspolymer; CAS No. 68956-02-6</td>
<td>The cross polymer formed by the reaction of silica (reviewed by CIR – safe as used56), dimethylsilanol, and methylsilanol</td>
<td>Not reported</td>
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### Table 1. Dimethiconol and its Esters and Reaction Products

<table>
<thead>
<tr>
<th>Chemical Names</th>
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<tbody>
<tr>
<td>Dimethiconol mohwa butterate; CAS No. 225233-88-5*</td>
<td>Reaction product of dimethiconol and the fatty acids derived from mohwa butter</td>
<td>Skin-conditioning agents-emollient</td>
</tr>
<tr>
<td>Dimethiconol panthenol</td>
<td>Reaction product of dimethiconol and panthenol (reviewed by CIR – safe as used61,62)</td>
<td>Hair conditioning agents</td>
</tr>
<tr>
<td>Dimethiconol sal butterate</td>
<td>Reaction product of dimethiconol and the fatty acids derived from sal butter</td>
<td>Skin-conditioning agents-emollient</td>
</tr>
<tr>
<td>Dimethiconol/silica cross polymer</td>
<td>Copolymer of dimethiconol and silica (reviewed by CIR – safe as used60)</td>
<td>Film formers</td>
</tr>
<tr>
<td>Dimethiconol/silsesquioxane copolymer; CAS No. 68554-67-6</td>
<td>Siloxane polymer consisting of methyl trimethoxysilane and dimethyl siloxane</td>
<td>Antistatic agents; film formers; hair fixatives; skin-conditioning agents-miscellaneous</td>
</tr>
<tr>
<td>Dimethiconol stearate; siloxanes and silicones, dimethyl, [(1-oxooctadecyl)oxy]-terminated; CAS No. 130169-63-0</td>
<td>Ester of dimethiconol and stearic acid (reviewed by CIR – safe as used63,62) – See figure 1B</td>
<td>Skin conditioning agents-occlusive</td>
</tr>
<tr>
<td>Dimethiconol/stearyl methicone/phenyl trimethicone copolymer</td>
<td>Polymer formed from dimethiconol, stearyl methicone (reviewed by CIR – safe as used64), and phenyl trimethicone (reviewed by CIR – safe as used65,62)</td>
<td>Suspending agents-nonsurfactant</td>
</tr>
<tr>
<td>Hydrolyzed collagen PG-propyl dimethiconol</td>
<td>Silicone polymer that conforms generally to the structure, where R represents the hydrolyzed collagen (reviewed by CIR – safe as used66,62) moiety – See figure 1B</td>
<td>Emulsion stabilizers; hair conditioning agents; skin-conditioning agents-humectants; surfactants-suspending agents</td>
</tr>
<tr>
<td>Isopolyglyceryl-3 dimethiconol</td>
<td>Silicone polymer that conforms to the structure in figure 1B</td>
<td>Hair conditioning agents; skin conditioning agents-emollient; surfactants-cleansing agents; surfactants-emulsifying agents; surfactants-solubilizing agents; skin-conditioning agents-humectants; viscosity increasing agents-aqueous</td>
</tr>
<tr>
<td>Trimethylsiloxysilicate/dimethiconol crosspolymer; CAS No. 68440-70-0</td>
<td>Dimethiconol crosslinked with trimethylsiloxysilicate</td>
<td>Film formers; viscosity increasing agents-nonaqueous</td>
</tr>
<tr>
<td>Acrylates/dimethiconol acrylate copolymer</td>
<td>Copolymer of dimethiconol acrylate and one or more monomers consisting of acrylic acid, methacrylic acid (reviewed by CIR – safe with qualifications67), or one of its simple esters</td>
<td>Film formers</td>
</tr>
</tbody>
</table>

* Source (CAS numbers): Siltech Personal Care68
Table 2. Composition of Oil/Butter Sources of Dimethiconol FA Moieties*

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Fatty Acid Composition of Oil/Butter Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimethiconol borageate</td>
<td><em>Borago officinalis</em> seed oil: 11.26% palmitic acid (C16:0), 4.52% stearic acid (18:0), 19.57% oleic acid (18:1), 36.12% linoleic acid (18:2), 18.46% gama-linolenic acid ((\gamma) 18:3), 4.22% arachidoleic acid (20:1), and 2.70% erucic acid (22:1)</td>
</tr>
<tr>
<td>Dimethiconol dhupa butterate</td>
<td>Dhup (Vateria indica) butter: 9% palmitic acid, 46.9% stearic acid, 41.4% oleic acid, 1.3% linoleic acid, and 1.4% eicosanoic acid (20:0)</td>
</tr>
<tr>
<td>Dimethiconol illipe butterate</td>
<td>Illipe (Shorea stenoptera) butter: 15 to 19% palmitic acid, 42 to 48% stearic acid, 32 to 38% oleic acid, and 0 to 1.2% linoleic acid</td>
</tr>
<tr>
<td>Dimethiconol kokum butterate</td>
<td>Kokum (Garcinia indica) butter: 15 to 19% palmitic acid, 42 to 48% stearic acid, 32 to 38% oleic acid, and 0 to 1.2% linoleic acid</td>
</tr>
<tr>
<td>Dimethiconol meadowfoamate</td>
<td>Meadowfoam (Limnanthes alba) seed oil: 58 to 64% cis-11 eicosenoic acid (20:1, (\Delta_5)), 3 to 6% erucic acid (22:1, (\Delta_5)), 10 to 14% erucic acid (22:1, (\Delta_{13})), and 15 to 21% docosadienoic acid (22:2, (\Delta_5\Delta_{13}))</td>
</tr>
<tr>
<td>Dimethiconol mohwa butterate</td>
<td>Mohwa (Madhuca longifolia) oil: 20 to 25% palmitic acid, 20 to 25% stearic acid, 41 to 51% oleic acid, 10 to 14% linoleic acid, and 0 to 3.3% eicosanoic acid</td>
</tr>
<tr>
<td>Dimethiconol sal butterate</td>
<td>Sal (Shorea robusta) butter: 4 to 7% palmitic acid, 41 to 47% stearic acid, 37 to 43% oleic acid, and 0 to 4% linoleic acid</td>
</tr>
</tbody>
</table>

*The Cosmetic Ingredient Review (CIR) Expert Panel has evaluated the safety of palmitic acid, stearic acid, and oleic acid and concluded that each is safe as used in personal care products.63

Table 3. Properties of Dimethiconol and Dimethiconol Compounds

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dimethiconol</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Density</td>
<td>0.956g/cm³</td>
<td>STN International¹⁰</td>
</tr>
<tr>
<td>Refractive index</td>
<td>1.3968</td>
<td>&quot;</td>
</tr>
</tbody>
</table>

**Dimethiconol (60%) in anionic surfactant emulsion**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Particle size</td>
<td>1µm max (for D50); 2µm max (for D90)</td>
<td>Anonymous¹¹</td>
</tr>
<tr>
<td>Polymer viscosity</td>
<td>1.0 x 10⁶ to 1.8 x 10⁹ cps</td>
<td>&quot;</td>
</tr>
<tr>
<td>pH</td>
<td>6 to 8</td>
<td>&quot;</td>
</tr>
<tr>
<td>Nonvolatiles</td>
<td>58% to 62%</td>
<td>&quot;</td>
</tr>
<tr>
<td>Silicones (as polydimethylsiloxane)</td>
<td>58% to 62%; target value = 60%</td>
<td>&quot;</td>
</tr>
<tr>
<td>Cyclomethicone (as tetramer)</td>
<td>1% max</td>
<td>&quot;</td>
</tr>
</tbody>
</table>
### Table 3. Properties of Dimethiconol and Dimethiconol Compounds

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dimethiconol Beeswax</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Form</td>
<td>Off white waxy solid</td>
<td>SafePharm Laboratories&lt;sup&gt;76&lt;/sup&gt;</td>
</tr>
<tr>
<td>Density of liquids and solids</td>
<td>956 kg/m³ @ 19.7 ± 0.5°C</td>
<td>&quot;</td>
</tr>
<tr>
<td>Water solubility</td>
<td>&lt; 6.0 x 10⁻⁴ g/l of solution at 20.0 ± 0.5°C</td>
<td>&quot;</td>
</tr>
<tr>
<td>Boiling point</td>
<td>&gt; 673 ± 0.5 K @ 101.61 to 102.02 kPa</td>
<td>&quot;</td>
</tr>
<tr>
<td>Melting point/melting range</td>
<td>301 to 349 ± 0.5 K</td>
<td>&quot;</td>
</tr>
<tr>
<td><strong>Dimethiconol Behenate</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical state</td>
<td>Soft paste</td>
<td>Personal Care Products Council&lt;sup&gt;77&lt;/sup&gt;</td>
</tr>
<tr>
<td>Appearance and odor</td>
<td>Off-white, bland odor</td>
<td>&quot;</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>~ 0.99 @ 25°C</td>
<td>&quot;</td>
</tr>
<tr>
<td>Water solubility</td>
<td>Insoluble</td>
<td>&quot;</td>
</tr>
<tr>
<td>Freezing/melting point</td>
<td>63 ºC</td>
<td>&quot;</td>
</tr>
<tr>
<td>% Volatile</td>
<td>Nil</td>
<td>&quot;</td>
</tr>
<tr>
<td>Acid value</td>
<td>20.0 maximum</td>
<td>&quot;</td>
</tr>
<tr>
<td><strong>Dimethiconol/silsesquioxane copolymer (5%) and dimethiconol (20%) in anionic surfactant emulsion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Particle size</td>
<td>0.043µm max (for D50); 0.05µm max (for D90)</td>
<td>Anonymous&lt;sup&gt;12&lt;/sup&gt;</td>
</tr>
<tr>
<td>Polymer viscosity</td>
<td>1.0 x 10⁶ to 3.5 x 10⁶ cps; target value = 2.0 x 10⁶ cps</td>
<td>&quot;</td>
</tr>
<tr>
<td>pH</td>
<td>6.5 to 8; target value = 7</td>
<td>&quot;</td>
</tr>
<tr>
<td>Nonvolatiles</td>
<td>38% to 43%</td>
<td>&quot;</td>
</tr>
<tr>
<td>Silicones (as polydimethylsiloxane)</td>
<td>25% to 27%; target value = 26%</td>
<td>&quot;</td>
</tr>
<tr>
<td>Cyclomethicone (as tetramer)</td>
<td>1.8% max</td>
<td>&quot;</td>
</tr>
</tbody>
</table>
Table 4. Properties of Materials registered Under Dimethiconol INCI Name\textsuperscript{78}

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Composition</th>
<th>Molecular Weight</th>
<th>Solubility</th>
<th>Production Method</th>
<th>Impurities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dow Corning® 1401 Fluid</td>
<td>10-30% CAS 70131-67-8 (Dimethyl Siloxane, Hydroxy-terminated) - the rest is a mixture of cyclics (primarily D4 (CAS 556-67-2) and D5 (CAS 541-02-6))</td>
<td>530,000 to 570,000</td>
<td>Soluble in non-polar solvents</td>
<td>Dimethyl cyclics are polymerized and then endblocked with -OH fluid. Catalyst is neutralized</td>
<td>D4, D5, D6</td>
</tr>
<tr>
<td>Dow Corning® 1403 fluid</td>
<td>10-30% CAS 70131-67-8 - the rest is PDMS (CAS 63148-62-9)</td>
<td>720,000 to 760,000</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
<tr>
<td>Dow Corning® 1501 fluid</td>
<td>15-40% CAS 70131-67-8; &gt;60% D5 (CAS 541-02-6)</td>
<td>530,000 to 570,000</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
<tr>
<td>Dow Corning® 7-3100 Gum Blend HIP Emulsion</td>
<td>10-30% CAS 70131-67-7; 10-30% Water; &gt;60% D5 (CAS 541-02-6); Low level of preservatives and additives</td>
<td>530,000 to 570,000</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
<tr>
<td>Dow Corning® 1784 emulsion</td>
<td>40-70% CAS 70131-67-8; 10-30% Water; Low level of preservatives and additives</td>
<td>250,000 to 290,000</td>
<td>&quot;</td>
<td>Linearis are polymerized in-situ to form polymer</td>
<td>D4, D5</td>
</tr>
<tr>
<td>Dow Corning® CB-1502 Fluid</td>
<td>15-40% CAS 70131-67-8; 15-70% Naptha (CAS 64742-48-9)</td>
<td>530,000 to 570,000</td>
<td>&quot;</td>
<td>Dimethyl cyclics are polymerized and then endblocked with -OH fluid. Catalyst is neutralized</td>
<td>D4, D5, D6</td>
</tr>
<tr>
<td>Dow Corning® CB-1556 Fluid</td>
<td>10-30% CAS 70131-67-8; &gt;60% Phenyl siloxane (CAS 73559-47-4)</td>
<td>530,000 to 570,000</td>
<td>&quot;</td>
<td>&quot;</td>
<td>&quot;</td>
</tr>
<tr>
<td>Dow Corning® CB-1596 Fluid</td>
<td>40-70% CAS 70131-67-8; 40-70% Trisiloxane (CAS 17955-88-3)</td>
<td>530,000 to 570,000</td>
<td>Soluble in non-polar solvents</td>
<td>Dimethyl cyclics are polymerized and then endblocked with -OH fluid. Catalyst is neutralized</td>
<td>D4, D5, D6</td>
</tr>
<tr>
<td>Dow Corning® 9546 Silicone Elastomer Blend</td>
<td>1% CAS 70131-67-8; &gt;60% D5 (CAS 541-02-6)</td>
<td>300,000 cSt - viscosity</td>
<td>Not available</td>
<td>Cold blend of 1501 Fluid and D5 – dimethiconol only 1% of final formulation</td>
<td>D4, D5, D6 in the 1501 Fluid</td>
</tr>
<tr>
<td>Dow Corning® 1-1254 Fluid</td>
<td>&gt;60% CAS 70131-67-8; 1-5% D5 (CAS 541-02-6); 1-5% D4 (CAS 556-67-2)</td>
<td>≥1000 (40 cSt - viscosity)</td>
<td>Low water solubility</td>
<td>Re-label of 4-2797. 4-2797 is produced by high pressure and high temperature equilibrium reaction of D4 cyclics with sodium hydroxide solution. Excess cyclics are stripped away.</td>
<td>D4, D5, D6</td>
</tr>
</tbody>
</table>
### Table 4. Properties of Materials registered Under Dimethiconol INCI Name

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Composition</th>
<th>Molecular Weight</th>
<th>Solubility</th>
<th>Production Method</th>
<th>Impurities</th>
</tr>
</thead>
<tbody>
<tr>
<td>α,Ω-Dihydroxy-polydimethylsiloxane (i.e. Polydimethylsiloxanediol or Siloxanes and silicones, di-Me, OH-group terminated; Polymer FD 80; CAS 70131-67-8)</td>
<td>≥98% 70131-67-8; ≤2% dimethylcyclosiloxanes CAS 69430-24-6</td>
<td>70000 to 75000 (80000 mPa - viscosity)</td>
<td>virtually insoluble at 20 °C (68 °F)</td>
<td>Information on silicone synthesis is publicly available</td>
<td>Dimethycyclosiloxanes (CAS No. 69430-24-6)</td>
</tr>
<tr>
<td>Material X (name CBI)</td>
<td>CBI</td>
<td>100,000 (20,000 to 24,000 mm2/s - viscosity)</td>
<td>Not available</td>
<td>Process (CBI)</td>
<td>D4, residual monomer, residual catalyst</td>
</tr>
</tbody>
</table>

### Table 5. Tested Materials Not Used In Cosmetics That Contain Dimethyl Siloxane, Hydroxy-Terminated

<table>
<thead>
<tr>
<th>Trade Name/Comments</th>
<th>Chemical Composition (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dow Corning® 60,000CS, NO CO-SOLVENT</td>
<td>≥95% Dimethyl Siloxane, Hydroxy-Terminated (CAS No. 70131-67-8) - the rest is a mixture of cyclics (primarily D4 (CAS 556-67-2) and D5 (CAS 541-02-6))</td>
</tr>
<tr>
<td>Dow Corning® 7-9192</td>
<td>≥95% CAS 70131-67-8 - the rest is a mixture of cyclics (primarily D4 (CAS 556-67-2) and D5 (CAS 541-02-6))</td>
</tr>
<tr>
<td>Dow Corning Q4-2797 (4-2797 INT and PA Fluid)</td>
<td>≥95% CAS 70131-67-8 - the rest is a mixture of cyclics (primarily D4 (CAS 556-67-2) and D5 (CAS 541-02-6))</td>
</tr>
<tr>
<td>Trade Name/Comments</td>
<td>Chemical Composition (%)</td>
</tr>
<tr>
<td>---------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Silastic® Medical Adhesive Silicone, Type A</td>
<td>&gt;60% CAS 70131-67-8; 10-30% Methylated Silica (CAS 68611-44-9); 3-7% Methyltriacetoxysilane; 3-7% Ethyltriacetoxysilane (CAS 17689-77-9)</td>
</tr>
<tr>
<td>Dow Corning® 2-1845 Microemulsion</td>
<td>15-40% CAS 70131-67-8; 10-30% Triethanolamine dodecylbenzene sulfonate (CAS 27323-41-7); 3-7% Polyethylene oxide lauryl ether (CAS 9002-92-0); 40-70% Water</td>
</tr>
<tr>
<td>Dow Corning® 22 Emulsion</td>
<td>38% CAS 70131-67-8; &gt;40% Water; 5% Toluene; 5% Perchloroethylene</td>
</tr>
<tr>
<td>Dow Corning® 35 Emulsion</td>
<td>13% CAS 70131-67-8; &gt;50% Dimethyl siloxane, dimethylvinylsiloxane-terminated (CAS 68083-19-2); &gt;20% treated silica (CAS 68909-20-6)</td>
</tr>
<tr>
<td>Dow Corning® PA Fluid</td>
<td>≥95% CAS 70131-67-8 - the rest is a mixture of cyclics (primarily D4(CAS 556-67-2) and D5 (CAS 541-02-6))</td>
</tr>
<tr>
<td>Dow Corning materials - TX-102A, TX-102B, and TX-102C</td>
<td>82.1% CAS 70131-67-8 - the rest is catalyst, curing agent, and vulcanizer</td>
</tr>
<tr>
<td>Dow Corning® 4-2797 INT</td>
<td>≥95% CAS 70131-67-8 - the rest is a mixture of cyclics (primarily D4(CAS 556-67-2) and D5 (CAS 541-02-6))</td>
</tr>
<tr>
<td>Dow Corning® X7-9192</td>
<td>≥95% CAS 70131-67-8 - the rest is a mixture of cyclics (primarily D4(CAS 556-67-2) and D5 (CAS 541-02-6))</td>
</tr>
<tr>
<td>Dow Corning® 360 Medical Fluid (This material does not contain dimethiconol - it is used as a solvent.)</td>
<td>PDMS (CAS 63148-62-9)</td>
</tr>
<tr>
<td>Dow Corning® X3-5040 Sealant</td>
<td>~75% CAS 70131-67-8 - the rest is a treated silica</td>
</tr>
<tr>
<td>Dow Corning® 386</td>
<td>~65% CAS 70131-67-8 with tetrapropyl orthosilicate and diatomaceous silica</td>
</tr>
<tr>
<td>Dow Corning® 5392</td>
<td>~95% CAS 70131-67-8 and ethyl polysilicate</td>
</tr>
<tr>
<td>Dow Corning® XET-40002</td>
<td>~16% CAS 70131-67-8; ~20% Methylhydrogen siloxane (CAS 63148-57-2); &gt;40% Water; 5% Toluene; 5% Perchloroethylene</td>
</tr>
<tr>
<td>Dow Corning special polymer 5-26-64</td>
<td>≥95% CAS 70131-67-8 - the rest is a mixture of cyclics (primarily D4(CAS 556-67-2) and D5 (CAS 541-02-6))</td>
</tr>
<tr>
<td>Dow Corning special polymer</td>
<td>≥95% CAS 70131-67-8 - the rest is a mixture of cyclics (primarily D4(CAS 556-67-2) and D5 (CAS 541-02-6))</td>
</tr>
<tr>
<td>Dow Corning® 9546 Silicone Elastomer Blend</td>
<td>1% CAS 70131-67-8; &gt;60% D5 (CA 541-02-6)</td>
</tr>
<tr>
<td>Dow Corning® 1501 Fluid</td>
<td>15-40% CAS 70131-67-8; &gt;60% D5 (CAS 541-02-6)</td>
</tr>
<tr>
<td>Dow Corning® 1503 Fluid</td>
<td>10-30% CAS 70131-67-8; &gt;60% PDMS (CAS 63148-62-9)</td>
</tr>
<tr>
<td>Dow Corning® Q1-3563</td>
<td>≥95% CAS 70131-67-8 - the rest is a mixture of cyclics (primarily D4(CAS 556-67-2) and D5 (CAS 541-02-6))</td>
</tr>
<tr>
<td>Product category</td>
<td>2010 uses (total number of products in category)</td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td><strong>Dimethiconol</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Baby products</strong></td>
<td></td>
</tr>
<tr>
<td>Lotions, oils, powders, and creams</td>
<td>4 (151)</td>
</tr>
<tr>
<td><strong>Bath products</strong></td>
<td></td>
</tr>
<tr>
<td>Bubble baths</td>
<td>-</td>
</tr>
<tr>
<td><strong>Eye makeup</strong></td>
<td></td>
</tr>
<tr>
<td>Eyebrow pencil</td>
<td>1 (153)</td>
</tr>
<tr>
<td>Eyeliner</td>
<td>3 (834)</td>
</tr>
<tr>
<td>Eye shadow</td>
<td>19 (1,343)</td>
</tr>
<tr>
<td>Eye lotion</td>
<td>11 (260)</td>
</tr>
<tr>
<td>Eye makeup remover</td>
<td>2 (133)</td>
</tr>
<tr>
<td>Mascara</td>
<td>37 (528)</td>
</tr>
<tr>
<td>Other</td>
<td>24 (412)</td>
</tr>
<tr>
<td><strong>Fragrance products</strong></td>
<td></td>
</tr>
<tr>
<td>Perfumes</td>
<td>1 (742)</td>
</tr>
<tr>
<td>Powders</td>
<td>-</td>
</tr>
<tr>
<td>Other</td>
<td>9 (641)</td>
</tr>
<tr>
<td><strong>Noncoloring hair care products</strong></td>
<td></td>
</tr>
<tr>
<td>Conditioners</td>
<td>114 (1,313)</td>
</tr>
<tr>
<td>Sprays/aerosol fixatives</td>
<td>5 (321)</td>
</tr>
<tr>
<td>Rinses</td>
<td>1 (34)</td>
</tr>
<tr>
<td>Shampoos</td>
<td>60 (1,487)</td>
</tr>
<tr>
<td>Tonics, dressings, etc.</td>
<td>112 (1,321)</td>
</tr>
<tr>
<td>Other</td>
<td>73 (838)</td>
</tr>
<tr>
<td><strong>Hair coloring products</strong></td>
<td></td>
</tr>
<tr>
<td>Bleaches</td>
<td>1 (147)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (168)</td>
</tr>
<tr>
<td>Product category</td>
<td>2010 uses (total number of products in category)</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td><strong>Makeup</strong></td>
<td></td>
</tr>
<tr>
<td>Blushers</td>
<td>4 (471)</td>
</tr>
<tr>
<td>Face powders</td>
<td>8 (724)</td>
</tr>
<tr>
<td>Foundations</td>
<td>24 (624)</td>
</tr>
<tr>
<td>Leg and body paints</td>
<td>1 (29)</td>
</tr>
<tr>
<td>Lipstick</td>
<td>3 (2,045)</td>
</tr>
<tr>
<td>Makeup bases</td>
<td>2 (126)</td>
</tr>
<tr>
<td>Makeup fixatives</td>
<td>-</td>
</tr>
<tr>
<td>Other</td>
<td>3 (536)</td>
</tr>
<tr>
<td><strong>Nail care products</strong></td>
<td></td>
</tr>
<tr>
<td>Basecoats and undercoats</td>
<td>1 (69)</td>
</tr>
<tr>
<td>Cuticle softeners</td>
<td>2 (30)</td>
</tr>
<tr>
<td>Nail extenders</td>
<td>-</td>
</tr>
<tr>
<td>Nail polish and enamel</td>
<td>4 (351)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (137)</td>
</tr>
<tr>
<td><strong>Personal hygiene products</strong></td>
<td></td>
</tr>
<tr>
<td>Deodorants (underarm)</td>
<td>3 (623)</td>
</tr>
<tr>
<td>Douches</td>
<td>-</td>
</tr>
<tr>
<td>Other</td>
<td>1 (925)</td>
</tr>
<tr>
<td><strong>Shaving products</strong></td>
<td></td>
</tr>
<tr>
<td>Aftershave lotion</td>
<td>14 (381)</td>
</tr>
<tr>
<td>Preshave lotions</td>
<td>2 (19)</td>
</tr>
<tr>
<td>Shaving cream</td>
<td>2 (128)</td>
</tr>
<tr>
<td>Shaving soap</td>
<td>-</td>
</tr>
<tr>
<td>Other</td>
<td>5 (126)</td>
</tr>
<tr>
<td><strong>Skin care products</strong></td>
<td></td>
</tr>
<tr>
<td>Skin cleansing creams, lotions, liquids, and pads</td>
<td>13 (1,528)</td>
</tr>
<tr>
<td>Product category</td>
<td>2010 uses (total number of products in category)</td>
</tr>
<tr>
<td>-----------------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Depilatories</td>
<td>4 (56)</td>
</tr>
<tr>
<td>Face and neck creams, lotions, and powders</td>
<td>95 (1,652)</td>
</tr>
<tr>
<td>Body and hand creams, lotions, and powders</td>
<td>76 (1,875)</td>
</tr>
<tr>
<td>Foot powders and sprays</td>
<td>1 (46)</td>
</tr>
<tr>
<td>Moisturizing creams, lotions, and powders</td>
<td>269 (2,750)</td>
</tr>
<tr>
<td>Night creams, lotions, and powders</td>
<td>40 (386)</td>
</tr>
<tr>
<td>Paste masks (mud packs)</td>
<td>3 (462)</td>
</tr>
<tr>
<td>Skin fresheners</td>
<td>2 (267)</td>
</tr>
<tr>
<td>Other</td>
<td>65 (1,446)</td>
</tr>
<tr>
<td><strong>Suntan products</strong></td>
<td></td>
</tr>
<tr>
<td>Suntan gels, creams, and liquids</td>
<td>4 (106)</td>
</tr>
<tr>
<td>Indoor tanning preparations</td>
<td>32 (247)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (61)</td>
</tr>
<tr>
<td><strong>Total uses/ranges for dimethiconol</strong></td>
<td>1169</td>
</tr>
</tbody>
</table>

**Amidimethiconol**

**Hair coloring products**

| Dyes and colors                                     | 21 (2,382)                                       | -                        |
| **Total uses/ranges for amidimethiconol**           | 21                                               |                          |

**Dimethiconol arginine**

**Noncoloring hair care products**

| Conditioners                                       | 2 (1,313)                                       | -                        |
| Sprays/aerosol fixatives                           | 1 (321)                                         | -                        |
| Shampoos                                           | 1 (1,487)                                       | -                        |
| **Total uses/ranges for dimethiconol arginine**    | 4                                                |                          |

**Dimethiconol beeswax**

**Bath products**

| Soaps and detergents                               | 9 (1,781)                                       | 0.8                      |

27
Table 6. Cosmetic Product uses\textsuperscript{15} and Use Concentrations\textsuperscript{16}

<table>
<thead>
<tr>
<th>Product category</th>
<th>2010 uses (total number of products in category)</th>
<th>2010 concentrations (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Noncoloring hair care products</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1 (838)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Personal hygiene products</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>4 (925)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Skin care products</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body and hand creams, lotions, and powders</td>
<td>-</td>
<td>0.9</td>
</tr>
<tr>
<td>Moisturizers</td>
<td>1 (2,750)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total uses/ranges for dimethiconol beeswax</strong></td>
<td>15</td>
<td>0.8 to 0.9</td>
</tr>
<tr>
<td><strong>Dimethiconol behenate</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Makeup</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lipstick</td>
<td>-</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Total uses/ranges for dimethiconol behenate</strong></td>
<td>-</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Dimethiconol cysteine</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Noncoloring hair care products</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conditioners</td>
<td>2 (1,313)</td>
<td>0.07</td>
</tr>
<tr>
<td>Sprays/aerosol fixatives</td>
<td>1 (321)</td>
<td>-</td>
</tr>
<tr>
<td>Shampoos</td>
<td>1 (1,487)</td>
<td>-</td>
</tr>
<tr>
<td>Tonics, dressings, etc.</td>
<td>2 (1,321)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total uses/ranges for dimethiconol cysteine</strong></td>
<td>6</td>
<td>0.07</td>
</tr>
<tr>
<td><strong>Dimethiconol meadowfoamate</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Eye makeup</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1 (412)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Noncoloring hair care products</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conditioners</td>
<td>6 (1,313)</td>
<td>0.5</td>
</tr>
<tr>
<td>Sprays/aerosol fixatives</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Straighteners</td>
<td>1 (181)</td>
<td>-</td>
</tr>
<tr>
<td>Tonics, dressings, etc.</td>
<td>1 (1,321)</td>
<td>0.5</td>
</tr>
<tr>
<td>Product category</td>
<td>2010 uses (total number of products in category)</td>
<td>2010 concentrations (%)</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------------------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Other</td>
<td>-</td>
<td>0.5</td>
</tr>
<tr>
<td>Total uses/ranges for dimethiconol meadowfoamate</td>
<td>9</td>
<td>0.5 to 1</td>
</tr>
</tbody>
</table>

**Dimethiconol methionine**

**Noncoloring hair care products**

<table>
<thead>
<tr>
<th>Product category</th>
<th>2010 uses (total number of products in category)</th>
<th>2010 concentrations (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conditioners</td>
<td>2 (1,313)</td>
<td>-</td>
</tr>
<tr>
<td>Sprays/aerosol fixatives</td>
<td>1 (321)</td>
<td>-</td>
</tr>
<tr>
<td>Shampoos</td>
<td>1 (1,487)</td>
<td>-</td>
</tr>
<tr>
<td>Total uses/ranges for dimethiconol methionine</td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

**Dimethiconol panthenol**

**Noncoloring hair care products**

<table>
<thead>
<tr>
<th>Product category</th>
<th>2010 uses (total number of products in category)</th>
<th>2010 concentrations (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conditioners</td>
<td>2 (1,313)</td>
<td>0.07</td>
</tr>
<tr>
<td>Sprays/aerosol fixatives</td>
<td>1 (321)</td>
<td>-</td>
</tr>
<tr>
<td>Shampoos</td>
<td>1 (1,487)</td>
<td>-</td>
</tr>
<tr>
<td>Tonics, dressings, etc.</td>
<td>2 (1,321)</td>
<td>-</td>
</tr>
<tr>
<td>Total uses/ranges for dimethiconol panthenol</td>
<td>6</td>
<td>0.07</td>
</tr>
</tbody>
</table>

**Dimethiconol/silsesquioxane copolymer**

**Noncoloring hair products**

<table>
<thead>
<tr>
<th>Product category</th>
<th>2010 uses (total number of products in category)</th>
<th>2010 concentrations (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tonics, dressings, etc.</td>
<td>2 (1321)</td>
<td>-</td>
</tr>
<tr>
<td>Conditioners</td>
<td>-</td>
<td>0.3</td>
</tr>
<tr>
<td>Total uses/ranges for dimethiconol/silsesquioxane copolymer</td>
<td>2</td>
<td>0.3</td>
</tr>
</tbody>
</table>

**Dimethiconol stearate**

**Eye makeup**

<table>
<thead>
<tr>
<th>Product category</th>
<th>2010 uses (total number of products in category)</th>
<th>2010 concentrations (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other</td>
<td>1 (412)</td>
<td>-</td>
</tr>
</tbody>
</table>

**Noncoloring hair care products**

<table>
<thead>
<tr>
<th>Product category</th>
<th>2010 uses (total number of products in category)</th>
<th>2010 concentrations (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conditioners</td>
<td>1 (1,313)</td>
<td>-</td>
</tr>
</tbody>
</table>

**Shaving products**

<table>
<thead>
<tr>
<th>Product category</th>
<th>2010 uses (total number of products in category)</th>
<th>2010 concentrations (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shaving cream (aerosol, brushless, and lather)</td>
<td>7 (128)</td>
<td>1</td>
</tr>
</tbody>
</table>
### Table 6. Cosmetic Product uses\textsuperscript{15} and Use Concentrations\textsuperscript{16}

<table>
<thead>
<tr>
<th>Product category</th>
<th>2010 uses (total number of products in category)</th>
<th>2010 concentrations (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total uses/ranges for dimethiconol stearate</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td><strong>Trimethylsiloxysilicate/dimethiconol crosspolymer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Eye makeup</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mascara</td>
<td>4 (528)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Skin care products</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body and hand creams, lotions, and powders</td>
<td>1 (1,875)</td>
<td>2</td>
</tr>
<tr>
<td>Moisturizers</td>
<td>1 (2,750)</td>
<td>-</td>
</tr>
<tr>
<td>Total uses/ranges for Trimethylsiloxysilicate/dimethiconol crosspolymer</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td><strong>Acrylates/dimethiconol acrylate copolymer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Nail care products</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basecoats and undercoats</td>
<td>-</td>
<td>0.5</td>
</tr>
<tr>
<td>Polish and enamel</td>
<td>-</td>
<td>0.5</td>
</tr>
<tr>
<td>Total uses/ranges for acrylates/dimethiconol acrylate copolymer</td>
<td>-</td>
<td>0.5</td>
</tr>
</tbody>
</table>
Figure 1A. Structures for Dimethiconol, examples of its reaction products and related, reviewed ingredients

Dimethicone (CIR reviewed)  Dimethiconol\textsuperscript{4}  Amodimethicone (CIR reviewed)

Reaction Product Type 1) End-capped homopolymers

Reaction Product Type 2) Copolymers

Examples

Dimethiconol Stearate

Dimethiconol Arginine, Dimethiconol Beeswax, Dimethiconol Behenate, Dimethiconol Borageate, Dimethiconol Candelillate, Dimethiconol Carnaubaate, Dimethiconol Cysteine, Dimethiconol Dhupa Butterate, Dimethiconol Hydroxystearate, Dimethiconol Illipe Butterate, Dimethiconol Isostearate, Dimethiconol Kokum Butterate, Dimethiconol Lactate, Dimethiconol Meadowfoamate, Dimethiconol Methionine, Dimethiconol Mohwa Butterate, Dimethiconol Panthenol, and Dimethiconol Sal Butterate

Hydrolyzed Collagen PG-Propyl Dimethiconol\textsuperscript{3}

Dimethiconol/ Methylsilanol/Silicate Crosspolymer, Dimethiconol/ Silica Crosspolymer, Dimethiconol/Silsesquioxane Copolymer, Dimethiconol/Stearyl Methicone/Phenyl Trimethicone Copolymer, Isopolyglyceryl-3 Dimethiconol, Trimethylsiloxysilicate/Dimethiconol Crosspolymer, and Acrylates/Dimethiconol Acrylate Copolymer
Figure 1B. Structures for Dimethiconol Polymers

- Dimethiconol Stearate
- Hydrolyzed Collagen PG-Propyl Dimethiconol
- Isopolyglyceryl-3 Dimethiconol
References


7. Silicones Environmental, Health and Safety Council of North America SEHSC. Information on materials that are registered under dimethiconol INCI name. Composition of materials that contain CAS No. 70131-67-8 and have toxicity data. UV absorption data for dimethiconol. Definition of dimethiconol/silsesquioxane copolymer. 2010;1-10.

8. Silicones Environmental, Health and Safety Council of North America SEHSC. Information on materials that are registered under dimethiconol INCI name. Composition of materials that contain CAS No. 70131-67-8 and have toxicity data. UV absorption data for dimethiconol. Definition of dimethiconol/silsesquioxane copolymer. 2010;1-10.


15. Food and Drug Administration (FDA). Information supplied to FDA by industry as part of the VCRP. FDA database. 2010;Washington, D.C.: FDA.


17. Food and Drug Administration (FDA). Information supplied to FDA by industry as part of the VCRP. FDA database. 2009;Washington, D.C.: FDA.


22. Dow Corning Corporation. Acaricidal and insecticidal activity of various silicone fluids with cover letter dated 4/20/94. 1975;NTIS Report No.OTS0572228:


29. International Research and Development Corporation. An acute dermal toxicity study of Dow Corning 2-1845 microemulsion in rabbits, with cover letter dated 11/14/95. 1995;NTIS Report No.OTS0558305:


32. Food and Drug Research Laboratories, Inc. Chronic (8-month) feeding studies with DC special siloxane polymer in rabbits with cover letter dated 04/20/94. 1966;NTIS Report No.OTS0556539:

33. Dow Corning Corporation. Eye irritation potential of several dow corning emulsions with cover letter dated 042094. NTIS Report No. OTS0556579. 1968;


49. Food and Drug Research Laboratories, Inc. Chronic (1-year) feeding studies with Dow Corning special polysiloxane in rats with cover letter dated 04/20/94. 1966;NTIS Report No.OTS0556494:


64. Andersen, F. A. Final report on the safety assessment of stearoxy dimethicone, dimethicone, methicone, amino bispropyl dimethicone, aminopropyl dimethicone, amodimethicone, amodimethicone hydroxystearate, behenoxy dimethicone, C24-28 alkyl methicone, C30-45 alkyl methicone, C30-45 alkyl dimethicone, cetaryl methicone, cetyl dimethicone, dimethoxyisilyl ethylenediaminopropyl dimethicone, hexyl methicone, hydroxypropylidimethicone, stearamidopropyl dimethicone, stearyl dimethicone, stearyl methicone, and vinylmethicone. International Journal of Toxicology. 2003;22:11-35.


68. Siltech personal Care. Siloxanes - Consumption, toxicity and alternatives. 11-29-2009;


70. Description/specification of dhupa butter seeds.2010.


75. Sal butter profile and information.2010.


78. Silicones Environmental, Health and Safety Council of North America SEHSC. Information on materials that are registered under dimethiconol INCI name. Composition of materials that contain CAS No. 70131-67-8 and have toxicity data. UV absorption data for dimethiconol. Definition of dimethiconol/silsesquioxane copolymer. 2010;1-10.

79. Silicones Environmental, Health and Safety Council of North America SEHSC. Information on materials that are registered under dimethiconol INCI name. Composition of materials that contain CAS No. 70131-67-8 and have toxicity data. UV absorption data for dimethiconol. Definition of dimethiconol/silsesquioxane copolymer. 2010;1-10.
Memorandum

TO: F. Alan Andersen, Ph.D.
   Director - COSMETIC INGREDIENT REVIEW (CIR)

FROM: John Bailey, Ph.D.
       Industry Liaison to the CIR Expert Panel

DATE: September 14, 2010

SUBJECT: Comments on the Tentative Report on Dimethiconol and its Esters and Reaction Products

It would be helpful to include the abstract in the tentative report so the public had the opportunity to read the abstract and provide comments.

p.1 - As Dimethiconol/Stearyl Methicone/Phenyl Trimethicone copolymer includes three monomers, please change “copolymers consist of two monomers” to “copolymers consist of at least two monomers”.

p.1 - As use of Dimethiconol/Silsesquioxane Copolymer was reported to the FDA, please delete “dimethiconol/silsesquioxane copolymer” from the list of ingredients reported to be used in the Council survey, but not reported to the FDA VCRP.

p.2, 18, Table 3 - Please correct the spelling of “silsequioxane” (twice on p.2, and in Table 3).

p.2, 13 - In p.2 it correctly states “octanol-water partition coefficients on these compounds are not included”. Therefore, the statement on p.13 that the CIR Expert Panel reviewed octanol-water partition coefficients is not correct, as there are no partition coefficients included in this report. The following statement in the post August meeting announcement “The available data on octanol-water partition coefficients and molecular weights suggested that the ingredients reviewed do not penetrate the skin...” is also not correct.

p.3 - Table 6 indicates that the VCRP has 6 uses of Trimethylsiloxysilicate/Dimethiconol Crosspolymer, while 2 uses are indicated in the text on p.3. The VCRP uses (2) of Dimethiconol/Silsesquioxane Copolymer should also be mentioned on p. 3.

p.4 - As unpublished information is also included in this CIR report, it is not necessary to say “in the published literature” (found in the sentence under the Absorption, Distribution, Metabolism and Excretion heading and the second paragraph of the summary of the Animal Toxicology section).

p.4 - As the material tested was only 80% Dimethiconol, it is misleading to state that the highest dose that did not cause death was 16 ml/kg.

p.5 - In the summary of the Acute Dermal Exposure section, it would be helpful to state that the LD_{50} values were for mixtures containing up to 95% Dimethiconol.

p.6 - Why does the summary of the Ocular Irritation section focus on the study that Dow Coming
considered inappropriate? More recent studies of materials containing higher concentrations of Dimethiconol (up to 95%) classified the materials as non-irritating. The Dimethiconol Stearate ocular irritation study (described on p.7) should be mentioned in the summary.

p.10 - As the letter from SEHSC incorrectly stated that rabbits were used in the 1-year feeding study, it would be appropriate to add [rats] after rabbits in the quote from this letter.

p.10 - In the Summary of the Skin Irritation and Sensitization section, please indicate that a lip product containing 0.5% Dimethiconol Behenate was tested.

p.13 - The information on the chronic implantation studies is stated twice (on p.12-13 and in the first complete paragraph on p.13).

p.13 - The Discussion should not state that there was an absence of carcinogenicity data. As stated twice in the Summary, there were some implantation studies that were negative.

p.17, Table 3 - When describing Dimethiconol Beeswax, please correct “Of white” to “Off white”.

p.20, Table 5 - As the study on Dow Corning 2-1870 HV Microemulsion has been removed from the report, this material needs to be removed from Table 5 too.