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# Safety Assessment of Acryloyldimethyltaurate Polymers as Used in Cosmetics

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Status: Draft Tentative Report for Panel Review  
Release Date: September 2, 2016  
Panel Meeting Date: September 26-27, 2016

The 2016 Cosmetic Ingredient Review Expert Panel members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Ronald A. Hill, Ph.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Director is Lillian J. Gill, D.P.A. This report was prepared by Lillian C. Becker, Scientific Analyst/Writer.



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## MEMORANDUM

To: CIR Expert Panel and Liaisons

From: Lillian C. Becker, M.S.  
Scientific Analyst and Writer

Date: September 2, 2016

Subject: Safety Assessment of Acryloyldimethyltaurate Polymers as Used in Cosmetics

Attached is the Draft Tentative Report of Acryloyldimethyltaurate Polymers as used in cosmetics. [ACTAPY092016Rep] These ingredients are reported mostly to function as dispersing agent – nonsurfactant, emulsion stabilizers, opacifying agent, and viscosity increasing agents – aqueous.

In April 2016, the Panel issued an Insufficient Data Announcement with the following data needs:

- Molecular weight ranges
- Impurities data, including data on any residual acrylamide, vinyl formamide, and methacrylamidolauric acid monomers
- Sensitization data for Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer at 4.3% or greater

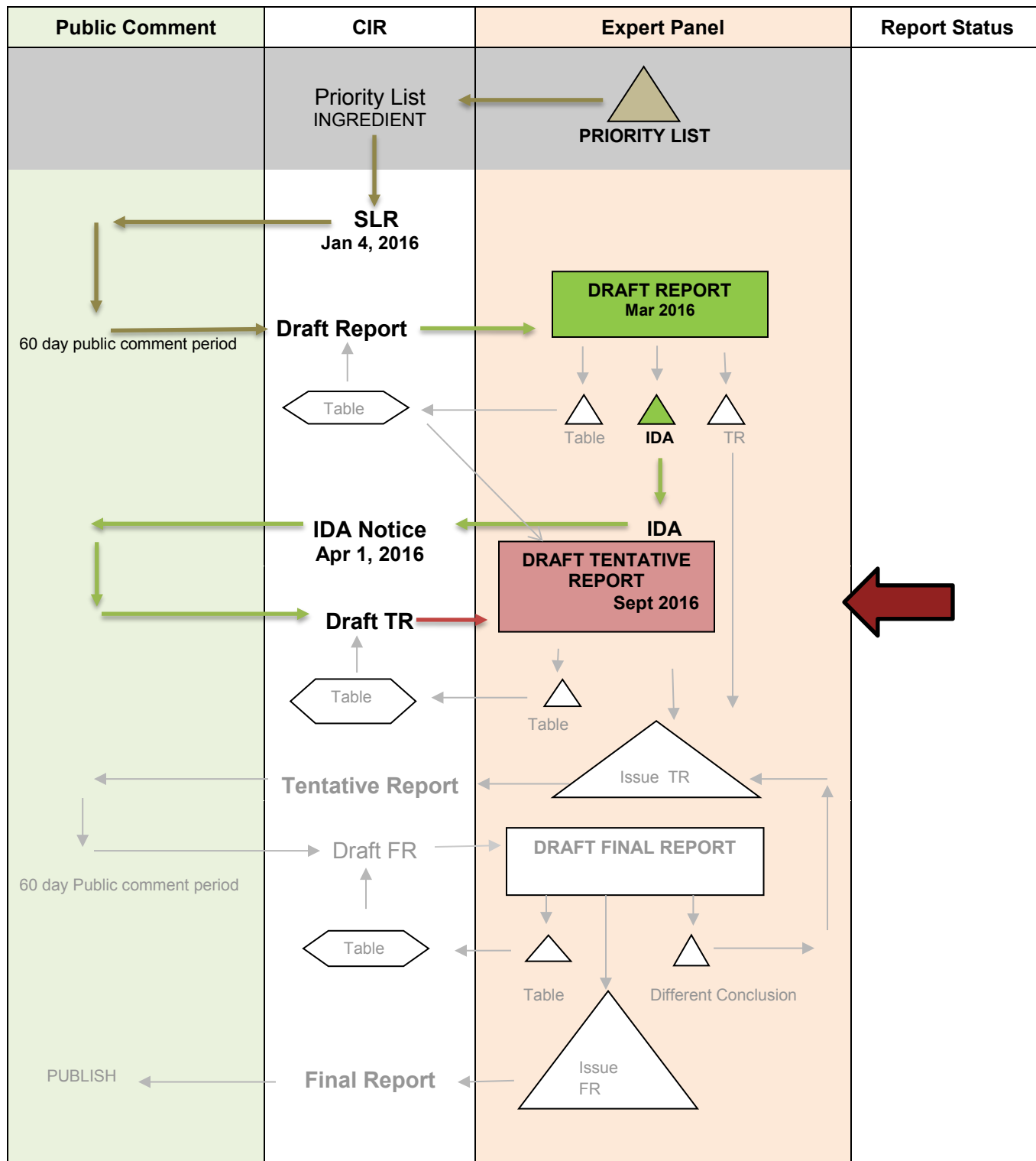
Data on molecular weight, impurities, dermal/oral toxicity, genotoxicity, and/or sensitization of Sodium Polyacryloyldimethyl Taurate and Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer were submitted by the Council and incorporated into the report (marked with vertical bars in the text). Updated concentration of use data were also submitted; there were minimal changes to the previously submitted data. [ACTAPY092016Data\_1,2,3,4]

The Panel is to examine this report and decide if the new information meets the data needs. The Panel is to come to a conclusion on the safety of these ingredients, develop the basis for the Discussion, and issue a Tentative Report. If the conclusion is that there is still insufficient data, then the Panel is to list the data that are needed for the Discussion.

# SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY Acryloyldimethyltaurate Polymers

MEETING Sept 2016



## History – Acryloyldimethyltaurate Polymers

**January, 2016** – SLR was issued with the following data requests:

- Clarification that the CAS no. 58374-69-9 is actually ammonium acryloyldimethyltaurate/vinyl formamide copolymer. Data related to this CAS no. have been found but the associated chemical appears not to be a polymer.
- Ingredient-specific method of manufacture and impurity data for cosmetics for each of these ingredients
- Dermal penetration data
- Repeated dose dermal and inhalation toxicity data for each of these ingredients at or above the reported concentrations of use
- Reproductive and developmental toxicity data for each of these ingredients at or above the reported concentrations of use
- Additional dermal and ocular irritation data for any of these ingredients for which there is no data at or above the reported concentrations of use
- Additional irritation and sensitization data for any of these ingredients for which there is no data at or above the reported concentrations of use

**March, 2016** – The Council confirmed that CAS no. 58374-69-9 does not belong to any of these ingredients.

The Panel issued an Insufficient Data Announcement asking for:

- Molecular weight ranges
- Impurities data, including data on any residual acrylamide, vinyl formamide, and methacrylamidolauric acid monomers
- Sensitization data for Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer at 4.3% or greater

Polyacryloyldimethyltaurate Polyoxymethylene Melamine was removed from the report because it is the salt of two polymers and did not fit in with the rest of the ingredients.

**September, 2016** - The Panel examines the Draft Tentative Report.

Some data on molecular weight, impurities, dermal/oral toxicity, genotoxicity, and/or sensitization of Sodium Polyacryloyldimethyl Taurate and Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer were submitted. Updated concentration of use data were also submitted.

[illegible]

[illegible]

## Search Strategy – Acryloyldimethyltaurate Polymers

### SciFinder

Compounds searched by identifiers (text and structure):

1562414-82-7 – 0 hits

1509895-12-8 – 1 hit, not useful

1453194-38-1 – 2 hits, not useful

1417986-34-5 – 0 hits

1258874-55-3 – 2 hits, not useful

882176-38-7 – 2 hits, 0 hits

869772-40-7 – 1 hit, not useful

683748-07-4 0 hits

600172-76-7 – 4 hits, 0 useful

187725-30-0 – 9 hits, 0 useful

159157-50-3 – 3 hits, 0 useful

111286-86-3 – 216 hits, selected biological/tox/properties – 203 hits, removed patents – 4 hits, 0 useful

92815-97-9 – 32 hits, removed patents – 3 hits, 0 useful

92815-96-8 – 52 hits, removed patents – 7 hits, 0 useful

77019-71-7 – 74 hits, removed patents – 6 hits, 0 useful

Compounds searched by identifiers (text and structure):

1234 hits – removed patents, 312 hits.

Refine “toxicity” 2 hits, 0 useful

Refine “repro\*” 0 hits

Refine “geno\*” 0 hits

Refine “carcinogen” 0 hits

Refine “bio” 1 hit, not useful

### NICNAS

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer

Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer

Ammonium Acryloyldimethyltaurate/Vinyl Formamide Copolymer (2-Acrylamido-2-methylpropanesulfonic acid, ammonium salt)

Ammonium Acryloyldimethyltaurate/VP Copolymer (Aristoflex AVC)

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer

Sodium Acrylate/Acryloyldimethyltaurate/ Dimethylacrylamide Crosspolymer

### Cosing Database

Hits on: Acrylamide/Sodium Acryloyldimethyltaurate Copolymer, Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer, Sodium Acrylate/Sodium Acryloyldimethyl Taurate/Acrylamide Copolymer, Sodium Acryloyldimethyl Taurate/ Acrylamide/VP Copolymer

## Transcripts - Acryloyldimethyltaurate Polymers March, 2016

### Dr. Marks' Team

DR. MARKS: So, we had a draft report on the acryloyldimethyltaurate polymers. This is the first review of these ingredients, and so the first question would be for Ron, Ron, and Tom. This list of these ingredients, these polymers that is a little over a page -- are there any ingredients in that list which you think do not fit and should be removed?

DR. HILL: Which table are you looking at, just so we're looking at the same place?

DR. MARKS: Page 19 I went to. Let's see if that corresponds. No, that's -- I'm sorry.

DR. HILL: Page 9?

DR. MARKS: It is 9.

MS. BURNETT: And page 9 will work.

DR. MARKS: Okay. 19 is the use, yes. Okay. Sure, page 9 or I actually was looking at the one where it tabulates what testing had been done. But are there any of these ingredients which you feel should be eliminated from this group of these 22?

DR. EISENMANN: The one that I thought was different is this polyacryloyldimethyltaurate polyoxymethylene melamine. It's too polymers.

DR. HILL: Oh, yes, I forgot about that one. I forgot about that.

DR. EISENMANN: It's two -- it's a salt of two polymers. It's not a --

DR. HILL: Sorry.

DR. EISENMANN: So, we have two polymers linked by charges. It's a little bit different than the others. That's why I -- I just thought it was different, so I don't know if it belongs.

DR. BERGFELD: Which one is that again?

DR. MARKS: It's the second column, the second one down? Is that right, Carol, the hydroxyethyl acrylate?

DR. EISENMANN: No, it's --

DR. HILL: No, the other one.

MS. BECKER: The the third one down.

DR. MARKS: Oh, the third one.

DR. HILL: Polyacryloyldimethyltaurate.

DR. EISENMANN: Acryloyl -- correct.

DR. MARKS: Okay, thank you. Third one down. The polyacryloyldimethyltaurate poly.

DR. HILL: My note on this says that if it's to stay in -- I was looking for direct information about the molecular weight of that component as well as the other bit about method of manufacture, some impurities, and maybe based on that information a little bit more to be determined. So, if they want it out, I'm okay with that, too.

DR. MARKS: So, Ron Shank and Tom, you like the idea of removing that since it's structurally different?

MS. BECKER: If you want to look at the structure, page 16 of the PDF at Table 1.

DR. HILL: Thank you.

DR. MARKS: Ron Shank, what do you think?

DR. SHANK: And you call that salt? I'm having a hard time picturing what that is.

DR. HELDRETH: So, the sulfate on the first polymeric residue would be deprotonated, whereas one of those nitrogens on the melamine would be protonated. So, they're going to be attracted to each other. It's not going to be like chlorotic salt. But you're going to have opposite charges that are going to keep those two bodies in close approximation.

DR. SHANK: Okay, so what's polymeric about all of this? The sulfate is ionized and then binds to point 2 or 3 of the hydroxyl groups on the other?



DR. HELDRETH: One of the nitrogens. One of the nitrogens will be protonated.

DR. SHANK: Okay. Yeah, it's interesting, because it's not repeated. Or just two molecules together.

DR. HELDRETH: The polyacryloyldimethyltaurate polymer, and it will have essentially --

DR. MARKS: 01M.

DR. HELDRETH: -- a negative charge to it, and then the melamine polymer with essentially a net positive charge to it, and those opposite charges will keep those two polymers together.

DR. SHANK: Okay, so the values of x and y are greater than 1.

DR. HELDRETH: Certainly greater than 1. It would be on that window. We need specific information.

DR. SHANK: Okay, thank you.

DR. HELDRETH: Sure.

DR. MARKS: So, remove -- or keep in?

DR. BERGFELD: It's your first draft. Maybe you can call for that information.

DR. HILL: My thinking was along the lines of since we are at the point of probably asking for more information on a number of these -- but maybe I'm the only one who thinks that, but I'm thinking we're going to ask for some more information. We could make the decision after we see what we get, because if you toss it out, when if ever will it be reviewed? Is it in use? I thought it was not, but --

DR. MARKS: Ron Shank, what's your feeling?

DR. HILL: Not in use.

DR. MARKS: So, we aren't going to receive information more than likely.

DR. BERGFELD: And I believe --

DR. SHANK: Well, for all of them I would like to know the range of molecular weights of these.

DR. MARKS: Okay, so shall we leave this -- yeah, we'll get to what the needs are. I just want to -- So, Bart, why did you include it since you -- and that's what we're talking about, structurally. Usually these are made that they're structurally similar, chemically similar.

DR. HELDRETH: Right, so when we're looking at these polymers, you know, if in reality it ends up that they're of significant size and we're not worried about systemic absorption and its global effects, then what we're probably most concerned with outside from irritation and sensitization is residual monomer, or monomer that may be cleaved off of the polymer. And so I grouped all these ingredients together that share a certain type of monomer in common, and in this case they all have at least a taurate monomer in common.

Now, this specific ingredient that we're talking about is really two polymers. One of those does have that taurate core monomeric repeat unit in it. The other one does not that forms the salt. So, it is like the other ingredients in that it has that shared monomeric starting material but, unlike the other ingredients, it also has some additional polymer that forms the salt.

DR. EISENMANN: That additional polymer has a CIR insufficient data conclusion also.

DR. SHANK: As insufficient?

DR. EISENMANN: Data conclusion already.

DR. SHANK: So, they know me.

DR. EISENMANN: Right. Right, so you have two polymers together on one (inaudible). The one that's attached to it has insufficient data conclusion.

DR. MARKS: Seems like that's enough that we should remove it.

DR. SLAGA: Remove it. I would.

DR. MARKS: Okay, let me --

DR. HELDRETH: I mean, it's your choice to remove it, or you could keep it in and by default it's going to be insufficient as well so that there's -- if we don't get data on it, you'll have a conclusion that says "insufficient, zero use."

DR. HILL: At a level of -- if we don't mind split conclusions, I like the idea of keeping it in and landing there, because then if somebody does decide they want to use it or it is in fact in use, the (inaudible) will take a couple of years and then come back and support it.

DR. HELDRETH: Well, in this case, if there are zero uses, there's no reason to wait. It's a final.

DR. HILL: No, I know, I get that. I'm saying leave it in, it's just whether they like split conclusion or not -- because I think we'll end up with the rest of them probably being fined.

DR. MARKS: I'd remove it, but Tom, Ron, what do you want to do? Do you want to -- since we're going to come to an insufficient if we keep it?

DR. SLAGA: Remove.

DR. HILL: Yeah.

DR. SHANK: I agree.

DR. MARKS: Okay, so we'll plan on removing that one. That's page 9. Let me go back --

DR. BERGFELD: Excuse me, but it is in the dictionary, correct?

DR. SHANK: Yes.

DR. HELDRETH: Mm-hmm.

DR. BERGFELD: So, my opinion for this team is that you maybe ought to leave it in so it's covered, if it doesn't take too much work. I mean, this is the first draft.

DR. MARKS: Ron? Tom?

DR. SHANK: Leave it in? Now?

DR. SLAGA: Remove.

DR. MARKS: Okay, so --

DR. SHANK: Well, in the entire group, it's the only salt, is it not?

DR. HELDRETH: It's the only salt of this type, yes, where you have two polymers that coordinate.

DR. SHANK: Polymers?

DR. HILL: They all had to be salts, because we've got the sulfate.

DR. HELDRETH: The sulfate, excuse me. This is just the only one where the cation is --

DR. HILL: So, another polymer.

DR. MARKS: Remove. So, tomorrow I'm going to say remove and will -- and then I think, Ron Hill, Wilma, you can express an opinion about leaving it in, and we'll see how we land on that. And that was, again, the language. I mean, that's -- I don't have to -- oh, here it is (inaudible) get it here. Poly polyacryloyldimethyltaurate. Okay. Do you have it? Thank you.

Now, needs. I heard Ron Shank earlier mention you would like the molecular weights. So, if we need --

DR. SHANK: The range?

DR. MARKS: Yeah, molecular weight range. And obviously the reason there is that they're a low molecular range, in the low molecular weight range. Then we would need absorption, et cetera.

DR. SHANK: Correct.

DR. MARKS: Need for absorption. Any other needs? Go ahead, Ron.

DR. HILL: Well, just because it fits, yeah, impurities, and I note here that the EU has a restriction on acrylamide levels as an impurity. And I also notice that there's one of these that has a vinyl formamide monomer rather than acrylamide. So, those are really the main ones that we'd be concerned with here.

DR. MARKS: So, repeat that, Ron. You would want to --

DR. HILL: Impurities really directed toward acrylamide and vinyl formamide.

DR. MARKS: And so in that case, Ron Hill, you want to know whether acrylamide or vinyl acrylamide is an impurity and, if so, how much or you want none of that.

DR. HILL: It will be an impurity. And, like I say, the EU restricts levels to .3 percent I think it is. I just -- I don't think they have a similar restriction on the vinyl formamide, but there's one of these that has that in there as a monomer, and the reactivity would be expected to be similar.

- DR. HELDRETH: Yes, and this Panel has also concluded that acrylamide monomers should be not greater than 5 ppm [ppm] in polyacrylamides.
- DR. HILL: Yeah, okay.
- DR. MARKS: Yeah, that's --
- DR. HILL: (Inaudible) we landed, so.
- DR. MARKS: Yeah, previous conclusion on page 9 was nonirritating, and acrylamide monomer is not greater than 5 parts per million.
- DR. HILL: You're right.
- DR. MARKS: So, I guess the question there is do we repeat that in this document, or do you want the impurities anyway? We're going to end up with that statement without a doubt.
- DR. HILL: I would still like -- because I think that information will be out there, and I realize I'm asking a couple people to do some work, but I still think we should have -- because these are different polymers than the others we've looked at. And then due diligence suggests we look and see what's known about that, because I'm pretty sure people will be paying attention and will have some data.
- DR. MARKS: Okay. So, that's two needs. Any other needs?
- DR. HILL: And also, again, that other monomer that's in there in that one ingredient.
- DR. MARKS: Any -- go ahead.
- MS. BECKER: Which one? The other one?
- DR. HILL: Yeah, it's -- hang on, I'm trying to find the full ingredient name because I have it flagged in the structure table.
- MS. BECKER: Page 9?
- DR. HILL: Well, I'm going back to page 9, but we're headed flagged ones in the structure table.
- MS. BECKER: Is that the vinyl formamide.
- DR. HILL: Yeah. There's only one that says "vinyl" actually. I just searched it and then I got -- I abandoned the search. I closed the search, so --
- MS. BECKER: Okay.
- DR. HILL: But, yeah, that's the only one, and I was looking to see if it was in use is why I moved off of that.
- You got it?
- MS. BECKER: Um-hmm.
- DR. HILL: Okay.
- MS. BECKER: Mm-hmm. Thank you.
- DR. MARKS: Any other needs?
- DR. HILL: It's not in use, so we'll probably not get that information. At least we don't have a record of its use.
- DR. BERGFELD: Are you going to make some kind of statement, depending on the molecular weight, whether you'll need absorption, blah-blah-blah? Is it -- it's not a weighted document with a lot of information.
- DR. MARKS: Yeah, basically what I interpreted -- that's why I had asked Ron -- we need -- the first need was molecular weight range to decide on the need for absorption data basically, and then obviously it's absorbed, and then we need to know the tox from that. And then, second, the impurities, the acrylamide and vinyl acrylamide levels.
- DR. HILL: Let me just say this also about the absorption on that, because I'm not looking for that information. We've got a polymer that has the sulfonate groups on them, every one of which is very strongly acidic, which means effectively a permanent negative charge, and there are many of those negative charges sitting on the polymer, so the chances that they would be drug even through a mucous membrane is quite small.
- DR. MARKS: So, you wouldn't need them --

DR. HILL: I'm not worried about that or anything systemic.

DR. MARKS: Shall we, Ron Shank, just leave it as an 8 and see what the reaction we get back as?

We're going to -- I think at this point I will be moving for an insufficient data notice so we can see the reaction we get back if what you're saying, Ron Hill, is acceptable.

DR. HILL: I mean, they may just come back and give us these high molecular weights some extensive negative charges and use that as their rationale, and I would be comfortable with that response.

DR. MARKS: Yeah.

DR. SLAGA: That would be fine with me.

DR. MARKS: Okay, and then any other needs, Tom? Do you need any from a --

DR. SLAGA: I think there's plenty of acute toxicity (inaudible) genotoxin.

DR. MARKS: Do you think we're going to have a -- it's -- the irritation and sensitization data were okay, and I only asked Lillian and I asked her -- prepped her for this question. There's a number of the sensitization data, the HRIPTs. In parentheses it said assume at a hundred percent, and I wondered how we got that assumption a hundred percent. They're actually used at relatively low concentrations somewhere around -- of the ones that are used the most, those over a 150 uses, 165 to 456 -- used as the concentration is from 2.3 to 4 percent in the leave-on. So, I was reassured that all the sensitization data was okay, but it seems like a hundred percent is a lot when it's only being used in the 3 to 4 percent range. But at any rate, Lillian, do you want to comment on the assumption that the sensitivity testing was done at a hundred percent?

MS. BECKER: The sources I have are NICNAS summaries, and they give the ingredient and the test and the results and without saying what was tested or if there was a vehicle or anything else. So, if they're just saying this was applied, I'm assuming a hundred percent, but I have no definitive. So, that's why I just put -- didn't say a hundred percent; I said assumed.

DR. MARKS: Is that okay with you guys? I was reassured by that.

Okay, any other comments about these ingredients?

MR. BEST: My only comment is that (inaudible) we have we standards from other (inaudible) or Australia that are sort of put out there. It would be nice to have some -- since they're being used here at a higher rate that there be some discussion of, you know, if we decide that's okay why it's okay or why the levels were drawn where they were by other prohibitive bodies, because that always jumps out at me.

DR. MARKS: Okay, so tomorrow we'll -- did we capture that, your concerns?

MR. BEST: Sure.

DR. MARKS: And where would you put those in the discussion?

MR. BEST: Sorry, it's on page 11 for us to discuss, right -- both the Australian and the EU body?

DR. MARKS: Mm-hmm.

MR. BEST: Talk about where it -- what safe levels there are. There are no -- they're being used, right?

The use tables are slightly higher levels for some of those ingredients here?

DR. MARKS: Yeah.

MR. BEST: So, if you have I think maybe just even under where you say what the levels are for the bodies we could -- if the panelists are saying they're safe as used at the concentrations, you know, as used now, we could say why the EU in Australia drew this level -- why this level -- why the Panel thinks this higher level is okay that were being used at, I think, even just right there where it is.

MS. BECKER: Very often, the limits are the requested limits by the applicants, and they didn't look at any higher use as such --

MR. BEST: Yeah, I know, and that's been before this Panel before. I think that would be fine, I mean unless you guys think it's inappropriate. But it seems like a red flag, I think (inaudible) with this, you know, even as I'm sort of learning this and doing this. I mean, I -- and I remember that

coming up before, but it might be just good to have a sentence that explains that. I think it makes it seem less mysterious, less frightening.

DR. GILL: Michael, sometimes we don't know.

MR. BEST: Right.

DR. GILL: And I think when our Panel looks at the data presented to them and they've drawn a conclusion based on the data in front of them, which is what we typically say based on what was reviewed and presented, I'd be a little cautious in getting into how they've made their decision and everything that they -- that went into their decision-making. So, it may be a little sticky for our Panel to start concluding why the Europeans and Australians and others made their decisions and how.

MR. BEST: No, fair enough. I just -- I think (inaudible), it seems odd, right? I mean, it seems odd that, okay, if you're at these other places, and I think there sometimes is a general idea that maybe you're (inaudible). I don't think that's always true, actually, but, you know what I mean? So, it doesn't raise a flag in my head (inaudible) so I just thought I'd bring it up, but maybe there's no good way to address it.

DR. GILL: And I think that's a legitimate point, because we often get asked that question. It's just sometimes we don't always know. Their decision-making process is a little different than ours. When we look at some of their decisions -- and we'll look at one today -- we can elaborate a little more on that. But I think a general statement might be beyond what the Panel can say at the time.

MR. BEST: Okay, thank you.

DR. HILL: I would like to add to my monomer list --

DR. GILL: Yes.

DR. HILL: Methacrylamidolauric acid.

DR. MARKS: Metha --

DR. HILL: Methacrylamidolauric acid. It's looking at -- it's the last entry in the structured table -- no, it's not either. Last entry on page 17, the first page of Table 1 I think.

DR. GILL: Hmm-mm, no.

DR. HILL: No, it's not either. It's somewhere in the middle of Table 1.

DR. MARKS: What page is Table 1?

DR. HILL: It starts on page 14, I believe -- 14.

DR. GILL: To what, 17, because that's where the --

DR. MARKS: Yeah.

DR. HILL: Let me look at -- the iPad is actually quicker at this. All right, so it starts on page 14, and I believe that's the last entry on page 17. Yes, the last entry on page 17.

DR. MARKS: Okay, so I think at this point what I'll be doing for our team tomorrow is moving an insufficient data notice that we are moved from the ingredient list to polyacryloyldimethyltaurate polyoxymethylene methane. Is that correct? I kind of stumbled through that long name.

DR. BERGFELD: Language.

DR. MARKS: And then the needs are, one, the molecular range, the (inaudible) if absorption data is needed, and then, two, the impurities that acrylamide vinyl acrylamide and the methacrylamide acid levels.

And, Ron, I asked you to comment on those three I have.

And that will be -- and we'll see what the Belsito team -- how they react. Does that sound good, team members?

DR. SHANK: Sounds good. We have some sensitization data. Can we use that to cover all of the compounds in the list?

DR. MARKS: Yeah, I thought it was, because we had the -- we have the compounds with the most use, highest use, and we have a range in there. So, I thought it was fine.

DR. HILL: Well, I did have a note in here. Felt like I was being a malcontent today, but I did have a note in here that I felt like we ought to have sensitization data to cover the full range of monomers, at least the reactive monomers. So -- but that was just my thinking. So then in that case, that are a few more that you'd like to see the testing on, but -- so, are we making any requests for additional sensitization data at all right now? We didn't say that for our team, right?

DR. MARKS: Correct.

DR. HILL: Okay.

DR. BERGFELD: Ron, can you answer how stable are these?

DR. HILL: I think the polymers are stable, and we wouldn't be worried about that. It would just be residual. If there's any sensitization, I strongly believe, based on everything I know, it would be coming from any residual monomers. So, for me it was stepwise if we had good characterization of that, and we knew because, again, that won't be zero but it'll be some small level. If we had that data, we wouldn't necessarily need any more of the sensitization, and it isn't the way I was thinking about that.

DR. SLAGA: You already asked for those impurities.

DR. HILL: I did. So, that was my thinking on how that went -- I guess a chemistry way of looking at it instead of a sensitization way.

But I'm good with omitting that, partly because I think the other team may ask for it. (Laughter) And if not, I'm still good because I've asked for impurities. If we don't get that, then I'd like to see sensitization of the full range of monomers.

DR. MARKS: Okay, any other comments? So, we're going to have it in an insufficient data notice, so we're going to be saying ingredients, these 21 ingredients, and assuming that we remove the one ingredient we didn't like. Okay? Any other comments?

### **Dr. Belsito's Team**

DR. BELSITO: So 22 ingredients dispensing agents non surfactants emulsion stabilizers of pacifying viscosity the lead ingredient is hydroxyethylate is used in 474 formulations 451 are leave on. Two products in bath have the highest concentration, 4.3 percent depilatories, the highest leave on, I guess, is 3.6 in an eyeliner. Women with acute toxicity geno irritation and sensitization of repro or developmental or carcinogenicity and I guess what we can discuss while my windows are starting is industry has asked us to reconsider whether the Polyacryloyldimethyltaurate Polyoxymethylene Melamine should remain in this report because it is a salt of two powders.

SPEAKER: Polymers.

DR. BELSITO: That's right, polymers, I'm sorry.

COURT REPORTER: Just for the record could you pronounce that?

DR. BELSITO: Cryloydimethyltaurate Polymers. Dan, do you want to comment on industries caurate?

DR. SNYDER: Taurate.

DR. BELSITO: Taurate, yes, sorry.

DR. LIEBLER: I agree, the melamine containing salt of two polymers should be excluded from this report.

All of the others are polymers of this basic structure and they do have either ammonium or sodium salt whereas the polymer combination involving melamine is, the melamine polymer is a strip of basic polymer that would form salts with the acidic taurate polymer and so the safety consideration for that one would be driven as much by the melamine polymer as it would be by the taurate polymers and since this report is really about the taurate polymers and their safety I think the melamine taurate salt is doesn't really belong in this group so I think it should be excluded.

DR. BELSITO: Okay. Paul? Curt? Do you agree.

DR. SNYDER: I agree.

DR. KLAASSEN: Fine.

DR. BELSITO: So we will exclude that and we already addressed that question. It's used in products that could be inhaled so we will need a respiratory boilerplate there.

DR. SNYDER: Sprays and powders.

DR. BELSITO: Right, sprays and powders. We don't have sensitization data for the ATA polymer which is the most frequently used and in the highest leave on concentration and I thought that was peculiar that we don't have data for the most frequent and highly used one. I don't think these are issues because I don't think they are going to get into the skin but I'm just pointing out that we have no sensitization data.

DR. LIEBLER: No impurities and no --

DR. BELSITO: No method of manufacturing or impurities.

DR. LIEBLER: No absorption.

DR. BELSITO: No absorption and apparently we need those based on large molecules. So overall I say insufficient for manufacturing and impurities. They are large molecules so do we want to ask for 28-day dermal absorption and as long as we are going insufficient, I thought you really should have some sensitization data for the most frequently used product in the category. So I ask for sensitization of the HEA co-polymer at the highest concentration of use.

DR. LIEBLER: I agree. Method of manufacture, impurities, particularly residual monomers and we might as well ask for the absorption if these come back documented big and low residual monomers the absorption concern goes away and then I will defer to Don on the sensitization data but I support per the insufficient request.

DR. SNYDER: That's what I have.

DR. BELSITO: So manufacturing impurities, especially monomers, absorption and sensitization in use concentration for the HEA co-polymer. When we are writing it up we can add the respiratory boilerplate and we are getting rid of the melamine compound.  
Anything else?

DR. BELSITO: Okay, ...

## Day Two

DR. BERGFELD: Good discussion, thank you. The next item or ingredient on the list under reports advancing is the dimethyltaurate polymers, Dr. Marks?

DR. MARKS: So this is the first review of these 21 ingredients and our team -- first the issue of you seeing Lillian Becker's memo there at the next to last paragraph, we felt that we should remove the polyacrylo dimethyltaurate polyoxymethalyn melamine. These two polymers didn't really belong with these other ingredients so we felt that we should issue a -- and I'll make this a motion of insufficient data notice. We wanted to find out what the molecular range of these ingredients were to decide on need for absorption data.

We wanted to know more about the impurities, particularly the monomers, the acrylamide, the bi-acrylamide, the methyl acrylamide acid levels, particularly in light of the restrictions and that was it. Those two data needs so an insufficient data notice for our team.

DR. BELSITO: We had those two and then on the fence, but as long as we are asking for insufficient sensitization that uses concentration of the highest and most frequently used, which is the AGA polymer copolymer which I found odd that it has the significantly highest number of uses. It's used in the highest concentration and we have no sensitization data on it so we are requesting that as well.

DR. BERGFELD: I'm sorry, you're seconding the motion with that addition?

DR. BELSITO: Yes.

DR. BERGFELD: And I see a shake of the head by Jim and he --

DR. BELSITO: And agree with the deletion of the melamine, we did not think it belonged in that report.

DR. BERGFELD: Okay, any further discussion regarding this ingredient? Okay, Lillian?

MS. BECKER: Just a clarification, I thought I heard Dr. Marks' team want to remove and I thought I heard

Dr. Belsito say just remove the melamine?

DR. BELSITO: It was one large polymer that you wanted remove, right?

DR. MARKS: Correct.

MS. BECKER: Okay.

DR. BELSITO: It was the melamine, that ended with melamine?

DR. MARKS: That's correct.

DR. BELSITO: And it was on the basis of the melamine component of that polymer that we felt it should be removed.

DR. BERGFELD: Anything else? I'll call to question then. All those in favor? Unanimous.

(Motion passed unanimously)



## Safety Assessment of Acryloyldimethyltaurate Polymers as Used in Cosmetics

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Status: Draft Tentative Report for Panel Review  
Release Date: September 2, 2016  
Panel Meeting Date: September 26-27, 2016

The 2016 Cosmetic Ingredient Review Expert Panel members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Ronald A. Hill, Ph.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Director is Lillian J. Gill, D.P.A. This report was prepared by Lillian C. Becker, Scientific Analyst/Writer.

## ABSTRACT

This is a review of the safety of 21 acryloyldimethyltaurate polymers as used in cosmetics. The reported functions of these ingredients include dispersing agent – nonsurfactant, emulsion stabilizers, opacifying agent, and viscosity increasing agents – aqueous. The Cosmetic Ingredient Review (CIR) Expert Panel (Panel) concluded that acryloyldimethyltaurate polymers are [Conclusion to be determined]

## INTRODUCTION

This is a review of the scientific literature and unpublished data provided by Industry relevant to assessing the safety of 21 acryloyldimethyltaurate polymers as used in cosmetics. This group of ingredients comprises homopolymers, copolymers, and crosslinked polymers, the monomers of which are at least partially composed of acryloyldimethyltaurate monomers. According to the *International Cosmetic Ingredient Dictionary and Handbook*, the functions of these ingredients include dispersing agent – nonsurfactant, emulsion stabilizer, opacifying agent, and viscosity increasing agent – aqueous (Table 1).<sup>1</sup> The ingredients in this safety assessment are:

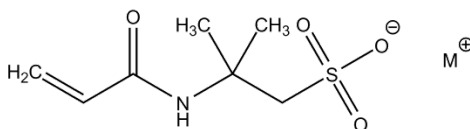
|                                                                     |                                                                         |
|---------------------------------------------------------------------|-------------------------------------------------------------------------|
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer                 | HEA/Sodium Acryloyldimethyltaurate/Steareth-20                          |
| Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer    | Methacrylate Copolymer                                                  |
| Ammonium Acryloyldimethyltaurate/Beheneth-25                        | Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer         |
| Methacrylate Crosspolymer                                           | Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer |
| Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer | Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer               |
| Ammonium Acryloyldimethyltaurate/Laureth-7                          | Sodium Acrylate/Sodium Acryloyldimethyl Taurate/Acrylamide Copolymer    |
| Methacrylate Copolymer                                              | Sodium Acryloyl Dimethyl Taurate/PEG-8 Diacrylate Crosspolymer          |
| Ammonium Acryloyldimethyltaurate/Steareth-25                        | Sodium Acryloyldimethyl Taurate/Acrylamide/VP Copolymer                 |
| Methacrylate Crosspolymer                                           | Sodium Acryloyldimethyltaurate/Methacrylamidolauric Acid Copolymer      |
| Ammonium Acryloyldimethyltaurate/Steareth-8                         | Sodium Acryloyldimethyltaurate/VP Crosspolymer                          |
| Methacrylate Copolymer                                              | Sodium Polyacryloyldimethyl Taurate                                     |
| Ammonium Acryloyldimethyltaurate/Vinyl Formamide Copolymer          |                                                                         |
| Ammonium Acryloyldimethyltaurate/VP Copolymer                       |                                                                         |
| Ammonium Polyacryloyldimethyl Taurate                               |                                                                         |
| Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer      |                                                                         |

The Panel has previously reviewed polymers that are similar to the acryloyldimethyltaurate polymers (Table 2). Some of the ingredients in this report are copolymers with acrylate monomers; the Panel has reviewed the polyacrylates, and other acrylate copolymers, and concluded that they are safe as used when formulated to be non-irritating.<sup>2</sup> Some other ingredients in this report are copolymers with acrylamide monomers; polyacrylamides were found to be safe as used if the concentration of residual acrylamide monomers in formulation is not greater than 5 ppm and Polyvinylpyrrolidone (PVP; another polymer with vinyl-type amide monomers) was found to be safe as used.<sup>3,4</sup> The Panel has also previously reviewed components/monomers of the acryloyldimethyltaurate polymers. The alkyl taurate amides and taurate salts were found to be safe when formulated to be non-irritating.<sup>5</sup>

## CHEMISTRY

### Definition and Structure

The acryloyldimethyltaurate polymers are composed of homopolymers, copolymers and crosslinked polymers, the monomers of which are at least partially composed of acryloyldimethyltaurate monomers.



acryloyldimethyltaurate

**Figure 1.** This monomer is common to all acryloyldimethyltaurate polymers, where M is a sodium cation or ammonium.

The definitions and structures of these acryloyldimethyltaurate polymers ingredients are presented in Table 1.

### Physical and Chemical Properties

The characteristics of acryloyldimethyltaurate polymers may vary greatly with manufacturing methods. For instance, the fluidity, solubility, and swelling capacity of these polymers can be determined by the degree of polymerization and crosslinking. In other words, altering manufacturing conditions, such as temperature, reaction time, and/or stoichiometric ratios, may result in significantly different physical forms even when the same monomers are used (i.e., even included under one ingredient name). It is also possible that these polymers are manufactured *in situ* to produce hydrogels. Accordingly, only cosmetic ingredient-specific data on the chemical and physical properties (including the molecular weight) of these ingredients are useful and cannot be assumed.

Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer and Ammonium Acryloyldimethyltaurate/VP Copolymer are reported to be white powders (Table 3).<sup>6,7</sup>

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer is reported to be soluble in water, at up to 27%, and forms an aqueous clear colorless liquid.<sup>8</sup>

These ingredients are large (2000  $\mu\text{m}$ ; >1000 to >1,000,000 g/mol) molecules and should not be absorbed by the skin. None of the particle diameters of Ammonium Acryloyldimethyltaurate/VP Copolymer were >2000  $\mu\text{m}$ , 97.2% were <2000  $\mu\text{m}$ , 81.3% were <1000  $\mu\text{m}$ , 11.8% were <200  $\mu\text{m}$ , and 0.5% were <100  $\mu\text{m}$ .<sup>6</sup> For Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer, 90.8% of the particles were <100  $\mu\text{m}$  and 84.5% were <10  $\mu\text{m}$ , and had an overall median diameter of 2.8  $\mu\text{m}$ .<sup>7</sup> Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer is reported have a molecular weight of approximately 250,000 g/mol.<sup>8</sup> The molecular weight of Sodium Polyacryloyldimethyl Taurate was reported to be >1,000,000 g/mol.<sup>9</sup>

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, and a Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer mixture were reported to be stable under normal environmental conditions.<sup>10-12</sup> Under normal conditions of use in personal care products, Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer is not expected to degrade; however, it does have functional groups that can be hydrolyzed in the pH range of 4-9.<sup>10</sup> Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer and Ammonium Acryloyldimethyltaurate/VP Copolymer were also reported to be stable under normal conditions, but may release ammonia under alkaline conditions.<sup>6,7</sup>

### Method of Manufacture

Information on the methods of manufacture of these ingredients was not found in the published literature and no unpublished data were provided. However, it is likely that radical type polymerization is commonly used, as it is for polyacrylamide and other vinyl-type polymers. This type of synthesis begins with formaldehyde and acetylene, and proceeds through 2-butyne-1,4-diol and  $\gamma$ -butyrolactone to  $\alpha$ -pyrrolidone and *N*-vinyl-2-pyrrolidone (the monomer), which is then polymerized to form the polymer. Usually, the monomer is polymerized in water; however, commercial polymerization may be carried out in isopropyl alcohol. The alcoholic solution is subsequently wetted to an aqueous solution by steam distillation and then either spray or drum dried.<sup>4,13,14</sup>

### Composition/Impurities

One supplier reported that Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer is supplied as an aqueous solution containing 25% to 27% of the polymer and the preservative sodium methylparaben (0.2%).<sup>8</sup> This polymer is also reported to be supplied as an aqueous solution at 24%.<sup>12</sup>

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer is reported to be supplied in a trade name mixture at <60%; the lowest concentration is not specified.<sup>11</sup>

Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer is reported to be supplied in a trade name mixture at <45%; the lowest concentration is not specified.<sup>10</sup>

Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer was reported to be >90% pure; data on the remaining <10% was not provided.<sup>7</sup>

Sodium Polyacryloyldimethyl Taurate is reported to contain <2000 ppm 2-acrylamido-2-methylpropane sulfonic acid (AMPS) and <10 ppm (detection limit) acrylamide.<sup>9</sup>

### USE

#### Cosmetic

The safety of the cosmetic ingredients included in this safety assessment is evaluated based on the data the Panel receives from the U.S. Food and Drug Administration (FDA) and the cosmetics Industry on the expected cosmetic use of ingredients. The FDA collects data from manufacturers on the use of individual ingredients in cosmetics by cosmetic product category in its Voluntary Cosmetic Registration Program (VCRP). Those data received from the cosmetic Industry are submitted in response to a survey conducted by the Personal Care Products Council (Council) of the maximum reported use concentrations by category.

According to VCRP data received from the FDA in 2016, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer was reported to be used in 474 formulations, including use in 451 leave-on products, 21 rinse-off products, and 2 products used in the bath (Table 4).<sup>15</sup> Ingredients with the next highest reported use are Ammonium

Acryloyldimethyltaurate/VP Copolymer with 456 uses (428 leave-on and 28 rinse-off products), Acrylamide/Sodium Acryloyldimethyltaurate Copolymer, with 236 uses (229 leave-on and 7 rinse-off products), Ammonium Polyacryloyldimethyl Taurate, with 197 uses (185 leave-on and 12 rinse-off products), and Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer with 165 uses (159 leave-on and 6 rinse-off products). All other ingredients are reported to be used in 49 or fewer products.

The results of a concentration of use survey conducted by the Council in 2015 indicate Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer has the highest reported maximum concentration of use; it is reported to be used at up to 4.3% in depilatories (rinse-off products) and up to 3.6% in eyeliner and eye shadow (leave-on products).<sup>16</sup> The reported maximum concentrations of use for the other ingredients range from 0.015%-3% in leave-on products and 0.078%-3.2% in rinse-off products.

In some cases, reports of uses were received from the VCRP, but concentration of use data were not reported in the use concentration survey.<sup>15,17</sup> For example, Sodium Acryloyldimethyltaurate/VP Crosspolymer is reported to be used in 8 cosmetic formulations, but no use concentrations were reported. In other cases, no uses were reported to the VCRP, but concentration of use data were reported by Industry; for example, Sodium Acryloyldimethyl Taurate/Acrylamide/VP Copolymer had no reported uses in the VCRP, but a use concentration (0.65%) in the category of other suntan preparations was provided in the Industry survey. Therefore, it is assumed that there is at least one use in every cosmetic product category for which a concentration was reported.

The ingredients not in use, based on the data from both the VCRP and the Industry survey, are listed in [Table 5](#).

Several of these ingredients were reported to be used in products that are used around the eye (the highest maximum reported concentration is 3.6% for Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer) and in products that come in contact with mucus membranes (the highest maximum reported concentration 2.4% Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer). Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer was reported to be used in 1 baby product (no concentration of use was reported).

Acrylamide/Sodium Acryloyldimethyltaurate Copolymer, Ammonium Polyacryloyldimethyl Taurate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, and Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer are reported to be used in powder products, in which the highest reported concentration of use was 0.7% Acrylamide/Sodium Acryloyldimethyltaurate Copolymer in face powders. Conservative estimates of inhalation exposures to respirable particles during the use of loose powder cosmetic products are 400-fold to 1000-fold less than protective regulatory and guidance limits established for talc particles and nuisance dusts in the workplace.<sup>18,19</sup> Additionally, some of the acryloyldimethyltaurate polymers are used in cosmetic sprays and could possibly be inhaled; for example, Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer is reported to be used at up to 3% in perfume and Ammonium Acryloyldimethyltaurate/VP Copolymer at up to 0.4% in tonics, dressings and other hair grooming aids. In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters >10 µm, with propellant sprays yielding a greater fraction of droplets/particles <10 µm compared with pump sprays.<sup>20,21</sup> Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and thoracic regions of the respiratory tract and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount.<sup>22,23</sup>

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) of Australia concluded that there is low concern to public health when Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer is used in rinse-off cosmetics at ≤2% and when Ammonium Acryloyldimethyltaurate/VP Copolymer is used in cosmetics at 0.5% to 1.2% (the concentrations requested to be reviewed by the suppliers) based on toxicity and environmental data.<sup>6,7</sup> NICNAS also concluded that Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer is safe in cosmetics at <3% and that Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer is safe in cosmetics when used as a component of hair styling products for salon and home use at 1%-2% (the concentrations requested by the suppliers) based on toxicity and environmental data.<sup>11,12</sup>

Acrylamide/Sodium Acryloyldimethyltaurate Copolymer, Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer, Sodium Acrylate/Sodium Acryloyldimethyl Taurate/Acrylamide Copolymer, and Sodium Acryloyldimethyl Taurate/Acrylamide/VP Copolymer are restricted in Europe according to the European Union (EU) Annex III/66.<sup>24</sup> The amount of residual acrylamide content is limited to 0.1 mg/kg in leave-on cosmetics used on the body and 0.5 mg/kg in other cosmetic products that are used on specific body parts (e.g., eye, face, and hand).

According to the EU regulations on labelling and packaging of substances and mixtures, if Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer is present in a product in a non-stabilized form, the name of the substance is to be followed by the words "non-stabilized" on the label.<sup>25</sup> According to the Commission directive, certain substances, which are susceptible to spontaneous polymerization or decomposition, are generally placed on the market in a stabilized form. It is in this form that they are listed in Annex I. However, such substances are sometimes placed on the market in a non-stabilized form.

### Non-Cosmetic

Acrylamide/Sodium Acryloyldimethyltaurate Copolymer may be used as a component of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding dry food not to exceed 0.015 weight percent of dry fiber. [21CFR176.180]

## **TOXICOKINETICS**

### **Absorption, Distribution, Metabolism, and Excretion**

Toxicokinetic data were not found in the published literature and no unpublished data were submitted.

## **TOXICOLOGICAL STUDIES**

### **Acute Toxicity**

Acute dermal and oral toxicity studies are summarized in [Table 6](#).

#### ***Dermal***

The acute dermal LD<sub>50</sub> for a solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (24% in water) was reported to be >5000 mg/kg (1200 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer) in rats.<sup>12</sup>

The acute dermal LD<sub>50</sub> for a solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% in water) was reported to be >5000 mg/kg (1250 to 1350 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer) in rats.<sup>26</sup>

#### ***Oral***

The acute oral LD<sub>50</sub> for a solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (24% in water) was reported to be >5000 mg/kg (>1200 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer) in rats.<sup>12</sup> The acute oral LD<sub>50</sub> for Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer and Ammonium Acryloyldimethyltaurate/VP Copolymer was reported to be >2000 mg/kg in rats; the oral LD<sub>50</sub> for Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (<60%) in a trade name mixture was reported to be <1200 mg/kg.<sup>6,7,11</sup>

The acute oral LD<sub>50</sub> for a solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% in water) was reported to be >5000 mg/kg (>1250 to >1350 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer) in rats.<sup>26</sup>

### **Short-Term to Chronic Toxicity**

Short-term, subchronic, and chronic toxicity data were not found in the published literature and no unpublished data were submitted.

## **DEVELOPMENTAL AND REPRODUCTIVE TOXICITY (DART) STUDIES**

Developmental and reproductive toxicity data were not found in the published literature and no unpublished data were submitted.

## **GENOTOXICITY STUDIES**

### ***In Vitro***

*In vitro* genotoxicity studies are summarized in [Table 7](#).

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer, Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer, Ammonium Acryloyldimethyltaurate/VP Copolymer, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, and Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer were not mutagenic in bacterial reverse mutation assays using *Salmonella typhimurium* and *Escherichia coli*.<sup>6,7,10-12</sup>

A solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27%) was not mutagenic in an Ames test at up to 5000 µg/plate (1250 to 1350 µg/plate).<sup>26</sup>

## **CARCINOGENICITY STUDIES**

Carcinogenicity data were not found in the published literature and no unpublished data were submitted.

## **DERMAL IRRITATION AND SENSITIZATION STUDIES**

### **Irritation**

#### ***Animal***

Dermal irritation studies in rabbits are summarized in [Table 8](#).

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (24%), Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer (100%), and Ammonium Acryloyldimethyltaurate/VP Copolymer (assumed applied at 100%, not specified) were slightly or not irritating to rabbit skin.<sup>6,7,12</sup>

A solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% in water; assumed applied at 100%, not specified) was not irritating to rabbit skin.<sup>26</sup>

An solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% in

water; assumed applied at 100%, not specified) was not irritating to rat skin after 24 h of exposure.<sup>26</sup>

### Human

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer was not irritating in a human irritation assay.<sup>11</sup> No further details were provided.

### Sensitization

Animal and human sensitization studies are summarized in [Table 9](#).

### Animal

Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer (25%) and Ammonium Acryloyldimethyltaurate/VP Copolymer (assumed applied at 100%, not specified) were not sensitizing to guinea pigs.<sup>6,7</sup>

### Human

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (24%), Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer (<2.25%), and Sodium Polyacryloyldimethyl Taurate (30% to 40%) were not sensitizing in human repeated insult patch tests (HRIPT).<sup>9,10,12</sup>

An aqueous solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% in water; assumed applied at 100%, not specified) was not sensitizing in an HRIPT.<sup>26</sup>

A trade name mixture containing Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (<60%; assumed administered at 100%, not specified) was not sensitizing in a human sensitization assay.<sup>11</sup>

### OCULAR IRRITATION STUDIES

*In vitro* and animal ocular irritation studies are summarized in [Table 10](#).

### In Vitro

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer was not an ocular irritant in an unspecified *in vitro* assay.<sup>11</sup> Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer (<2.25%) was not considered an eye irritant in a Hens Eggs Test-Chorioallantoic Membrane (HET-CAM) assay.<sup>10</sup>

### Animal

In ocular irritation assays, Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer, Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer, and Ammonium Acryloyldimethyltaurate/VP Copolymer were not irritating or slightly irritating in rabbit eyes.<sup>6,7,12</sup>

A solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% in water; assumed tested at 100%, not specified) was not irritating, according to OECD TG criteria, or minimally irritating, according to US EPA criteria, to rabbit eyes.<sup>26</sup>

### SUMMARY

This is a review of the scientific literature and unpublished data provided by Industry for assessing the safety of 21 acryloyldimethyltaurate polymers as used in cosmetics. This group of ingredients is composed of homopolymers, copolymers, and crosslinked polymers, the monomers of which are at least partially composed of acryloyldimethyltaurate monomers. The reported functions of these ingredients include dispersing agent – nonsurfactant, emulsion stabilizer, opacifying agent, and viscosity increasing agent – aqueous.

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer is reported have a molecular weight of approximately 250,000 Da. None of the particles of Ammonium Acryloyldimethyltaurate/VP Copolymer were >2000 µm, 97.2% were <2000 µm, 81.3% were <1000 µm, 11.8% were <200 µm, and 0.5% were <100 µm. For Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer, 90.8% of the particles of were <100 µm and 84.5% were <10 µm, and had a median diameter of 2.8 µm. The molecular weight of Sodium Polyacryloyldimethyl Taurate was reported to be >1,000,000.

Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer was reported to be >90% pure. Sodium Polyacryloyldimethyl Taurate is reported to contain <2000 ppm AMPS and <10 ppm acrylamide.

According to VCRP data received in 2016, Hydroxyethyl Acrylate/Sodium Acryloyldimethyltaurate Copolymer was reported to be used in 474 formulations, including 451 leave-on products, 21 rinse-off products, and 2 products used in the bath. The ingredients with next highest reported number of uses are Ammonium Acryloyldimethyltaurate/VP Copolymer with 456 uses, Acrylamide/Sodium Acryloyldimethyltaurate Copolymer, with 236 uses, Ammonium Polyacryloyldimethyl Taurate, with 197 uses, and Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer with 165 uses. All other in-use ingredients are reported to be used in 49 or fewer products.

The results of a concentration of use survey conducted by the Council in 2015 indicate Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer has the highest reported maximum concentration of use; it is reported to be



used at up to 4.3% in depilatories (a rinse-off product) and up to 3.6% in eyeliner and eye shadow (leave-on products). The reported maximum concentrations of use for the remaining ingredients range from 0.015%-3% for leave-on products and 0.078%-3.2% in rinse-off products.

The acute dermal LD<sub>50</sub> for Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer was reported to be >5000 mg/kg in rats. The acute dermal LD<sub>50</sub> for a product containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27%) was >5000 mg/kg (>1250 to >1350 mg/kg) in rats.

The acute dermal LD<sub>50</sub> for a solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (24% in water) was reported to be >5000 mg/kg (>1200 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer) in rats. The acute oral LD<sub>50</sub> for a solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27%) was reported to be >5000 mg/kg (>1250 to >1350 mg/kg) in rats.

The acute oral LD<sub>50</sub> for a solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (24% in water) was reported to be >5000 mg/kg (>1200 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer) in rats. The acute oral LD<sub>50</sub> for Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer and Ammonium Acryloyldimethyltaurate/VP Copolymer was reported to be >2000 mg/kg in rats; the oral LD<sub>50</sub> for Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (<60%) in a trade name mixture was reported to be >1200 mg/kg. The acute oral LD<sub>50</sub> for a solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% in water) was reported to be >5000 mg/kg (>1250 to >1350 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer) in rats.

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer, Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer, Ammonium Acryloyldimethyltaurate/VP Copolymer, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, and Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer were not mutagenic in bacterial reverse mutation assays. A product containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27%) was not mutagenic in an Ames test.

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (up to 27%), Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer (100%), and Ammonium Acryloyldimethyltaurate/VP Copolymer (assumed applied at 100%, not specified) were slightly or not irritating to rabbit skin. A solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% in water; assumed applied at 100%, not specified) was not irritating to rat skin.

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer was not irritating in a human assay.

In a Buehler test, Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer was not sensitizing to guinea pigs at 25%. Ammonium Acryloyldimethyltaurate/VP Copolymer was not sensitizing to guinea pigs at 100%.

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (assumed 100%), Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer (<2.25%), and Sodium Polyacryloyldimethyl Taurate (30% to 40%) were not sensitizing in human repeated insult patch tests HRIPTs. Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer was not sensitizing in a human sensitization assay. A product containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27%) was not sensitizing in an HRIPT.

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (up to 27%), Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer (<2.25%), and Sodium Polyacryloyldimethyl Taurate (30% to 40%) were not sensitizing in HRIPTs. A trade name mixture containing Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (<60%; assumed administered at 100%, not specified) was not sensitizing in a human sensitization assay.

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer was not an ocular irritant in an unspecified *in vitro* assay. Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer (<2.25%) was not considered an eye irritant in a HET-CAM assay.

In ocular irritation assays Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer, Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer, and Ammonium Acryloyldimethyltaurate/VP Copolymer were not irritating or slightly irritating to rabbit eyes. A solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% in water; assumed tested at 100%, not specified) was not irritating, according to OECD TG criteria, or minimally irritating, according to US EPA criteria, to rabbit eyes.

## **DISCUSSION**

*To be further developed at the September, 2016 Panel meeting.*

The Panel examined data on dermal, oral and inhalation acute toxicity, genotoxicity, dermal and ocular irritation, and sensitization. There were no studies that elicited concern.

These ingredients are large (2000 µm; >1000 to >1,000,000 g/mol) molecules and should not be absorbed by the skin.

The Panel expressed concern about residual monomers and impurities including acrylamide, vinyl formamide, and methacrylamidolauric acid monomers. They stressed that the cosmetics industry should continue to use current good manufacturing practices (cGMPs) to limit impurities.

The Panel discussed the issue of incidental inhalation exposure from perfumes; tonics, dressings and other hair

grooming aids; body and hand products; and face powders. There were no inhalation toxicity data available. The Panel believes that the sizes of a substantial majority of the particles of these ingredients, as manufactured, are larger than the respirable range and/or aggregate and agglomerate to form much larger particles in formulation. These ingredients are reportedly used at concentrations up to 0.4% in cosmetic products that may be aerosolized and up to 0.7% in other products that may become airborne. The Panel noted that droplets/particles from spray and loose-powder cosmetic products would not be respirable to any appreciable amount. Furthermore, these ingredients are not likely to cause any direct toxic effects in the upper respiratory tract, based on the properties of the acryloyldimethyltaurate polymers and on data that shows that these ingredients are not irritants. Coupled with the small actual exposure in the breathing zone and the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. They noted the lack of irritation or sensitization in tests of dermal exposure, no systemic toxicity at 5000 mg/kg, and the absence of genotoxicity in Ames tests. In addition, these ingredients are large molecules and insoluble in water, which supports the view that they are unlikely to be absorbed or cause local effects in the respiratory tract. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at <http://www.cir-safety.org/cir-findings>.

### **CONCLUSION**

The CIR Expert Panel concluded that the following ingredients are [*To be determined.*]

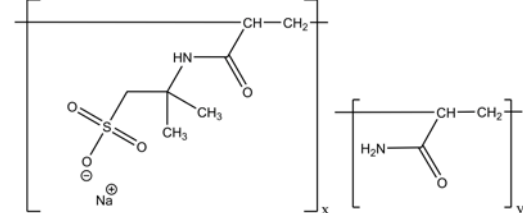
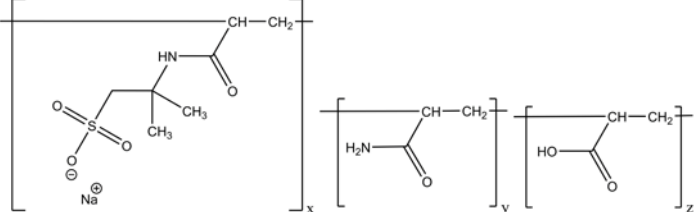
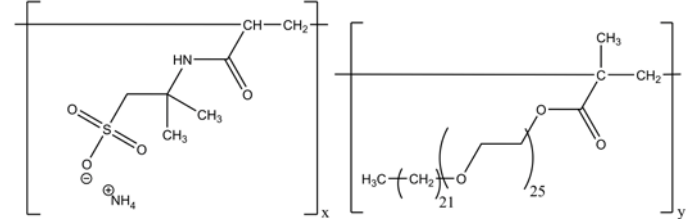
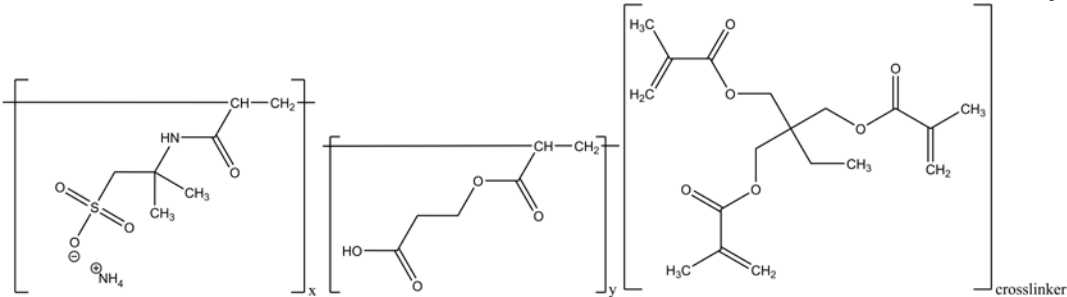
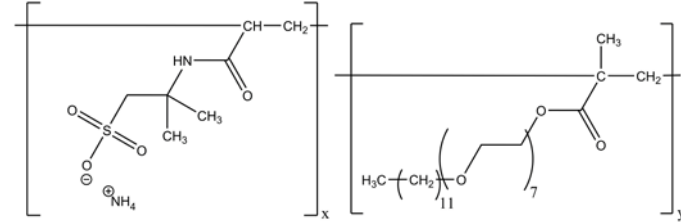
|                                                                        |                                                                         |
|------------------------------------------------------------------------|-------------------------------------------------------------------------|
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer                    | HEA/Sodium Acryloyldimethyltaurate/Steareth-20                          |
| Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer*      | Methacrylate Copolymer                                                  |
| Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer | Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer         |
| Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer    | Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer |
| Ammonium Acryloyldimethyltaurate/Laureth-7 Methacrylate Copolymer*     | Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer               |
| Ammonium Acryloyldimethyltaurate/Steareth-25 Methacrylate Crosspolymer | Sodium Acrylate/Sodium Acryloyldimethyl Taurate/Acrylamide Copolymer    |
| Ammonium Acryloyldimethyltaurate/Steareth-8 Methacrylate Copolymer     | Sodium Acryloyl Dimethyl Taurate/PEG-8 Diacrylate Crosspolymer*         |
| Ammonium Acryloyldimethyltaurate/Vinyl Formamide Copolymer*            | Sodium Acryloyldimethyl Taurate/Acrylamide/VP Copolymer                 |
| Ammonium Acryloyldimethyltaurate/VP Copolymer                          | Sodium Acryloyldimethyltaurate/Methacrylamidolauric Acid Copolymer      |
| Ammonium Polyacryloyldimethyl Taurate                                  | Sodium Acryloyldimethyltaurate/VP Crosspolymer                          |
| Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer         | Sodium Polyacryloyldimethyl Taurate                                     |

\* 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.



## TABLES AND FIGURES

**Table 1.** Definitions, idealized structures, and functions of acryloyldimethyltaurate polymers in this safety assessment.<sup>1; CIR Staff</sup>

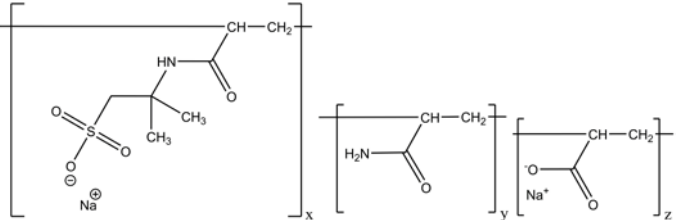
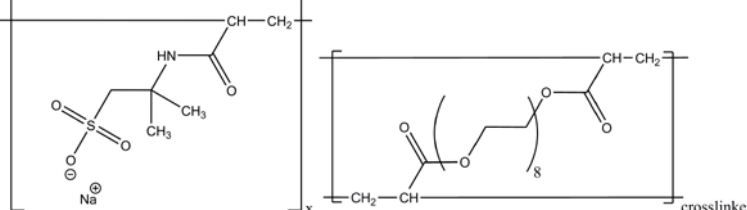
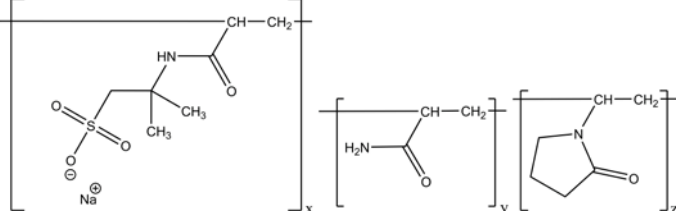
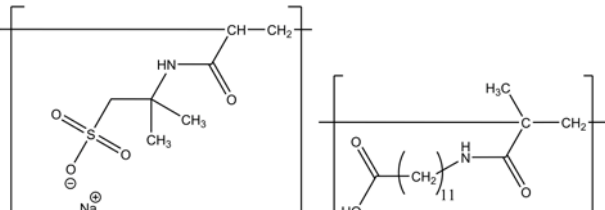
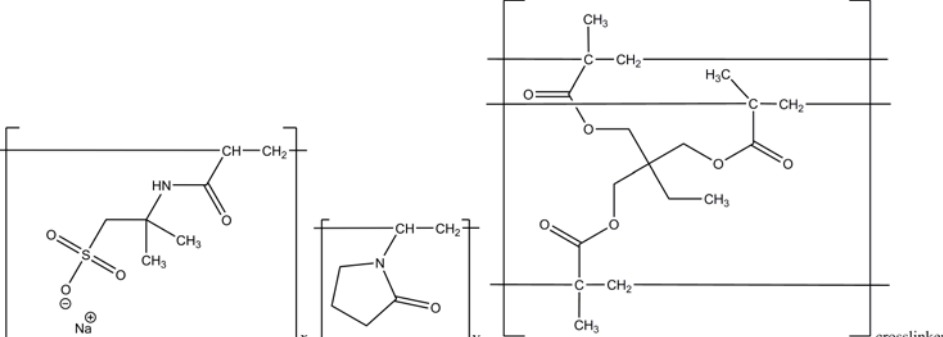
| Ingredient CAS No.                                                                               | Definition & Monomer Residue Structures                                                                                                                                                                                                                                                            | Function(s)                                                            |
|--------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer<br>38193-60-1<br>[1258874-55-3; 159157-50-3] | <p>Acrylamide/Sodium Acryloyldimethyltaurate Copolymer is a copolymer of acrylamide and sodium acryloyldimethyltaurate monomers.</p>                                                                             | Emulsion stabilizer; viscosity increasing agent - aqueous              |
| Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer<br>[1453194-38-1; 1417986-34-5] | <p>Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer is a copolymer of acrylamide, sodium acryloyldimethyltaurate and acrylic acid monomers.</p>                                                  | Film former; hair fixative                                             |
| Ammonium Acryloyldimethyltaurate/ Beheneth-25 Methacrylate Crosspolymer                          | <p>Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer is a copolymer of ammonium acryloyldimethyltaurate and beheneth-25 methacrylate monomers.</p>                                         | Emulsion stabilizer                                                    |
| Ammonium Acryloyldimethyltaurate/ Carboxyethyl Acrylate Crosspolymer                             | <p>Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer is a copolymer of ammonium acryloyl dimethyltaurate and carboxyethyl acrylate crosslinked with trimethylolpropane trimethacrylate.</p>  | Dispersing agent – nonsurfactant; viscosity increasing agent - aqueous |
| Ammonium Acryloyldimethyltaurate/ Laureth-7 Methacrylate Copolymer<br>683748-07-4                | <p>Ammonium Acryloyldimethyltaurate/Laureth-7 Methacrylate Copolymer is a copolymer of ammonium acryloyldimethyltaurate and laureth-7 methacrylate monomers.</p>                                               | Abrasive                                                               |

**Table 1.** Definitions, idealized structures, and functions of acryloyldimethyltaurate polymers in this safety assessment.<sup>1: CIR Staff</sup>

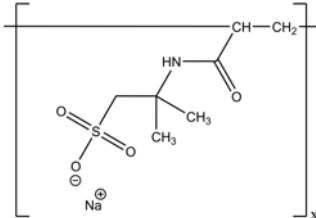
| Ingredient CAS No.                                                        | Definition & Monomer Residue Structures                                                                                                                                                             | Function(s)                                               |
|---------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| Ammonium Acryloyldimethyltaurate/ Steareth-25 Methacrylate Crosspolymer   | <p>Ammonium Acryloyldimethyltaurate/Steareth-25 Methacrylate Crosspolymer is a copolymer of ammonium acryloyldimethyltaurate and steareth-25 methacrylate monomers.</p>                             | Emulsion stabilizer                                       |
| Ammonium Acryloyldimethyltaurate/ Steareth-8 Methacrylate Copolymer       | <p>Ammonium Acryloyldimethyltaurate/Steareth-8 Methacrylate Copolymer is a copolymer of ammonium acryloyldimethyltaurate and steareth-8 methacrylate monomers.</p>                                  | Emulsion stabilizer; viscosity increasing agent - aqueous |
| Ammonium Acryloyldimethyltaurate/ Vinyl Formamide Copolymer [600172-76-7] | <p>Ammonium Acryloyldimethyltaurate/Vinyl Formamide Copolymer is a copolymer of ammonium acryloyldimethyltaurate and vinyl formamide monomers.</p>                                                  | Emulsion stabilizer; viscosity increasing agent - aqueous |
| Ammonium Acryloyldimethyltaurate/ VP Copolymer [1509895-12-8; 53845-64-0] | <p>Ammonium Acryloyldimethyltaurate/VP Copolymer is a copolymer of ammonium acryloyldimethyltaurate and vinylpyrrolidone monomers.</p>                                                              | Viscosity increasing agent - aqueous                      |
| Ammonium Polyacryloyldimethyl Taurate [62152-14-1]                        | <p>Ammonium Polyacryloyldimethyl Taurate is the polymer that conforms generally to the formula. [Ammonium Polyacryloyldimethyl Taurate is the homopolymer of ammonium acryloyldimethyltaurate.]</p> | Emulsion stabilizer; viscosity increasing agent - aqueous |



**Table 1.** Definitions, idealized structures, and functions of acryloyldimethyltaurate polymers in this safety assessment.<sup>1; CIR Staff</sup>

| Ingredient CAS No.                                                                                   | Definition & Monomer Residue Structures                                                                                                                                                                                                                               | Function(s)                                                                                                   |
|------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| Sodium Acrylate/Sodium Acryloyldimethyl Taurate/Acrylamide Copolymer<br>[1453194-38-1; 1417986-34-5] | <p>Sodium Acrylate/Sodium Acryloyldimethyl Taurate/Acrylamide Copolymer is a copolymer of sodium acrylate, sodium acryloyldimethyltaurate and acrylamide monomers.</p>              | Dispersing agent – nonsurfactant; emulsion stabilizer; opacifying agent; viscosity increasing agent – aqueous |
| Sodium Acryloyl Dimethyl Taurate/PEG-8 Diacrylate Crosspolymer                                       | <p>Sodium Acryloyl Dimethyl Taurate/PEG-8 Diacrylate Crosspolymer is a polymer of sodium acryloyl dimethyl taurate crosslinked by PEG-8 diacrylate.</p>                             | Skin-conditioning agent – miscellaneous                                                                       |
| Sodium Acryloyldimethyl Taurate/Acrylamide/VP Copolymer<br>[92815-97-9]                              | <p>Sodium Acryloyldimethyl Taurate/Acrylamide/VP Copolymer is a copolymer of sodium acryloyldimethyltaurate, acrylamide and vinylpyrrolidone monomers.</p>                         | Dispersing agent – nonsurfactant; emulsion stabilizer; opacifying agent; viscosity increasing agent – aqueous |
| Sodium Acryloyldimethyltaurate/Methacrylamidolauric Acid Copolymer<br>[882176-38-7]                  | <p>Sodium Acryloyldimethyltaurate/Methacrylamidolauric Acid Copolymer is a copolymer of sodium acryloyldimethyltaurate and methacrylamidolauric acid monomers.</p>                | Opacifying agent                                                                                              |
| Sodium Acryloyldimethyltaurate/VP Crosspolymer                                                       | <p>Sodium Acryloyldimethyltaurate/VP Crosspolymer is a copolymer of sodium acryloyldimethyltaurate and vinylpyrrolidone crosslinked by 1,1,1-trimethylolpropane triacrylate.</p>  | Emulsion stabilizer                                                                                           |

**Table 1.** Definitions, idealized structures, and functions of acryloyldimethyltaurate polymers in this safety assessment.<sup>1</sup>; CIR Staff

| Ingredient CAS No.                                  | Definition & Monomer Residue Structures                                                                                                                                                                                                                                         | Function(s)                                             |
|-----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
| Sodium Polyacryloyldimethyl Taurate<br>[35641-59-9] | <p>Sodium Polyacryloyldimethyl Taurate is the polymer that conforms generally to the formula. [Sodium Polyacryloyldimethyl Taurate is the homopolymer of sodium acryloyldimethyltaurate.]</p>  | Emulsion stabilizer; viscosity increasing agent-aqueous |

**Table 2.** Previous safety assessments of similar ingredients and components/monomers of acryloyldimethyltaurate polymers in this safety assessment.

| Constituent and ingredient group report | Conclusion                                                                               | Maximum reported concentration of use reported for ingredients in the safety assessment                                                                     | Reference |
|-----------------------------------------|------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Alkyl Taurate Amides And Taurate Salts  | Safe when formulated to be non-irritating                                                | 28% sodium methyl oleoyl taurate in bath products; 11% Calcium lauroyl taurate in leave-on products; 13% sodium methyl cocoyl taurate in rinse-off products | 5         |
| Acrylates Copolymers                    | Safe when formulated to be non-irritating                                                | 40% acrylates copolymer <sup>a</sup>                                                                                                                        | 2         |
| Polyacrylamide And Acrylamide Residues  | Safe as used if the level of acrylamide monomer in formulation is not greater than 5 ppm | 2.8% polyacrylamide in leave-on formulations                                                                                                                | 3         |
| Polyvinylpyrrolidone (PVP)              | Safe as used                                                                             | >5%-10% in leave-on eye products                                                                                                                            | 4         |

<sup>a</sup> Not known if leave-on or rinse-off product(s)**Table 3.** Chemical and physical properties of acryloyldimethyltaurate polymers.

| Property                                                                   | Value                                                 | Reference |
|----------------------------------------------------------------------------|-------------------------------------------------------|-----------|
| <b>Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer</b>    |                                                       |           |
| Molecular Weight g/mol                                                     | ~250,000                                              | 8         |
| Water Solubility                                                           | Forms an aqueous clear colorless liquid at 25% to 27% | 8         |
| <b>Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer</b> |                                                       |           |
| Physical Form                                                              | Powder                                                | 7         |
| Color                                                                      | White                                                 | 7         |
| Molecular Weight g/mol                                                     | >10,000                                               | 7         |
| Bulk Density kg/m <sup>3</sup> @ 25 °C                                     | 237                                                   | 7         |
| Melting Point °C                                                           | >250 (decomposition)                                  | 7         |
| Water Solubility g/L @ 20°C                                                | 200                                                   | 7         |
| <b>Ammonium Acryloyldimethyltaurate/VP Copolymer</b>                       |                                                       |           |
| Physical Form                                                              | Powder                                                | 6         |
| Color                                                                      | White                                                 | 6         |
| Molecular Weight g/mol                                                     | >1000                                                 | 6         |
| Bulk Density kg/m <sup>3</sup>                                             | 230                                                   | 6         |
| Water Solubility g/L @ 20°C                                                | >5                                                    | 6         |

**Table 3.** Chemical and physical properties of acryloyldimethyltaurate polymers.

| Property                                                                       | Value          | Reference |
|--------------------------------------------------------------------------------|----------------|-----------|
| <b>Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer</b>         |                |           |
| Physical Form                                                                  | Viscous liquid | 11        |
| Color                                                                          | White          | 11        |
| Odor                                                                           | Characteristic | 11        |
| Molecular Weight g/mol                                                         | >10,000        | 11        |
| Bulk Density g/kg @ 25°C                                                       | 1100           | 11        |
| Melting Point °C                                                               | 6              |           |
| Water Solubility                                                               | Dispersible    | 11        |
| <b>Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer</b> |                |           |
| Molecular Weight g/mol                                                         | >10,000        | 10        |
| Density/Specific Gravity kg/m <sup>3</sup> @ 25°C                              | 1100           | 10        |
| Melting Point °C                                                               | >200           | 10        |
| <b>Sodium Polyacryloyldimethyl Taurate</b>                                     |                |           |
| Molecular Weight g/mol                                                         | >1,000,000     | 9         |

**Table 4.** Frequency of use according to duration and exposure of acryloyldimethyltaurate polymers.<sup>16,27</sup>

| Use type                         | Maximum Concentration (%)                           |                            | Maximum Concentration (%)                                               |                           | Maximum Concentration (%)                                            |           | Maximum Concentration (%)                                               |                  |
|----------------------------------|-----------------------------------------------------|----------------------------|-------------------------------------------------------------------------|---------------------------|----------------------------------------------------------------------|-----------|-------------------------------------------------------------------------|------------------|
| Uses                             |                                                     |                            | Uses                                                                    |                           |                                                                      | Uses      |                                                                         |                  |
|                                  | Acrylamide/Sodium Acryloyldimethyltaurate Copolymer |                            | Ammonium Acryloyldimethyltaurate /Beheneth-25 Methacrylate Crosspolymer |                           | Ammonium Acryloyldimethyltaurate /Carboxyethyl Acrylate Crosspolymer |           | Ammonium Acryloyldimethyltaurate/ Steareth-25 Methacrylate Crosspolymer |                  |
| <b>Total/range</b>               | <b>236</b>                                          | <b>0.34-3.2</b>            | <b>49</b>                                                               | <b>0.1-2.5</b>            | <b>1</b>                                                             | <b>NR</b> | <b>3</b>                                                                | <b>0.6-1.3</b>   |
| <i>Duration of use</i>           |                                                     |                            |                                                                         |                           |                                                                      |           |                                                                         |                  |
| Leave-on                         | 229                                                 | 0.34-3.2                   | 47                                                                      | 0.1-2.5                   | NR                                                                   | NR        | 3                                                                       | 0.6-1.3          |
| Rinse-off                        | 7                                                   | 0.38-1.6                   | 2                                                                       | 0.2-0.75                  | 1                                                                    | NR        | NR                                                                      | 1                |
| Diluted for (bath) use           | NR                                                  | NR                         | NR                                                                      | NR                        | NR                                                                   | NR        | NR                                                                      | NR               |
| <i>Exposure type<sup>a</sup></i> |                                                     |                            |                                                                         |                           |                                                                      |           |                                                                         |                  |
| Eye area                         | 44                                                  | 0.71-1.8                   | 13                                                                      | 0.4-0.66                  | NR                                                                   | NR        | 1                                                                       | 0.8-0.94         |
| Incidental ingestion             | NR                                                  | NR                         | NR                                                                      | NR                        | NR                                                                   | NR        | NR                                                                      | NR               |
| Incidental Inhalation-sprays     | 1; 114 <sup>b</sup> ; 38 <sup>c</sup>               | 0.47-1.5 <sup>b</sup>      | 13 <sup>b</sup> ; 16 <sup>c</sup>                                       | 0.2; 0.1-0.5 <sup>b</sup> | NR                                                                   | NR        | 1 <sup>b</sup> ; 1 <sup>c</sup>                                         | NR               |
| Incidental inhalation-powders    | 4; 38 <sup>c</sup>                                  | 0.7; 0.54-1.8 <sup>d</sup> | 16 <sup>c</sup>                                                         | 0.3-2.5 <sup>d</sup>      | NR                                                                   | NR        | 1 <sup>c</sup>                                                          | 0.6 <sup>d</sup> |
| Dermal contact                   | 230                                                 | 0.34-3.2                   | 43                                                                      | 0.1-2.5                   | 1                                                                    | NR        | 3                                                                       | 0.6-1.3          |
| Deodorant (underarm)             | NR                                                  | NR                         | NR                                                                      | NR                        | NR                                                                   | NR        | NR                                                                      | NR               |
| Hair-noncoloring                 | 4                                                   | 0.47-1.7                   | NR                                                                      | 0.5-0.8                   | NR                                                                   | NR        | NR                                                                      | NR               |
| Hair-coloring                    | NR                                                  | NR                         | NR                                                                      | 0.2                       | NR                                                                   | NR        | NR                                                                      | 1                |
| Nail                             | NR                                                  | NR                         | NR                                                                      | NR                        | NR                                                                   | NR        | NR                                                                      | NR               |
| Mucous Membrane                  | 1                                                   | NR                         | NR                                                                      | NR                        | NR                                                                   | NR        | NR                                                                      | NR               |
| Baby                             | NR                                                  | NR                         | NR                                                                      | NR                        | NR                                                                   | NR        | NR                                                                      | NR               |

**Table 4.** Frequency of use according to duration and exposure of acryloyldimethyltaurate polymers.<sup>16,27</sup>

| Use type                      | Maximum Concentration (%)                                              |                   | Maximum Concentration (%)                                       |                           | Maximum Concentration (%)                                                 |                      | Maximum Concentration (%)                                       |                           |
|-------------------------------|------------------------------------------------------------------------|-------------------|-----------------------------------------------------------------|---------------------------|---------------------------------------------------------------------------|----------------------|-----------------------------------------------------------------|---------------------------|
|                               | Uses                                                                   |                   | Uses                                                            |                           | Uses                                                                      |                      | Uses                                                            |                           |
|                               | Ammonium Acryloyldimethyltaurate/ Steareth-8 Methacrylate Copolymer    |                   | Ammonium Acryloyldimethyltaurate /VP Copolymer                  |                           | Ammonium Polyacryloyldimethyl Taurate                                     |                      | Dimethylacrylamide/ Sodium Acryloyldimethyltaurate Crosspolymer |                           |
| <b>Total/range</b>            | <b>1</b>                                                               | <b>0.42-0.65</b>  | <b>456</b>                                                      | <b>0.016-3</b>            | <b>197</b>                                                                | <b>0.015-2.3</b>     | <b>7</b>                                                        | <b>0.06-3</b>             |
| <i>Duration of use</i>        |                                                                        |                   |                                                                 |                           |                                                                           |                      |                                                                 |                           |
| Leave-on                      | 1                                                                      | 0.42-0.65         | 428                                                             | 0.016-3                   | 185                                                                       | 0.015-2.3            | 6                                                               | 0.06-3                    |
| Rinse-off                     | NR                                                                     | NR                | 28                                                              | 0.3-1.8                   | 12                                                                        | 0.078-1.5            | 1                                                               | 3                         |
| Diluted for (bath) use        | NR                                                                     | NR                | NR                                                              | NR                        | NR                                                                        | NR                   | NR                                                              | NR                        |
| <i>Exposure type</i>          |                                                                        |                   |                                                                 |                           |                                                                           |                      |                                                                 |                           |
| Eye area                      | NR                                                                     | 0.42              | 58                                                              | 1.4-3                     | 26                                                                        | 0.025-2              | 4                                                               | 1-2                       |
| Incidental ingestion          | NR                                                                     | NR                | 2                                                               | 1.5                       | NR                                                                        | NR                   | NR                                                              | NR                        |
| Incidental Inhalation-sprays  | 1 <sup>b</sup>                                                         | NR                | 1; 168 <sup>b</sup> ; 153 <sup>c</sup>                          | 0.096-1; 0.4 <sup>b</sup> | 63 <sup>b</sup> ; 57 <sup>c</sup>                                         | 1.2 <sup>b</sup>     | 2 <sup>c</sup>                                                  | 0.35-3; 0.72 <sup>b</sup> |
| Incidental inhalation-powders | NR                                                                     | 0.65 <sup>d</sup> | 1; 1 <sup>d</sup> ; 153 <sup>c</sup>                            | 0.18-2 <sup>d</sup>       | 1; 57 <sup>c</sup>                                                        | 0.024-2 <sup>d</sup> | 2 <sup>c</sup>                                                  | 0.65-3 <sup>d</sup>       |
| Dermal contact                | 1                                                                      | 0.42-0.65         | 451                                                             | 0.016-3                   | 197                                                                       | 0.015-2.3            | 7                                                               | 0.06-3                    |
| Deodorant (underarm)          | NR                                                                     | NR                | NR                                                              | NR                        | NR                                                                        | NR                   | NR                                                              | 0.6 <sup>e</sup>          |
| Hair-noncoloring              | NR                                                                     | NR                | NR                                                              | 0.4                       | NR                                                                        | 1.2                  | NR                                                              | 0.72                      |
| Hair-coloring                 | NR                                                                     | NR                | NR                                                              | NR                        | NR                                                                        | NR                   | NR                                                              | NR                        |
| Nail                          | NR                                                                     | NR                | NR                                                              | NR                        | NR                                                                        | NR                   | NR                                                              | NR                        |
| Mucous Membrane               | NR                                                                     | NR                | 4                                                               | 1.5                       | 2                                                                         | 1.2                  | NR                                                              | NR                        |
| Baby                          | NR                                                                     | NR                | 1                                                               | NR                        | NR                                                                        | NR                   | NR                                                              | NR                        |
|                               | HEA/Sodium Acryloyldimethyltaurate/ Steareth-20 Methacrylate Copolymer |                   | Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer |                           | Sodium Acrylate/ Acryloyldimethyltaurate /Dimethylacrylamide Crosspolymer |                      | Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer       |                           |
| <b>Total/range</b>            | <b>NR</b>                                                              | <b>0.18</b>       | <b>474</b>                                                      | <b>0.15-4.3</b>           | <b>1</b>                                                                  | <b>1.6</b>           | <b>165</b>                                                      | <b>0.023-3.2</b>          |
| <i>Duration of use</i>        |                                                                        |                   |                                                                 |                           |                                                                           |                      |                                                                 |                           |
| Leave-on                      | NR                                                                     | 0.18              | 451                                                             | 0.15-3.6                  | 1                                                                         | 1.6                  | 159                                                             | 0.023-2.4                 |
| Rinse-off                     | NR                                                                     | NR                | 21                                                              | 0.2-4.3                   | NR                                                                        | NR                   | 6                                                               | 0.6-3.2                   |
| Diluted for (bath) use        | NR                                                                     | NR                | 2                                                               | NR                        | NR                                                                        | NR                   | NR                                                              | NR                        |
| <i>Exposure type</i>          |                                                                        |                   |                                                                 |                           |                                                                           |                      |                                                                 |                           |
| Eye area                      | NR                                                                     | NR                | 33                                                              | 0.15-3.6                  | NR                                                                        | NR                   | 18                                                              | 0.18-1.2                  |
| Incidental ingestion          | NR                                                                     | NR                | 11                                                              | 1.4                       | NR                                                                        | NR                   | 1                                                               | NR                        |
| Incidental Inhalation-sprays  | NR                                                                     | NR                | 216 <sup>b</sup> ; 124 <sup>c</sup>                             | 0.38-1 <sup>b</sup>       | 1 <sup>b</sup>                                                            | NR                   | 33 <sup>b</sup> ; 76 <sup>c</sup>                               | 0.45-0.6 <sup>b</sup>     |
| Incidental inhalation-powders | NR                                                                     | NR                | 2; 124 <sup>c</sup>                                             | 0.19-2.9 <sup>d</sup>     | NR                                                                        | NR                   | 5; 1 <sup>d</sup> ; 76 <sup>c</sup>                             | 0.088-1.1 <sup>d</sup>    |
| Dermal contact                | NR                                                                     | NR                | 448                                                             | 0.15-4.3                  | NR                                                                        | NR                   | 157                                                             | 0.023-2.4                 |
| Deodorant (underarm)          | NR                                                                     | NR                | NR                                                              | NR                        | NR                                                                        | NR                   | NR                                                              | NR                        |
| Hair-noncoloring              | NR                                                                     | 0.18              | 11                                                              | 0.74                      | 1                                                                         | 1.6                  | 5                                                               | 0.6-3.2                   |
| Hair-coloring                 | NR                                                                     | NR                | NR                                                              | 0.94-1.4                  | NR                                                                        | NR                   | NR                                                              | 2.3                       |
| Nail                          | NR                                                                     | NR                | 3                                                               | NR                        | NR                                                                        | NR                   | NR                                                              | NR                        |
| Mucous Membrane               | NR                                                                     | NR                | 17                                                              | 0.2-1.4                   | NR                                                                        | NR                   | 1                                                               | 2.4                       |
| Baby                          | NR                                                                     | NR                | NR                                                              | NR                        | NR                                                                        | NR                   | 1                                                               | NR                        |

**Table 4.** Frequency of use according to duration and exposure of acryloyldimethyltaurate polymers.<sup>16,27</sup>

| Table 1: Frequency of use according to duration and exposure of acryloyldimethyltaurate polymer. |                                                                      |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
|--------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|---------------------------------------------------------------------|------------------------|-------------------------------------------------|----|
| Use type                                                                                         | Maximum Concentration (%)                                            |                      | Maximum Concentration (%)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                   | Maximum Concentration (%)                                           |                        | Maximum Concentration (%)                       |    |
|                                                                                                  | Uses                                                                 |                      | Uses                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                   | Uses                                                                |                        | Uses                                            |    |
|                                                                                                  | Sodium Acrylate/Sodium Acryloyldimethyl Taurate/Acrylamide Copolymer |                      | Sodium Acryloyldimethyl Taurate/Acrylamide/VP Copolymer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                   | Sodium Acryloyldimethyltaurate /Methacrylamidolauric Acid Copolymer |                        | Sodium Acryloyldimethyltaurate/ VP Crosspolymer |    |
| Total/range                                                                                      | 6                                                                    | 0.3-1.5              | NR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 0.65              | NR                                                                  | 0.28-0.35              | 8                                               | NR |
| Duration of use                                                                                  |                                                                      |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Leave-on                                                                                         | 6                                                                    | 0.3-1.5              | NR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 0.65              | NR                                                                  | 0.28-0.35              | 8                                               | NR |
| Rinse-off                                                                                        | NR                                                                   | 0.3                  | NR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | NR                | NR                                                                  | NR                     | NR                                              | NR |
| Diluted for (bath) use                                                                           | NR                                                                   | NR                   | NR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | NR                | NR                                                                  | NR                     | NR                                              | NR |
| Exposure type                                                                                    |                                                                      |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Eye area                                                                                         | NR                                                                   | 0.58-0.75            | NR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | NR                | NR                                                                  | NR                     | 1                                               | NR |
| Incidental ingestion                                                                             | NR                                                                   | NR                   | NR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | NR                | NR                                                                  | NR                     | NR                                              | NR |
| Incidental Inhalation-sprays                                                                     | 1 <sup>b</sup> ; 1 <sup>c</sup>                                      | NR                   | NR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 0.65 <sup>b</sup> | NR                                                                  | NR                     | 4 <sup>b</sup> ; 3 <sup>c</sup>                 | NR |
| Incidental inhalation-powders                                                                    | 1 <sup>c</sup>                                                       | 0.3-1.5 <sup>d</sup> | NR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | NR                | NR                                                                  | 0.28-0.35 <sup>d</sup> | 3 <sup>c</sup>                                  | NR |
| Dermal contact                                                                                   | 6                                                                    | 0.3-1.5              | NR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 0.65              | NR                                                                  | 0.28-0.35              | 7                                               | NR |
| Deodorant (underarm)                                                                             | NR                                                                   | NR                   | NR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | NR                | NR                                                                  | NR                     | NR                                              | NR |
| Hair-noncoloring                                                                                 | NR                                                                   | 1.2                  | NR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | NR                | NR                                                                  | NR                     | NR                                              | NR |
| Hair-coloring                                                                                    | NR                                                                   | NR                   | NR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | NR                | NR                                                                  | NR                     | NR                                              | NR |
| Nail                                                                                             | NR                                                                   | NR                   | NR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | NR                | NR                                                                  | NR                     | NR                                              | NR |
| Mucous Membrane                                                                                  | NR                                                                   | NR                   | NR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | NR                | NR                                                                  | NR                     | NR                                              | NR |
| Baby                                                                                             | NR                                                                   | NR                   | NR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | NR                | NR                                                                  | NR                     | NR                                              | NR |
|                                                                                                  |                                                                      |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
|                                                                                                  | Sodium Polyacryloyldimethyl Taurate                                  |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Total/range                                                                                      | 38                                                                   | 1.4                  | NR = Not Reported; Totals = Rinse-off + Leave-on + Diluted for Use Product Uses.<br>Note: Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure type uses may not equal the sum total uses.<br><sup>a</sup> Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.<br><sup>b</sup> It is possible these products <u>may</u> be sprays, but it is not specified whether the reported uses are sprays.<br><sup>c</sup> Not specified whether a powder or a spray, so this information is captured for both categories of incidental inhalation.<br><sup>d</sup> It is possible these products <u>may</u> be powders, but it is not specified whether the reported uses are powders.<br><sup>e</sup> Not sprays. |                   |                                                                     |                        |                                                 |    |
| Duration of use                                                                                  |                                                                      |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Leave-on                                                                                         | 37                                                                   | 1.4                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Rinse-off                                                                                        | 1                                                                    | NR                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Diluted for (bath) use                                                                           | NR                                                                   | NR                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Exposure type                                                                                    |                                                                      |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Eye area                                                                                         | NR                                                                   | NR                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Incidental ingestion                                                                             | NR                                                                   | NR                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Incidental Inhalation-sprays                                                                     | 31 <sup>b</sup> ; 3 <sup>c</sup>                                     | NR                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Incidental inhalation-powders                                                                    | 3 <sup>c</sup>                                                       | 1.4 <sup>d</sup>     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Dermal contact                                                                                   | 38                                                                   | 1.4                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Deodorant (underarm)                                                                             | NR                                                                   | NR                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Hair-noncoloring                                                                                 | NR                                                                   | NR                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Hair-coloring                                                                                    | NR                                                                   | NR                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Nail                                                                                             | NR                                                                   | NR                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Mucous Membrane                                                                                  | NR                                                                   | NR                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |
| Baby                                                                                             | NR                                                                   | NR                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                   |                                                                     |                        |                                                 |    |

**Table 5.** Acryloyldimethyltaurate polymers with no reported uses.<sup>15,16</sup>

|                                                                   |                                                                   |
|-------------------------------------------------------------------|-------------------------------------------------------------------|
| Acrylamide/Sodium Acryloyldimethyltaurate/ Acrylic Acid Copolymer | Ammonium Acryloyldimethyltaurate/Laureth-7 Methacrylate Copolymer |
| Ammonium Acryloyldimethyltaurate/Vinyl Formamide Copolymer        | Sodium Acryloyl Dimethyl Taurate/PEG-8 Diacrylate Crosspolymer    |



**Table 6.** Acute toxicity data on acryloyldimethyltaurate polymers.

| Ingredient                                                                                                                                                           | Animal; Methods                                                | Results                                                                                                                                                                                                                                                                                                      | Reference |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| <b>Dermal</b>                                                                                                                                                        |                                                                |                                                                                                                                                                                                                                                                                                              |           |
| Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (aqueous solution containing ingredient at 24%)                                                     | Rats (strain and n not specified); OECD TG 402                 | LD <sub>50</sub> >5000 mg/kg (>1200 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer)                                                                                                                                                                                                  | 12        |
| Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (aqueous solution containing ingredient at 25% to 27%; assumed applied at 100%, not specified).     | Rats (strain and n not specified); 24 h exposure under patch.) | No deaths. All rats gained weight and there were no clinical signs (gross toxicity, dermal irritation, adverse pharmacologic effects, or abnormal behavior). Necropsy was unremarkable. LD <sub>50</sub> >5000 mg/kg (>1250 to >1350 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer) | 26        |
| <b>Oral</b>                                                                                                                                                          |                                                                |                                                                                                                                                                                                                                                                                                              |           |
| Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (aqueous solution containing ingredient at 24%)                                                     | Rats (strain and n not specified); OECD TG 425                 | LD <sub>50</sub> >5000 mg/kg (>1200 mg/kg polymer)                                                                                                                                                                                                                                                           | 12        |
| Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (aqueous solution containing ingredient at 25% to 27%; assumed administered at 100%, not specified) | Rats (strain and n not specified); method not specified        | LD <sub>50</sub> >5000 mg/kg (>1250 to >1350 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer)                                                                                                                                                                                         | 26        |
| Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer                                                                                                  | HanRcc:WIST (SPF) Rats (n=3); OECD TG 423                      | LD <sub>50</sub> >2000 mg/kg; 5 h after treatment, 3 rats showed slight ruffled fur; no other clinical signs were observed and no macroscopic findings were observed at necropsy. Body weight of the rats was within range commonly recorded for this strain and age.                                        | 7         |
| Ammonium Acryloyldimethyltaurate/VP Copolymer                                                                                                                        | Rats; OECD TG 401                                              | LD <sub>50</sub> >2000 mg/kg                                                                                                                                                                                                                                                                                 | 6         |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (trade name mixture containing ingredient at <60%)                                                   | Rats (strain and n not specified); method not specified        | LD <sub>50</sub> >2000 mg/kg (<1200 mg/kg)                                                                                                                                                                                                                                                                   | 11        |

OECD TG = Organization for Economic Co-operation and Development Test Guideline

**Table 7.** In vitro genotoxicity assays of acryloyldimethyltaurate polymers.

| Ingredient                                                                                                                                                      | Assay/Method                                                                                                                        | Results                                                                                                                                                          | Reference |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (aqueous solution containing ingredient at 24%; assumed applied at 100%, not specified)        | Bacterial reverse mutation assay (OECD TG 471)                                                                                      | Not mutagenic                                                                                                                                                    | 12        |
| Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (aqueous solution containing ingredient at 25% to 27%; assumed applied at 100%, not specified) | Ames test. <i>S. typhimurium</i> (TA98, TA100, TA1535, and TA1537) and <i>E. coli</i> (WP2uvrA)                                     | Not mutagenic up to 5000 µg/plate (1250 to 1350 µg/plate Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer) with and without metabolic activation | 26        |
| Ammonium Acryloyldimethyltaurate/ Carboxyethyl Acrylate Crosspolymer (concentration not provided)                                                               | Bacterial reverse mutation assay (OECD TG 471) <i>S. typhimurium</i> (TA98, TA100, TA1535, and TA1537) and <i>E. coli</i> (WP2uvrA) | Not mutagenic up to 2000 µg/plate with and without metabolic activation                                                                                          | 7         |
| Ammonium Acryloyldimethyltaurate/VP Copolymer (concentration not provided)                                                                                      | Bacterial reverse mutation assay (OECD TG 471)                                                                                      | Not mutagenic                                                                                                                                                    | 6         |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (trade name mixture at <60%; concentration not provided)                                        | Bacterial reverse mutation assay;                                                                                                   | Not mutagenic                                                                                                                                                    | 11        |
| Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer (trade name mixture at <45%; assumed applied at 100%, not specified)                    | Bacterial reverse mutation assay (OECD TG 471) in a trade name mixture at <45%; assumed applied at 100%, not specified              | Not mutagenic or cytotoxic up to 5000 µg/plate (<2250 µg/plate Sodium Acrylate/Acryloyldimethyltaurate /Dimethylacrylamide Crosspolymer)                         | 10        |

OECD TG = Organization for Economic Co-operation and Development Test Guideline

**Table 8.** Dermal irritation studies of acryloyldimethyltaurate polymers in rabbits.

| Ingredient (concentration)                                                                                                                                         | Animal; method                                                           | Results                                                                                                                                                                                                                     | Reference |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Acrylamide/Sodium Acryloyldimethyltaurate/<br>Acrylic Acid Copolymer (aqueous solution<br>containing ingredient at 24%; assumed applied<br>at 100%, not specified) | Rabbits (n and strain not<br>specified); primary skin<br>irritation test | Exhibited very slight to well-defined erythema and<br>very slight edema 1 h after patch removal. All signs<br>of dermal irritation were resolved at 48 h after patch<br>removal. The PII according to Draize score was 1.2. | 12        |
| Acrylamide/Sodium Acryloyldimethyltaurate/<br>Acrylic Acid Copolymer (aqueous solution at<br>25% to 27%; assumed administered at 100%,<br>not specified)           | Rabbits (n and strain not<br>specified); method not specified            | US EPA: minimal irritant; OECD TG: Nonirritant                                                                                                                                                                              | 26        |
| Ammonium Acryloyldimethyltaurate/<br>Carboxyethyl Acrylate Crosspolymer (100%<br>moistened with water when administered)                                           | New Zealand White rabbit<br>(n=3); OECD TG 404                           | Mild signs of irritation (erythema formation)<br>observed in all rabbits; no longer evident at day 7<br>after treatment.                                                                                                    | 7         |
| Ammonium Acryloyldimethyltaurate/VP<br>Copolymer (assumed 100%, not specified)                                                                                     | Rabbit (n and strain not<br>specified); OECD TG 404                      | Not irritating                                                                                                                                                                                                              | 6         |

OECD TG = Organization for Economic Co-operation and Development Test Guideline

PII = Primary Irritation Index

**Table 9.** Sensitization studies of acryloyldimethyltaurate polymers.

| Ingredient (concentration)                                                                                                                                         | Assay; n<br>Animal                                                                           | Results                                                                                   | Reference |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|-----------|
| Ammonium Acryloyldimethyltaurate/Carboxyethyl<br>Acrylate Crosspolymer (25% in petrolatum)                                                                         | Buehler Test OECD TG 406 in<br>Pirbright-White guinea<br>pigs/HsdPoc:DH; n=19;<br>control=10 | Not sensitizing                                                                           | 7         |
| Ammonium Acryloyldimethyltaurate/VP<br>Copolymer (assumed 100%, not specified)                                                                                     | OECD TG 406 in guinea pigs; n<br>and strain not specified                                    | No signs of irritation or sensitization                                                   | 6         |
| <b>Human</b>                                                                                                                                                       |                                                                                              |                                                                                           |           |
| Acrylamide/Sodium Acryloyldimethyltaurate/<br>Acrylic Acid Copolymer (aqueous solution<br>containing ingredient at 24%; assumed applied at<br>100%, not specified) | HRIPT; n not specified                                                                       | No evidence of sensitization.                                                             | 12        |
| Acrylamide/Sodium Acryloyldimethyltaurate/<br>Acrylic Acid Copolymer (25% to 27% in water;<br>assumed administered at 100%, not specified)                         | HRIPT; 102                                                                                   | Not sensitizing                                                                           | 26        |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl<br>Taurate Copolymer (in a trade name mixture at<br><60%; assumed administered at 100%, not<br>specified)            | Not specified; not specified                                                                 | Not sensitizing                                                                           | 11        |
| Sodium Acrylate/Acryloyldimethyltaurate/<br>Dimethylacrylamide Crosspolymer (<2.25%; in a<br>trade name mixture at <45%; tested at 5% in water)                    | HRIPT; 50                                                                                    | One reaction of erythema/edema was<br>observed in 1 subject on Day 40.                    | 10        |
| Sodium Polyacryloyldimethyl Taurate (30% to<br>40%)                                                                                                                | HRIPT; 100                                                                                   | No adverse reactions were observed<br>during the study. Not irritating or<br>sensitizing. | 9         |

HRIPT = Human repeated insult patch test.

**Table 10.** *In vitro* and animal ocular irritation assays.

| <b>Ingredient (concentration)</b>                                                                                                                       | <b>Animal; method</b>                                                 | <b>Results</b>                                                                                                                                                                                                                                                                                               | <b>Reference</b> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| <b><i>In vitro</i></b>                                                                                                                                  |                                                                       |                                                                                                                                                                                                                                                                                                              |                  |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (trade name mixture <60%; assumed applied at 100%, not specified)                       | Not specified                                                         | Not an ocular irritant                                                                                                                                                                                                                                                                                       | 11               |
| Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer (<2.25%; in a trade name mixture at <45%; tested at 5% in water)                | HET-CAM                                                               | No signs of hyperemia, hemorrhage, or coagulation were observed in any of the membranes tested. The test substance was not considered an eye irritant.                                                                                                                                                       | 10               |
| <b><i>Animal</i></b>                                                                                                                                    |                                                                       |                                                                                                                                                                                                                                                                                                              |                  |
| Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (aqueous solution containing ingredient at 24%; assumed tested at 100%, not specified) | Rabbit eyes (n and strain not specified); OECD TG 405                 | Not irritating                                                                                                                                                                                                                                                                                               | 12               |
| Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (solution containing 25% to 27% in water; assumed tested at 100%, not specified)       | Rabbit eyes (n and strain not specified); primary eye irritation test | After a single instillation, no corneal opacity or iritis was noted for any treated eye during the study. ~1 h after instillation, conjunctivitis was observed in all treated eyes. All signs of ocular irritation were resolved by 48 h.<br>US EPA scoring: Minimal irritant; OECD TG scoring: nonirritant. | 26               |
| Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer (assumed tested at 100%, not specified)                                             | New Zealand White rabbit eyes (n=3); OECD TG 405                      | Slight to moderate reddening and slight swelling of the conjunctivae in all rabbits at 1 h; resolved 72 h after treatment. It was concluded that this polymer is slightly irritating to the eye.                                                                                                             | 7                |
| Ammonium Acryloyldimethyltaurate/VP Copolymer (assumed tested at 100%, not specified)                                                                   | Rabbit eyes (n and strain not specified); OECD TG 405                 | Not irritating                                                                                                                                                                                                                                                                                               | 6                |

HET-CAM = Hens Eggs test-Chorio-Allantoic Membrane

OECD TG = Organization for Economic Co-operation and Development Test Guideline

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## 2016 VCRP Data – Acryloyldimethyltaurate Polymers

|                                                                  |                                                        |     |
|------------------------------------------------------------------|--------------------------------------------------------|-----|
| 03B - Eyeliner                                                   | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 2   |
| 03C - Eye Shadow                                                 | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 9   |
| 03D - Eye Lotion                                                 | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 18  |
| 03F - Mascara                                                    | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 2   |
| 03G - Other Eye Makeup Preparations                              | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 13  |
| 04C - Powders (dusting and talcum,<br>excluding aftershave talc) | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 1   |
| 04E - Other Fragrance Preparation                                | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 1   |
| 05G - Tonics, Dressings, and Other Hair<br>Grooming Aids         | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 1   |
| 05H - Wave Sets                                                  | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 1   |
| 05I - Other Hair Preparations                                    | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 2   |
| 07A - Blushers (all types)                                       | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 4   |
| 07B - Face Powders                                               | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 3   |
| 07C - Foundations                                                | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 1   |
| 07F - Makeup Bases                                               | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 1   |
| 07I - Other Makeup Preparations                                  | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 3   |
| 10A - Bath Soaps and Detergents                                  | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 1   |
| 11A - Aftershave Lotion                                          | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 3   |
| 11G - Other Shaving Preparation Products                         | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 1   |
| 12A - Cleansing                                                  | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 2   |
| 12C - Face and Neck (exc shave)                                  | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 21  |
| 12D - Body and Hand (exc shave)                                  | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 17  |
| 12F - Moisturizing                                               | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 91  |
| 12G - Night                                                      | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 19  |
| 12H - Paste Masks (mud packs)                                    | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 2   |
| 12I - Skin Fresheners                                            | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 1   |
| 12J - Other Skin Care Preps                                      | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 14  |
| 13A - Suntan Gels, Creams, and Liquids                           | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 1   |
| 13B - Indoor Tanning Preparations                                | ACRYLAMIDE/SODIUM<br>ACRYLOYLDIMETHYLTAURATE COPOLYMER | 1   |
|                                                                  |                                                        | 236 |

|                                             |                                                                            |    |
|---------------------------------------------|----------------------------------------------------------------------------|----|
| 03D - Eye Lotion                            | AMMONIUM ACRYLOYLDIMETHYLTAURATE/<br>BEHENETH-25 METHACRYLATE CROSSPOLYMER | 5  |
| 03F - Mascara                               | AMMONIUM ACRYLOYLDIMETHYLTAURATE/<br>BEHENETH-25 METHACRYLATE CROSSPOLYMER | 6  |
| 03G - Other Eye Makeup Preparations         | AMMONIUM ACRYLOYLDIMETHYLTAURATE/<br>BEHENETH-25 METHACRYLATE CROSSPOLYMER | 2  |
| 11A - Aftershave Lotion                     | AMMONIUM ACRYLOYLDIMETHYLTAURATE/<br>BEHENETH-25 METHACRYLATE CROSSPOLYMER | 1  |
| 11G - Other Shaving Preparation<br>Products | AMMONIUM ACRYLOYLDIMETHYLTAURATE/<br>BEHENETH-25 METHACRYLATE CROSSPOLYMER | 2  |
| 12C - Face and Neck (exc shave)             | AMMONIUM ACRYLOYLDIMETHYLTAURATE/<br>BEHENETH-25 METHACRYLATE CROSSPOLYMER | 14 |
| 12D - Body and Hand (exc shave)             | AMMONIUM ACRYLOYLDIMETHYLTAURATE/<br>BEHENETH-25 METHACRYLATE CROSSPOLYMER | 2  |
| 12F - Moisturizing                          | AMMONIUM ACRYLOYLDIMETHYLTAURATE/<br>BEHENETH-25 METHACRYLATE CROSSPOLYMER | 8  |
| 12G - Night                                 | AMMONIUM ACRYLOYLDIMETHYLTAURATE/<br>BEHENETH-25 METHACRYLATE CROSSPOLYMER | 4  |
| 12J - Other Skin Care Preps                 | AMMONIUM ACRYLOYLDIMETHYLTAURATE/<br>BEHENETH-25 METHACRYLATE CROSSPOLYMER | 4  |
| 13B - Indoor Tanning Preparations           | AMMONIUM ACRYLOYLDIMETHYLTAURATE/<br>BEHENETH-25 METHACRYLATE CROSSPOLYMER | 1  |
|                                             |                                                                            | 49 |

|                 |                                                                           |   |
|-----------------|---------------------------------------------------------------------------|---|
| 12A - Cleansing | AMMONIUM<br>ACRYLOYLDIMETHYLTAURATE/CARBOXYETHYL<br>ACRYLATE CROSSPOLYMER | 1 |
|-----------------|---------------------------------------------------------------------------|---|

|                                        |                                                                            |   |
|----------------------------------------|----------------------------------------------------------------------------|---|
| 03G - Other Eye Makeup<br>Preparations | AMMONIUM ACRYLOYLDIMETHYLTAURATE/<br>STEARETH-25 METHACRYLATE CROSSPOLYMER | 1 |
| 12C - Face and Neck (exc shave)        | AMMONIUM ACRYLOYLDIMETHYLTAURATE/<br>STEARETH-25 METHACRYLATE CROSSPOLYMER | 1 |
| 12G - Night                            | AMMONIUM ACRYLOYLDIMETHYLTAURATE/<br>STEARETH-25 METHACRYLATE CROSSPOLYMER | 1 |
|                                        |                                                                            | 3 |

|                    |                                                                        |   |
|--------------------|------------------------------------------------------------------------|---|
| 12F - Moisturizing | AMMONIUM ACRYLOYLDIMETHYLTAURATE/ STEARETH-8<br>METHACRYLATE COPOLYMER | 1 |
|--------------------|------------------------------------------------------------------------|---|

|                                               |                                                |     |
|-----------------------------------------------|------------------------------------------------|-----|
| 01B - Baby Lotions, Oils, Powders, and Creams | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 1   |
| 03B - Eyeliner                                | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 10  |
| 03D - Eye Lotion                              | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 28  |
| 03E - Eye Makeup Remover                      | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 2   |
| 03F - Mascara                                 | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 3   |
| 03G - Other Eye Makeup Preparations           | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 15  |
| 04E - Other Fragrance Preparation             | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 1   |
| 07B - Face Powders                            | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 1   |
| 07C - Foundations                             | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 1   |
| 07D - Leg and Body Paints                     | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 1   |
| 07E - Lipstick                                | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 2   |
| 07I - Other Makeup Preparations               | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 4   |
| 10E - Other Personal Cleanliness Products     | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 2   |
| 11A - Aftershave Lotion                       | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 6   |
| 11D - Preshave Lotions (all types)            | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 1   |
| 11G - Other Shaving Preparation Products      | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 5   |
| 12A - Cleansing                               | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 12  |
| 12C - Face and Neck (exc shave)               | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 122 |
| 12D - Body and Hand (exc shave)               | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 31  |
| 12F - Moisturizing                            | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 117 |
| 12G - Night                                   | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 39  |
| 12H - Paste Masks (mud packs)                 | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 6   |
| 12I - Skin Fresheners                         | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 3   |
| 12J - Other Skin Care Preps                   | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 34  |
| 13B - Indoor Tanning Preparations             | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 8   |
| 13C - Other Suntan Preparations               | AMMONIUM ACRYLOYLDIMETHYLTAURATE /VP COPOLYMER | 1   |
|                                               |                                                | 456 |



|                                           |                                       |     |
|-------------------------------------------|---------------------------------------|-----|
| 03D - Eye Lotion                          | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 12  |
| 03G - Other Eye Makeup Preparations       | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 14  |
| 07B - Face Powders                        | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 1   |
| 07C - Foundations                         | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 9   |
| 07F - Makeup Bases                        | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 1   |
| 07G - Rouges                              | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 1   |
| 07I - Other Makeup Preparations           | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 2   |
| 10E - Other Personal Cleanliness Products | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 2   |
| 11A - Aftershave Lotion                   | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 1   |
| 11D - Preshave Lotions (all types)        | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 1   |
| 11G - Other Shaving Preparation Products  | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 1   |
| 12A - Cleansing                           | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 8   |
| 12C - Face and Neck (exc shave)           | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 48  |
| 12D - Body and Hand (exc shave)           | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 9   |
| 12F - Moisturizing                        | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 52  |
| 12G - Night                               | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 10  |
| 12I - Skin Fresheners                     | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 1   |
| 12J - Other Skin Care Preps               | AMMONIUM POLYACRYLOYLDIMETHYL TAURATE | 24  |
|                                           |                                       | 197 |

|                                     |                                                                |   |
|-------------------------------------|----------------------------------------------------------------|---|
| 03D - Eye Lotion                    | DIMETHYLACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE CROSSPOLYMER | 3 |
| 03G - Other Eye Makeup Preparations | DIMETHYLACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE CROSSPOLYMER | 1 |
| 12A - Cleansing                     | DIMETHYLACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE CROSSPOLYMER | 1 |
| 12C - Face and Neck (exc shave)     | DIMETHYLACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE CROSSPOLYMER | 2 |
|                                     |                                                                | 7 |

|                                     |                                                                 |    |
|-------------------------------------|-----------------------------------------------------------------|----|
| 02A - Bath Oils, Tablets, and Salts | HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER | 1  |
| 02D - Other Bath Preparations       | HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER | 1  |
| 03C - Eye Shadow                    | HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER | 1  |
| 03D - Eye Lotion                    | HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER | 24 |
| 03F - Mascara                       | HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER | 1  |
| 03G - Other Eye Makeup Preparations | HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER | 7  |
| 05A - Hair Conditioner              | HYDROXYETHYL ACRYLATE/SODIUM                                    | 2  |

|                                                       |                                                                    |     |
|-------------------------------------------------------|--------------------------------------------------------------------|-----|
|                                                       | ACRYLOYLDIMETHYL TAURATE COPOLYMER                                 |     |
| 05G - Tonics, Dressings, and Other Hair Grooming Aids | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 6   |
| 05I - Other Hair Preparations                         | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 3   |
| 07A - Blushers (all types)                            | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 1   |
| 07B - Face Powders                                    | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 2   |
| 07C - Foundations                                     | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 14  |
| 07D - Leg and Body Paints                             | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 2   |
| 07E - Lipstick                                        | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 11  |
| 07F - Makeup Bases                                    | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 2   |
| 07G - Rouges                                          | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 2   |
| 07I - Other Makeup Preparations                       | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 10  |
| 08B - Cuticle Softeners                               | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 1   |
| 08C - Nail Creams and Lotions                         | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 1   |
| 08G - Other Manicuring Preparations                   | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 1   |
| 10E - Other Personal Cleanliness Products             | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 4   |
| 11A - Aftershave Lotion                               | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 4   |
| 11G - Other Shaving Preparation Products              | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 1   |
| 12A - Cleansing                                       | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 8   |
| 12C - Face and Neck (exc shave)                       | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 84  |
| 12D - Body and Hand (exc shave)                       | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 40  |
| 12F - Moisturizing                                    | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 116 |
| 12G - Night                                           | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 37  |
| 12H - Paste Masks (mud packs)                         | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 6   |
| 12I - Skin Fresheners                                 | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 1   |
| 12J - Other Skin Care Preps                           | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 24  |
| 13A - Suntan Gels, Creams, and Liquids                | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 6   |
| 13B - Indoor Tanning Preparations                     | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 48  |
| 13C - Other Suntan Preparations                       | HYDROXYETHYL ACRYLATE/SODIUM<br>ACRYLOYLDIMETHYL TAURATE COPOLYMER | 2   |
|                                                       |                                                                    | 474 |

|                                                               |                                                                             |     |
|---------------------------------------------------------------|-----------------------------------------------------------------------------|-----|
| 05G - Tonics, Dressings, and Other Hair Grooming Aids         | SODIUM ACRYLATE/ACRYLOYLDIMETHYLTAURATE/<br>DIMETHYLACRYLAMIDE CROSSPOLYMER | 1   |
| 01B - Baby Lotions, Oils, Powders, and Creams                 | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 1   |
| 03B - Eyeliner                                                | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 1   |
| 03D - Eye Lotion                                              | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 7   |
| 03F - Mascara                                                 | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 2   |
| 03G - Other Eye Makeup Preparations                           | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 8   |
| 04C - Powders (dusting and talcum, excluding aftershave talc) | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 4   |
| 05G - Tonics, Dressings, and Other Hair Grooming Aids         | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 3   |
| 05I - Other Hair Preparations                                 | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 2   |
| 07B - Face Powders                                            | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 1   |
| 07C - Foundations                                             | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 4   |
| 07E - Lipstick                                                | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 1   |
| 07I - Other Makeup Preparations                               | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 4   |
| 11A - Aftershave Lotion                                       | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 2   |
| 11G - Other Shaving Preparation Products                      | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 3   |
| 12A - Cleansing                                               | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 1   |
| 12C - Face and Neck (exc shave)                               | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 40  |
| 12D - Body and Hand (exc shave)                               | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 36  |
| 12F - Moisturizing                                            | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 26  |
| 12G - Night                                                   | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 2   |
| 12H - Paste Masks (mud packs)                                 | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 2   |
| 12J - Other Skin Care Preps                                   | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 13  |
| 13A - Suntan Gels, Creams, and Liquids                        | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 1   |
| 13B - Indoor Tanning Preparations                             | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL<br>TAURATE COPOLYMER                | 1   |
|                                                               |                                                                             | 165 |

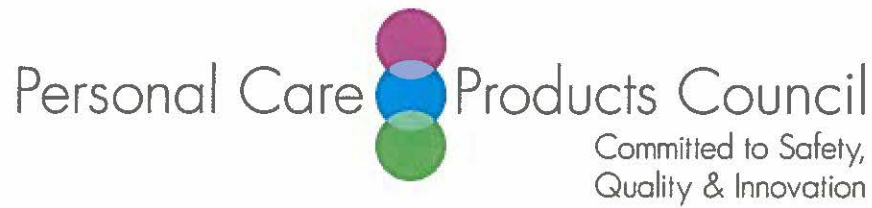
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|----------------------------------------|----------------------------------------------------------------------|---|
| 12C - Face and Neck (exc shave)        | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE/ACRYLAMIDE COPOLYMER | 1 |
| 12J - Other Skin Care Preps            | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE/ACRYLAMIDE COPOLYMER | 4 |
| 13A - Suntan Gels, Creams, and Liquids | SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE/ACRYLAMIDE COPOLYMER | 1 |
|                                        |                                                                      | 6 |

|                                     |                                                |   |
|-------------------------------------|------------------------------------------------|---|
| 03G - Other Eye Makeup Preparations | SODIUM ACRYLOYLDIMETHYLTAURATE/VP CROSSPOLYMER | 1 |
| 12C - Face and Neck (exc shave)     | SODIUM ACRYLOYLDIMETHYLTAURATE/VP CROSSPOLYMER | 1 |
| 12D - Body and Hand (exc shave)     | SODIUM ACRYLOYLDIMETHYLTAURATE/VP CROSSPOLYMER | 2 |
| 12F - Moisturizing                  | SODIUM ACRYLOYLDIMETHYLTAURATE/VP CROSSPOLYMER | 2 |
| 13B - Indoor Tanning Preparations   | SODIUM ACRYLOYLDIMETHYLTAURATE/VP CROSSPOLYMER | 2 |
|                                     |                                                | 8 |

|                                        |                                     |    |
|----------------------------------------|-------------------------------------|----|
| 12A - Cleansing                        | SODIUM POLYACRYLOYLDIMETHYL TAURATE | 1  |
| 12D - Body and Hand (exc shave)        | SODIUM POLYACRYLOYLDIMETHYL TAURATE | 3  |
| 12F - Moisturizing                     | SODIUM POLYACRYLOYLDIMETHYL TAURATE | 26 |
| 12J - Other Skin Care Preps            | SODIUM POLYACRYLOYLDIMETHYL TAURATE | 3  |
| 13A - Suntan Gels, Creams, and Liquids | SODIUM POLYACRYLOYLDIMETHYL TAURATE | 1  |
| 13B - Indoor Tanning Preparations      | SODIUM POLYACRYLOYLDIMETHYL TAURATE | 4  |
|                                        |                                     | 38 |

**There were no reported uses in the 2016 VCRP for:**

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer  
Ammonium Acryloyldimethyltaurate/Laureth-7 Methacrylate Copolymer  
Ammonium Acryloyldimethyltaurate/Vinyl Formamide Copolymer  
Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer  
HEA/Sodium Acryloyldimethyltaurate/Steareth-20 Methacrylate Copolymer  
Polyacryloyldimethyltaurate Polyoxymethylene Melamine  
Sodium Acryloyl Dimethyl Taurate/PEG-8 Diacrylate Crosspolymer  
Sodium Acryloyldimethyl Taurate/Acrylamide/VP Copolymer  
Sodium Acryloyldimethyltaurate/Methacrylamidolauric Acid Copolymer



**Memorandum**

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

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

A handwritten signature in purple ink that reads "Beth A. Lange".

**DATE:** April 18, 2016

**SUBJECT:** Sodium Polyacryloyldimethyl Taurate

Anonymous. 2016. Summary information Sodium Polyacryloyldimethyl Taurate.

April 15, 2016

### **Summary Information Sodium Polyacryloyldimethyl Taurate**

**Molecular weight:** All batches have molecular weights above 1,000,000 Da

Impurities from the polymerization process are measured regularly with the following results:

**AMPS (2-acrylamido-2-methylpropane sulfonic acid):** below 2000 ppm  
**acrylamide:** below limit of quantification 10 ppm (other measures indicated a probable quantity below 0.5 ppm, but the current method is validated with 10 ppm as the quantification limit for this specific matrix)

#### **Summary of a human repeat insult patch test on a formulation containing 30-40% Sodium Polyacryloyldimethyl Taurate**

A Repeat Insult Patch test was carried out on 100 human subject to evaluate Skin irritation/sensitization (occlusive patch) following Good Clinical Practice and COLIPA guidelines, and the Appraisal of the Safety of Chemicals, Food, Drugs and Cosmetics, published by the Association of Food and Drugs officials of the United States, 1965 (modified). No adverse reactions of any kind were noted during the course of the study an the final result was non-primary irritation and non-primary sensitization to the skin.



**Memorandum**

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

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

**DATE:** April 18, 2016

**SUBJECT:** Updated Concentration of Use by FDA Product Category: Acryloyldimethyltaurate Polymers

**Concentration of Use by FDA Product Category – Acryloyldimethyltaurate Polymers\***

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer  
 Ammonium Acryloyldimethyltaurate/VP Copolymer  
 Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer  
 Acrylamide/Sodium Acryloyldimethyltaurate Copolymer  
 Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer  
 Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer  
 Ammonium Acryloyldimethyltaurate/Laureth-7 Methacrylate Copolymer  
 Ammonium Acryloyldimethyltaurate/Steareth-8 Methacrylate Copolymer  
 Ammonium Acryloyldimethyltaurate/Steareth-25 Methacrylate Crosspolymer  
 Ammonium Acryloyldimethyltaurate/Vinyl Formamide Copolymer  
 Ammonium Polyacryloyldimethyl Taurate  
 Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer  
 Polyacryloyldimethyltaurate Polyoxymethylene Melamine  
 Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer  
 Sodium Acrylate/Sodium Acryloyldimethyl Taurate/Acrylamide Copolymer  
 Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer  
 Sodium Acryloyldimethyl Taurate/Acrylamide/VP Copolymer  
 Sodium Acryloyldimethyltaurate/Methacrylamidolauric Acid Copolymer  
 Sodium Acryloyl Dimethyl Taurate/PEG-8 Diacrylate Crosspolymer  
 Sodium Acryloyldimethyltaurate/VP Crosspolymer  
 Sodium Polyacryloyldimethyl Taurate

| <b>Ingredient</b>                                               | <b>Product Category</b>                        | <b>Maximum Concentration of Use</b> |
|-----------------------------------------------------------------|------------------------------------------------|-------------------------------------|
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Eyeliners                                      | 1.2-3.6%                            |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Eye shadow                                     | 3.6%                                |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Eye lotion                                     | 0.15-1.5%                           |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Other eye makeup preparations                  | 2.3%                                |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Tonics, dressings and other hair grooming aids | 0.74%                               |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Hair dyes and colors                           | 0.94-1.4%                           |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Blushers                                       | 0.57%                               |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Foundations                                    | 0.21-1.2%                           |
| Hydroxyethyl Acrylate/Sodium                                    | Lipstick                                       | 1.4%                                |



|                                                                 |                                                                   |                 |
|-----------------------------------------------------------------|-------------------------------------------------------------------|-----------------|
| Acryloyldimethyl Taurate Copolymer                              |                                                                   |                 |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Makeup bases                                                      | 0.75%           |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Bath soaps and detergents                                         | 0.2%            |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Aftershave lotions                                                | 0.88-1.2%       |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Other shaving preparations                                        | 0.94%           |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 1.2%            |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Depilatories                                                      | 4.3%            |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Face and neck products<br>Not spray<br>Not spray, not powder      | 0.19-2.9%<br>3% |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Body and hand products<br>Not spray                               | 0.2-1.3%        |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Moisturizing products<br>Not spray                                | 0.44-2.6%       |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Night products<br>Not spray                                       | 0.94-1.9%       |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Pastes masks and mud packs                                        | 0.5-1.9%        |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Other skin care preparations                                      | 0.19-2.6%       |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Suntan products<br>Not spray                                      | 0.15-3%         |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Indoor tanning preparations                                       | 0.38-1%         |
| Ammonium Acryloyldimethyltaurate/VP Copolymer                   | Eye lotion                                                        | 1.5-3%          |
| Ammonium Acryloyldimethyltaurate/VP Copolymer                   | Eye makeup remover                                                | 1.4%            |
| Ammonium Acryloyldimethyltaurate/VP Copolymer                   | Perfume                                                           | 1%              |
| Ammonium Acryloyldimethyltaurate/VP Copolymer                   | Tonics, dressings and other hair grooming aids<br>Spray           | 0.4%            |
| Ammonium Acryloyldimethyltaurate/VP Copolymer                   | Foundations                                                       | 0.016-1%        |
| Ammonium Acryloyldimethyltaurate/VP Copolymer                   | Lipstick                                                          | 1.5%            |
| Ammonium Acryloyldimethyltaurate/VP Copolymer                   | Makeup bases                                                      | 1.5%            |
| Ammonium Acryloyldimethyltaurate/VP                             | Aftershave lotions                                                | 1%              |

|                                                     |                                                                   |                    |
|-----------------------------------------------------|-------------------------------------------------------------------|--------------------|
| Copolymer                                           |                                                                   |                    |
| Ammonium Acryloyldimethyltaurate/VP Copolymer       | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.3-1.8%           |
| Ammonium Acryloyldimethyltaurate/VP Copolymer       | Face and neck products<br>Not spray                               | 0.18-2%            |
| Ammonium Acryloyldimethyltaurate/VP Copolymer       | Body and hand products<br>Not spray<br>Spray                      | 0.2-1.7%<br>0.096% |
| Ammonium Acryloyldimethyltaurate/VP Copolymer       | Moisturizing products<br>Not spray                                | 0.93-2%            |
| Ammonium Acryloyldimethyltaurate/VP Copolymer       | Night products<br>Not spray                                       | 0.25%              |
| Ammonium Acryloyldimethyltaurate/VP Copolymer       | Paste masks and mud packs                                         | 0.3%               |
| Ammonium Acryloyldimethyltaurate/VP Copolymer       | Other skin care preparations                                      | 0.8-1.5%           |
| Ammonium Acryloyldimethyltaurate/VP Copolymer       | Suntan products<br>Not spray                                      | 1.2%               |
| Ammonium Acryloyldimethyltaurate/VP Copolymer       | Indoor tanning preparations                                       | 0.4%               |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer | Eye shadow                                                        | 0.71%              |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer | Eye lotion                                                        | 1.4-1.8%           |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer | Hair conditioners                                                 | 0.74%              |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer | Tonics, dressings and other hair grooming aids<br>Not spray       | 0.47-1%<br>1.7%    |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer | Blushers                                                          | 0.7%               |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer | Face powders                                                      | 0.7%               |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer | Foundations                                                       | 0.7-0.76%          |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer | Makeup bases                                                      | 1%                 |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer | Aftershave lotions                                                | 0.34-1%            |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 1.6%               |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer | Face and neck products<br>Not spray                               | 1.6-1.8%           |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer | Body and hand products<br>Not spray                               | 0.54-1.8%          |

|                                                                        |                                                |          |
|------------------------------------------------------------------------|------------------------------------------------|----------|
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer                    | Moisturizing products<br>Not spray             | 3.2%     |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer                    | Night products<br>Not spray                    | 2%       |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer                    | Paste masks and mud packs                      | 0.38%    |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer                    | Other skin care preparations                   | 1.2%     |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer                    | Suntan products<br>Not spray                   | 0.57%    |
| Acrylamide/Sodium Acryloyldimethyltaurate Copolymer                    | Indoor tanning preparations                    | 1.5%     |
| Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer | Eye shadow                                     | 0.66%    |
| Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer | Eye lotion                                     | 0.4%     |
| Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer | Tonics, dressings and other hair grooming aids | 0.5%     |
|                                                                        | Not spray                                      | 0.8%     |
| Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer | Hair rinses (coloring)                         | 0.2%     |
| Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer | Foundations                                    | 1.8%     |
| Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer | Face and neck products<br>Not spray            | 0.3-2.5% |
|                                                                        | Spray                                          | 0.2%     |
| Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer | Body and hand products<br>Not spray            | 0.9%     |
|                                                                        | Spray                                          | 0.2%     |
| Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer | Paste masks and mud packs                      | 0.75%    |
| Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer | Indoor tanning preparations                    | 0.1%     |
| Ammonium Acryloyldimethyltaurate/Steareth-8 Methacrylate Crosspolymer  | Eye lotion                                     | 0.42%    |
| Ammonium Acryloyldimethyltaurate/Steareth-8 Methacrylate Crosspolymer  | Face and neck products<br>Not spray            | 0.65%    |
| Ammonium Acryloyldimethyltaurate/Steareth-8 Methacrylate Crosspolymer  | Suntan products<br>Not spray                   | 0.46%    |
|                                                                        | Eye lotion                                     | 0.8%     |
| Ammonium Acryloyldimethyltaurate/Steareth-25 Methacrylate Crosspolymer | Mascara                                        | 0.94%    |
| Ammonium Acryloyldimethyltaurate/Steareth-25 Methacrylate Crosspolymer | Hair dyes and colors                           | 1%       |
| Ammonium Acryloyldimethyltaurate/Steareth-25 Methacrylate Crosspolymer | Face and neck products<br>Not spray            | 0.6%     |

|                                                                            |                                                                         |            |
|----------------------------------------------------------------------------|-------------------------------------------------------------------------|------------|
| Ammonium Acryloyldimethyltaurate/<br>Steareth-25 Methacrylate Crosspolymer | Moisturizing products<br>Not spray                                      | 1%         |
| Ammonium Acryloyldimethyltaurate/<br>Steareth-25 Methacrylate Crosspolymer | Night products<br>Not spray                                             | 1.3%       |
| Ammonium Polyacryloyldimethyl Taurate                                      | Eye brow pencil                                                         | 0.59%      |
| Ammonium Polyacryloyldimethyl Taurate                                      | Eye lotion                                                              | 0.06-2%    |
| Ammonium Polyacryloyldimethyl Taurate                                      | Eye makeup remover                                                      | 0.49%      |
| Ammonium Polyacryloyldimethyl Taurate                                      | Other eye makeup preparations                                           | 0.025%     |
| Ammonium Polyacryloyldimethyl Taurate                                      | Tonics, dressings and other hair<br>grooming aids                       | 1.2%       |
| Ammonium Polyacryloyldimethyl Taurate                                      | Blushers                                                                | 0.015%     |
| Ammonium Polyacryloyldimethyl Taurate                                      | Foundations                                                             | 0.026-1.2% |
| Ammonium Polyacryloyldimethyl Taurate                                      | Makeup bases                                                            | 0.3%       |
| Ammonium Polyacryloyldimethyl Taurate                                      | Bath soaps and detergents                                               | 1.2%       |
| Ammonium Polyacryloyldimethyl Taurate                                      | Aftershave lotions                                                      | 0.69%      |
| Ammonium Polyacryloyldimethyl Taurate                                      | Other shaving preparations                                              | 0.78%      |
| Ammonium Polyacryloyldimethyl Taurate                                      | Skin cleansing (cold creams,<br>cleansing lotions, liquids and<br>pads) | 1.5%       |
| Ammonium Polyacryloyldimethyl Taurate                                      | Face and neck products<br>Not spray                                     | 0.024-1.5% |
| Ammonium Polyacryloyldimethyl Taurate                                      | Body and hand products<br>Not spray                                     | 0.16-2%    |
| Ammonium Polyacryloyldimethyl Taurate                                      | Moisturizing products<br>Not spray                                      | 0.6%       |
| Ammonium Polyacryloyldimethyl Taurate                                      | Night products<br>Not spray                                             | 0.14-2.3%  |
| Ammonium Polyacryloyldimethyl Taurate                                      | Paste masks and mud packs                                               | 0.078%     |
| Ammonium Polyacryloyldimethyl Taurate                                      | Suntan products<br>Not spray                                            | 1.5%       |
| Dimethylacrylamide/Sodium<br>Acryloyldimethyltaurate Crosspolymer          | Eye lotion                                                              | 1%         |
| Dimethylacrylamide/Sodium<br>Acryloyldimethyltaurate Crosspolymer          | Mascara                                                                 | 2%         |
| Dimethylacrylamide/Sodium<br>Acryloyldimethyltaurate Crosspolymer          | Perfume                                                                 | 3%         |
| Dimethylacrylamide/Sodium<br>Acryloyldimethyltaurate Crosspolymer          | Other fragrance preparations                                            | 0.35%      |
| Dimethylacrylamide/Sodium<br>Acryloyldimethyltaurate Crosspolymer          | Tonics, dressings and other hair<br>grooming aids                       | 0.72%      |
| Dimethylacrylamide/Sodium<br>Acryloyldimethyltaurate Crosspolymer          | Foundations                                                             | 1%         |
| Dimethylacrylamide/Sodium<br>Acryloyldimethyltaurate Crosspolymer          | Makeup bases                                                            | 0.6%       |
| Dimethylacrylamide/Sodium<br>Acryloyldimethyltaurate Crosspolymer          | Other makeup preparations                                               | 0.96%      |

|                                                                                |                                                                         |            |
|--------------------------------------------------------------------------------|-------------------------------------------------------------------------|------------|
| Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer                 | Deodorants<br>Not spray                                                 | 0.06%      |
| Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer                 | Face and neck products<br>Not spray                                     | 3%         |
| Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer                 | Body and hand products<br>Not spray                                     | 0.65%      |
| Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer                 | Moisturizing products<br>Not spray                                      | 0.7%       |
| Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer                 | Paste masks and mud packs                                               | 3%         |
| Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer                 | Suntan products<br>Not spray                                            | 0.9%       |
| Sodium Acrylate/<br>Acryloyldimethyltaurate/Dimethylacrylamide<br>Crosspolymer | Tonics, dressings and other hair<br>grooming aids<br>Not spray          | 1.6%       |
| Sodium Acrylate/Sodium Acryloyldimethyl<br>Taurate/Acrylamide Copolymer        | Eye lotions                                                             | 0.58-0.75% |
| Sodium Acrylate/Sodium Acryloyldimethyl<br>Taurate/Acrylamide Copolymer        | Tonics, dressings and other hair<br>grooming aids<br>Not spray          | 1.2%       |
| Sodium Acrylate/Sodium Acryloyldimethyl<br>Taurate/Acrylamide Copolymer        | Foundations                                                             | 1.5%       |
| Sodium Acrylate/Sodium Acryloyldimethyl<br>Taurate/Acrylamide Copolymer        | Skin cleansing (cold creams,<br>cleansing lotions, liquids and<br>pads) | 0.3%       |
| Sodium Acrylate/Sodium Acryloyldimethyl<br>Taurate/Acrylamide Copolymer        | Face and neck products<br>Not spray                                     | 0.52-1.5%  |
| Sodium Acrylate/Sodium Acryloyldimethyl<br>Taurate/Acrylamide Copolymer        | Body and hand products<br>Not spray                                     | 0.3%       |
| Sodium Acrylate/Sodium Acryloyldimethyl<br>Copolymer Taurate/Acrylamide        | Suntan products<br>Not spray                                            | 1.2%       |
| Sodium Acrylate/Sodium Acryloyldimethyl<br>Taurate Copolymer                   | Eye liner                                                               | 0.19%      |
| Sodium Acrylate/Sodium Acryloyldimethyl<br>Taurate Copolymer                   | Eye shadow                                                              | 0.19%      |
| Sodium Acrylate/Sodium Acryloyldimethyl<br>Taurate Copolymer                   | Eye lotion                                                              | 0.34-1.2%  |
| Sodium Acrylate/Sodium Acryloyldimethyl<br>Taurate Copolymer                   | Mascara                                                                 | 0.18-0.56% |
| Sodium Acrylate/Sodium Acryloyldimethyl<br>Taurate Copolymer                   | Hair conditioners                                                       | 3.2%       |
| Sodium Acrylate/Sodium Acryloyldimethyl<br>Taurate Copolymer                   | Tonics, dressings and other hair<br>grooming aids                       | 0.6%       |
| Sodium Acrylate/Sodium Acryloyldimethyl<br>Taurate Copolymer                   | Hair dyes and colors                                                    | 2.3%       |
| Sodium Acrylate/Sodium Acryloyldimethyl<br>Taurate Copolymer                   | Foundations                                                             | 0.023-2.4% |

|                                                                    |                                                                   |             |
|--------------------------------------------------------------------|-------------------------------------------------------------------|-------------|
| Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer          | Makeup bases                                                      | 1.5%        |
| Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer          | Other personal cleanliness products                               | 2.4%        |
| Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer          | Skin cleansing (cold creams, cleansing lotions, liquids and pads) | 0.6%        |
| Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer          | Face and neck products<br>Not spray                               | 1-1.1%      |
| Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer          | Body and hand products<br>Not spray                               | 0.088-0.75% |
| Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer          | Moisturizing products<br>Not spray                                | 0.94-1.2%   |
| Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer          | Night products<br>Not spray                                       | 1.2-1.9%    |
| Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer          | Other skin care preparations                                      | 0.6-1.1%    |
| Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer          | Indoor tanning preparations                                       | 0.45%       |
| Sodium Acryloyldimethyl Taurate/Acrylamide/VP Copolymer            | Other suntan preparations                                         | 0.65%       |
| Sodium Acryloyldimethyltaurate/Methacrylamidolauric Acid Copolymer | Makeup bases                                                      | 0.35%       |
| Sodium Acryloyldimethyltaurate/Methacrylamidolauric Acid Copolymer | Face and neck products<br>Not spray                               | 0.35%       |
| Sodium Acryloyldimethyltaurate/Methacrylamidolauric Acid Copolymer | Body and hand products<br>Not spray                               | 0.28%       |
| Sodium Polyacryloyldimethyl Taurate                                | Body and hand products<br>Not spray                               | 1.4%        |

\*Ingredients included in the title of the table but not found in the table were included in the survey, but no uses were reported.

Information collected in 2015

Table prepared October 8, 2015

Table updated January 22, 2016: Ammonium Polyacryloyldimethyl Taurate corrected suntan product 1.5% which is not a spray product

Updated April 18, 2016: Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer: high concentration for moisturizing products and other skin care products changed from 3% to 2.6%  
Ammonium Acryloyldimethyltaurate/VP Copolymer: body and hand products low concentration changed from 0.25% to 0.2%



**Memorandum**

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

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

A handwritten signature in black ink, appearing to read "Beth A. Lange".

**DATE:** April 25, 2016

**SUBJECT:** Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer

Rohm and Haas Company. 2006. Acudyne™ SCP hair styling conditioning polymer technical data sheet.

(states that Acudyne SCP contains 25-27% solids (Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer) in water)

Rohm and Haas Company. 2007. Acudyne™ SCP Polymer: Toxicology Summary.

(Acudyne™ SCP Polymer - containing 25-27% Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer was tested in the studies (including the HRIPT) described in this summary)



## Personal Care

### ACUDYNE™ SCP Hair Styling Conditioning Polymer

#### Description

#### THE CHALLENGE...

In today's hair styling products, there is a trade-off between good hold and great feel. Current ingredients offer strong hold, but do not impart a natural feel, often causing dullness and noticeably increased flaking.

#### THE SOLUTION...

#### Introducing ACUDYNE SCP – Styling Conditioning Polymer

Developed specifically for high-performance hair styling products, ACUDYNE SCP delivers:

|                                      |                                                                                |
|--------------------------------------|--------------------------------------------------------------------------------|
| <b>Tunable Hold</b>                  | Get the hold you want - from <b>soft</b> to <b>strong</b> .                    |
| <b>Conditioned Feel</b>              | Unique conditioning polymers leave hair feeling natural and soft to the touch. |
| <b>Shine</b>                         | Incorporate shine to the hair without additives.                               |
| <b>High Humidity Style Retention</b> | Superior style retention even at high humidity levels.                         |
| <b>Non-flaking</b>                   | Critical non-flaking properties.                                               |
| <b>Non-sticky Style</b>              | Great style control without stickiness on wet or dry hair.                     |

#### Features and Mechanism

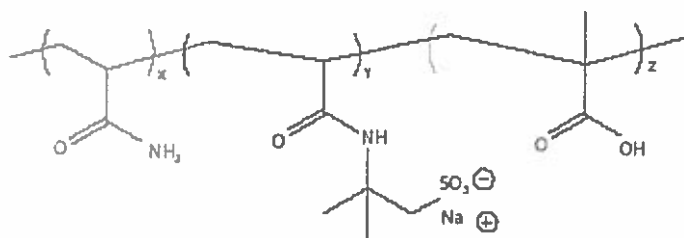
ACUDYNE SCP is a novel anionic polymer for hair gels, mousses, lotions, puttys, and pomades. Supplied as a pre-neutralized aqueous solution, ACUDYNE SCP enables firm hold, conditioned hair feel, superior humidity resistance — and all without flaking.

| <b>Benefit</b>                             | <b>Enabling Mechanism</b>                                                                                                                                                  |
|--------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Tunable Hold                               | Anionic polymer chemistry designed to hydrogen bond and adhere to the hair fiber. This combined with dual Tg, (glass transition temperature), gives firm hold to the hair. |
| Conditioned Feel on Hair                   | Designed so that slight hydration provides a conditioned feel. Enables a simpler formula with better clarity.                                                              |
| Shine                                      | Simple formula means less buildup on the hair to detract from shine, and uniform film enhances hair shine.                                                                 |
| Non-flaking                                | Self plasticized polymer eliminates flaking.                                                                                                                               |
| Formulation Compatibility (Blend partners) | Compatible with ACULYN™ and Carbopol™ rheology modifiers. Compatible with selected cationic additives, PVP, PVP/VA.                                                        |

#### Chemical and Physical Properties

ACUDYNE SCP is a linear anionic terpolymer of acrylamide, acrylamidomethyl propanesulfonic acid (sodium salt), and methacrylic acid. It is supplied pre-neutralized and is water soluble. It is manufactured as a low viscosity solution in water. It is easy to formulate into liquids or gels without any further neutralization.





## Film Properties

The ACUDYNE SCP polymer has two glass transition temperatures ( $T_g$ ), caused by hydration of the polymer film (Figure 1). This duality imparts a self-plasticizing characteristic. The plasticized phase eliminates flaking, and the non-plasticized phase maintains hold under high humidity conditions.

Figure 2 shows that the ACUDYNE SCP film has a significantly higher resistance to deform (modulus value) versus a PVP film at 55% relative humidity. This indicates a more humidity resistant film when exposed to humidity.

**Acudyne™ SCP's Unique DUAL Glass Transition Temperatures at Different Relative Humidities vs. PVP**

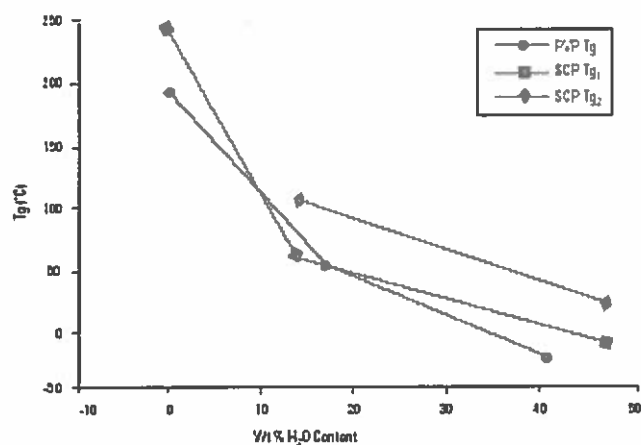


Figure 1

**Acudyne™ SCP Film is Stiffer than PVP at 55% Relative Humidity**

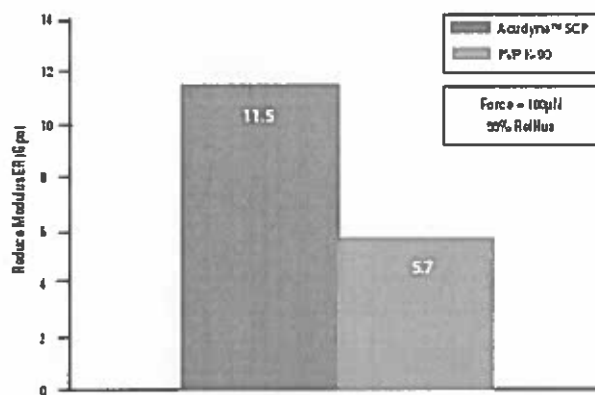


Figure 2

## Physical Description

These properties are typical but do not constitute specifications.

|                                       |                                                                  |
|---------------------------------------|------------------------------------------------------------------|
| Tradename:                            | ACUDYNE SCP polymer                                              |
| INCI Name:                            | Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer |
| Appearance:                           | Clear colorless liquid                                           |
| Solids:                               | 25 - 27% in water                                                |
| Molecular Weight (Mw):<br>(Wgt. Avg.) | ~ 250,000                                                        |
| Preservative:                         | 0.2% Sodium Methylparaben                                        |

**Hair Gel Application Data**

**High Humidity and Style Retention**

Hair treated with ACUDYNE SCP gel shows excellent humidity resistance versus commercial hair fixative resins and commercially available hair gels.

**Acudyne™ SCP has Excellent Humidity Resistance**



*Time = 0*

|                  |                             |
|------------------|-----------------------------|
| <u>Left Side</u> | <u>Right Side</u>           |
| Acudyne™ SCP Gel | PVP Based<br>Commercial Gel |



*Time = 4 hr @ 90%  
Relative Humidity*

|                  |                             |
|------------------|-----------------------------|
| <u>Left Side</u> | <u>Right Side</u>           |
| Acudyne™ SCP Gel | PVP Based<br>Commercial Gel |

**Distinctive Hair Aesthetics**

**Superior Styling and Conditioned Feel**

Salon tests demonstrate that ACUDYNE SCP delivers superior wet feel and combing versus a PVP-based commercial gel. Hair treated with the ACUDYNE SCP gel is also less sticky than with the PVP-based commercial gel.

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March 2005  
PC0012004\_EUR

2 October 2007

**ACUDYNE™ SCP Polymer**  
**Toxicology Summary**

*Acrylamide / Sodium Acryloyldimethyl taurate /*  
*Acrylic Acid copolymer*

ACUDYNE™ SCP Polymer was tested in a number of non-clinical and clinical tests to evaluate potential hazards associated with handling and use of the material in personal care applications.

ACUDYNE™ SCP Polymer was non-toxic by a single oral or dermal dose, produced minimal to slight irritation to the eyes and skin, non-irritating and non-sensitizing in a human patch report, and non-mutagenic in the Ames assay.

Acute Toxicity Profile

| Test/Species                  | Results                                   |
|-------------------------------|-------------------------------------------|
| Oral LD <sub>50</sub> – rat   | >5000 mg/kg                               |
| Dermal LD <sub>50</sub> – rat | >5000 mg/kg                               |
| Eye irritation - rabbit       | Non irritant (EEC), Minimal irritant (US) |
| Dermal irritation – rabbit    | Non irritant (EEC), Minimal irritant (US) |

US = US Environmental Protection Agency

EEC = European Economic Community

Human Toxicity Profile

| Test/Species | Results                            |
|--------------|------------------------------------|
| HR IPT       | Non sensitizing and Non irritating |

Genetic Toxicity Profile

| Test/Species | Results                                             |
|--------------|-----------------------------------------------------|
| Ames Test    | Not mutagenic with and without metabolic activation |

This material was last tested in animals June, 2003. This material has not been tested in animals to support cosmetic applications since 2003.

ACUDYNE™ SCP Polymer has approval to be used in a mousse formulation. That's because this product form delivers a \*foam\*, which cannot be inhaled.

**Study Details**Acute toxicity

An acute oral toxicity test (Up and Down Procedure) was conducted on ACUDYNE™ SCP Polymer. An initial limit dose of 5000 mg/kg of ACUDYNE™ SCP Polymer was administered to one female rat by oral gavage. Due to the absence of mortality in this animal, two additional animals received an oral dose of 5000 mg/kg. All animals survived, gained weight and appeared active and healthy. There were no signs of gross toxicity, adverse pharmacologic effects or abnormal behavior. Gross necropsy findings at terminal sacrifice were unremarkable.

ACUDYNE™ SCP Polymer was non-toxic by a single oral dose to rats, i.e., the female rat acute oral LD<sub>50</sub> > 5000 mg/kg.

An acute dermal toxicity test was conducted on ACUDYNE™ SCP Polymer. A single dermal dose of 5000 mg/kg body weight of ACUDYNE™ SCP Polymer was applied to the skin with an occluded patch to five male and five female rats for 24 hours. The test material was removed from the skin after the 24 hr exposure. All animals survived for 14 days, gained weight and appeared active and healthy. There were no signs of gross toxicity, dermal irritation, adverse pharmacologic effects or abnormal behaviour. Gross necropsy findings at terminal sacrifice were unremarkable. ACUDYNE™ SCP Polymer was non-toxic by a single dermal dose to rats, i.e., the male and female rat acute dermal LD50 > 5000 mg/kg.

Subchronic toxicity (e.g. details about NOAEL, LOAEL)

No study conducted.

Skin irritation

A primary skin irritation test was conducted with rabbits. Five-tenths of a milliliter of ACUDYNE™ SCP Polymer was applied to the skin of three healthy rabbits (one male, two females) on an occluded patch for 4 hours. The test material was removed from the skin after the 4 hr exposure. Dermal irritation was evaluated by the method of Draize et. al., 1944. One hour after patch removal, all three treated sites exhibited very slight to well-defined erythema and very slight edema. The overall incidence and severity of irritation decreased with time. All animals were free of dermal irritation by 48 hours. ACUDYNE™ SCP Polymer produced minimal to slight irritation to the skin of rabbits.

Eye irritation

A primary eye irritation test was conducted with rabbits. One-tenth of a milliliter of ACUDYNE™ SCP Polymer was instilled into the conjunctival sac of the right eye of three healthy rabbits. The left eye remained untreated and served as a control. Ocular irritation was evaluated by the method of Draize et. al., 1944. No corneal opacity or iritis was noted for any treated eye during the study. Approximately one hour after test substance instillation, conjunctivitis was observed in all treated eyes. The overall incidence and severity of irritation decreased with time. All animals were free of ocular irritation within 48 hours. ACUDYNE™ SCP Polymer produced minimal to slight irritation to the eyes of rabbits.

Skin sensitization

ACUDYNE™ SCP Polymer produced no irritation to the skin of humans. (study summary under Clinical studies)

Mutagenicity

ACUDYNE™ SCP Polymer was tested in a bacterial reverse mutation assay using Salmonella typhimurium tester strains TA98, TA100, TA1535 and TA1537 and Escherichia coli tester strain WP2 uvrA in the presence and absence of Aroclor-induced rat liver S9. In the initial assay, the dose levels tested were 2.5, 7.5, 25, 75, 200, 600, 1800, and 5000 µg/plate. In the confirmatory assay, the dose levels tested were 75, 200, 600, 1800, and 5000 µg/plate. Neither precipitate nor appreciable toxicity was observed in either the initial or the confirmatory assays. ACUDYNE™ SCP Polymer was not mutagenic in an Ames assay with and without metabolic activation.

Penetration

No study conducted.



### Clinical studies

A human repeated insult occlusive patch study was conducted with ACUDYNE™ SCP Polymer.

The study material was applied to a 2 cm x 2 cm Webril pad attached to a non-porous plastic film adhesive bandage (3M medical tape). The patch was secured with hypoallergenic tape (Micropore), as needed. The patch was applied to the infrascapular area of the back, either to the right or left of the mid-line.

Subjects participated in the study over a 6-week period involving three phases: (1) Induction, (2) Rest and (3) Challenge. Prior to study entry, the subjects were screened to ensure that they met the inclusion/exclusion criteria. Informed consent was obtained. Each subject was provided with a schedule of the study activities. All subjects were told to avoid wetting the patches and were asked not to engage in activities that caused excessive perspiration. They were instructed to notify the staff if they experienced any discomfort beyond mild itching or observed any adverse changes at the evaluation sites while on the study or within two weeks of completing the study.

The Induction Phase consisted of 9 consecutive applications of the study material and subsequent evaluations of the patch sites. Prior to application of the patches, the sites were outlined with a skin marker, i.e., gentian violet. The subjects were required to remove the patches approximately 24 hours after application. They returned to the facility at 48-hour intervals to have the sites evaluated and identical patches applied to the same sites. Patches applied on Friday were removed by subjects after 24 hours and sites were evaluated on the following Monday, i.e., 72 hours after patch application. Following the ninth evaluation, the subjects were dismissed for a 14-16 day rest period.

The Challenge Phase was initiated during the sixth week of the study. Identical patches were applied to sites previously unexposed to the study material. The patches were removed by the subjects after 24 hours and the sites graded after additional 24-hour and 48-hour periods (i.e., 48 and 72 hours after application). Re-challenge was not required.

To be considered a completed case, a subject must have had 9 applications and no fewer than 8 subsequent readings during induction and 1 application and 2 readings during challenge. Only completed cases were used to assess sensitization.

One hundred and thirteen subjects between the ages of 18 and 75 were enrolled in the study. One hundred and two subjects completed the study. Under the conditions employed in this study, there was no evidence of sensitization or significant irritation to ACUDYNE™ SCP Polymer.