Amended Safety Assessment of Lanolin-Derived Ingredients as Used in Cosmetics

Status:	Draft Amended Report for Panel Review
Release Date:	March 4, 2024
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The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Thomas J. Slaga, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D., and the Senior Director is Monice Fiume. This safety assessment was prepared by Christina Burnett, M.S., Senior Scientific Analyst/Writer, CIR.

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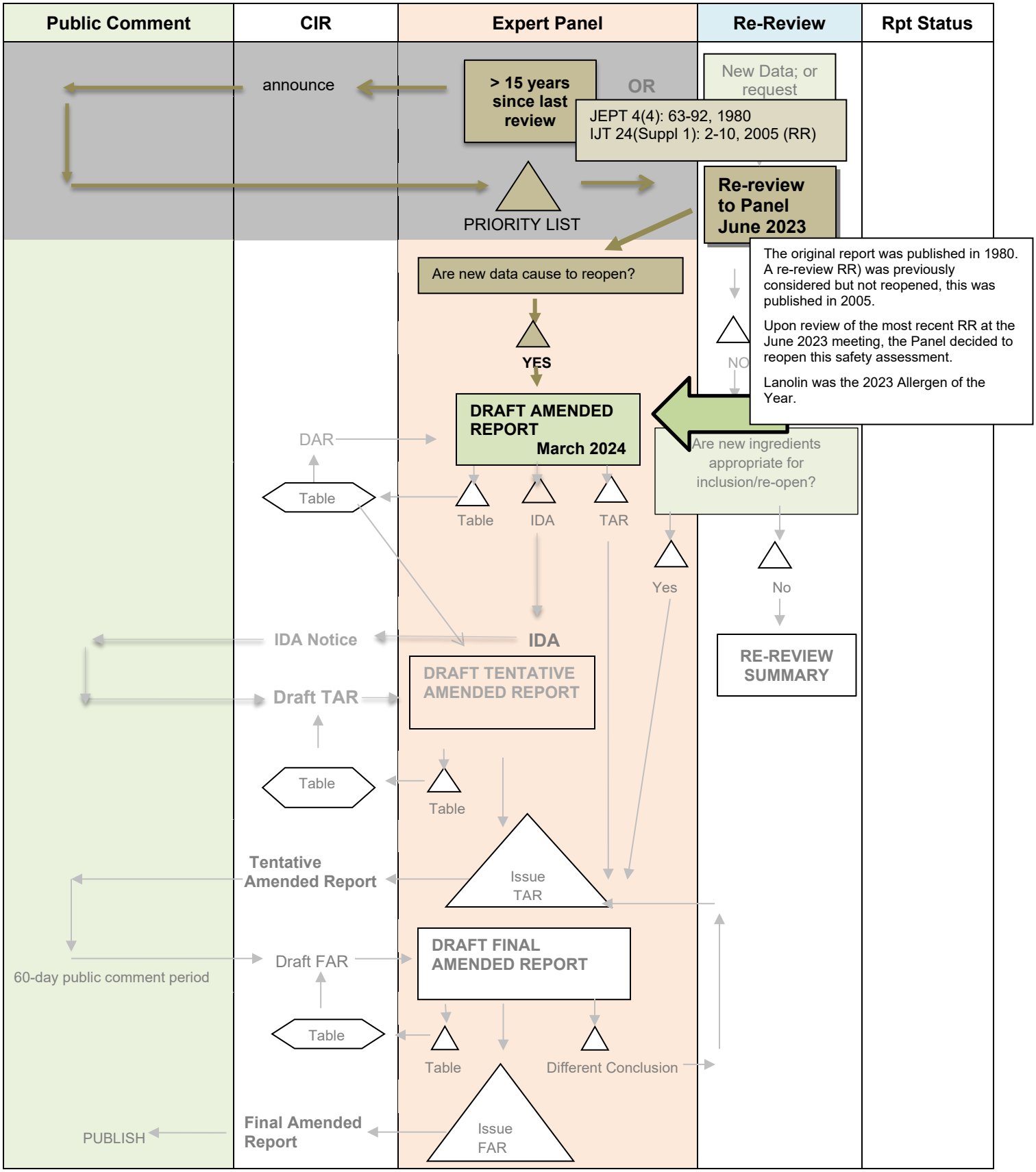
RE-REVIEW FLOW CHART

INGREDIENT/FAMILY Lanolin-Derived Ingredients

MEETING March 2024



Cosmetic Ingredient Review

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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Christina L. Burnett, MSES, Senior Scientific Analyst/Writer, CIR
Date: March 4, 2024
Subject: Amended Safety Assessment of Lanolin-Derived Ingredients as Used in Cosmetics

The Panel previously reviewed the safety of 9 lanolin-derived ingredients in an assessment that was published in 1980 (identified as *originalreport_Lanolin_032024* in the pdf document) and concluded that these ingredients "are safe for topical application to humans in the present practices of use and concentration" (as described in the assessment). This conclusion was re-affirmed at the February 2003 Panel meeting; a re-review summary was published in 2005 (*RRsum2005_Lanolin_032024*). In accordance with its Procedures, the Panel evaluates the conclusions of previously-issued reports approximately every 15 years, and last June it had been at least 15 years since this assessment was last reviewed.

At the June 2023 meeting, the Panel re-opened the safety assessment for these ingredients to reassess the safety of these ingredients. Accordingly, enclosed is the Draft Amended Report on the Safety Assessment of Lanolin-Derived Ingredients as Used in Cosmetics (*report_Lanolin_032024*). It should be noted that data from the original 1980 report, and data from the re-review evaluated by the Panel prior to publishing the 2005 re-review summary (data document included herein as *RRdata_Lanolin_032024*), have been summarized in the Draft Amended Report, in *italicized text*.

According to the 2023 VCRP survey data, Lanolin has the most reported uses in cosmetic products, with a total of 285 formulations; the majority of the uses are in leave-on formulations. Acetylated Lanolin Alcohol has the second most reported uses in cosmetic products, with a total of 196; the majority of these uses are also in leave-on formulations. The frequencies of use for both of these ingredients have greatly changed since the Panel last reviewed these ingredients in 2003; Lanolin was reported to have 782 uses, and Acetylated Lanolin Alcohol was reported to have 356 uses. The results of the concentration of use survey conducted by the Council in 2022 indicate Lanolin Oil has the highest maximum concentration of use in a leave-on formulations; it is used at up to 47% in lipsticks (*data_Lanolin_032024*). Lanolin is reported to be used at up to 40% in leave-on nail creams and lotions. When the Panel last reviewed these ingredients in 2003, the maximum leave-on use concentration for Lanolin Oil was 65% in lipstick; the maximum leave-on use concentration for Lanolin was 37% in body and hand skin care preparations.

Since the June 2023 meeting, no additional new unpublished data have been submitted for this ingredient.

Additional supporting documents for this report package include a flow chart (*flow_Lanolin_032024*), report history (*history_Lanolin_032024*), a search strategy (*search_Lanolin_032024*), a data profile (*dataprofile_Lanolin_032024*), transcripts from the meeting at which this re-review was discussed (*transcripts_Lanolin_032024*), and the minutes from all the meetings at which lanolin-derived ingredients were discussed during the original review and first re-review (*originalminutes_Lanolin_032024*).

If no further data are needed to reach a conclusion of safety, the Panel should formulate a Discussion and issue a Tentative Amended Report. However, if additional data are required, the Panel should be prepared to identify those needs and issue an Insufficient Data Announcement.

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Lanolin-Derived Ingredients History

1980– The CIR's Final Report of the Safety Assessment for Acetylated Lanolin Alcohol and Related Compounds was published in the *Journal of Environmental Pathology and Toxicology* in 1980. Based on the available animal data and human experience, the Panel concluded that Lanolin and related Lanolin materials are safe for topical application to humans in the present practice of use and concentration.

February 2003 – The Panel reviewed the available published data since the 1980 report was published in accordance to CIR Procedures regarding re-review of ingredients after ~15 years. The Panel unanimously concluded that the Final Safety Assessment on Lanolin and its related ingredients should not be reopened. The Panel addressed the following concerns in the re-review summary that was published in 2005: pesticide and biological contaminants and hair spray particle size that would not be respirable.

June 2023 – Review of the available published literature since 2003 re-review was conducted in accordance to CIR Procedures regarding re-review of ingredients after ~15 years. The Panel re-opened the safety assessment for this ingredient in order to update the 40+ year-old report.

Lanolin-Derived Ingredients Data Profile* – March 2024 – Christina Burnett

				Toxicokinetics			Acute Tox			Repeated Dose Tox			DART		Genotox		Carci		Dermal Irritation			Dermal Sensitization				Ocular Irritation		Clinical Studies	
	Reported Use	Method of Mfg	Impurities	log P/log K_{ow}	Dermal Penetration	ADME	Dermal	Oral	Inhalation	Dermal	Oral	Inhalation	Dermal	Oral	In Vitro	In Vivo	Dermal	Oral	In Vitro	Animal	Human	In Vitro	Animal	Human	Phototoxicity	In Vitro	Animal	Retrospective/ Multicenter	Case Reports
Acetylated Lanolin	X O	O		X				O												O	X			O			O		
Acetylated Lanolin Alcohol	X O	O		X				O												O	O		O				O		
Hydrogenated Lanolin	X O	O	O	X				O												O	X O		O	O			O		
Hydroxylated Lanolin	X O	O		X			O	X O												O				O	O		X O		
Lanolin	X O	O	X O					O												O	O			O			O	X O	
Lanolin Acid	X O	O	O	X				X O			X			X	X					O			X	O	O		O		
Lanolin Alcohol	X O	O	O					X O			X			X	X				X	O				O	O		O	X O	X
Lanolin Oil	X O	O	O				O	O												O							O		
Lanolin Wax	X O	O	O					O												O	O		O	O			O		

* "X" indicates that new data were available in a category for the ingredient. "O" indicates data were reported in the original safety assessment.

Lanolin-Derived Ingredients

Ingredient	CAS #	INCIpedia	PubMed	FDA	HPVIS	NIOSH	NTIS	NTP	FEMA	EU	ECHA	ECETOC	SIDS	SCCS	AICIS	FAO	WHO	Web
Acetylated Lanolin	61788-48-5	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Acetylated Lanolin Alcohol	61788-49-6	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Hydrogenated Lanolin	8031-44-5	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Hydroxylated Lanolin	68424-66-8	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Lanolin	8006-54-0	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Lanolin Acid	68424-43-1	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Lanolin Alcohol	8027-33-6	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Lanolin Oil	8038-43-5 70321-63-0	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Lanolin Wax	68201-49-0	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

Lanolin and Lanolin-derived Ingredients were not restricted from use in the European Union. No opinions were discovered.

Search (from 2000 on)

PubMed

Acetylated Lanolin
((“Acetylated Lanolin”) OR (61788-48-5[EC/RN Number])) - 3 hits; 2 relevant
Acetylated Lanolin Alcohol
((“Acetylated Lanolin Alcohol”) OR (61788-49-6[EC/RN Number])) – 1 hit; 0 relevant
Hydrogenated Lanolin
((“Hydrogenated Lanolin”) OR (8031-44-5[EC/RN Number])) – 1 hit; 0 relevant
Hydroxylated Lanolin
((“Hydroxylated Lanolin”) OR (68424-66-8[EC/RN Number])) – 2 hits; 0 relevant
Lanolin
((“Lanolin”) OR (8006-54-0[EC/RN Number])) –287 hits; 93 relevant
Lanolin Acid
((“Lanolin Acid”) OR (68424-43-1[EC/RN Number])) – 64 hits; 11 relevant
Lanolin Alcohol
((“Lanolin Alcohol”) OR (8027-33-6[EC/RN Number])) – 89 hits; 56 relevant
Lanolin Oil
((“Lanolin Oil”) OR (8038-43-5[EC/RN Number]) OR (70321-63-0[EC/RN Number])) – 39 hits; 16 relevant
Lanolin Wax
((“Lanolin Wax”) OR (68201-49-0[EC/RN Number])) – 19 hits; 11 relevant

ECHA

Acetylated Lanolin
Entry for CAS# 61788-48-5 resulted in finding a dossier for “lanolin, acetate”. Data from the dossier that were not already in the original report were for Lanolin Acid and Lanolin Alcohol.
Acetylated Lanolin Alcohol

Entry for CAS# 61788-49-6 resulted in finding a dossier for "acetic acid, esters with lanolin alcs." Data from the dossier that were not already in the original report were for Lanolin Alcohol.
Hydrogenated Lanolin
Entry for CAS# 8031-44-5 resulted in finding a dossier for "lanolin, hydrogenated". Data from the dossier that were not already in the original report were for Lanolin Alcohol.
Hydroxylated Lanolin
Entry for CAS #68424-66-8 resulted in finding a dossier for "lanolin, hydroxylated". Data from a comedogenicity study described above, other data already described in original report.
Lanolin
No dossier.
Lanolin Acid
Entry for CAS # 68424-43-1resulted in finding a dossier for "fatty acids, lanolin". Data on endpoints not already in the original report are summarized in the table above.
Lanolin Alcohol
Entry for CAS #8027-33-6 resulted in finding a dossier for "alcohols, lanolin". Data on endpoints not already in the original report are summarized in the table above.
Lanolin Oil
No dossier.
Lanolin Wax
No dossier.

LINKS

Search Engines

- Pubmed (- http://www.ncbi.nlm.nih.gov/pubmed)

appropriate qualifiers are used as necessary
search results are reviewed to identify relevant documents

Pertinent Websites

- wINCI - http://webdictionary.personalcarecouncil.org
- FDA databases http://www.ecfr.gov/cgi-bin/ECFR?page=browse
- FDA search databases: http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234631.htm;,
- Substances Added to Food (formerly, EAFUS): https://www.fda.gov/food/food-additives-petitions/substances-added-food-formerly-eafus
- GRAS listing: http://www.fda.gov/food/ingredientspackaginglabeling/gras/default.htm
- SCOGS database: http://www.fda.gov/food/ingredientspackaginglabeling/gras/scogs/ucm2006852.htm
- Indirect Food Additives: http://www.accessdata.fda.gov/scripts/fdcc/?set=IndirectAdditives
- Drug Approvals and Database: http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
- FDA Orange Book: https://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm
- (inactive ingredients approved for drugs: http://www.accessdata.fda.gov/scripts/cder/iig/
- HPVIS (EPA High-Production Volume Info Systems) - https://iaspub.epa.gov/oppthpv/public_search.html_page
- NIOSH (National Institute for Occupational Safety and Health) - http://www.cdc.gov/niosh/
- NTIS (National Technical Information Service) - http://www.ntis.gov/
  - technical reports search page: https://ntrl.ntis.gov/NTRL/
- NTP (National Toxicology Program) - http://ntp.niehs.nih.gov/
- Office of Dietary Supplements https://ods.od.nih.gov/
- FEMA (Flavor & Extract Manufacturers Association) GRAS: https://www.femaflavor.org/fema-gras
- EU CosIng database: http://ec.europa.eu/growth/tools-databases/cosing/
- ECHA (European Chemicals Agency – REACH dossiers) – http://echa.europa.eu/information-on-chemicals;jsessionid=A978100B4E4CC39C78C93A851EB3E3C7.live1

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

JUNE 2023 PANEL MEETING – NEW RE-REVIEW

Belsito Team – June 12, 2023

DR. BELSITO: Then we're moving on to lanolin. And again, we received some Wave 3 comments here. So, since I wrote Lanolin as Allergen of The Year article for this year, I feel very comfortable in commenting on this. So, there's a lot of new data, a lot of reports on sensitization. Let me address first the comment about increase in sensitization.

So, we have switched, as have some groups, from testing lanolin allergy using 30 percent wool wax alcohols to using 50 percent Amerchol L101, which is not 50 percent wool wax alcohol. Amerchol L 101 is 10 percent wool wax alcohol mixed one-to-one with -- or is, yeah, 10 percent wool wax alcohol mixed one-to-one with a mineral oil.

And so, actually 50 percent Amerchol L101 is only 5 percent lanolin alcohol. And it's thought that mineral oil -- and when you test with Amerchol L101 you see more patch test reactions in almost every study that's looked at. So, it's not the incidences necessarily increasing, it's that we've changed what we patch test with and we're seeing a higher incidence with that.

And it's been argued that the mineral oil is irritating and what we're seeing is an irritating effect. And it's been argued that the mineral oil increases penetration through the stratum corneum and that's why we're seeing this increase.

What is clear, is that all of these reports that you're seeing are in diseased populations. Okay, so they're applying lanolin on diseased skin and there's what's called the lanolin paradox. And that is when you can take an individual allergic to lanolin, and put lanolin on diseased skin and see a reaction, and put it on normal skin and see absolutely nothing. So first of all, patch testing is very difficult.

There is one article that you didn't pick up because you would not pick it up with a literature search. And it has to do with a study that RIFM funded called the EDEN study, where they were looking at fragrance allergy in the general population of Europe. And I've included the reference for you. So, this was two centers in Germany and one each in Sweden, Netherlands, Portugal, and Italy. Over 3,000 normal people. They were tested for lanolin alcohol allergies using T.R.U.E. testing. It was 0.4 percent of a general -- diseased and non-diseased. This was just the general population.

DR. SNYDER: So, when you say diseased/non-diseased, you're talking about in the same patient? Or are you talking about a diseased patient and a non-diseased patient?

DR. BELSITO: So, all of the reports that Christina mentioned were people were patch tested because they had skin issues. So, they were a diseased population. This was a general population.

DR. SNYDER: Okay.

DR. BELSITO: Where they went into -- so, for instance, in Sweden it was done in Malmo. And so, they looked at what is the age and gender distribution, and they tried to recruit people into the study that matched their population, irrespective of whether they had or did not have dermatitis. They were specifically looking -- it was sponsored by the Fragrance Association and then the hair dye people got in there, too, because they wanted some information on PPD.

But it's the best general population estimate. So anyway, general population is 0.4 percent at least in Europe. So, it's not this epidemic. And you know allergens of the year are named -- in the case of lanolin, it's because of the lanolin paradox, the fact that we still don't know what the best patch test preparation is, lots of issues. But it's not a bad actor and the bottom line is I do not think we need to reopen the lanolin report.

DR. RETTIE: Based on what you just told us, which I didn't know about, I agree with you. I had a yes down and I'm happy to go with no.

DR. BELSITO: I don't think so. And then they're all -- many companies now, particularly, if they're marketing products that are going to be used on diseased skin, like they're using highly purified anhydrous lanolin, which reduces the percentage of wool wax alcohols, which are the allergens, down to 1.5 percent. So, I just don't see this as an issue.

DR. RETTIE: Yeah, I find this pretty interesting background reading. Took me back to my sheep shearing days.

DR. BELSITO: I figured coming from Scotland you would like this.

DR. SNYDER: I got the worst ked infestation in my life after participating in that process.

DR. RETTIE: I was the fleas.

DR. BELSITO: Okay, so --

MS. BURNETT: For the re-review summary then, should it be a little bit more robust with explaining the lanolin paradox? Because if you look at the original report, because it was one of the very first reports written by the panel.

DR. BELSITO: It says that there was no sensitization.

MS. BURNETT: Right.

DR. BELSITO: Yeah.

MS. BURNETT: It is up in the Discussion, but it doesn't really -- or they didn't have a Discussion section, it was all in the abstract. And the first re-review doesn't mention any sensitization at all, so this would be the opportunity to maybe fully discuss it?

DR. BELSITO: Yeah, to discuss that there are reports of allergy. You know, that there are -- so when we decide not to reopen there will be a certain discussion, right, so that you see from my report that there are certain populations that are at risk. The elderly, because of stasis dermatitis and leg ulcers. Anogenital disease patients, atopic patients, which is why (inaudible). So, I think in the discussion you should put, individuals manufacturing products that could be used in the anogenital area, diseased skin should be aware of the increased potential for sensitization and the panel would recommend using HPA lanolin or avoiding lanolin.

I mean, I think HPA lanolin would be fine in products that are intended in those populations. I mean, I think we need to point out that there is sensitization. Because you're right, the old reports say it was, like, hey, this was like nothing. And that the apparent increase -- I don't even know that you need to get into that. I mean, I have the reference for you on the incidents in the general population, which I would bring in as well.

I think when you're mentioning all of the studies it's important that it be pointed out that these are diseased populations. I mean, it's just like if you were doing a study on people with glaucoma, and that was your population, everyone would have increased interocular pressure. It wouldn't be a side effect of what you were treating them with, right?

MS. BURNETT: And I observed in the studies that a lot of the incidences were either in children with sensitive skin or geriatric patients that have other --

DR. BELSITO: Right. And then a lot of the studies you quoted were specifically looking at at-risk populations where you were going to see higher numbers.

MS. BURNETT: Right.

DR. BELSITO: I mean the studies that were of a general disease population were like the North American Contact Dermatitis Group studies and the German IBDK (phonetic) studies. But a lot of the others, and a lot of the ones in the review article that I wrote are diseased populations to point out that you have to be concerned about those people, number one, and number two, patch testing the lanolin on normal skin may give you a negative reaction even in people who are reacting to it.

But it doesn't need to be reopened. There are a lot of other things out there that are -- okay.

MS. BURNETT: Great. Thank you.

Cohen Team – June 12, 2023

DR. COHEN: All right. I know you're all disappointed to hear this, but we are on the last one. Lanolin. The Panel reviewed Lanolin, Acetylated Lanolin alcohol and related compounds in 1980, and concluded that it was safe for topical application to humans in the present practices of use and concentration. We reconsidered a re-review of the nine ingredients and that 1980 conclusion was reaffirmed.

In April, a world literature search was performed, going back to 2000. Many new studies were identified, the majority relating to contact dermatitis and Lanolin. And most notably, Lanolin was the 2023 allergen of the year.

We have updated frequency of use. It is frequently used, but it's decreased down substantially. The majority of use is of leave-on product. The concentration, in 2002, is 37 percent and 16 percent at rinse-off, and now it's 40 percent and 10 percent. So the question is, do we reopen? And I can open it up before I can let you know what I think.

DR. BERGFELD: We could guess what you think?

DR. COHEN: Yeah.

DR. BELSITO: Reopen.

DR. COHEN: Yeah.

DR. ROSS: It's (inaudible) of uses, it's yes on contact allergens there, so. And then I have a note, ask David and Wilma.

DR. TILTON: We don't usually review allergic reaction.

DR. COHEN: Yeah, no, so I think we have to reopen. The old reports ironically don't talk much about allergic contact dermatitis and the literature's flooded with information about allergic contact dermatitis.

DR. BERGFELD: The old literature -- very old literature was a lot of contact from the (inaudible) that we used then. I think it was then refined somehow in the '60s, '70s. And it became of an allergen, now it's an allergen again.

DR. COHEN: Well, the question is, how much can you refine this?

DR. BERGFELD: I don't know.

DR. COHEN: And I have to tell you this allergen of the year has created great consternation out there.

DR. BERGFELD: Yeah, you have to open it. Prove it one way or the other. And relate to the concentrations and the various other ingredient types that are in it.

DR. COHEN: Lanolin is an interesting contact allergen because there's a few allergens that have this strange paradox where you could just apply it to intact skin. It's very hard to elicit a reaction. But if you put it on compromised skin, repeatedly, it worsens dermatitis.

So, on patch testing, it's tricky. We use high concentrations to elicit it. We use amerchol. I think it's worthy of a re-review considering the dearth of information in there. And the report needs to be updated.

DR. BERGFELD: Well, the question I have is, why didn't the contact dermatitis group identify this earlier if it's been such a strong contact and it's been in the literature for the last few years.

DR. COHEN: If you look at the reports on the prevalence of reactivity over the last ten years, it's doing this. So there really has been a change in the frequency of reactivity.

DR. BERGFELD: So, something has changed about it.

DR. COHEN: Something has changed about it. It's either something about the products that are coming out or the uses that are coming out.

DR. BERGFELD: I mean, what if it was the base of corticosteroids?

DR. COHEN: You wouldn't see it quite as much.

DR. BERGFELD: Instead of vasoline that's used.

DR. COHEN: It's a tricky one.

DR. BERGFELD: It'll be fun.

DR. COHEN: I know it's created a lot of concern.

DR. BERGFELD: Done.

DR. COHEN: Tom, we're going to go with a reopen. Is that consistent with what you thought?

DR. SLAGA: I had no problem with it, but obviously the allergenic effect is quite common. Should we reopen it just to deal with that or to --

DR. COHEN: Yes.

DR. BERGFELD: It's a public response issue.

DR. SLAGA: Yeah.

DR. BERGFELD: The public needs to hear.

DR. HELDRETH: It's timely.

DR. COHEN: It's very timely and it's a report, when we're done, that we should get into press as soon as possible.

DR. BERGFELD: It'll be interesting to go through the old reports, that aren't published, and find which ones we think ought to have priority over the others. I mean, that could be a real interesting task. This might be the first of -- and we could go through -- aluminum was last year's. We have an aluminum document.

DR. COHEN: Did we reopen aluminum?

DR. BERGFELD: We could look at it. I know we had.

DR. TILTON: When would we expect to see Lanolin?

DR. COHEN: What's that again?

DR. TILTON: When would it come back?

MS. BURNETT: If it's reopened -- give me a moment. Probably in December.

DR. COHEN: December would be a final report by December?

MS. BURNETT: No. The next time you look at it, it would be a draft and then --

DR. HELDRETH: Draft report.

DR. COHEN: Draft amended. And then it would need one more iteration to go to final, no?

DR. HELDRETH: It'd have to go tentative and final.

DR. COHEN: So, not until the end of --

MS. BURNETT: March at least.

DR. COHEN: This is -- right. So publishing it, 25?

DR. HELDRETH: I mean, if we got it done by June of next year, finalized, I can get it in to the third issue of JT and get it out next year.

DR. COHEN: Okay. That's good. Okay.

Full Panel – June 13, 2023

DR. BELSITO: This is another one of these re-reviews, because it's been more than 15 years. We got a huge amount of data on Lanolin, largely dealing with sensitization and individuals with dermatitis. Despite that, though, I think it's important to realize that it is not a common allergen.

It was nominated as Allergen of the Year. I actually wrote the paper, primarily to point out that lanolin paradox, where even individuals' allergic to it, can put it on normal skin without issues.

I provided a multi-center European study for Christina that looked at the general population, including patients potentially with dermatitis, the incidents were 0.4 percent. I don't think we need to reopen this document.

DR. BERGFELD: That's a motion.

DR. COHEN: I'm not going to second that right now. I'd like to have a little discussion. I wish this wasn't the first re-review we were talking about, because -- the issue on some of these re-reviews is these reports are 40, 45 years old. And, the re-review summaries are minuscule, they're a paragraph. And, for us to, I think, reiterate the findings of a 45 year report, when there's voluminous new data, I think doesn't serve the consumer of the report very well.

Now, look, MIBK, there's not going to be too many people looking at that report, industry will look at it. But, when we look at items that have common use, the consumers of the report are consumers, they're dermatologists, they're toxicologists, they're industry and formulators.

This report in 1980 does not reflect the modern understanding of the uses of Lanolin. And just a couple of things. Since the report is issued, there are 160 peer-reviewed articles on allergic contact dermatitis, as you mentioned, 160. There are 479 peer-reviewed articles on the use of Lanolin that include use in nursing mothers, use in genital care, use on eyelids, use on lips.

And then, of course, Don, you're sort of the Jedi Master of the CIR, are the author of the Allergen of the Year for this. And, it did light a fire under dermatologists and patients alike. And the 1980 reports said they have low acute toxicity, that's true, and are nonsensitizing to animal skin. It's not until later on in the report do we start discussing sensitization.

I think a Lanolin reopen is valuable because there's probably -- maybe I'm being a little hyperbolic -- there's probably not a human in North America who isn't touched by Lanolin in some way. And these frequencies of use are just not correct, right. Everyone's getting routinely exposed to Lanolin in some way, shape, or form. I think it makes sense for us to update a 45-year-old report.

DR. BERGFELD: Any further comment from the Belsito Team?

DR. BELSITO: I mean, in a re-review we will include all of these references, or not? How would that work?

DR. BERGFELD: You do.

DR. HELDRETH: The references get included, but there's limited space for discussion.

DR. BELSITO: Right. I think that with limited space for discussion it can be reviewed. We can point out that there are certain groups, you know, the application of Lanolin to ulcerated and clean skin to perianal, perigenital areas may pose risk and recommend that highly purified anhydrous lanolin should be used in products designed for application to damage skin. We can discuss all of that. I just don't think we need to open up a full report.

DR. COHEN: It's going to come up again in another one. I think there's just a consumer need for -- you know, first of all your article on Lanolin was great, right. There's a lot of data in there, and you can't take that report on Allergen of the Year

and compress that into a paragraph. And the majority of what's in there is not in the old report. I just think there's just too much attention on Lanolin, and it really sparked a fire.

DR. BERGFELD: Can I ask briefly from Courtney, consumers' representative here, about your comment.

MS. GRIFFIN: I think the doctor's point is well taken. This is a product that consumers are routinely exposed to. And, in this particular instance, they also are going to be looking to the report for more information. And, so, yes, I think his point is well taken that reopening it would be helpful from a consumer's perspective.

DR. BERGFELD: Any other comments from other team members? Curt, I'm sorry to interrupt.

DR. KLAASSEN: I also feel that some of these documents that were written in '85, and you read them in 2025, don't read very well. And, yes, you can insert this and insert that, but I don't think it looks very good for us either. I think, I mean, it's kind of like an old house, you can kind of patch this up and patch that up, but it's just not like a new house. I would like to see a few of these important chemicals that were written in the 80's to be rewritten from step one.

DR. BELSITO: Okay, if Consumer Federation of America is requesting that we reopen this, I'm fine with that. So, we'll reopen.

DR. BERGFELD: All right. Is there a list of --

DR. BELSITO: Polyquaternium --

DR. BERGFELD: No, no, no. The Lanolin, you presented the first proposal, that's Don, now, seconded by David Cohen.

DR. BELSITO: Great. Change my proposal to reopen.

DR. BERGFELD: Oh, so, you amended it.

DR. COHEN: Second.

DR. BERGFELD: Now we have second, any further discussion about reopening Lanolin? I'll call the question, all those in favor of reopening? Thank you, it's unanimous.

MARCH 27-28, 1978 PANEL MEETING

Dr. Bergfeld reported that the team will need information on the breakdown product and contaminants found in lanolin. Dr. Beyer asked if detergents are used in stripping the lanolin from the wool. Dr. Winstead stated he would explore this question and report back to the Panel.

Dr. Bergfeld stated that they should be able to complete their initial review of lanolin by the time the Panel next meets.

JUNE 12-13, 1978 PANEL MEETING

Dr. Bergfeld and team members (Drs. Hoffmann and Roudabush) reported that there is sufficient information and data available to them to write a report on the ingredient and its related compounds. They anticipate having a report available to the Expert Panel for review and discussion at the September meeting of the Panel.

Dr. Bergfeld stated that the Scientific Literature Review (which includes the summary and bibliography), the abstracts of all the scientific articles and copes of selected articles, and the industry comments provided to the Expert Panel as a basis for preparation of a draft were a good base from which to work.

Mr. Grief reported that the North American Contact Dermatitis Group is presently conducting a study for FDA on the number of reported contact dermatitis cases associated with cosmetic products. He will provide FDA's statistical summary of this study to Dr. Bergfeld as it relates to lanolin and to the entire Panel as I relates to other ingredients.

SEPTEMBER 18-19, 1978 PANEL MEETING

Drs. Bergfeld, Hoffmann, and Roudabush presented to the Panel their report on Acetylated Lanolin Alcohol, Hydrogenated Lanolin, Lanolin Acid, Lanolin Wax, Hydrogenated Lanolin Alcohol, Hydroxylated Lanolin, Acetylated Lanolin, Lanolin, Lanolin Alcohol, and Lanolin Oil. Some revisions were suggested.

There was a discussion as to the potential sensitivity of lanolin. Dr. Fine pointed out that lanolin is a known sensitizer; there is clinical evidence of hypersensitivity. Dr. Bergfeld stated that there is additional available literature on the subject and suggested that that matter be further pursued.

Acceptance of the team report by the full Panel was deferred until the above matter is resolved.
Staff will prepare a further draft reflecting the revisions discussed for distribution to and consideration by the full Panel prior to its acceptance of the report.

APRIL 27-28, 1979 PANEL MEETING

(Under "Director's Remarks") Dr. Elder reported that the 90-day public comment period had recently expired on three Tentative Reports [including] Acetylated Lanolin Alcohol Group.

JULY 23 1979 EXECUTIVE SESSION

(Under "Status Report") Dr. Elder reported that…another three Tentative Reports will be issued as Final Reports [including] Acetylated Lanolin Alcohol and Related Ingredients…within the next month or so.

FEBRUARY 6-7, 2003 PANEL MEETING – RE-REVIEW

Full Panel Meeting

A Final Report with the following conclusion on these ingredients was published in 1980: based on the available animal data and human experience, the Panel concludes that Lanolin and related Lanolin materials described herein are safe for topical application to humans in the present practices of use and concentration.

Dr. Belsito noted that new ingredient uses in hair sprays are included in the re-review document that was provided, and recommended that the discussion section in the Annual Review contain a statement indicating the particle size for a hair spray that would not be respirable.

Drs. Bergfeld and Marks noted that current limitations on pesticide, prion, or hormone contaminants that are being used by the Panel should be incorporated into the discussion section for each animal-derived or botanical ingredient (where applicable) that is included in the Annual Review.

After reviewing data that have been published since the Final Report was issued, the Panel unanimously concluded that the CIR Final Safety Assessment on these ingredients should not be reopened. It was also agreed that the following concerns will be addressed in the discussion section of the Annual Review: (1) pesticide and biological contaminants and (2) hair spray particle size that would not be respirable.

Amended Safety Assessment of Lanolin-Derived Ingredients as Used in Cosmetics

Status: Draft Amended Report for Panel Review
Release Date: March 4, 2024
Panel Meeting Date: March 28-29, 2024

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Thomas J. Slaga, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D., and the Senior Director is Monice Fiume. This safety assessment was prepared by Christina Burnett, M.S., Senior Scientific Analyst/Writer, CIR.

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ABBREVIATIONS

CIR	Cosmetic Ingredient Review
Council	Personal Care Products Council
CPSC	Consumer Product Safety Commission
DEA	diethanolamine
ECHA	European Chemicals Agency
FDA	Food and Drug Administration
HRIPT	human repeated-insult-patch -test
LLNA	local lymph node assay
NACDG	North American Contact Dermatitis Group
NOAEL	no-observable-adverse-effect level
OECD	Organisation for Economic Co-operation and Development
OTC	over-the-counter
Panel	Expert Panel for Cosmetic Ingredient Safety
PEG	polyethylene glycol
PII	primary irritation index
ROAT	repeated open application test
SPIN	significance-prevalence index
TG	test guideline
VCRP	Voluntary Cosmetic Registration Program
wINCI *Dictionary*	web-based *International Cosmetic Ingredient Dictionary and Handbook*

INTRODUCTION

The Expert Panel for Cosmetic Ingredient Safety (Panel) previously reviewed the safety of 9 lanolin-derived ingredients in a report that was published in 1980.[1] At that time, the Panel concluded "Lanolin and related Lanolin materials… are safe for topical application to humans in the present practices of use and concentration" (as described in that assessment). The Panel first considered a re-review of this report in February 2003, and the Panel reaffirmed the original conclusion, as published in 2005.[2] In accordance with its Procedures, the Panel evaluates the conclusions of previously-issued reports approximately every 15 years, and it has been at least 15 years since this assessment was last reviewed. This report has been reopened to reassess the safety of the 9 lanolin-derived ingredients (listed below) included in the original report as used in cosmetics. According to the web-based *International Cosmetic Ingredient Dictionary and Handbook* (wINCI; *Dictionary*; see Table 1), most of these ingredients are reported to function in cosmetics as skin conditioning agents-emollient and hair conditioning agents; other cosmetic functions are also reported.[3]

Acetylated Lanolin
Acetylated Lanolin Alcohol
Hydrogenated Lanolin
Hydroxylated Lanolin
Lanolin
Lanolin Acid
Lanolin Alcohol
Lanolin Oil
Lanolin Wax

The Panel has also reviewed related ingredients. The Panel concluded that polyether lanolin ingredients are safe in the practices of use and concentration described in a safety assessment that was published in 2018.[4] In a report that was published in 2013, the Panel concluded that lanolinamide diethanolamine (DEA) is safe with several qualifications.[5] Additionally, the Panel determined laneth polyethylene glycol (PEG) ethers are safe when formulated to be nonirritating in a report that was published in 2012.[6]

This safety assessment includes relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an extensive search of the world's literature; a search was last conducted in February 2024. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that the Panel typically evaluates, is provided on the Cosmetic Ingredient Review (CIR) website (https://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites; https://www.cir-safety.org/supplementaldoc/cir-report-format-outline). Unpublished data are provided by the cosmetics industry, as well as by other interested parties.

Some of the data included in this safety assessment were found on the European Chemicals Agency (ECHA) website.[7-12] Please note that the ECHA website provides summaries of information generated by industry, and it is those summary data that are reported in this safety

Excerpts of data from the original 1980 safety assessment are summarized throughout the text of this document, as appropriate, as are pertinent information from the original re-review document[13] considered by the Panel in February 2003. These data are identified using *italicized text*. (This information is not included in the tables or the summary section.) For complete and detailed information, the original 1980 report can be accessed on the CIR website (https://wwwcir-safety.org/ingredients).

CHEMISTRY

Definition and Structure

The definitions of the lanolin-derived ingredients included in this review are provided in Table 1. Lanolin is a fat-like sebaceous secretion of sheep.

Chemical Properties

Chemical properties of several of the lanolin-derived ingredients are described in Table 2. Lanolin-derived ingredients generally are insoluble in water and have large log P_{ow} values.[7-12]

Acetylated Lanolin

Acetylated Lanolin is more hydrophobic than Lanolin since many of the hydrophilic hydroxyl groups in the latter substance have been esterified to acetate.[1] Acetylated Lanolin, therefore, fails to form water/oil emulsions and is soluble in cold mineral oil. Acetylated Lanolin forms a water-resistant film when applied to the skin resulting in the reduction of transepidermal water loss.

Hydrogenated Lanolin

Hydrogenated Lanolin is soluble in ethyl ether and chloroform but insoluble in water.[1] Hydrogenated Lanolin retains the emollient and adhering characteristics of Lanolin but loses odor, taste, color, and tackiness of Lanolin.

Hydroxylated Lanolin

The introduction of highly polar hydroxyl groups renders Hydroxylated Lanolin more hydrophilic than Lanolin.[1] The product becomes more amphoteric resulting in increased inter-facial and surface activities. Hydroxylated Lanolin is superior to Lanolin in forming stable water/oil emulsions.

Lanolin

The raw material Lanolin is referred to as Adeps lanae, wool wax, wool fat, or wool grease.[1] Lanolin comprises 10 to 25% of the weight of sheared wool. When heated in a steam bath, Lanolin separates into two layers with the lower layer being water. Additional heating drives off this water phase; if not more than 0.25% water remains, the material is classified as anhydrous Lanolin. Lanolin is not soluble in water or mineral oil but is miscible without phase separation with about twice its weight of water. It is sparingly soluble in cold alcohol and more so in hot alcohol. Lanolin is highly soluble in chloroform and ether. Lanolin displays strong emollient, penetrating and emulsifying properties. It blends well with nearly all other substances used in cosmetic formulations. Lanolin possesses adhesive and tackifying characteristics as well.

Lanolin Acid

The constituent fatty acids of Lanolin Acid are polar molecules that yield amphoteric properties to this ingredient.[1]

Lanolin Oil

Lanolin Oil, or liquid Lanolin, is less tacky and has less drag than whole Lanolin.[1] However, it retains the emollient characteristics of Lanolin and displays a high spreading coefficient. Liquid Lanolin is soluble in mineral and vegetable oils and in silicone fluids.

Lanolin Wax

Lanolin Wax is a better water/oil emulsifying agent than whole Lanolin.[1]

Method of Manufacture

Acetylated Lanolin

Lanolin undergoes acetylation when reacted with acetic anhydride.[1] Ester bonds are formed between the acetate moieties and the hydroxyl groups of the Lanolin hydroxyesters. The free alcohols in a Lanolin sample may also undergo esterification with acetic anhydride. These two reactive groups (hydroxyesters and free alcohols) make up nearly 38% of crude Lanolin. Total acetylation of Lanolin would result, then, in the chemical alteration of over one-third of the original sample.

Acetylated Lanolin Alcohol

Once Lanolin has been fractionated into its alcohol and fatty acid components, the former group can be further processed by reacting it with acetic anhydride.[1] Each free hydroxyl group can potentially form an ester linkage with acetate. Since Lanolin Alcohol is a mixture of mono-, di-, and polyols, Acetylated Lanolin Alcohol will contain mono-, di-, and polyacetates.

Hydrogenated Lanolin

Exposing Lanolin to hydrogen at high temperature and pressure in the presence of nickel or chromium catalyst results in a sequence of 4 chemical reactions.[1] First, most unsaturated double-bonds become saturated with hydrogen. Second, the Lanolin esters undergo hydrogenolysis. Third, the resulting free fatty acids are reduced to fatty alcohols. Fourth, some of these alcohols, as well as some of those resulting from the ester cleavage step, are further reduced to simple hydrocarbons.

Hydroxylated Lanolin

The hydroxylation of Lanolin involves the addition of 2 hydroxyl groups across a double-bond.[1] The resulting compound is a glycol (dial). Lanolin is mixed with acetic acid, hydrogen peroxide, and sulfuric acid (catalyst). The active reactant, peracetic acid (acetyl hydroperoxide), is formed in situ in the reaction medium and is consumed immediately as it is generated. Peracetic acid mediates the opening of the unsaturated bond and the concomitant addition of two hydroxyl groups.

Lanolin

Lanolin is obtained by solvent extraction of wool fleece.[1] It can also be obtained by scouring wool with soap or neutral detergent followed by centrifugation of the resulting emulsion, breaking of the emulsion with acid, or production of foam (with air) and collection of the froth.

Lanolin Acid

Saponification of Lanolin with alcoholic or hydroalcoholic alkali results in the hydrolytic cleavage of its constituent esters.[1] The reaction product is a mixture of alkaline soaps of fatty acids and unsaponifiable alcohols. The fatty alcohols can be extracted (such as with ethyl acetate, trichloroethane or aliphatic hydrocarbon solvents) from the acid-alcohol mixture leaving behind the lanolin soaps. These alkali soaps are reacted with sulfuric or phosphoric acid and then water washed to remove excess mineral acid and resultant salts. The Lanolin Acid is then dried and further refined.

Lanolin Alcohol

Lanolin Alcohol is derived from Lanolin via hydrolysis followed by extraction.[1]

Lanolin Oil and Lanolin Wax

Lanolin Oil is the liquid-phase resulting from solvent fractionation (such as with ethyl acetate) of crude Lanolin via vacuum distillation or solvent crystallization.[1] *Lanolin Wax is the solid-phase product of this separatory process.*

Composition and Impurities

Lanolin and related materials may contain additives and contaminants which may vary widely.[1] *These include detergents and the antioxidants butylated hydroxytoluene and alpha-tocopherol. Chlorophyll, pesticides from the fleece, and trace metals such as copper, nickel, and chromium might also be present.*

Hydrogenated Lanolin

Hydrogenated Lanolin has never been fully characterized chemically, but its low saponification value indicates the nearly total absence of esters.[1] *Additionally, the high hydroxyl value of Hydrogenated Lanolin suggests the presence of a high percentage of free alcohols (94 to 99.8%).*

Lanolin

Lanolin is a complex mixture of a large number of compounds.[1] *High molecular weight esters make up approximately 87% of a typical Lanolin sample. The remainder of the mixture is comprised of 11% free compounds (aliphatic alcohols, sterols, fatty acids, and hydrocarbons) and of 2% unidentified compounds. Since Lanolin is composed predominantly of high molecular weight esters, it is classified chemically as a wax arid not as a fat. The esters have not been characterized. The approximate typical composition of whole Lanolin is as follows: 35.4% esters of sterols and triterpene alcohols; 23.7% esters of aliphatic alcohols; 20.0% monohydroxyesters of sterols and of triterpene and aliphatic alcohols; 7.9% di- and polyhydroxyesters and free diols; 5.6% free aliphatic alcohols; 4.1% free sterols; 0.6% free hydrocarbons; 0.5% free fatty acids, and 2.2% unknown.*

Pesticides were noted to be an impurity of concern in Lanolin products.[13] *At least 28 different pesticides have been used to control sheep pests. Detection was claimed at 20 to 97 ng/g. At the time of the study, the European Pharmacopoeia limits were 50 ng/g for individual organochlorine pesticides, 500 ng/g for other individual pesticides, and 1000 ng/g for total pesticides. The authors noted that the limits were higher than the amount determined in 3 of 4 Lanolin samples analyzed.*

Lanolin and lanolin-containing nipple care products were analyzed for pesticide contamination.[14] Of the 4 different materials analyzed none were found to have any of the 21 organochloro-pesticides included in the screening protocol. However, trace residues of the diazinon (up to 0.69 mg/kg), ethion (0.27 mg/kg), piperonyl butoxide (up to 1.30 mg/kg), diflubenzuron (0.02 mg/kg), triflumuron (0.02 mg/kg), cypermethrin (0.09 mg/kg), and chlorpyrifos-ethyl (1.50 mg/kg) were detected. The materials were also analyzed for free Lanolin Alcohol, which varied in concentration from 0.61 to 4.50%. Peroxide values, acid values, and anisidine values ranged from 6.60 - 12.63, 0.40 - 0.90, and 2.83 - 8.50, respectively.

Lanolin Acid

Lanolin Acid is a mixture of long-chain fatty acids in which the non-hydroxylated species predominates.[1] *Approximately 63% of the Lanolin fatty acids are non-hydroxylated, while 32% are mono--hydroxylated at either the alpha or omega carbon. The predominant non-hydroxylated fatty acids are of the anteiso (containing an isobutyl group) and the iso (containing an isopropyl group) types. The mono-hydroxylated acids (alpha and omega) are mainly of the normal (straight-chain) type. The length of the Lanolin fatty acid chain varies from 7 to 41 carbon atoms. The main fatty acids are palmitic (Cl6), stearic (Cl8) and longer molecules (C20 to C32).*

Lanolin Alcohol

Lanolin Alcohol is a mixture of alcohols comprised of about two-thirds sterols and one-fourth aliphatic alcohols.[1] *It should be noted that neither squalene nor glycerol is found in Lanolin. Approximately 26% of the Lanolin Alcohols are aliphatic structures: 17% monohydric alcohols and 9% diols. The anteiso and iso forms are the predominant types of mono- and di-hydric alcohols found in Lanolin. Most of the aliphatic alcohols are long-chain molecules (C16 and greater). Over 68% of the Lanolin Alcohols are sterols: 42% dimethyl sterols (cholesterols) and 26% pentamethyl sterols (lanosterols). The latter group is also referred to as the triterpene alcohols.*

Lanolin Oil

The approximate typical composition of Lanolin Oil is as follows: 44.0% esters of sterols and triterpene alcohols; 16.0% esters of aliphatic alcohols; 15.0% monohydroxyesters of sterols and of triterpene and aliphatic alcohols; 7.7% di- and polyhydroxyesters and free diols; 10.4% free aliphatic alcohols; 4.4% free sterols; 0.3% free hydrocarbons; 0.7% free fatty acids, and 1.5% unknown.[1]

Lanolin Wax

Lanolin Wax has a similar approximate composition: 28.9% esters of sterols and triterpene alcohols; 13.9% esters of aliphatic alcohols; 16.4% monohydroxyesters of sterols and of triterpene and aliphatic alcohols; 9.3% di- and

polyhydroxyesters and free diols; 20.2% free aliphatic alcohols; 5.3% free sterols; 0.4% free hydrocarbons; 1.0% free fatty acids, and 4.6% unknown.[1]

USE

Cosmetic

The safety of the cosmetic ingredients addressed in this assessment is evaluated based on data received from the US Food and Drug Administration (FDA) and the cosmetics industry on the expected use of these ingredients in cosmetics, and does not cover their use in airbrush delivery systems. Data are submitted by the cosmetic industry via the FDA's Voluntary Cosmetic Registration Program (VCRP) database (frequency of use) and in response to a survey conducted by the Personal Care Products Council (Council) (maximum use concentrations). The data are provided by cosmetic product categories, based on 21CFR Part 720. For most cosmetic product categories, 21CFR Part 720 does not indicate type of application and, therefore, airbrush application is not considered. Airbrush delivery systems are within the purview of the US Consumer Product Safety Commission (CPSC), while ingredients, as used in airbrush delivery systems, are within the jurisdiction of the FDA. Airbrush delivery system use for cosmetic application has not been evaluated by the CPSC, nor has the use of cosmetic ingredients in airbrush technology been evaluated by the FDA. Moreover, no consumer habits and practices data or particle size data are publicly available to evaluate the exposure associated with this use type, thereby preempting the ability to evaluate risk or safety.

According to 2023 VCRP survey data, Lanolin has the most reported uses in cosmetic products, with a total of 285 formulations; the majority of the uses are in leave-on products (Table 3).[15] Acetylated Lanolin Alcohol has the second most reported uses in cosmetic products, with a total of 196; the majority of these uses are also in leave-on formulations. The frequencies of use for both of these ingredients have markedly decreased since the Panel last reviewed these ingredients in 2003; Lanolin was reported to have 782 uses, and Acetylated Lanolin Alcohol was reported to have 356 uses.[2] The results of the concentration of use survey conducted by the Council in 2022 indicate Lanolin Oil has the highest maximum concentration of use in a leave-on formulations; it is used at up to 47% in lipsticks.[16] Lanolin is reported to be used at up to 40% in leave-on nail creams and lotions. When the Panel last reviewed these ingredients in 2003, the maximum leave-on use concentration for Lanolin Oil was 65% in lipstick; the maximum leave-on use concentration for Lanolin was 37% in body and hand skin care preparations.[2]

Lanolin-derived ingredients may be used in products that can be incidentally ingested or be used near the eye or mucous membranes. For example, Lanolin has been reported to be used in lipsticks at up to 20.7% and in eyeliners at up to 32%, and Lanolin Oil has been reported to be used in lipsticks at up to 47% and in eye shadows at up to 11.1%.[15,16] Additionally, some of the Lanolin may be used in cosmetic sprays and powders, and could possibly be inhaled; for example, Lanolin is reported to be used at 1.6% in hair sprays and at 0.0099% in face powders, and Lanolin Oil is reported to be used in a fragrance preparation (no reported concentration) and in face powders at 0.3%. In practice, as stated in the Panel's respiratory exposure resource document (https://www.cir-safety.org/cir-findings), most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and tracheobronchial regions and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount. Conservative estimates of inhalation exposures to respirable particles during the use of loose powder cosmetic products are 400-fold to 1000-fold less than protective regulatory and guidance limits for inert airborne respirable particles in the workplace.

Although products containing some of these ingredients may be marketed for use with airbrush delivery systems, this information is not available from the VCRP or the Council survey. Without information regarding the frequency and concentrations of use of these ingredients (and without consumer habits and practices data or particle size data related to this use technology), the data are insufficient to evaluate the exposure resulting from cosmetics applied via airbrush delivery systems.

All of the lanolin-derived ingredients named in the report are not restricted from use in any way under the rules governing cosmetic products in the European Union.[17]

Non-Cosmetic

According to the US FDA, Lanolin is a food additive permitted for direct addition to food for human consumption as a plasticizing material (softener) in chewing gum base (21CFR Part 172.615). It is also an indirect food additive in adhesives and components of coatings (21CFR Part 175.300), in components of paper and paperboard (21CFR Part 176.170, 176.210), in polymers (21CFR Part 177.1200, 177.2600), and in adjuvant, production aids, and sanitizers (21CFR Part 178.3910). In the US, Lanolin may be used as an active ingredient in over-the-counter (OTC) drug products.[3] When used as an active drug ingredient, the established drug name is *Lanolin*. Lanolin is approved for OTC use as an active ingredient in anorectal drug products (21CFR Part 346.14), in skin protectants (21CFR Part 347.10), and in ophthalmic drug products (21CFR Part 349.14). Lanolin may be present in ingredients used in over-the-counter hair growers and/hair loss prevention, treatments for boils, drug products for poison ivy, poison oak and poison sumac; but there is a lack of adequate data to establish general recognition of the safety and effectiveness of this ingredient for these intended uses (21CFR Part 310.527, 310.531, 310.545).

Several sources have described the use of Lanolin-containing products (especially highly purified materials) for the prevention and treatment of nipple pain in breastfeeding mothers.[14,18-22] Lanolin has also been studied for use in coatings and

synthetic membranes for drug delivery systems for oral and transdermal drug treatments, respectively.[23-25] Lanolin and Lanolin Alcohol have been evaluated in multiple studies for use in wound treatment[26-32] and barrier cream for barrier deficient skin, such as that found in neonates.[33-35]

TOXICOKINETIC STUDIES

Toxicokinetics studies were not included in the original report and were not found in the updated literature search, and unpublished data were not submitted.

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

The acute dermal LD_{50} of Lanolin Oil as applied to the rabbit skin has been determined to be in excess of 10 ml/kg.[1] In a 2-dose (1 or 2 g/kg) study in rats, the LD_{50} of Hydroxylated Lanolin was found to be greater than 2.0 g/kg.

Each of the 9 lanolin ingredients has been tested in rats for acute oral toxicity in a variety of studies.[1] All exhibit low oral toxicity. Only the most pertinent acute oral LD_{50} for each ingredient will be reported: undiluted Lanolin (> 64 ml/kg), undiluted Lanolin Oil (46.5 ml/kg), 50% Lanolin Wax in corn oil (> 32 g/kg), undiluted Lanolin Acid (56.5 ml/kg), 66% Lanolin Alcohol in corn oil (> 42.7 g/kg), undiluted Acetylated Lanolin (> 64 ml/kg), undiluted Acetylated Lanolin Alcohol (> 64 ml/kg), undiluted Hydrogenated Lanolin (> 64 ml/kg), and undiluted Hydroxylated Lanolin > 10 ml/kg).

Acute toxicity studies on lanolin-derived ingredients are summarized in Table 4. In dermal rat studies, the LD_{50}s of Lanolin Acid and Lanolin Alcohol (each tested in arachis oil) were both > 2000 mg/kg (the highest dose tested).[10,11] No dermal irritation was observed in these studies. In oral studies, the LD_{50} for undiluted Hydroxylated Lanolin was > 10 ml/kg in rats.[7] The LD_{50} for Lanolin Alcohol was > 5000 mg/kg.[11]

Subchronic Toxicity Studies

Oral

Lanolin Acid

In a 90-d oral repeated-dose study performed in accordance with OECD TG 408, groups of 10 male and 10 female RccHan™:WIST(SPF) rats received 0, 100, 300, or 1000 mg/kg bw/d Lanolin Acid in corn oil via gavage.[11] The animals were observed for clinical signs of toxicity, and body weights and feed consumption were measured. Ophthalmoscopic examinations (control and high dose groups only) were conducted pre-treatment and before study end, and neurobehavioral examinations were conducted at the end of treatment. Blood and urine were collected at the end of the treatment period for hematology and clinical chemistry evaluations. All rats were killed at the end of the study for gross pathology and histopathology examinations.

One rat died in the 300 mg/kg group due to dosing error. No other mortalities were reported. No clinical signs of toxicity were reported. No adverse effects observed in body weight gains, feed consumption, ophthalmology, hematology, clinical biochemistry, or urinalysis. No treatment-related changes were observed with gross pathology or histopathology. The no-observable-adverse-effect level (NOAEL) for Lanolin Acid in this study was greater than 1000 mg/kg bw/d.[10]

Lanolin Alcohol

In another 90-d oral repeated-dose study, groups of 10 male and 10 female Wistar Han™:RccHan™:WIST rats received 0, 100, 300, or 1000 mg/kg bw/d Lanolin Alcohol in arachis oil via gavage.[11] This study was performed in accordance with OECD TG 408 in a similar manner as that described above. The animals were observed for clinical signs of toxicity, and body weights, feed consumption, and water consumption were measured. Ophthalmoscopic examinations (control and high dose groups only) were conducted pre-treatment and before study end, and neurobehavioral examinations were conducted pre-treatment and at weekly intervals thereafter. Blood was collected at the end of the treatment period for hematology and clinical chemistry evaluations. All rats were killed at the end of the study for gross pathology and histopathology examinations.

No mortalities or clinical signs of toxicity were observed. No adverse effects on body weight, feed/water consumption, ophthalmology, hematology, clinical chemistry, or gross pathology were observed. Minimal or mild alveolar macrophages were observed in 300 and 1000 mg/kg dose females, which were attributed to accidental inhalation of the test material during dosing. The NOAEL for Lanolin Alcohol in this study was greater than 1000 mg/kg bw/d.[11]

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY STUDIES

Oral

Lanolin Acid

In an oral developmental toxicity study performed in accordance with OECD TG 414, groups of 22 pregnant RccHan™:WIST(SPF) rats received 0, 100, 300, or 1000 mg.kg bw/d Lanolin Acid in corn oil on days 6-20 of gestation via gavage.[10] The dams were observed for clinical signs of toxicity during the treatment period, and body weights and feed

consumption were measured. The dams were killed on gestation day 21 and the ovaries, uterine content, and fetuses were examined.

All dams survived until day 21 termination. No clinical signs of toxicity were observed. No adverse effects on feed consumption or body weights were noted. No effects to relevant reproductive parameters or gross pathological exams were observed. There were no treatment-related effects observed in fetal sex ratio or in the fetuses during examination. The NOAEL for maternal and developmental toxicity for Lanolin Alcohol in this study was ≥ 1000 mg/kg bw/d.[10]

Lanolin Alcohol

In an oral developmental toxicity study performed in accordance with OECD TG 414, groups of 24 pregnant Sprague-Dawley Crl:CD (SD) IGS BR rats received 0, 100, 300, or 1000 mg.kg bw/d Lanolin Alcohol in arachis oil on days 5-19 of gestation via gavage.[11] The dams were observed for clinical signs of toxicity during the treatment period, and body weights, feed consumption, and water consumption were measured. The dams were killed on gestation day 20 and the ovaries, uterine content, and fetuses were examined.

All dams survived until termination. No treatment-related clinical signs of toxicity were observed. No treatment-related effects of feed consumption or body weights were noted. No effects to relevant reproductive parameters or gross pathological exams were observed. There were no treatment-related effects on offspring survival measured by the mean numbers of early or later resorptions, live litter size, and post-implantation losses. There was also no adverse effect in sex ratio. In all dose groups, there were no significant treatment-related trends in the proportion of fetuses or litters with evidence of external, visceral, or skeletal anomalies. There were no findings of known malformations. The NOAEL for maternal and developmental toxicity for Lanolin Alcohol in this study was ≥ 1000 mg/kg bw/d.[11]

GENOTOXICITY STUDIES

In vitro genotoxicity studies on lanolin-derived ingredients are summarized in Table 5. Lanolin Acid and Lanolin Alcohol were not mutagenic in Ames tests when tested at up to 5000 µg/plate, with or without metabolic activation.[10,11] No mutagenicity to Lanolin Acid (at up to 600 µg/ml) or Lanolin Alcohol (at up to 937.5 µg/ml) was observed in mammalian gene mutation tests using mouse lymphoma L5178 cells, with and without metabolic activation. Additionally, Lanolin Acid (at up to 2500 µg/ml) and Lanolin Alcohol (at up to 1250 µg/ml) were not clastogenic in mammalian chromosome aberration tests using human lymphocytes, with and without metabolic activation.

CARCINOGENICITY STUDIES

Carcinogenicity studies were not included in the original report and were not found in the updated literature search, and unpublished data were not submitted.

ANTI-CARCINOGENICITY STUDIES

A study reported that 3-methylcholanthrene dissolved in anhydrous Lanolin was less carcinogenic when painted on the skin of mice as compared to its carcinogenic effect when benzene was the vehicle.[1] The concentration of 3-methyl-cholanthrene in Lanolin applied in these studies was one-half that of the compound in benzene. However, the volume of the benzene solution applied was twice that of the Lanolin solution. A similar diminution in the carcinogenic potency of methylcholanthrene was observed when Lanolin was used as a diluent. The inhibitory effect was reported even with concentrations that exceeded the concentration of the carcinogen in benzene used as a positive control. Similar results were obtained with another carcinogen, 7,12-dimethylbenz(α)anthracene, on mice.

OTHER RELEVANT STUDIES

Comedogenicity

The acnegenic properties of cosmetics containing Lanolin and Lanolin-related materials were tested in a few studies.[1] Comedogenic effects were described for these ingredients.

Hydroxylated Lanolin

A comedogenicity assay was conducted using 6% w/w Hydroxylated Lanolin solution in cottonseed oil.[7] The right ear of 6 New Zealand White rabbits were treated with the test material and the left ear was dosed with cottonseed oil (positive control) on 5 consecutive d/wk for 3 consecutive wk. The ears were scored for hyperkeratosis and comedone formation each day prior to application of the test material. At study end, the control and treated ears were excised and subsequently subjected to histological examination for comedones. All rabbits appeared active and healthy throughout the test period. No signs of gross toxicity, adverse pharmacologic effects, or abnormal behavior were observed. Transient, mild hyperkeratosis (scores 1 - 2) was noted during the second and third weeks of dosing. The average "in-life" scores for the test and control ears were 0.19 and 0.16, respectively. The total number of visible comedones at test termination was 0 for treated and control ears. Histological examination showed that all ears (treated and control) were negative with respect to comedone formation although hyperkeratosis with scores of 1 - 2 was noted in all but one treated section and in 6 out of 12 control sections. The average group histology scores for treated and control ears were 1.1 and 0.5, respectively. The total number of

comedones identified histologically was 0 for both treated and control ears. Hydroxylated Lanolin was considered to be non-comedogenic in this study.

Efficacy Studies on Wound Healing

In rodent efficacy studies of different compounds used in wound healing, Lanolin was used in vehicle solutions and as a control.[27-31] Concentrations tested were reported to be as high as 30% (anhydrous form) and the rodents were treated with the test materials for as long as 3 wk. No adverse effects to Lanolin as used as a vehicle or control were reported.

DERMAL IRRITATION AND SENSITIZATION STUDIES

With one exception, the Lanolin ingredients are either non-irritating or at most mildly irritating to the skin of experimental animals.[1] The exception is Lanolin Acid which is a moderate skin irritant; it should be noted that Lanolin Acid is seldom, if at all, found in cosmetic formulations as the free acid. In five tests conducted on undiluted Lanolin Acid, the primary irritation index (PII) ranged from 0.78 to 2.2 (maximum of 8). The highest PII value obtained for other undiluted Lanolin ingredients is as follows: Lanolin (0.71), Lanolin Oil (1.0), Lanolin Wax (0.67), Lanolin Alcohol (1.5), Acetylated Lanolin (1.62), Acetylated Lanolin Alcohol (2.3), Hydrogenated Lanolin (0.6), and Hydroxylated Lanolin (0.0).

Neither Lanolin Oil applied 15 times to the rabbits skin at concentrations of 5, 15, or 50% nor 50% Hydroxylated Lanolin applied 65 times to the rat skin caused any local skin irritation effects.[1]

A skin sensitization study with 8 guinea pigs was done with Acetylated Lanolin Alcohol suspended in physiological saline.[1] Ten intracutaneous injections on alternate days followed by challenge injection 2 wk later showed no sensitization. Hydrogenated Lanolin was not a sensitizer when applied to the skin of guinea pigs 3 times/wk for 7 or more applications. A 2% solution in 1:1:3 acetone:dioxane:corn oil was used. The challenge was applied 2 wk after the last induction dose. The sensitization potential of Lanolin Wax suspended in corn oil was evaluated using 10 guinea pigs; Lanolin Wax had an average score of 0.95 (scores between 0.1 and 2.0 are mild sensitizers). The material was injected intracutaneously 3 times/wk for a total of 10 injections with an eleventh challenge injection 2 wk later.

Numerous patch tests were conducted on volunteers with Lanolin and related cosmetic ingredients.[1] Undiluted Lanolin showed no evidence of primary irritation or sensitization in over 250 subjects. Lanolin Oil has been skin tested in more than 300 volunteers without adverse reactions. Undiluted Lanolin Wax showed extremely low irritation potential and no evidence of sensitization in over 200 subjects. Of the 115 subjects exposed topically to Lanolin Acid, three showed increased reaction not considered sensitization and one showed sensitization. There were no adverse effects noted when 50 volunteers were exposed to undiluted Lanolin Alcohol in a human repeated-insult-patch-test (HRIPT). Questionable evidence of fatiguing was found in 2 of 53 subjects exposed to Acetylated Lanolin. Acetylated Lanolin Alcohol caused an extremely low level of irritation in over 60 individuals. In an HRIPT on 50 subjects, undiluted Hydrogenated Lanolin presented no suggestions of irritation, fatiguing, or sensitization. There were no visible skin changes observed in 53 subjects exposed to Hydroxylated Lanolin at up to 100%.

Dermal irritation and sensitization studies are summarized in Table 6. Lanolin Alcohol (concentration not reported) in mineral oil was irritating in a modified Draize study in New Zealand White rabbits on intact and abraded skin.[11] No irritation was observed in 20 subjects that received nano-emulsions containing 2.0% Acetylated Lanolin. In a dermal tolerance test, Hydrogenated Lanolin did not cause erythema when applied to the palm of the hands of 14 subjects.[8] None of the subjects complained of itching or other signs of intolerance. Lanolin Acid was determined to be non-sensitizing in a local lymph node assay (LLNA) in mice when tested at up to 50% in dimethylformamide.[10]

Photosensitization/Phototoxicity

Human

Two product formulations, each containing 0.75% Lanolin Acid, 3.0% Lanolin Alcohol, and 0.5% Hydroxylated Lanolin, were tested for phototoxicity on 20 human subjects and for photosensitization on 25 human subjects.[1] There was no evidence of either phototoxicity or photosensitivity.

OCULAR IRRITATION STUDIES

Animal

With one exception, all the Lanolin ingredients were either non-irritating or at most mildly irritating to the eyes of experimental animals.[1] In 3 of 4 ocular irritation studies conducted on rabbits, undiluted Lanolin Acid was found to be a mild or moderately severe irritant. For the other 8 Lanolin ingredients, no or only mild transient reactions were reported.

In a study to determine whether Lanolin-containing ophthalmic materials, applied topically, could be incorporated into the cornea, a series of provocative animal tests were performed.[1] It was concluded that no Lanolin-containing ointment was trapped in the cornea unless the surface of the cornea was directly and repeatedly disrupted and abraded.

Hydroxylated Lanolin

In an ocular irritation study, 3 New Zealand albino rabbits received instillations of 0.1 ml Hydroxylated Lanolin (20%) in mineral oil in the right eye while the left eye was untreated and served as control.[7] The eyes were not rinsed. Changes to

the cornea, iris, and conjunctivae were evaluated and scored every 24 h for 4 d and then again on the 7th d. The mean scores for cornea opacity, iris, and conjunctivae chemosis were 0 for all animals at 24, 48, and 72 h. No irritation was observed.

CLINICAL STUDIES

Over the years of its use, Lanolin has been observed to produce allergic or hypersensitivity reactions.[1] The first reports of Lanolin skin sensitization were published in 1930. Since then, numerous reports of Lanolin allergy have been published. The incidence of hypersensitivity among persons exposed has been a matter of great uncertainty.

Three large European retrospective studies of dermatology patients with Lanolin Alcohol hypersensitivity reported incidences of 0.70, 2.38, and 1.82%.[1] Using numerous assumptions, the incidence in the general population was estimated to be no more than 9.7 cases per million people.

For the detection of Lanolin allergy, the use of 30% wool wax alcohol in petrolatum was suggested as the testing agent for Lanolin materials in patch testing.[1] With this Lanolin fraction, Lanolin sensitivity was successfully identified. It was noted that addition of salicylic acid to the Lanolin fraction produced false-positive reactions.

A study concluded that the greatest allergenic reaction is given by C14-C16 Lanolin Alcohols.[1] A European study group noted that the incidence of hypersensitivity to topical medicaments was 14% (560/4000) in clinic patients with eczema. Positive test reactions were reported for wool alcohols (3%). The difference between these total values of 12%, and the overall total of 14% was not stated.

The North American Contact Dermatitis Group (NACDG) has issued a series of reports on results of diagnostic patch testing of dermatitis patients using a standard array of test substances.[1] Out of 1200 patients tested over an 18-mo period ending in June 1972, wool wax alcohols (30% in petrolatum) ranked eighth in frequency of reaction with 3% of the patients reacting. In the subsequent 2-yr testing period, wool wax alcohol ranked eleventh, again experiencing a 3% reaction rate in 3165 patients tested. A preliminary report from a testing period of July 1,1975 - June 30, 1976 showed wool alcohol ranking thirteenth with a reaction incidence of 2.9% in 900 - 2000 patients tested. An unpublished tabulation of 1976 - 1977 data from the groups shows a sensitivity index of 2% for wool alcohol and 1% for 100% hydrous Lanolin.

It has been demonstrated in Lanolin-sensitive patients that the removal of free fatty Lanolin Alcohols and detergents reduced the incidence of detectable hypersensitivity by 96%.[1] An anonymous submission suggested that parabens may increase or be responsible for Lanolin hypersensitivity. Estimates of the extent of hypersensitivity vary according to the type of provocative patch test applied or according to the populations tested.

Salicylic acid as a keratolytic agent has been used to increase the sensitivity to Lanolin in patch testing systems with differing results according to the type of Lanolin material used (Lanolin esters or alcohols).[1] It has even been suggested that autoxidation products may contribute to the allergenicity of Lanolin.

The Panel has previously reviewed data on efficacy studies with Lanolin in wound care and skin protective materials.[13] Several multicenter and retrospective studies reported the sensitization rates of Lanolin and Lanolin Alcohol in patients with allergic contact dermatitis.

Lanolin was named the Contact Allergen of the Year in 2023 by the American Contact Dermatitis Society.[36] The allergenic components in Lanolin are mainly the free lanolin alcohols, especially alkane-α,β-diols and alkane-α.ω-diols. Detection of Lanolin-induced contact dermatitis in diseased skin by patch testing on normal skin may lead to false negative results. Lanolin is a weak sensitizer but has high-risk concomitant conditions in patients with stasis dermatitis, leg ulcers, perianal/genital dermatitis, and atopic dermatitis. Children and the elderly have a greater risk of developing contact allergy to Lanolin due to comorbidities.

Clinical Reports

In a study of 10 subjects with history of contact allergy to a trademarked Lanolin product (a Lanolin derivative comprised of 10% Lanolin Alcohol and mineral oil), the subjects were re-tested in a dose-response manner followed by a comprehensive transcriptomic analysis of samples of skin reactions.[37] Positive reactions were observed in 8 subjects in the re-test. Most of the positive patch tests had an allergy signature with strong activation of gene modules associated with adaptive immunity and down regulation of cornification pathway genes. Gene modulation was correlated with the magnitude of patch test reactions and the concentration applied. Some positive patch reactions to the test material had no or few allergy biomarkers, suggesting induction of an irritant skin inflammation response.

A trademarked Lanolin product was studied to evaluate its ability to serve as a marker for Lanolin allergy in a repeated open application test (ROAT).[38] The ROAT was designed as a double-blind, randomized case-control study. Patch tests were performed with the trademarked Lanolin product at up to 100%, Lanolin products at up to 50% pet., Lanolin Alcohol at up to 30% pet., and "as-is" products prior to the 4-wk ROAT with Lanolin samples and base creams. Irritant dermatitis was induced by sodium lauryl sulfate. Twelve test patients with previous strong reactions and 14 controls completed the study. In the patch test, 11 subjects had a positive reaction with Lanolin at 100% and 5 subjects were positive to Lanolin at 50% pet. Only 3 subjects had positive reaction to patch test preparations other than Lanolin. No positive reactions were observed in controls. In the ROAT, no reactions were observed to any of the cream products containing Lanolin.

In a study of 430 patients with known cosmetic contact dermatitis, female facial melanoderma, cosmetic contact dermatitis anamnesis, and other dermatological diseases, the patients were patch-tested with 24 lanolin-derived substances.[11] These included Acetylated Lanolin, Acetylated Lanolin Alcohol, Hydrogenated Lanolin, Lanolin, Lanolin Acid, and Lanolin Alcohol at either 30% concentration, undiluted, or both. Control subjects (number not reported) were also patch-tested. The patches were either Finn chambers or Torii patch test plaster and the test sites were occluded. The test materials were applied to the upper back of the patients for 48 h. The test sites were observed at 1 and 24 h and 1 wk after the patches were removed. Very mild reactions for Lanolin Alcohol were observed in the subjects that already experienced dermatitis. Various lanolin fractions and derivatives produced different degrees of reaction (+ to greater than ++). Refined Lanolin Acid (30%) had the highest percentage of ++/+++ responses at 11.6% and + responses at 37.5%. Lanolin Alcohol (30%) had the next highest percentage of ++/+++ responses at 2.3% and + responses at 6.8%.

In a randomized study of 60 in-patients with venous leg ulcers in Croatia, 30 patients had allergic contact dermatitis and 30 did not have signs of contact allergy.[39] Patch testing was performed using a standard series of allergens and a special series of allergens that included Lanolin 20% pet. Two positive reactions to Lanolin were recorded in each the allergic contact dermatitis group and the control group. Total positivity was 6.66%.

Clinical trials have been performed evaluating the efficacy of the use of Lanolin for treatment of nipple pain in breastfeeding women.[19-22] No adverse effects due to Lanolin were reported.

The efficacy of Lanolin for treatment of side effects on the lips from chemotherapy was also studied.[26] Patients (n = 24) received Lanolin treatment 6 times/d from the beginning of chemotherapy until 2 wk after the end of chemotherapy. No adverse effects from the use of Lanolin were reported.

A clinical trial on the safety of and efficacy of pure Lanolin and another treatment for foot xerosis was performed in a double-blind randomized test.[32] The pure Lanolin was used twice daily on one foot of 67 patients with bilateral conditions for up to 4 wk. The other treatment was used on the opposite foot under the same conditions. Pruritis, burning, and redness were reported in 21 patients; however, the study authors did not provide details as to which treatment was associated with which adverse effects other than to say they were comparable between the 2 study groups.

The effects of topical therapy with an ointment containing Lanolin Alcohol were studied in neonates.[34] This study specifically investigated the prevention of nosocomial infections in infants born before week 33 of gestation. No adverse effects were observed in the 157 neonates that received the ointment that contained Lanolin Alcohol. In another topical therapy study in neonates, 58 infants between the ages of 25 and 36 wk gestation were tested for up to 4 wk with a cream containing 70% Lanolin and 30% olive oil.[35] Application of the cream was well tolerated by the infants.

Retrospective and Multicenter Studies

The results of numerous multicenter and retrospective studies conducted over more than 50 years are summarized in Table 7. These studies were primarily performed using Lanolin Alcohol, with a few on Lanolin or a trademarked Lanolin product. Sensitization to Lanolin and Lanolin Alcohol has been observed around the globe, with sensitization rates in patients with contact dermatitis varying, independent of region or span of time.[8,40-63] Using North America as an example, a multicenter study from the NACDG of patients with suspected allergic contact dermatitis found the positive reactivity rate for Lanolin Alcohol (50% pet.) to be 4.6% from 2011 to 2012 and 3.7% from 2019 to 2020. [43,44] In patients with suspected allergic contact dermatitis, the Netherlands has reported a positivity rate for Lanolin Alcohol (31% pet.) as high as 14.7% (2016 to 2017)[62] and Tunisia reported positivity rates from 52 to 63% over a 7-yr period (dates not reported).[63] Positivity rates in children were notably higher than those observed in adults.[41,47,53,61]

In addition to the retrospective and multicenter studies, literature review studies of irritant and allergic contact dermatitis have been performed. Lanolin and Lanolin Alcohol were identified as common allergens in wound care-related materials and moisturizers.[64] Lanolin Alcohol is also a common sensitizer in the elderly, with increased sensitization rates observed over adult patients.[65] In a systematic review of patch test results in 34 published studies, from 1997 to 2012, Lanolin was included in the most common allergens in children aged up to 19-yr-old.[66]

Case Reports

In a case report, a 19-yr-old female presented with widely distributed, erythematous, papular, and confluent eruptions on both backs of her hands following dermal exposure to several items, including propolis cream that contained Lanolin Alcohol.[67] The patient also had edema on the left hand with vesicular eruptions and inflammatory, itchy, papular lesions on the cheeks and feet. Patch test results were +++ on days 3 and 5 for Lanolin Alcohol (30%). The patient also had positive patch results for *Myroxylon pereirae*, colophonium, fragrance mix 1 and 2, clove oil, lemon grass oil, sorbitan sesquioleate, farnesol, propolis cream, and unguentum lanalcoli.

Comedogenic Effects

The comedogenicity of a finished product that contained Lanolin (concentration not reported) was assessed in a double-blind randomized controlled trial with 15 subjects.[68] The subjects applied the test material 3 times/wk for up to 4 wk. No adverse effects to the product containing Lanolin were reported. The finished product was non-comedogenic.

Occupational Exposure

No scientific reports of adverse reactions among persons occupationally-exposed during production or use of Lanolin over a 50-yr period have been reported.[1] *Similarly, there have been no reported adverse experiences in several studies of multiple year exposure by workers or customers for Lanolin Oil, Lanolin Wax, Lanolin Acid, Lanolin Alcohol, Acetylated Lanolin, or Acetylated Lanolin Alcohol.*

SUMMARY

The Panel previously reviewed the safety of 9 lanolin-derived ingredients in a report that was published in 1980. At that time, the Panel concluded "Lanolin and related Lanolin materials… are safe for topical application to humans in the present practices of use and concentration" (as described in that assessment). The Panel first considered a re-review of this report in February 2003, and the Panel reaffirmed the original conclusion, as published in 2005. In accordance with its Procedures, the Panel evaluates the conclusions of previously-issued reports approximately every 15 years, and it has been at least 15 years since this assessment was last reviewed. This report has been reopened to reassess the safety of the 9 lanolin-derived ingredients (listed below) included in the original report as used in cosmetics. According to the *Dictionary*, most of these ingredients are reported to function in cosmetics as skin conditioning agents-emollient and hair conditioning agents; other cosmetic functions are also reported.

According to 2023 VCRP survey data, of the ingredients named in this report, Lanolin has the most reported uses in cosmetic products, with a total of 285 formulations; the majority of the uses are in leave-on products. Acetylated Lanolin Alcohol has the second most reported uses in cosmetic products, with a total of 196; the majority of these uses are also in leave-on formulations. The frequencies of use for both of these ingredients have markedly decreased since the Panel last reviewed these ingredients in 2003; Lanolin was reported to have 782 uses, and Acetylated Lanolin Alcohol was reported to have 356 uses. The results of the concentration of use survey conducted by the Council in 2022 indicate Lanolin Oil has the highest maximum concentration of use in a leave-on formulations; it is used at up to 47% in lipsticks. Lanolin is reported to be used at up to 40% in leave-on nail creams and lotions. When the Panel last reviewed these ingredients in 2003, the maximum leave-on use concentration for Lanolin Oil was 65% in lipstick; the maximum leave-on use concentration for Lanolin was 37% in body and hand skin care preparations.

All of the lanolin-derived ingredients named in the report are not restricted from use in any way under the rules governing cosmetic products in the European Union. In the United States, Lanolin is permitted to be used as direct and indirect food additives. Lanolin is approved as an active ingredient in several over-the-counter products.

In acute dermal rat studies, the LD_{50}s of Lanolin Acid and Lanolin Alcohol (each tested in arachis oil) were both > 2000 mg/kg. No dermal irritation was observed in these studies. In acute oral studies, the LD_{50} for undiluted Hydroxylated Lanolin was > 10 ml/kg in rats. The LD_{50} for Lanolin Alcohol was > 5000 mg/kg. In separate 90-d rat studies, the oral NOAEL was determined to be greater than 1000 mg/kg bw/d for Lanolin Acid and Lanolin Alcohol. The NOAEL for material and developmental toxicity was also $\geq$ 1000 mg/kg bw/d in separate oral studies in rats for Lanolin Acid and Lanolin Alcohol.

Lanolin Acid and Lanolin Alcohol were not mutagenic in Ames tests when tested at up to 5000 µg/plate, with or without metabolic activation. No mutagenicity to Lanolin Acid (at up to 600 µg/ml) or Lanolin Alcohol (at up to 937.5 µg/ml) was observed in mammalian gene mutation tests using mouse lymphoma L5178 cells, with and without metabolic activation. Additionally, Lanolin Acid (at up to 2500 µg/ml) and Lanolin Alcohol (at up to 1250 µg/ml) were not clastogenic in mammalian chromosome aberration tests using human lymphocytes, with and without metabolic activation.

Hydroxylated Lanolin at 6% in cottonseed oil was considered to be non-comedogenic in a rabbit study. No adverse effects were reported in efficacy studies of wound healing products where Lanolin was used in vehicle solutions and controls.

Lanolin Alcohol (concentration not reported) in mineral oil was irritating in a modified Draize study in New Zealand White rabbits on intact and abraded skin. No irritation was observed in 20 subjects that received nano-emulsions containing 2.0% Acetylated Lanolin. In a dermal tolerance test, Hydrogenated Lanolin did not cause erythema when applied to the palm of the hands of 14 subjects. None of the subjects complained of itching or other signs of intolerance. Lanolin Acid was determined to be non-sensitizing in an LLNA in mice when tested at up to 50% in dimethylformamide. No ocular irritation was observed in a study in rabbits with 20% Hydrogenated Lanolin.

Lanolin was named as the Contact Allergen of the Year in 2023 by the American Contact Dermatitis Society. The allergenic components in Lanolin are mainly the free lanolin alcohols, especially alkane-α,β-diols and alkane-α.ω-diols. Detection of Lanolin-induced contact dermatitis in diseased skin by patch testing on normal skin may lead to false negative results. Lanolin is a weak sensitizer but has high-risk concomitant conditions in patients with stasis dermatitis, leg ulcers, perianal/genital dermatitis, and atopic dermatitis. Children and the elderly have a greater risk of developing contact allergy to Lanolin due to comorbidities.

Clinical studies of Lanolin products observed some positive reactions to these ingredients. No adverse effects were observed in efficacy studies of Lanolin for use in treatment in breastfeeding mothers or topical therapies in neonates. Numerous multicenter and retrospective studies have reported sensitization to Lanolin and Lanolin Alcohol around the globe,

with sensitization rates in patients with contact dermatitis varying, independent of region or span of time. In literature review studies, Lanolin and Lanolin Alcohol were identified as common allergens in wound care-related materials and moisturizers. Lanolin and Lanolin Alcohol are common sensitizers in the elderly and in children aged up to 19-yr-old. A case report of a 19-yr-old patient was positive for Lanolin Alcohol 30%. A finished product that contained an unreported concentration of Lanolin was non-comedogenic in a double-blind randomized controlled trial of 15 subjects.

Toxicokinetic and carcinogenicity studies on lanolin-derived ingredients were not included in the original report and were not found in the updated literature search, and unpublished data were not submitted.

ORIGINAL 1980 CONCLUSION

Based on the available animal data and human experience, the Panel concludes that Lanolin and related Lanolin materials described herein are safe for topical application to humans in the present practice of use and concentration.[1]

DISCUSSION/CONCLUSION FROM 2005 RE-REVIEW SUMMARY

… The Panel reviewed new studies…, along with updated information regarding types and concentrations of use.[2] *The Panel determined to not reopen this safety assessment.*

The CIR Expert Panel acknowledged that there are current uses of Lanolin compounds that may include aerosols. The effects of inhaled aerosols depend on the specific chemical species, the concentration, the duration of exposure, and site of deposition within the respiratory system. Particle size is the most important factor affecting the location of deposition. The mean aerodynamic diameter of pump hair spray particles is ≥80 μ and the diameter of anhydrous spray particles is 60 to 80 μ. Typically, less than 1% are below 10 μ, which is the upper limit for respirable particles. Based on the particle size, lanolin and related compounds would not be respirable in formulation.

The Panel also noted that animal derived products may contain residues present in the plant material ingested by the animal. Manufacturers are reminded that cosmetic products containing plant or animal derived ingredients should be formulated to limit the presence of pesticide/heavy metal residues as follows: lead ≤ 10 ppm, arsenic ≤ 3 ppm, mercury ≤ 1 ppm, total PCB/pesticide contamination ≤ 40 ppm with ≤ 10 ppm for any specific residue. In addition, the CIR Expert Panel has recently stressed that animal-derived ingredients must be free of detectible pathogens and/or infectious agents (e.g., prions). Suppliers and users of these ingredients should assure that these ingredients are risk-free. Tests to assure the absence of a pathogenic agent in the ingredients, or controls to assure deviation from pathogen-free sources are two approaches that should be considered…[2]

DISCUSSION

To be developed.

CONCLUSION

To be determined.

TABLES

Table 1. Definitions and reported function of the ingredients in this safety assessment.

Ingredient & CAS No.	Definition	Function(s)
Acetylated Lanolin 61788-48-5	Acetylated Lanolin is the acetyl ester of Lanolin.	hair conditioning agent; skin-conditioning agent - emollient; skin-conditioning agents - occlusive
Acetylated Lanolin Alcohol 61788-49-6	Acetylated Lanolin Alcohol is the acetyl ester of Lanolin Alcohol.	hair conditioning agent; skin-conditioning agent - emollient; skin-conditioning agents - occlusive
Hydrogenated Lanolin 8031-44-5	Hydrogenated Lanolin is the end product of controlled hydrogenation of Lanolin.	fragrance ingredient; hair conditioning agent; skin-conditioning agent - occlusive
Hydroxylated Lanolin 68424-66-8	Hydroxylated Lanolin is the product obtained by controlled hydroxylation of Lanolin.	binder; skin-conditioning agent - misc.
Lanolin 8006-54-0 (anhydrous)	Lanolin is a refined derivative of the unctuous fat-like sebaceous secretion of sheep. It consists of a highly complex mixture of esters of high molecular weight aliphatic, steroid or triterpenoid alcohols and fatty acids.	emulsion stabilizer; hair conditioning agent; skin protectant; skin-conditioning agent – emollient; surfactant - emulsifying agent
Lanolin Acid 68424-43-1	Lanolin Acid is a mixture of organic acids obtained from the hydrolysis of Lanolin.	surfactant - cleansing agent
Lanolin Alcohol 8027-33-6	Lanolin Alcohol is a mixture of organic alcohols obtained from the hydrolysis of Lanolin.	binder; emulsion stabilizer; hair conditioning agent; skin-conditioning agent - misc.; viscosity increasing agent - nonaqueous
Lanolin Oil 8038-43-5 70321-63-0	Lanolin Oil is the liquid fraction of lanolin obtained by physical means from whole lanolin.	hair conditioning agent; skin-conditioning agent - emollient
Lanolin Wax 68201-49-0	Lanolin Wax is the semisolid fraction of lanolin obtained by physical means from whole lanolin.	binder; hair conditioning agent; skin-conditioning agent - emollient; viscosity increasing agent - nonaqueous

Table 2. Chemical properties

Property	Value	Reference
	Acetylated Lanolin	
Physical Form	Yellow-brown paste	9
Specific Gravity @ 20 ºC)	0.95	9
Melting Point ºC	30 - 40 31 - 55	1 9
Boiling Point ºC	128 (decomposition)	9
Vapor Pressure (mm Hg @ 20 ºC)	9.75×10^{-5}	9
log P_{ow}	> 10.0 (calculated)	9
Water Solubility (g/L @ 20 ºC & pH 6)	$< 1.0 \times 10^{-3}$	9
	Acetylated Lanolin Alcohol	
Physical Form	Lemon-yellow to straw-colored, oily hydrophobic liquid with a characteristic bland odor Yellow solid	1 12
Specific Gravity (@ 25 ºC (@ 20 ºC)	0.850 - 0.880 0.904 - 1.00	1 12
Melting Point ºC	45 - 80	12
Boiling Point ºC	220 - 420	12
Vapor Pressure (mm Hg @ 20 ºC)	1.85×10^{-5}	12
log P_{ow}	> 7.2 (calculated)	12
Water Solubility (mg/L @ 20 ºC & pH 8)	< 1.20	12
Refractive Index (@ 20 ºC)	1.4445 - 1.4485	1
	Hydrogenated Lanolin	
Physical Form	Light yellow to white tacky solid White, odorless paste	1 8
Specific Gravity (@ 20 ºC)	0.906	8
Vapor Pressure (mm Hg @ 25 ºC)	4.2×10^{-5}	8
Melting Point ºC	48 - 53 27 - 61	1 8
Boiling Point ºC	100 - 315	8
log P_{ow}	7 - 10 (calculated)	8
Water Solubility (mg/L @ 20 ºC & pH 7)	1.24	8

Table 2. Chemical properties

Property	Value	Reference
Hydroxylated Lanolin		
Physical Form	Yellow-brown solid crystalline	7
Specific Gravity (@ 20 ºC)	0.963	7
Vapor Pressure (mm Hg @ 25 ºC)	5.5×10^{-5}	7
Melting Point ºC	39 - 46 32 - 59	1 7
Boiling Point ºC	155 (decomposition)	7
log P_{ow} (@ 40 ºC)	> 10 (calculated)	7
Water Solubility (g/L @ 20 ºC & pH 6)	< 0.001	7
Lanolin		
Physical Form	Ointment-like material with a slight, characteristic odor; in anhydrous form, transparent to yellow, tenacious, unctuous mass	1
Melting Point ºC	36 - 42	1
Lanolin Acid		
Physical Form	Hard, waxy, yellow-tan solid with a mild waxy odor Brown waxy solid	1 10
Specific Gravity (@ 20 ºC)	0.908	10
Vapor Pressure (mm Hg @ 20 ºC)	< 5.25	10
Melting Point ºC	40 - 62 35 - 60	1 10
Boiling Point ºC	320 - 430	10
log P_{ow} (@ 30 ºC)	1.35 to > 6.5 (calculated)	10
Water Solubility (mg/L @ 20 ºC & pH 7)	0.21	10
Lanolin Alcohol		
Physical Form	Firm, waxy, amber solid with a characteristic odor Yellow waxy solid	1 11
Specific Gravity (@ 20 ºC)	0.904 - 0.953	11
Vapor Pressure (mm Hg @ 20 ºC)	2.7	11
Melting Point ºC	47 - 65 45 - 80	1 11
Boiling Point ºC	220 - 420	11
Water Solubility (mg/L @ 20 ºC & pH 7)	0.14 - 0.38	11
Lanolin Oil		
Physical Form	Clear, amber-colored liquid	1
Lanolin Wax		
Physical Form	Odorless, tasteless, ceraceous solid	1
Melting Point ºC	41 - 51	1

Table 3. Frequency (2023/2002) and concentration (2022/2003) of use according to likely duration and exposure and by product category

	Acetylated Lanolin				Acetylated Lanolin Alcohol				Hydrogenated Lanolin				Hydroxylated Lanolin			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2023[15]	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**
Totals*	**2**	**163**	**7.5-8**	**0.1-7**	**196**	**356**	**0.02-6.3**	**0.002-16**	**6**	**111**	**10.2**	**0.5-10**	**4**	**139**	**3.5-17.5**	**0.5-28**
summarized by likely duration and exposure**																
Duration of Use																
Leave-On	*2*	*144*	*7.5-8*	*0.1-7*	*191*	*328*	*0.02-6.3*	*0.002-16*	*6*	*104*	*10.2*	*1-10*	*4*	*137*	*3.5-17.5*	*0.5-28*
Rinse-Off	*NR*	*19*	*NR*	*0.1-1*	*5*	*28*	*0.61*	*0.01-1*	*NR*	*7*	*NR*	*0.5-1*	*NR*	*2*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type																
Eye Area	NR	6	NR	0.1-0.6	NR	33	0.38-6.3	0.002-0.9	NR	8	10.2	1-10	3	96	3.5-17.5	1-11
Incidental Ingestion	NR	33	7.5-8	5	1	100	1.1	2-3	2	30	NR	3-9	1	18	NR	0.5-28
Incidental Inhalation-Spray	1[a]	62[a]; 26[b]	NR	1-4[a]; 0.5-2[b]	168[a];15[b]	12; 52[a]; 57[b]	0.02-0.07	0.01-0.4; 0.01-5[a]; 0.1-6[b]	1[a]; 3[b]	1; 26[a]; 29[b]	NR	2[a]; 2-10[b]	NR	10[a]; 2[b]	NR	NR
Incidental Inhalation-Powder	NR	2; 1[c]; 26[b]	NR	0.2-0.3; 3[c]; 0.5-2[b]	6; 15[b]	16; 2[c]; 57[b]	0.1[c]	0.01-2; 0.01-16[c]; 0.1-6[b]	3[b]	29[b]	NR	2-10[b]	NR	3; 2[b]	NR	2
Dermal Contact	2	129	NR	0.1-7	195	231	0.02-6.3	0.01-16	4	72	10.2	1-10	3	111	10.8-17.5	2-11
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR	NR	1[a]	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	1	NR	NR	NR	18	NR	0.01-0.02	NR	3	NR	0.5	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	1	NR	NR	NR	NR	NR	1	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	2	0.25-0.61	0.01-0.1	NR	1	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	33	7.5-8	1-5	2	106	1.1	0.1-3	2	30	NR	3-9	1	18	NR	0.5-28
Baby Products	NR	1	NR	3	NR	2	NR	0.01-16	NR	NR	NR	NR	NR	NR	NR	2
as reported by product category																
Baby Products																
Baby Lotions/Oils/Powders/Creams	NR	1	NR	3	NR	2	NR	0.01-16								
Other Baby Products													NR	NR	NR	2
Bath Preparations (diluted for use)																
Bath Oils, Tablets, and Salts																
Bubble Baths																
Other Bath Preparations																
Eye Makeup Preparations																
Eyebrow Pencil					NR	NR	NR	0.1					3	3	NR	NR
Eyeliner					NR	NR	0.38	0.4	NR	2	NR	1	NR	73	10.8	5-10
Eye Shadow					NR	17	6.3	0.9	NR	NR	10.2	NR	NR	7	17.5	3-10
Eye Lotion	NR	1	NR	0.6	NR	1	NR	NR								
Eye Makeup Remover																
Mascara					NR	4	NR	0.002	NR	5	NR	NR	NR	10	3.5	1
Other Eye Makeup Preparations	NR	5	NR	0.1	NR	11	NR	NR	NR	1	NR	7-10	NR	3	11.1	2-11
Fragrance Preparations																
Cologne and Toilet Water					NR	5	0.02	0.07								
Perfumes							0.07									
Powders (dusting/talcum, excl aftershave talc)					NR	6	NR	0.01								
Sachets																
Other Fragrance Preparation					NR	3	NR	0.1-0.4	NR	1	NR	NR				
Hair Preparations (non-coloring)																
Hair Conditioner	NR	1	NR	NR	NR	1	NR	NR	NR	1	NR	0.5				
Hair Spray (aerosol fixatives)					NR	4	NR	0.01								
Hair Straighteners					NR	3	NR	NR								
Permanent Waves																
Rinses (non-coloring)									NR	1	NR	NR				
Shampoos (non-coloring)					NR	1	NR	0.02								
Tonics, Dressings, and Other Hair Grooming Aids					NR	6	NR	0.01	NR	1	NR	NR				

Table 3. Frequency (2023/2002) and concentration (2022/2003) of use according to likely duration and exposure and by product category

	Acetylated Lanolin				Acetylated Lanolin Alcohol				Hydrogenated Lanolin				Hydroxylated Lanolin			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2023[15]	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**
Wave Sets																
Other Hair Preparations					NR	3	NR	NR								
Hair Coloring Preparations																
Hair Dyes and Colors									NR	NR	NR	1				
Hair Tints																
Hair Rinses (coloring)																
Hair Shampoos (coloring)																
Hair Color Sprays (aerosol)																
Hair Bleaches																
Other Hair Coloring Preparation					NR	1	NR	NR								
Makeup Preparations																
Blushers (all types)					1	9	NR	0.3-0.8					NR	2	NR	3
Face Powders	NR	2	NR	0.2-0.3	6	10	NR	0.01-2					NR	3	NR	2
Foundations	NR	3	NR	3-7	NR	9	NR	1-2	NR	2	NR	NR	NR	2	NR	2
Leg and Body Paints																10
Lipstick	NR	33	7.5-8	5	1	100	1.1	2-3	2	30	NR	3-9	1	18	NR	0.5-28
Makeup Bases					NR	8	NR	NR	NR	1	NR	NR	NR	2	NR	NR
Rouges					NR	1	0.6	NR								
Makeup Fixatives													NR	1	NR	NR
Other Makeup Preparations	1	3	NR	0.5-3	NR	8	NR	0.1-3	NR	1	NR	NR	NR	1	NR	4
Manicuring Preparations (Nail)																
Basecoats and Undercoats																
Cuticle Softeners					NR	NR	0.25	0.1								
Nail Creams and Lotions									NR	1	NR	NR				
Nail Polish and Enamel					NR	2	NR	0.01								
Nail Polish and Enamel Removers					NR	NR	0.61	0.02								
Other Manicuring Preparations																
Personal Cleanliness Products																
Bath Soaps and Detergents	NR	NR	NR	1	1	4	NR	0.4								
Deodorants (underarm)									NR	1	NR	NR				
Feminine Deodorants																
Other Personal Cleanliness Products					NR	2	NR	0.1								
Shaving Preparations																
Aftershave Lotion					NR	2	NR	NR								
Shaving Cream					NR	3	NR	0.02								
Other Shaving Preparations																
Skin Care Preparations																
Cleansing	NR	14	NR	0.1	3	10	NR	< 1	NR	4	NR	NR	NR	2	NR	NR
Depilatories																
Face and Neck (exc shave)	NR	6	NR	1	4	4	NR	0.2-3	1	4	NR	10				
Body and Hand (exc shave)	NR	20	NR	0.5-2	11	53	0.1	0.1-6	2	25	NR	2	NR	2	NR	NR
Moisturizing	1	35	NR	1	167	33	NR	0.5-5	1	16	NR	NR	NR	6	NR	NR
Night	NR	23	NR	4	1	5	NR	0.1	NR	3	NR	NR	NR	3	NR	NR
Paste Masks (mud packs)	NR	4	NR	1	1	3	NR	0.01	NR	1	NR	NR				
Skin Fresheners					NR	2	NR	NR	NR	1	NR	NR				
Other Skin Care Preparations	NR	8	NR	3	NR	14	NR	0.01-0.4	NR	4	NR	2				
Suntan Preparations																
Suntan Gels, Creams, and Liquids									NR	3	NR	2	NR	1	NR	NR
Indoor Tanning Preparations																
Other Suntan Preparations									NR	2	NR	NR				

Table 3. Frequency (2023/2002) and concentration (2022/2003) of use according to likely duration and exposure and by product category

	Acetylated Lanolin				Acetylated Lanolin Alcohol				Hydrogenated Lanolin				Hydroxylated Lanolin			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2023[15]	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**

Table 3. Frequency (2023/2002) and concentration (2022/2003) of use according to likely duration and exposure and by product category

	Lanolin†				Lanolin Acid				Lanolin Alcohol				Lanolin Oil			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2023[15]	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**
Totals*	**285**	**782**	**0.0099-40**	**0.001-37**	**9**	**44**	**0.04-0.05**	**1-3**	**65**	**358**	**0.01-5**	**0.6-4**	**39**	**521**	**0.25-47**	**0.1-65**
summarized by likely duration and exposure**																
Duration of Use																
Leave-On	*262*	*627*	*0.0099-40*	*0.001-37*	*4*	*34*	*0.04*	*1-3*	*56*	*305*	*0.01-5*	*0.6*	*37*	*462*	*0.25-47*	*0.4-65*
Rinse-Off	*23*	*153*	*0.48-10*	*0.01-16*	*5*	*10*	*0.04-0.05*	*NR*	*9*	*46*	*0.5*	*4*	*2*	*48*	*NR*	*0.3-18*
Diluted for (Bath) Use	*NR*	*2*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*7*	*NR*	*NR*	*NR*	*11*	*NR*	*0.1-3*
Exposure Type*																
Eye Area	10	44	0.018-32	0.1-32	NR	21	NR	3	2	40	0.04-0.8	NR	NR	72	11.1	1-10
Incidental Ingestion	54	133	1.3-20.7	1-33	NR	2	NR	NR	3	18	0.36	NR	21	226	14.3-47	3-65
Incidental Inhalation-Spray	8; 74[a]; 32[b]	4; 176[a]; 114[b]	1.6; 0.5-15[a]	0.001; 0.2-19[a]; 2-37[b]	3[a]	6[a]	NR	NR	1; 18[a]; 8[b]	8; 76[a]; 63[b]	NR	0.6[b]	1; 6[a,b]	5; 54[a]; 31[b]	1[a]	0.8; 0.5-8[a]; 3[b]
Incidental Inhalation-Powder	4; 1[c]; 32[b]	10; 3[c]; 114[b]	0.0099; 0.2-7[c]	1-5; 0.2-4[c]; 2-37[b]	NR	NR	NR	NR	2; 8[b]	7; 2[c]; 63[b]	0.3; 0.01-1[c]	0.6[b]	2; 6[b]	13; 1[c]; 31[b]	0.25; 1-2[c]	2; 1[c]; 3[b]
Dermal Contact	152	507	0.0099-32	0.01-37	NR	21	NR	1	55	323	0.01-1	0.6	14	266	0.25-11.1	0.1-45
Deodorant (underarm)	NR	4[a]	NR	0.2[a]	NR	NR	NR	NR	NR	NR	NR	NR	NR	1[a]	NR	NR
Hair - Non-Coloring	65	124	0.5-15	0.001-19	8	8	0.04-0.05	NR	4	14	NR	NR	4	10	1-2	0.3-2
Hair-Coloring	7	8	0.5-0.91	0.4	1	NR	NR	NR	3	1	NR	4	NR	12	NR	0.8
Nail	3	7	1-40	0.3-20	NR	NR	NR	NR	NR	1	5	NR	NR	6	NR	2-25
Mucous Membrane	55	153	0.48-20.7	0.01-33	NR	2	NR	NR	7	31	0.36	NR	22	246	14.3-47	0.1-65
Baby Products	1	2	0.2	0.2-4	NR	NR	NR	NR	NR	2	0.2	NR	NR	1	NR	1
as reported by product category																
Baby Products																
Baby Lotions/Oils/Powders/Creams	1	3	0.2	0.2-4					NR	2	0.2	NR	NR	1	NR	1
Other Baby Products																
Bath Preparations (diluted for use)																
Bath Oils, Tablets, and Salts	NR	1	NR	NR					NR	7	NR	NR	NR	9	NR	0.1
Bubble Baths													NR	1	NR	NR
Other Bath Preparations	NR	1	NR	NR									NR	1	NR	3
Eye Makeup Preparations																
Eyebrow Pencil	1	16	4.4	6-7					NR	1	NR	NR	NR	2	NR	1
Eyeliner	1	6	32	10-32	NR	3	NR	NR	1	1	NR	NR	NR	8	NR	2-10
Eye Shadow	2	11	0.018-9	5-9	NR	4	NR	NR	NR	27	0.8	NR	NR	55	11.1	3-6
Eye Lotion	1	NR	NR	NR					NR	NR	0.04	NR				
Eye Makeup Remover									NR	3	NR	NR	NR	1	NR	NR
Mascara	4	3	NR	0.1-12	NR	13	NR	3	NR	1	NR	NR	NR	1	NR	1-3
Other Eye Makeup Preparations	1	8	NR	5	NR	1	NR	NR	1	7	NR	NR	NR	5	NR	6
Fragrance Preparations																
Cologne and Toilet Water																
Perfumes	4	NR	NR	NR												
Powders (dusting/talcum, excl aftershave talc)	NR	1	NR	NR									NR	1	NR	NR
Sachets	NR	9	NR	NR												
Other Fragrance Preparation	3	3	NR	NR					1	5	NR	NR	1	4	NR	NR
Hair Preparations (non-coloring)																
Hair Conditioner	12	33	0.9-10	0.2-10	3	4	0.04	NR	NR	8	NR	NR	1	5	NR	0.4-2
Hair Spray (aerosol fixatives)	1	1	1.6	0.001					NR	1	NR	NR				
Hair Straighteners	NR	7	NR	0.3	NR	3	NR	NR								
Permanent Waves	NR	2	NR	NR									NR	1	NR	1

Table 3. Frequency (2023/2002) and concentration (2022/2003) of use according to likely duration and exposure and by product category

	Acetylated Lanolin				Acetylated Lanolin Alcohol				Hydrogenated Lanolin				Hydroxylated Lanolin			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2023[15]	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**
Rinses (non-coloring)					1	NR	NR	NR								
Shampoos (non-coloring)	NR	9	NR	0.5	NR	NR	0.05	NR					NR	4	NR	0.3

	Lanolin†				Lanolin Acid				Lanolin Alcohol				Lanolin Oil			
Tonics, Dressings, and Other Hair Grooming Aids	33	69	0.5-15	0.5-19	3	NR	0.04	NR	NR	2	NR	NR	3	NR	1	0.5-2
Wave Sets	NR	2	NR	4												
Other Hair Preparations	19	1	NR	5	1	1	NR	NR	4	3	NR	NR	NR	NR	2	NR
Hair Coloring Preparations																
Hair Dyes and Colors	1	NR	0.91	NR												
Hair Tints	1	NR	NR	NR					1	NR	NR	NR				
Hair Rinses (coloring)	NR	NR	0.5	NR												
Hair Shampoos (coloring)					1	NR	NR	NR								
Hair Color Sprays (aerosol)													NR	1	NR	0.8
Hair Bleaches													NR	11	NR	NR
Other Hair Coloring Preparation	5	8	NR	0.4					2	1	NR	4				
Makeup Preparations																
Blushers (all types)	2	31	9	2-9					13	16	0.3	NR	NR	11	0.25	2-12
Face Powders	4	9	0.0099	1-5					2	7	0.3	NR	2	12	0.25	2
Foundations	1	17	NR	2-9	NR	2	NR	NR	2	28	NR	NR	NR	10	NR	0.7-2
Leg and Body Paints									1	NR	NR	NR				
Lipstick	54	133	1.3-20.7	1-33	NR	2	NR	NR	3	18	0.36	NR	21	226	24.3-47	3-65
Makeup Bases	NR	5	0.4-6	0.4-5					NR	22	NR	NR	NR	10	0.35	0.4
Rouges	NR	4	NR	5												
Makeup Fixatives									NR	4	NR	NR	NR	1	NR	NR
Other Makeup Preparations	24	12	NR	10-17	NR	1	NR	NR	NR	7	NR	NR	NR	8	NR	20-45
Manicuring Preparations (Nail)																
Basecoats and Undercoats													NR	2	NR	NR
Cuticle Softeners	NR	6	1	20					NR	1	NR	NR	NR	2	NR	2
Nail Creams and Lotions	2	1	40	0.3-3									NR	1	NR	5
Nail Polish and Enamel	1	NR	NR	15												
Nail Polish and Enamel Removers																
Other Manicuring Preparations									NR	NR	5	NR	NR	1	NR	3-25
Personal Cleanliness Products																
Bath Soaps and Detergents	NR	11	0.48	0.01-4					1	3	NR	NR	NR	9	NR	NR
Deodorants (underarm)	NR	4	NR	0.2									NR	1	NR	NR
Feminine Deodorants									NR	2	NR	NR				
Other Personal Cleanliness Products	1	7	NR	NR					3	1	NR	NR	1	NR	NR	NR
Shaving Preparations																
Aftershave Lotion	NR	2	NR	0.5					NR	3	NR	NR				
Shaving Cream	2	11	NR	0.5-2	NR	3	NR	NR	1	6	NR	NR	NR	4	NR	2
Other Shaving Preparations									NR	6	0.5	NR				
Skin Care Preparations																
Cleansing	1	48	NR	0.1-3					NR	10	NR	NR	NR	12	NR	3
Depilatories	NR	3	NR	NR					1	1						
Face and Neck (exc shave)	6	26	NR	2-4					4	9	0.08	NR	NR	4	1-2	3
Body and Hand (exc shave)	26	88	7	2-37					4	52	0.01-1	0.6	6	27	1-2	NR
Moisturizing	37	56	0.5-18	0.2-11	NR	4	NR	NR	18	40	0.25	NR	3	37	1	2
Night	4	32	NR	0.5-10	NR	1	NR	NR	NR	19	0.08	NR	NR	6	NR	1
Paste Masks (mud packs)	NR	12	NR	16					NR	7	NR	NR	NR	1	NR	18
Skin Fresheners																

Table 3. Frequency (2023/2002) and concentration (2022/2003) of use according to likely duration and exposure and by product category

	Acetylated Lanolin				Acetylated Lanolin Alcohol				Hydrogenated Lanolin				Hydroxylated Lanolin			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2023[15]	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**
Other Skin Care Preparations	30	51	NR	22	NR	1	NR	1	2	10	NR	NR	1	14	NR	10
Suntan Preparations																
Suntan Gels, Creams, and Liquids	NR	11	NR	NR	NR	1	NR	NR	NR	12	NR	NR	NR	6	NR	8
Indoor Tanning Preparations	NR	7	NR	2					NR	2	NR	NR	NR	1	NR	NR
Other Suntan Preparations	NR	1	NR	NR					NR	3	NR	NR	NR	4	1.1	1
	Lanolin Wax															
	# of Uses		*Max Conc of Use (%)*													
	2023[15]	**2002[2]**	**2023[15]**	**2002[2]**												
Totals*	**17**	**97**	**0.4-8.5**	**0.5-23**												
summarized by likely duration and exposure**																
Duration of Use																
Leave-On	*15*	*94*	*0.5-8.5*	*0.5-23*												
Rinse-Off	*2*	*3*	*0.4*	*NR*												
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*												
Exposure Type																
Eye Area	NR	11	NR	2-4												
Incidental Ingestion	NR	56	3.2	20-23												
Incidental Inhalation-Spray	14[a]	14[a]; 3[b]	0.6-8[a]	0.5[b]												
Incidental Inhalation-Powder	NR	1; 3[b]	0.5-2[c]	0.5[b]												
Dermal Contact	8	31	0.5-2	0.5-4												
Deodorant (underarm)	NR	NR	NR	NR												
Hair - Non-Coloring	7	4	0.4-8.5	NR												
Hair-Coloring	2	NR	NR	NR												
Nail	NR	NR	NR	NR												
Mucous Membrane	NR	56	3.2	20-23												
Baby Products	NR	NR	NR	NR												
as reported by product category																
Baby Products																
Baby Lotions/Oils/Powders/Creams																
Other Baby Products																
Bath Preparations (diluted for use)																
Bath Oils, Tablets, and Salts																
Bubble Baths																
Other Bath Preparations																
Eye Makeup Preparations																
Eyebrow Pencil																
Eyeliner	NR	4	NR	4												
Eye Shadow	NR	1	NR	4												
Eye Lotion																
Eye Makeup Remover																
Mascara	NR	6	NR	2												
Other Eye Makeup Preparations																
Fragrance Preparations																
Cologne and Toilet Water																
Perfumes																
Powders (dusting/talcum, excl aftershave talc)																
Sachets																
Other Fragrance Preparation																
Hair Preparations (non-coloring)																
Hair Conditioner																
Hair Spray (aerosol fixatives)																

Table 3. Frequency (2023/2002) and concentration (2022/2003) of use according to likely duration and exposure and by product category

	Acetylated Lanolin				Acetylated Lanolin Alcohol				Hydrogenated Lanolin				Hydroxylated Lanolin			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2023[15]	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**
Hair Straighteners																
Permanent Waves																
Rinses (non-coloring)																
Shampoos (non-coloring)	NR	NR	0.4	NR												
Tonics, Dressings, and Other Hair Grooming Aids	6	4	0.6-8	NR												
Wave Sets																
Other Hair Preparations	1	NR	8.5	NR												
Hair Coloring Preparations																
Hair Dyes and Colors	2	NR	NR	NR												
Hair Tints																
Hair Rinses (coloring)																
Hair Shampoos (coloring)																
Hair Color Sprays (aerosol)																
Hair Bleaches																
Other Hair Coloring Preparation																
Makeup Preparations																
Blushers (all types)	NR	2	0.5	4												
Face Powders	NR	1	NR													
Foundations	NR	2	NR	4												
Leg and Body Paints																
Lipstick	NR	56	3.2	20-23												
Makeup Bases	NR	NR	0.5	NR												
Rouges																
Makeup Fixatives																
Other Makeup Preparations	NR	1	NR	0.5												
Manicuring Preparations (Nail)																
Basecoats and Undercoats																
Cuticle Softeners																
Nail Creams and Lotions																
Nail Polish and Enamel																
Nail Polish and Enamel Removers																
Other Manicuring Preparations																
Personal Cleanliness Products																
Bath Soaps and Detergents																
Deodorants (underarm)																
Feminine Deodorants																
Other Personal Cleanliness Products																
Shaving Preparations																
Aftershave Lotion																
Shaving Cream																
Other Shaving Preparations																
Skin Care Preparations																
Cleansing	NR	2	NR	NR												
Depilatories																
Face and Neck (exc shave)			0.5													
Body and Hand (exc shave)	NR	3	2	0.5												
Moisturizing	8	6	NR	NR												
Night	NR	2	NR	NR												
Paste Masks (mud packs)	NR	1	NR	NR												
Skin Fresheners																

Table 3. Frequency (2023/2002) and concentration (2022/2003) of use according to likely duration and exposure and by product category

	Acetylated Lanolin				Acetylated Lanolin Alcohol				Hydrogenated Lanolin				Hydroxylated Lanolin			
	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	2023[15]	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**	**2023[15]**	**2002[2]**	**2022[16]**	**2003[2]**
Other Skin Care Preparations	NR	4	NR	NR												
Suntan Preparations																
Suntan Gels, Creams, and Liquids	NR	1	NR	NR												
Indoor Tanning Preparations																
Other Suntan Preparations	NR	1	NR	NR												

† Includes entries in the VCRP for Lanolin, Anhydrous; † Includes entries in the VCRP for Lanolin, Anhydrous

*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.

**likely duration and exposure is derived based on product category (see Use Categorization https://www.cir-safety.org/cir-findings)

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

[b] Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories

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

Table 4. Acute toxicity studies

Test Article	Vehicle	Animals/Group	Concentration/Dose	Protocol	LD_{50}/LC_{50}/Results	Reference
DERMAL						
Lanolin Acid	arachis oil	5 male and 5 female Wistar rats	2000 mg/kg bw	Acute dermal study performed in accordance with OECD TG 402; test sites clipped and semi-occluded; rats exposed to test material for 24 h, after which test material was wiped off; animals observed for signs of toxicity 0.5, 1, 2, 4 h and once daily for 14 d after dosing	> 2000 mg/kg bw; no clinical signs of toxicity or signs of dermal irritation; no abnormalities at necropsy and no mortalities during observation period	10
Lanolin Alcohol	arachis oil	5 male and 5 female Wistar rats	2000 mg/kg bw	Acute dermal study performed in accordance with OECD TG 402; test sites clipped and semi-occluded; rats exposed to test material for 24 h, after which test material was wiped off; animals observed for signs of toxicity 0.5, 1, 2, 4 h and once daily for 14 d after dosing	> 2000 mg/kg bw; no clinical signs of toxicity or signs of dermal irritation; no signs of toxicity at necropsy and no moralities during observation period	11
ORAL						
Hydroxylated Lanolin	none	1 male and 1 female Sherman-Wistar rat per dose group	2.5, 5.0, 10.0, 20.0, or 40.0 ml/kg	Acute oral gavage study performed in accordance with OECD TG 401; animals observed for 14 d	> 10 ml/kg bw; no deaths observed in any dose group	7
Lanolin Alcohol	sesame oil	5 male and 5 female Sprague-Dawley rats	2000 mg/kg bw	Acute oral gavage study performed in accordance with OECD TG 401; animals observed for 14 d before being killed for complete gross necropsy	> 2000 mg/kg bw; no substance-related findings, gross pathological changes, or mortality observed	11
Lanolin Alcohol	not reported	5 male and 5 female albino rats	5000 mg/kg bw	Acute oral study in accordance with OECD TG 401; no further details provided	> 5000 mg/kg bw; 2 females died during study, no further details provided	11

Table 5. Genotoxicity studies

Test Article	Vehicle	Concentration/Dose	Test System	Procedure	Results	Reference
IN VITRO						
Lanolin Acid	acetone	50-5000 µg/plate	*S. typhimurium* strains TA98, TA100, TA1535, TA1537 and *E. coli* strain WP2 uvrA	Ames test in accordance with OECD TG 471; with and without metabolic activation	Not mutagenic, with and without metabolic activation	10
Lanolin Acid	acetone	up to 600 µg/ml without metabolic activation; up to 400 µg/ml with metabolic activation	mouse lymphoma L5178 cells at the *tk* locus	Mammalian gene mutation test in accordance with OECD TG 476; with and without metabolic activation	Not mutagenic, with and without metabolic activation	10
Lanolin Acid	acetone	up to 2500 µg/ml	human lymphocytes	Mammalian chromosome aberration test in human lymphocytes in accordance with OECD TG 473; with and without metabolic activation	Not clastogenic, with and without metabolic activation	10
Lanolin Alcohol	acetone	50-5000 µg/plate	*S. typhimurium* strains TA98, TA100, TA1535, TA1537 and *E. coli* strain WP2 uvrA	Ames test in accordance with OECD TG 471; with and without metabolic activation	Not mutagenic, with and without metabolic activation	11
Lanolin Alcohol	acetone	up to 937.5 µg/ml	mouse lymphoma L5178 cells at the *tk* locus	Mammalian gene mutation test in accordance with OECD TG 476; with and without metabolic activation	Not mutagenic, with and without metabolic activation	11
Lanolin Alcohol	acetone	up to 1250 µg/ml	human lymphocytes	Mammalian chromosome aberration test in human lymphocytes in accordance with OECD TG 473; with and without metabolic activation	Not clastogenic, with and without metabolic activation	11

Table 6. Dermal irritation and sensitization studies

Test Article	Vehicle	Concentration/Dose	Test Population/System	Protocol	Results	Reference
IRRITATION						
ANIMAL						
Lanolin Alcohol	mineral oil	0.5 ml; no further details	6 New Zealand White rabbits	Modified Draize study; single application; test sites (2.5 cm^2) clipped, intact and abraded, and occluded for 24 h; animals observed for 72 h	Irritating; mean erythema scores of 3 for intact and abraded skin at 24 and 72 h, mean edema score of 2 and 1 on intact skin and 1.5 and 1 on abraded skin at 24 and 72 h, respectively	11
HUMAN						
nano-emulsion containing 2.0% Acetylated Lanolin,	nano-emulsion contained a mixture of raspberry, passion fruit, and peach oils (1:1:1), sorbitan monooleate, PEGs 15-30-, 36-, 40-, and 54-castor oil	50 µl	20 subjects	Test materials applied to areas of 13.80 cm^2 and evaluated 30-, 60-, 90-, and 150-min post-application. Irritation potential assessed with a Chromameter CR-200.	No irritation reactions observed	69
Hydrogenated Lanolin	not reported	25 g	14 subjects	Dermal tolerance test; test material applied to the palm of the hand; covered test site (4 cm^2) checked after 24 and 48 h for possible skin reactions	No erythema observed; none of the subjects complained about itching or other indications of intolerance	8
SENSITIZATION						
ANIMAL						
Lanolin Acid	dimethylformamide	10, 25, or 50%	female CBA mice	LLNA in accordance with OECD TG 429	Non-sensitizing; the stimulation indices for 10, 25, and 50% Lanolin Acid were 1.42, 1.77, and 2.35, respectively	10

Table 7. Multicenter and retrospective studies on Lanolin and Lanolin Alcohol

# Patients	Clinical Testing Type	Location	Years	Results	Reference
			Multicenter Studies		
			Children		
6708	Multicenter retrospective study of patch test results of children ages 1 to 18-yr old with suspected allergic contact dermatitis. Patients patch tested with basel-ne series.	Europe	2002 through 2010	Approximately 1.8% of patients had positive reactions to Lanolin Alcohol. In a subgroup (n = 210) tested with TRUE test allergens, 1% had positive reactions to lanolin Alcohol.	42
			Adults		
491	Multicenter study of patch testing reproducibility using TRUE Test™ system.	Uruguay	not reported	Lanolin Alcohol resulted in 7 positive concordant patch test reactions, 3 positive discordant reactions, and 4 irritant or doubtful reactions either on one or both sides	40
43,691	Multicenter study at NACDG clinics of patch test results for patients with suspected allergic contact dermatitis to Lanolin. Allergens in Allergens in testing protocols included a trademarked Lanolin product at 50% in pet. (2011-2018) and Lanolin Alcohol 30% pet. (2001-2010).	North America	2001 through 2018	1431 (3.3%) were allergic to Lanolin, of which 1238 (86.5%) were currently relevant to the patient's dermatitis. Allergic reactions and currently relevant reactions to Lanolin were significantly higher in children (n = 85 (4.5%) and n = 77(4.0%)) than adults (n = 1346 (3.2%) and n = 1161 (2.8%)). Common primary body sites affected by allergic reaction to Lanolin were the hands, scattered generalized distribution, and the face. The most common source of the Lanolin exposure to those with allergic reaction was personal care products (moisturizers/lotions/creams (23%) and lipsticks and lip balms (4%).	41
4238	Multicenter study of patch tests in patients tested with a series of 70 allergens, including Lanolin Alcohol 50% pet.	North America	January 1, 2011 through December 31, 2012	194 (4.6%) reactions to Lanolin Alcohol observed. Compared to 2 previous reporting periods, positive reaction rates increased for Lanolin Alcohol.	43
4116	Multicenter study of patients tested at NACDG clinics using standardized patch testing technique with 80 allergens that included a trademarked Lanolin product at 50% in pet.	North America	January 1, 2019 to December 31, 2020	3.7% had positive reactions to Lanolin Alcohol 50% pet. It was ranked 16th in the significance-prevalence index (SPIN 133). For comparison, methylisothiazolinone 0.2% aq ranked 1st with a SPIN of 683.	44
499	Multicenter study with patients that underwent a variety of surgical procedures followed by application of a wound healing ointment with Lanolin Alcohol without antibiotics.	United States	2010 (99 patients); 2019 (400 patients)	No allergic contact dermatitis was identified in the patients. Authors opined that the lack of reactions observed may have been due to the highly purified Lanolin Alcohol used in the study formulation.	45
			Retrospective Studies		
			Children		
1012	Retrospective analysis of children ages 0-17 yr with suspected contact dermatitis patch tested with the European baseline series or parts thereof and a supplementary series. Lanolin Alcohol 30% pet. and a trademarked Lanolin product at 50% in pet. were included in the tests.	Netherlands	1996 through 2013	Out of all children tested, the positivity rate was 6.2% to Lanolin Alcohol 30% pet and 8.8% to the trademarked Lanolin product. Children with atopic dermatitis had higher positivity rates to these ingredients (7.8% and 12.6%, respectively) than those who did not have atopic dermatitis (4.3% and 5.3%, respectively).	47
1634	Retrospective study of NACDG data of children aged less than 18 yr old. Of the 1634 patients, 237 had involvement of the hands. Patch tests included Lanolin Alcohol 50% pet.	North America	2000 through 2016	Lanolin Alcohol was in the top 5 most common currently relevant allergens. In a multivariable logistic regression model of the top 20 relevant allergens, hand eczema was associated with significantly higher odds of currently relevant reactions to Lanolin Alcohol.	49
833	Retrospective study of children ages 0-18 patch-tested with 65 or 70 allergen series, including Lanolin Alcohol 50% pet. and Lanolin Alcohol 30% pet.	North America	January 1, 2005 through December 31, 2012	5.5% of patients had positive patch test reactions to Lanolin Alcohol 50% pet. (5.1% relevant patch test reactions). 1.7% patients had positive reactions to Lanolin Alcohol 30% pet. (1.5% relevant patch test reactions). Reactions observed only in ages 6 and up.	53
100	Retrospective study of adolescents aged 13-18 yr who were consecutively patch tested. Patch tests performed on symptom-free patients using an environmental contact allergen series (87 patients) and an implantation and dental contact allergen series (13 patients) from the Brial-Allergen D-Greven Panel.	Hungary	January 1, 2007 through December 31, 2016	Contact hypersensitivity was observed in 51 patients. Most common contact allergens included Lanolin Alcohol in boys. Of the 47 patients were atopic dermatitis, 51.1% had contact hypersensitivity: the most common allergen in this group included Lanolin Alcohol (10.6%).	58

Table 7. Multicenter and retrospective studies on Lanolin and Lanolin Alcohol

# Patients	Clinical Testing Type	Location	Years	Results	Reference
1142	Retrospective study of patch test cases of children under the age of 18 yr. Patients were patch-tested to assess sensitizations to various allergens	United States	January 1, 2015 through December 31, 2015	Wool alcohol and Lanolin were ranked #8 and #9, respectively, out of the top 21 allergens in children. The relevant positive patch test result was 25 (4.6%) for wool alcohol and 26 (6.0%) for Lanolin.	61
		Adults			
756	Retrospective study of individuals tested to anhydrous Lanolin and 2 preparations of Hydrogenated Lanolin on intact skin of patients with contact dermatitis	Japan	January 1972 through June 1973	Individuals with a positive response more than ++ to any of the material were subjected to 2 series of further patch tests. The results showed incidence of skin sensitivity decreased with every stage of purification (no further detail). The results in 1972 showed incidence of sensitivity to Hydrogenated Lanolin was significantly higher than that to anhydrous Lanolin at the 1 % level, while no significant difference was found between both samples in 1973. Contamination by traces of copper, chromium and nickel in hydrogenated preparations may be the source of other possible allergens.	8
31,200	Analysis of the NACDG's patch test results for 153 compounds to determined trends over time for positive test reactions	North America	1984 through 2016	From 1994 to 2010, the positive reactivity proportion for Lanolin Alcohol (30% pet.) went from 3.3% to 2.5%	46
4094	Retrospective study of patients tested with baseline series, which included Lanolin Alcohol. Results compared to those tested from 1990 to 1994.	Switzerland	2000 through 2004	147 (3.6%) had positive reactions to Lanolin Alcohol. Reactions were more frequent in females (104/2388 (4.4%)) than males 43/1706 (2.5%). The rate of sensitization rose from 1.7% in 1990-1994.	48
532	Retrospective study of patients with acute contact dermatitis from topical drugs applied onto the (peri)anal/genital area that were tested with the European baseline series, with some additional series, and the topical medication used along with ingredients.	Belgium	January 2000 through December 10, 2018	44/473 with lesions in the (peri)anal/genital area had positive patch test results to topical drug preparations and/or their ingredients. Lanolin Alcohol (wool alcohol) was among the vehicle components that yielded positive reactions.	50
5264	Retrospective study of patients with lower leg dermatitis, chronic venous insufficiency, or chronic leg ulcers. Data compared to 4881 corresponding patients from 1994 to 2003. Control group without diagnoses numbered 55,510. Patch tests included 30% Lanolin Alcohol and a trademarked Lanolin product at 50%	Germany, Switzerland, and Austria	2003 through 2014	Allergic contact dermatitis was diagnosed less frequently in the study group than in the historical control group and contact sensitization to most allergens had declined. Lanolin Alcohol was still considered an important allergen (7.8% of positive reactions). Patch testing with additional series showed sensitization to a trademarked Lanolin product (9.7% of positive reactions).	51
9577	Retrospective study of consecutively patch tested dermatitis patients with Lanolin Alcohol 30% pet. and a trademarked Lanolin product at 50% in pet.	Denmark	January 1, 2004 through December 31, 2015	Prevalence of Lanolin allergy increased from 0.45% in 2004 to 1.81% in 2015. In age-adjusted and sex-adjusted analyses, weak, significant associations were found between atopic dermatitis and Lanolin and Lanolin Alcohol allergy, respectively, but no association with the trademarked product allergy was found. Out of 9286 dermatitis patients tested with both allergens, 108 had a positive reaction to either Lanolin Alcohol or the trademarked Lanolin product, whereas only 29 patients had positive reactions to both markers.	52
80	Retrospective study of pediatric atopic dermatitis patients. Patients patch tested with European baseline series, which included Lanolin Alcohol 30% pet.	Tunisia	January 2005 through April 2021	Lanolin Alcohol was one of top 5 allergens with 5% of patients having a positive reaction.	54
618	Retrospective study of a dermatology clinic of patients with allergic contact dermatitis. Patients were patched with the standard epicutaneous patch series, which included Lanolin	Brazil	January 2006 through December 2011	16 (2.59%) patients had positive reactions to Lanolin. Sensitization rates to Lanolin had a diminished sensitization rate ($p = 0.01$) during the time period.	55
94	Retrospective study of patients with chronic leg ulcers and contact dermatitis of the lower leg and foot. Testing performed with the European baseline series.	Lithuania	April 2006 through October 2008	Out of 35 patients with chronic leg ulcers, 6 (17.1%) had positive reactions to 30% Lanolin Alcohol. Out of 59 patients with contact dermatitis to the lower leg/foot, 2 (3.4%) had positive reactions to 30% Lanolin Alcohol.	56
10,124	Retrospective analysis of patients patch tested due to suspected intolerance reactions to leave-on cosmetics, including Lanolin Alcohol 30%. Control group without diagnoses numbered 14,728. Additional testing was done with the ointment base series in 7716 patients with a trademarked Lanolin product at 50% in pet. and in 7549 patients with Lanolin Alcohol 30%.	Germany, Switzerland, and Austria	2006 to 2011	246 (2.6%) patients had positive reactions to Lanolin Alcohol. Control group had reactions in 1.8% of the subjects. Results of the ointment base series had positive reactions in 4.1% of patients to the trademarked Lanolin product and positive reactions in 2.4% of patients to Lanolin Alcohol.	57

Table 7. Multicenter and retrospective studies on Lanolin and Lanolin Alcohol

# Patients	Clinical Testing Type	Location	Years	Results	Reference
5790	Retrospective study of individuals tested with the European environmental baseline series. Specific analysis was on preservative contact hypersensitivity and atopic dermatitis.	Hungary	2007 through 2021	In preservative contact hypersensitivity, Lanolin Alcohol (30%) was a common concomitant allergen (13/68 patients).	[59]
4355	Retrospective study of individuals tested with the European baseline series and additional trays. A trademarked Lanolin product at 50% in pet. was included in the European cosmetics tray.	Israel	2012 through 2020	The Lanolin product had 27 positive reactions out of 3752 tests performed. The study data indicated that out of the 27 patients, only 74% had a positive reaction to Lanolin. The authors stated that 26% of the reactions would have been missed if extended patch testing was not performed.	[60]
594	Retrospective analysis of patients patch tested with Lanolin Alcohol 30% pet., a trademarked Lanolin product at 50% in pet., and a supplementary series containing other Lanolin derivatives. Lanolin Alcohol and the trademarked product were tested in duplicate	Netherlands	January 1, 2016 through December 31, 2017	28.6% had a positive patch test reaction to at least one Lanolin derivative. Reactions to Lanolin Alcohol (14.7%) and the trademarked product (15.0%) were common in routinely tested series. The addition of the trademarked product to Lanolin Alcohol significantly increased the number of positive cases (odds ratio 1.79, $p < 0.001$).	[62]
1006	Retrospective study of individuals tested with European baseline series. Seasonal variation in patch test reactions analyzed.	Tunisia	7-yr period, yr not specified	63% were positive in winter vs 52% in summer. Lanolin Alcohol reactions varied seasonally, with weak positive reactions increasing in the spring.	[63]

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FINAL REPORT OF THE SAFETY ASSESSEMENT FOR ACETYLATED LANOLIN ALCOHOL AND RELATED COMPOUNDS

The results of tests on animals and humans with Acetylated Lanolin and its related cosmetic ingredients are reviewed.

This group of ingredients is used extensively in cosmetics as well as in many other consumer products. They have low acute toxicity and are nonsensitizing to animal skin. However, extensive clinical experience indicates that there is a low incidence of sensitivity to these materials among exposed persons. This experience would seem to involve mainly the lanolin alcohols.

Based on the available animal data and human experience, it is concluded that lanolin and related lanolin materials described in the report are safe for topical application to humans in the present practice of use and concentration.

CHEMICAL AND PHYSICAL PROPERTIES

This report covers the following group of related compounds:

Lanolin
Lanolin Oil
Lanolin Wax
Lanolin Acid
Lanolin Alcohol
Acetylated Lanolin
Acetylated Lanolin Alcohol
Hydrogenated Lanolin
Hydroxylated Lanolin

Structure

Lanolin Lanolin is the purified secretory product of the sheep sebaceous gland. The raw material is referred to as *Adeps lanae*, wool wax, wool fat or wool grease. Lanolin comprises 10 to 25% of the weight of sheared wool (Schlossman and McCarthy, 1977).

Lanolin is a complex mixture of a large number of compounds. High molecular weight esters make up aproximately 87% of a typical Lanolin sample (Table 1) (Chemtob, *et al.*, 1975; Fawaz *et al.*, 1973a). The remainder of the mixture is comprised of 11% free compounds (aliphatic alcohols, sterols, fatty acids and hydrocarbons) and of 2% unidentified compounds. Since Lanolin is composed predominantly of high molecular weight esters, it is classified chemically as a wax and not as a fat. The esters have not been characterized (Schlossman and McCarthy, 1977).

[1]Available upon request. Administrator, Cosmetic Ingredient Review, Suite 212, 1133 15th St., NW, Washington, DC 20005.

Crude Lanolin can be separated into Lanolin Wax and Lanolin Oil (Liquid Lanolin) by solvent fractionation or crystallization (Schlossman and McCarthy, 1977; Chemtob *et al.*, 1974, 1975). Lanolin Oil, Wax and Crude (Whole) Lanolin can be modified chemically to produce a large number of substances of interest to the cosmetic chemist. The constituent esters and free compounds of Lanolin Wax and Oil are listed in Table 1 for comparison with those of Whole Lanolin.

Although the exact chemical nature of the Lanolin esters still remains unknown, most of the constituent fatty acids and alcohols of these esters have been identified through the works of Fawaz, Chemtob and associates (Chemtob *et al.*, 1974, 1975; Fawaz *et al.*, 1973a, b; 1974a, b, c). Lanolin esters can be hydrolyzed by saponification. The saponification products of a typical sample of Lanolin are seen in Table 2 (Schlossman and McCarthy, 1977; Chemtob *et al.*, 1974, 1975; Fawaz *et al.*, 1973a, b; 1974a, b, c). The predominant ester acid is of the unsubstituted, saturated, aliphatic type. However, the predominant ester alcohol is the sterol. Further delineations of the component fatty acids and alcohols of Lanolin are found in Table 3 (Fawaz *et al.*, 1973b; 1974a) and Table 4 (Fawaz *et al.*, 1974b, c), respectively.

TABLE 1. Typical Compositions of Whole Lanolin, Lanolin Wax and Lanolin Oil (Chemtob *et al.*, 1975; Fawaz *et al.*, 1973a)

Group	Whole Lanolin (%)	Lanolin Wax (%)	Lanolin Oil (%)
Esters of sterols and triterpene alcohols	35.4	28.9	44.0
Esters of aliphatic alcohols	23.7	13.9	16.0
Monohydroxyesters of sterols and of triterpene and aliphatic alcohols	20.0	16.4	15.0
Di- and polyhydroxyesters and free diols	7.9	9.3	7.7
Free aliphatic alcohols	5.6	20.2	10.4
Free sterols	4.1	5.3	4.4
Free hydrocarbons	0.6	0.4	0.3
Free fatty acids	0.5	1.0	0.7
Unknowns	2.2	4.6	1.5
TOTAL	100.0	100.0	100.0

Approximately 63% of the Lanolin fatty acids are nonhydroxylated, while 32% are monohydroxylated at either the alpha or omega carbon (Table 3). The predominant nonhydroxylated fatty acids are of the anteiso (containing an isobutyl group) and the iso (containing an isopropyl group) types. The monohydroxylated acids (alpha and omega) are mainly of the normal (straight-chain)

TABLE 2. Typical Saponification Products of Lanolin (Schlossman and McCarthy, 1977; Chemtob *et al.*, 1974, 1975; Fawaz *et al.*, 1973a, b; 1974a, b, c)

Group	Subgroup	Percentage	
Fatty acid	Aliphatic	31.1	
	Alpha-hydroxy	13.8	
	Omega-hydroxy	2.6	
	Unsaturated	2.4	
	Others	1.1	Subtotal = 51%
Alcohols	Cholesterols	19.6	
	Lanosterols	12.6	
	Aliphatic	8.0	
	1,2 diols	4.1	
	Others	2.7	Subtotal = 47%
Unspecified	• • •	2.0	

type. The length of the Lanolin fatty acid chain varies from 7 to 41 carbon atoms. The main fatty acids are palmitic (C_{16}), stearic (C_{18}) and longer molecules (C_{20} to C_{32}) (Fawaz *et al.*, 1973b, 1974a).

Approximately 26% of the Lanolin Alcohols are aliphatic structures: 17% monohydric alcohols and 9% diols (Table 4). The anteiso and iso forms are the predominant types of mono- and di-hydric alcohols found in Lanolin. Most of the aliphatic alcohols are long-chain molecules (C_{16} and greater). Over 68% of the Lanolin alcohols are sterols: 42% dimethyl sterols (cholesterols) and

TABLE 3. Typical Fatty Acid Composition of Lanolin (Fawaz *et al.*, 1973b, 1974a)

Group	Subgroup	Percentage (%)	Carbon Chain Length Range	Predominant Constituents of Subgroup
Non-hydroxylated	nor	12.69	8-38	C_{24}(18.7[1]), C_{16}(18), C_{26}(15.5)
	iso	22.08	8-38	C_{20}(17), C_{16}(16.5), C_{26}14.6)
	ante	26.23	7-41	C_{25}(14.7), C_{19}(13.5), C_{27}(13.4)
	unsat	2.10	—	mostly C_{16} and C_{18}
Alpha-hydroxylated	nor	21.71	10-32	C_{16}(88.3)
	iso	4.48	12-34	C_{18}(71.9)
	ante	0.81	11-33	C_{23}(40.9), C_{25}(19.8)
Omega-hydroxylated	nor	3.05	22-36	C_{30}(45), C_{32}(21.8), C_{28}(16.1)
	iso	0.81	22-36	C_{30}(39.6), C_{32}(32.6)
	ante	1.34	23-35	C_{31}(36), C_{25}(26.9), C_{33}(16.3)
Poly-hydroxylated	all	4.70	—	not characterized
TOTAL		100.00		

[1]Percent of all within specified subgroup.

26% pentamethyl sterols (lanosterols). The latter group is also referred to as the triterpene alcohols (Fawaz *et al.*, 1974b, c).

Lanolin Oil and Lanolin Wax Lanolin Oil is the liquid-phase resulting from solvent fractionation (such as with ethyl acetate) of crude Lanolin via vacuum distillation or solvent crystallization. Lanolin Wax is the solid-phase product of this separatory process (Schlossman and McCarthy, 1977; Chemtob *et al.*, 1974, 1975; CTFA, 1978).

TABLE 4. Typical Alcohol Composition of Lanolin (Fawaz *et al.*, 1974b, c)

Class	Group	Subgroup	Percentage (%)	Carbon Chain Length Range	Predominant Constituents of Subgroup
Aliphatics	mono-OH	nor	1.59	14-34	C_{24}(41.1[1]), C_{26}(33.8)
		iso	6.46	14-36	C_{26}(34.6), C_{20}(34.3)
		ante	9.05	13-35	C_{21}(42), C_{27}(31), C_{25}(15)
	1,2 diol	nor	0.39	12-25	C_{16}(43), C_{20}(24), C_{18}(18)
		iso	5.87	12-30	C_{22}(32.4), C_{18}(30), C_{20}(17.5), C_{24}(17)
		ante	2.44	13-29	C_{23}(50), C_{21}(36.4)
Sterols	dimethyl	cholesterol	38.00		
		dihydrocholesterol	Trace		
		7-keto cholesterol	3.60		
	pentamethyl	lanosterol	14.80		
		dihydrolanosterol	10.30		
		7-keto lanosterol	1.60		
Others	polyols and unknowns	• • •	5.90		
TOTAL			100.00		

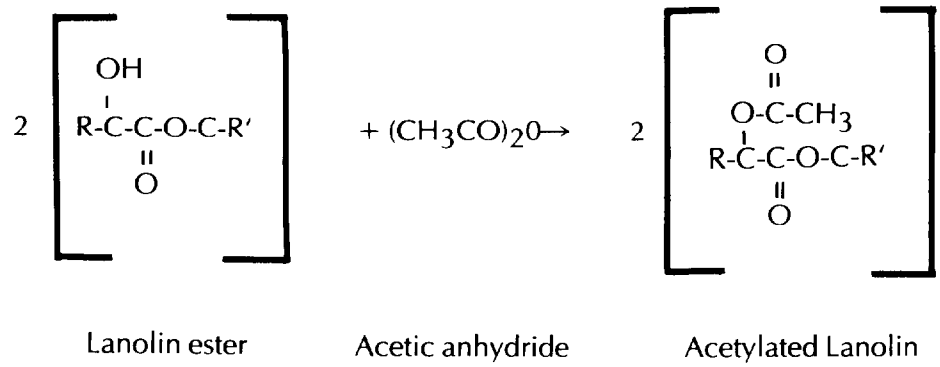
[1]Percent of all within specified subgroup.

Lanolin Acid Saponification of Lanolin with alcoholic or hydroalcoholic alkali results in the hydrolytic cleavage of its constituent esters. The reaction product is a mixture of alkaline soaps of fatty acids and unsaponifiable alcohols. The fatty alcohols can be extracted (such as with ethyl acetate, trichloroethane or aliphatic hydrocarbon solvents) from the acid-alcohol mixture leaving behind the lanolin soaps. These alkali soaps are reacted with sulfuric or phosphoric acid and then water washed to remove excess mineral acid and resultant salts. The Lanolin Acids are then dried and further refined. Lanolin Acid is a mixture of long-chain fatty acids in which the nonhydroxylated species predominates (Tables 2, 3) (Schlossman and McCarthy, 1977; Fawaz *et al.*, 1973b, 1974a, CTFA, 1978).

Lanolin Alcohol Lanolin Alcohol is derived from Lanolin via hydrolysis followed by extraction as described above. Lanolin Alcohol is a mixture of alcohols comprised of about two-thirds sterols and one-fourth aliphatic al-

cohols. It should be noted that neither squalene nor glycerol is found in Lanolin (Tables 2, 4) (Schlossman and McCarthy, 1977; Fawaz *et al.*, 1974b, c; CTFA, 1978).

Acetylated Lanolin Lanolin undergoes acetylation when reacted with acetic anhydride. Ester bonds are formed between the acetate moieties and the hydroxyl groups of the Lanolin hydroxyesters as seen below (Schlossman and McCarthy, 1977):



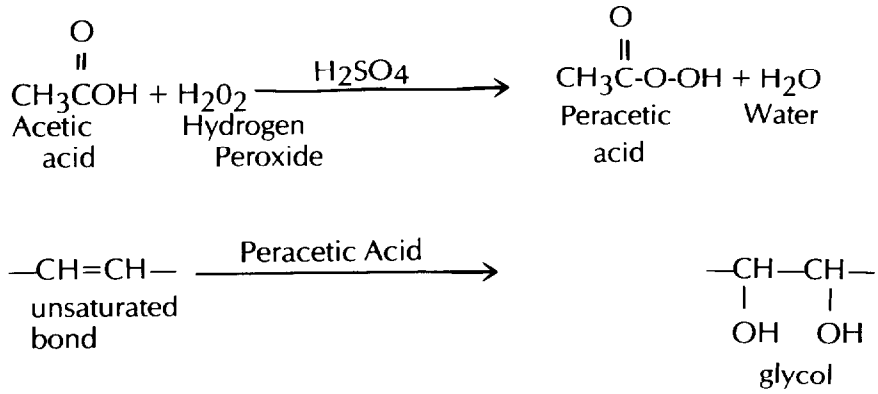
where *R* is hydroxyacid and R′ is alcohol.

The free alcohols in a Lanolin sample may also undergo esterification with acetic anhydride. These two reactive groups (hydroxyesters and free alcohols) make up nearly 38% (Table 1) of crude Lanolin. Total acetylation of Lanolin would result, then, in the chemical alteration of over one-third of the original sample (Schlossman and McCarthy, 1977; CTFA, 1978).

Acetylated Lanolin Alcohol Once Lanolin has been fractionated into its alcohol and fatty acid components, the former group can be further processed by reacting it with acetic anhydride. Each free hydroxyl group can potentially form an ester linkage with acetate. Since Lanolin Alcohol is a mixture of mono-, di- and polyols, Acetylated Lanolin Alcohol will contain mono-, di- and polyacetates (Schlossman and McCarthy, 1977; CTFA, 1978).

Hydrogenated Lanolin Exposing Lanolin to hydrogen at high temperature and pressure in the presence of nickel or chromium catalyst results in a sequence of four chemical reactions. First, most unsaturated double-bonds become saturated with hydrogen. Second, the Lanolin esters undergo hydrogenolysis. Third, the resulting free fatty acids are reduced to fatty alcohols. Fourth, some of these alcohols, as well as some of those resulting from the ester cleavage step, are further reduced to simple hydrocarbons. Hydrogenated Lanolin has never been fully characterized chemically, but its low saponification value indicates the nearly total absence of esters. Additionally, the high hydroxyl value of Hydrogenated Lanolin suggests the presence of a high percentage of free alcohols (94 to 99.8%) (Schlossman and McCarthy, 1977; CTFA, 1978).

Hydroxylated Lanolin The hydroxylation of Lanolin involves the addition of two hydroxyl groups across a double-bond. The resulting compound is a glycol (diol). Lanolin is mixed with acetic acid, hydrogen peroxide and sulfuric acid (catalyst). The active reactant, peracetic acid (acetyl hydroperoxide), is formed *in situ* in the reaction medium and is consumed immediately as it is generated. Peracetic acid mediates the opening of the unsaturated bond and the concomitant addition of two hydroxyl groups as indicated below (Schlossman and McCarthy, 1977, CTFA).



Properties

Lanolin is an ointment-like material which has a slight, characteristic odor. When heated in a steam bath, Lanolin separates into two layers with the lower layer being water. Additional heating drives off this water phase; if not more than 0.25% water remains, the material is classified as anhydrous Lanolin. While still warm, the Lanolin material is transparent. Upon cooling, it becomes a yellow, tenacious, unctous mass. Lanolin is not soluble in water or mineral oil but is miscible without phase separation with about twice its weight of water. It is sparingly soluble in cold alcohol and more so in hot alcohol. Lanolin is highly soluble in chloroform and ether (Schlossman and McCarthy, 1977). The melting range of Lanolin is 36.0 to 42.0°C (CTFA, 1978). Lanolin displays strong emollient, penetrating and emulsifying properties. It blends well with nearly all other substances used in cosmetic formulations. Lanolin possesses adhesive and tackifying characteristics as well (Schlossman and McCarthy, 1977).

Lanolin Oil Lanolin Oil is a clear, amber-colored liquid which is less tacky and has less drag than Whole Lanolin. However, it retains the emollient characteristics of Lanolin and displays a high spreading coefficient. Liquid Lanolin is soluble in mineral and vegetable oils and in silicone fluids (Schlossman and McCarthy, 1977).

Lanolin Wax Lanolin Wax is an odorless, tasteless, ceraceous solid which is a better water/oil (w/o) emulsifying agent than Whole Lanolin. The melting range is 41 to 51°C (Schlossman and McCarthy, 1977; CTFA, 1978).

Lanolin Acid Lanolin Acid is a hard, waxy, yellow-tan solid with a mild waxy odor. The melting range is 40 to 62°C. The constituent fatty acids are polar molecules giving amphoteric properties to Lanolin Acid (CTFA, 1978; Amerchol, 1976).

Lanolin Alcohol Lanolin Alcohol is a firm, waxy, amber solid with a characteristic odor. The melting range is 47 to 65°C (CTFA, 1978).

Acetylated Lanolin Acetylated Lanolin is more hydrophobic than Lanolin since many of the hydrophilic hydroxyl groups in the latter substance have been esterified to acetate. Acetylated Lanolin, therefore, fails to form w/o emulsions, is soluble in cold mineral oil and has a slightly lower melting range (30 to 40°C) than Lanolin. Acetylated Lanolin forms a water resistant film when applied to the skin resulting in the reduction of transepidermal water loss (Schlossman and McCarthy, 1977; CTFA, 1978).

Acetylated Lanolin Alcohol Acetylated Lanolin Alcohol is a lemon-yellow to straw-colored, oily, hydrophobic liquid with a characteristic bland odor. It has a refractive index of 1.4445 to 1.4485 at 20°C and a specific gravity of 0.850 to 0.880 at 25°C (CTFA, 1978).

Hydrogenated Lanolin Hydrogenated Lanolin is a light yellow to white tacky solid which is soluble in ethyl ether and chloroform but insoluble in water. Its melting range is 48 to 53°C. Hydrogenated Lanolin retains the emollient and adhering characteristics of Lanolin but loses the latter's odor, taste, color, and tackiness (Schlossman and McCarthy, 1977; CTFA, 1978).

Hydroxylated Lanolin The introduction of highly polar hydroxyl groups renders Hydroxylated Lanolin more hydrophilic than Lanolin. The product becomes more amphoteric resulting in increased interfacial and surface activities. Hydroxylated Lanolin is superior to Lanolin in forming stable w/o emulsions. Its melting range is 39 to 46°C (Schlossman and McCarthy, 1977; CTFA, 1978).

Reactivity

Since Lanolin products contain unsaturated fatty acids, alcohols, esters, sterols and terpenols, autoxidation may occur during storage and especially during exposure to sunlight. At present, the chemical nature of such autoxidation products is unknown; however, peroxides and epoxides have been suggested as likely structures (Stutsman, 1977). The addition of stabilizing agents such as alpha-tocopherol and BHT prevents the autoxidation of Lanolin products (Stutsman, 1977; Sugai and Higashi, 1975). BHT has been used in some preparations at the 200 to 500 ppm level. Some brands of Acetylated Lanolin Alcohol contain 4% by weight oleyl acetate and/or BHT (CTFA, 1978).

Analytical Methods

Spilker and Richey (1948) have described a number of analytic methods useful for Lanolin and Lanolin derivatives. These generally involve hydrolysis, fractionation, separation by chromatography and identification.

Manufacturing Methods

Lanolin is obtained by one of the following methods (Gillespie, 1948; Clark, 1971):

1. Solvent extraction of wool fleece.
2. Scouring of wool with soap or neutral detergent followed by:
   a. Centrifugation of the resulting emulsion. This may introduce small amounts of detergents as impurities in the Lanolin.
   b. Breaking of the emulsion with acid, or
   c. Production of foam (with air) and collection of the froth.

Impurities

Lanolin and related materials may contain additives and contaminants which may vary widely. These include detergents and the antioxidants BHT and alpha-tocopherol. Chlorophyll, pesticides from the fleece, and trace metals such as copper, nickel, and chromium might also be present.

Purpose and Extent of Use in Cosmetics

Cosmetic uses of Lanolin are discussed by a number of authors. Lanolin and its derivatives have been used as w/o emulsifiers and as emollients for skin protection and relief of dryness of the skin. They serve as vehicles for external (topical) use on skin, lips, nails, and hair, which may bring them into the proximity of mucous membranes and eyes (Fr. Demande, 1976; Bolderson, 1976; Bradner, 1976; Chalmers, 1972, 1976; Chen, 1976; Clark, 1974; Courtin, 1976; Kelly and Ritter, 1976; Mayer, 1976; McCarthy, 1976; McCarthy *et al.*, 1976; McCarthy and Schlossman, 1975; Moeller and Osberghaus, 1976; Mores and McCarthy, 1976; Roney, 1976; Scott, 1976; Tentsova *et al.*, 1977). Lanolin materials are used in over 5,000 formulations. For each of the materials, the approximate extent of use and concentrations used are summarized in Table 5 (FDA, 1976).

BIOLOGICAL PROPERTIES

General Effects

Lanolin and its derivatives are used for their emollient properties on the skin, nails, and hair. The principal emollient of the skin and nails is water, contained particularly in the stratum corneum. Hydration of the stratum corneum depends, in part, upon the rate at which water reaches the horny layer from the deeper dermal and epidermal layers and upon the rate of evaporation of water from the surface layers. It is thought that this water-binding capacity of

the stratum corneum depends upon the presence of hygroscopic water-soluble substances. Emollients act to decrease the rate of evaporation by forming a barrier or occlusive material on the skin surface permitting hydration or rehydration from the deeper layers (Kammerau *et al.*, 1976). Sebaceous gland excretions provide an emollient effect, presumably by virtue of the lipids they contain. The composition of the skin surface lipids varies considerably from site to site. A similar water-binding capacity effect is observed in the cuticle of the hair (Anonymous, 1973; Peter *et al.*, 1969).

TABLE 5. Product Formulation Data (FDA, 1976)

Ingredient	Cosmetic Product Type	Concentration (%)	Number of Product Formulations
Lanolin	Baby products (skin, hair, mucous membranes)	>0.1 to 10	9
	Bath preparations (skin, mucous membranes)	>0.1 to 5	4
	Eye makeup preparations (eye)	≤0.1 to >50	243
	Colognes and toilet waters (skin)	>0.1 to 10	37
	Hair preparations (noncoloring) (hair)	≤0.1 to 50	137
	Hair coloring preparations (hair)	>0.1 to >50	7
	Makeup preparations (not eye) (skin, lips)	≤0.1 to >50	1318
	Manicuring preparations (nails)	>0.1 to 50	18
	Personal cleanliness (mucous membranes, skin)	>0.1 to 5	23
	Shaving preparations (skin)	≤0.1 to 5	31
	Skin care preparations (creams, lotions, powders, and sprays) (skin)	≤0.1 to >50	531
	Suntan and sunscreen preparations (skin)	>0.1 to 50	31
Lanolin Oil	Baby products (skin, hair mucous membranes)	>0.1 to 5	6
	Bath preparations (skin, mucous membranes)	≤0.1 to 25	44
	Eye makeup preparations (eye)	≤0.1 to 50	135
	Colognes and toilet waters (skin)	>0.1 to 5	9
	Hair preparations (noncoloring) (hair)	≤0.1 to 5	17
	Hair coloring preparations (hair)	≤0.1 to 5	9

TABLE 5. (continued) Product Formulation Data (FDA, 1976)

Ingredient	Cosmetic Product Type	Concentration (%)	Number of Product Formulations
	Makeup preparations (not eye) (skin, lips)	>0.1 to >50	887
	Manicuring preparations (nails)	>0.1 to 50	10
	Personal cleanliness (mucous membranes, skin)	>1 to 5	3
	Shaving preparations (skin)	>0.1 to 5	2
	Skin care preparations (creams, lotions, powder, and sprays) (skin)	≤0.1 to 50	218
	Suntan and sunscreen preparations (skin)	>0.1 to 10	16
Lanolin Acid	Eye makeup preparations (eye)	>0.1 to 10	23
	Hair preparations (noncoloring) (hair)	>1 to 5	2
	Makeup preparations (not eye) (skin, lips)	>0.1 to 10	13
	Manicuring preparations (nails)	>1 to 5	2
	Shaving preparations (skin)	>0.1 to 1	1
	Skin care preparations (creams, lotions, powders and sprays) (skin)	>0.1 to 10	10
Lanolin Alcohol	Baby products (skin, hair, mucous membranes)	>0.1 to 5	2
	Bath preparations (skin, mucous membranes)	>0.1 to 10	28
	Eye makeup preparations (eye)	>0.1 to 25	120
	Colognes and toilet waters (skin)	>0.1 to 25	13
	Hair preparations (noncoloring) (hair)	≤0.1 to 25	15
	Hair coloring preparations (hair)	>0.1 to 1	4
	Makeup preparations (not eye) (skin, lips)	≤0.1 to 25	422
	Personal cleanliness (mucous membranes, skin)	≤0.1 to 5	6
	Shaving preparations (skin)	>0.1 to 5	7
	Skin care preparations (creams, lotions, powders, and sprays) (skin)	>0.1 to >50	115
	Suntan and sunscreen preparations (skin)	>0.1 to 5	6
Acetylated Lanolin	Baby products (skin, hair mucous membranes)	>0.1 to 1	2
	Bath preparations (skin, mucous membranes)	>1 to 5	2

TABLE 5. (continued) Product Formulation Data (FDA, 1976)

Ingredient	Cosmetic Product Type	Concentration (5)	Number of Product Formulations
	Eye makeup preparations (eye)	>0.1 to 50	5
	Colognes and toilet waters (skin)	>0.1 to 1	4
	Hair preparations (noncoloring) (hair)	>0.1 to 5	3
	Makeup preparations (not eye) (skin, lips)	>0.1 to 50	57
	Shaving preparations (skin)	≤0.1 to 1	6
	Skin care preparations (creams, lotions, powders, and sprays) (skin)	>0.1 to 25	50
Acetylated Lanolin Alcohol	Bath preparations (skin, mucous membranes)	>1 to 5	4
	Eye makeup preparations (eye)	>0.1 to 10	31
	Colognes and toilet waters (skin)	>0.1 to 25	16
Acetylated Lanolin Alcohol (cont'd)	Hair preparations (noncoloring) (hair)	>0.1 to 5	4
	Makeup preparations (not eye) (skin, lips)	>0.1 to 25	133
	Manicuring preparations (nails)	≤0.1 to 5	2
	Skin care preparations (creams, lotions, powders, and sprays) (skin)	≤0.1 to 50	105
	Suntan and sunscreen preparations (skin)	>0.1 to 5	11
Hydrogenated Lanolin	Eye makeup preparations (eye)	>5 to 10	1
	Colognes and toilet waters (skin)	>1 to 5	1
	Makeup preparations (not eye) (skin, lips)	>1 to 25	58
	Manicuring preparations (nails)	>1 to 5	1
	Shaving preparations (skin)	>0.1 to 1	1
	Skin care preparations (creams, lotions, powders, and sprays) (skin)	>0.1 to 10	15
	Suntan and sunscreen preparations (skin)	>0.1 to 5	4
Hydroxylated Lanolin	Makeup preparations (not eye) (skin, lips)	>5 to 25	7
	Skin care preparations (creams, lotions, powders, and sprays) (skin)	>0.1 to 5	5
Lanolin Wax	Suntan and sunscreen preparations (skin)	>10 to 25	2
	Colognes and toilet waters (skin)	>1 to 25	11

TABLE 5. (continued) Product Formulation Data (FDA, 1976)

Ingredient	Cosmetic Product Type	Concentration (5)	Number of Product Formulations
	Manicuring preparations (nails)	>1 to 5	1
	Shaving preparations (skin)	>1 to 5	1
	Eye makeup preparations (eye)	>0.1 to 25	41
	Skin care preparations (creams, lotions, powders, and sprays) (skin)	>0.1 to 5	9
	Hair preparations (noncoloring) (hair)	>0.1 to 1	3
	Makeup preparations (not eye) (skin, lips)	≤0.1 to 50	69

Emollient preparations are often chosen, in part, because of their compatability with normal skin surface lipids. Lanolin and its derivatives are not chemically similar to human sebum. Sebum contains approximately 50% glycerides; Lanolin contains none. The variations among derivatives of Lanolin lead to variations in properties from hydrophilic, water-soluble and nonocclusive to hydrophobic, oil-soluble and occlusive (Kammerau *et al.*, 1976).

Animal Toxicology

General Studies

Acute Oral Toxicity (Tables 6—14) Each of the nine Lanolin ingredients has been tested in rats for acute oral toxicity in a variety of studies. All exhibit low oral toxicity. Only the most pertinent acute oral LD50 for each ingredient will be reported: undiluted Lanolin (>64 cc/kg), undiluted Lanolin Oil (46.5 cc/kg), 50% Lanolin Wax in corn oil (>32 g/kg), undiluted Lanolin Acid (56.5 cc/kg), 66% Lanolin Alcohol in corn oil (>42.7 g/kg), undiluted Acetylated Lanolin (>64 cc/kg), undiluted Acetylated Lanolin Alcohol (>64 cc/kg), undiluted Hydrogenated Lanolin (>64 cc/kg), and undiluted Hydroxylated Lanolin (>10 cc/kg) (CTFA: Amerchol a,b,c,d,e; CTFA: Avon; CTFA: Croda a,b,c-,d,e,f,g; CTFA: Malmstrom a,b,c,d,e,f,g,h; CTFA: R.I.T.A.; CTFA: Robinson-Wagner a,b,c,d; CTFA: Westbrook a,b,c,d,e,f,g).

Acute Dermal Toxicity The acute dermal LD50 of Lanolin Oil as applied to the rabbit skin has been determined to be in excess of 10 ml/kg (CTFA: R.I.T.A.). In a two-dose (1 or 2 g/kg) study in rats, the LD50 of Hydroxylated Lanolin was found to be greater than 2.0 g/kg (CTFA: Avon).

Acute Skin Irritation (Tables 6—14) With one exception, the Lanolin ingredients are either nonirritating or at most mildly irritating to the skin of experimental animals. The exception is Lanolin Acid which is a mild skin irritant. It should be noted that Lanolin Acid is seldom, if at all, found in cosmetic formulations as the free acid. In the five tests conducted on undiluted

Lanolin Acid, the Primary Irritation Index (PII) ranged from 0.78 to 2.2 (maximum of 8) (CTFA: Amerchol, b; CTFA: Croda, c; CTFA: Malmstrom, d; CTFA: Westbrook, c). The highest PII value obtained for each of the other undiluted Lanolin ingredients is as follows: Lanolin (0.71), Lanolin Oil (1.0), Lanolin Wax (0.67), Lanolin Alcohol (1.5), Acetylated Lanolin (1.62), Acetylated Lanolin Alcohol (2.3), Hydrogenated Lanolin (0.6), and Hydroxylated Lanolin (0.0) (CTFA: Amerchol a,c,d; CTFA: Avon; CTFA: Croda a,b,d,e,f,g; CTFA: Malmstrom a,b,c,e,f,g,h; CTFA: R,I.T.A.; CTFA: Robinson-Wagner a,b,c,d; CTFA: Westbrook a,b,d,e,f,g).

Acute Eye Irritation (Tables 6—14) With one exception, all the Lanolin ingredients were either nonirritating or at most mildly irritating to the eyes of experimental animals. In three of four ocular irritation studies conducted on rabbits, undiluted Lanolin Acid was found to be a mild or moderately severe irritant (CTFA: Amerchol, b; CTFA: Croda, c; CTFA: Malmstrom, d; CTFA: Westbrook, c). For the other eight Lanolin ingredients, no or only mild transient reactions were reported (CTFA: Amerchol, a,c,d,e; CTFA: Avon; CTFA: Croda a,b,d,e,f,g; CTFA: Malmstrom a,b,c,e,f,g,h; CTFA: R.I.T.A.; CTFA: Robinson-Wagner a,b,c,d; CTFA: Westbrook a,b,d,e,f,g).

Subchronic Skin Irritation/Sensitization A skin sensitization study with eight guinea pigs was done with Acetylated Lanolin Alcohol suspended in physiological saline. Ten intracutaneous injections on alternate days followed by challenge injection two weeks later showed no sensitization (CTFA: Amerchol, d).

Hydrogenated Lanolin was not a sensitizer when applied to the skin of guinea pigs three times a week for seven or more applications. A 2% solution in 1:1:3 acetone:dioxane:corn oil was used. The challenge was applied two weeks after the last induction dose (CTFA: R.I.T.A.)

Neither Lanolin Oil applied 15 times to the rabbits skin at concentrations of 5, 15, or 50% nor 50% Hydroxylated Lanolin applied 65 times to the rat skin caused any local skin irritation effects (CTFA: R.I.T.A.; CTFA: Avon).

Lanolin Wax suspended in corn oil was a mild skin sensitizer in 10 guinea pigs as indicated by an average score of 0.95 (scores between 0.1 and 2.0 are mild sensitizers). The material was injected intracutaneously three times/week for a total of 10 injections with an eleventh challenge injection two weeks later (CTFA: Robinson-Wagner, c).

Special Studies Simpson *et al.* (1945) reported that 3-methylcholanthrene dissolved in anhydrous Lanolin was less carcinogenic when painted on the skin of mice as compared to its carcinogenic effect when benzene was the vehicle. The concentration of 3-methylcholanthrene in Lanolin applied in these studies was one-half that of the compound in benzene. However, the volume of the benzene solution applied was twice that of the Lanolin solution. Berenblum and Schoental (1947) observed a similar diminution in the carcinogenic potency of methylcholanthrene when Lanolin was used as a diluent. They reported the inhibitory effect even with concentrations that exceeded the concentration of the carcinogen in benzene used as a positive control. They obtained similar results with another carcinogen, 7,12-dimethylbenz(a)anthracene, on mice.

TABLE 6. Acute Animal Toxicity — Lanolin

		Acute Oral				Skin Irritation		Draize Woodard Calvery	Eye Irritation Draize		
Sample Number	Reference	LD50	Conc.	Dosage	Animals	Conc.	Animals	Irritation Index	Conc.	Animals	Comment
1	CTFA: Westbrook, a	>16 g/kg	40% in arachis oil	2 @ 10 and 16 g/kg	10 rats/ dose	undiluted	6 rabbits	0	undiluted	6 rabbits	no irritation
2	CTFA: Malmstrom, a	>32 g/kg	1:1 in corn oil	6 @ 2.0 — 64.0 cc/kg	5 rats/ dose	undiluted	6 rabbits	0	undiluted	9 rabbits	mild transient irritation
3	CTFA: Malmstrom, a	• • •	• • •	• • •	• • •	undiluted	6 rabbits	0	• • •	• • •	• • •
4	CTFA: Malmstrom, a	>32 g/kg	1:1 in corn oil	6 @ 2.0 — 64.0 cc/kg	5 rats/ dose	undiluted	6 rabbits	0	undiluted	9 rabbits	mild transient irritation
5	CTFA: Malmstrom, a	>32 g/kg	1:1 in corn oil	6 @ 2.0 — 64.0 cc/kg	5 rats/ dose	undiluted	6 rabbits	0.58 mild irritant	undiluted	9 rabbits	mild transient irritation
6	CTFA: Malmstrom, a	>64 cc/kg	undiluted	6 @ 4.0 — 64.0 cc/kg	5 rats/ dose	undiluted	6 rabbits	0	undiluted	9 rabbits	no damage
7	CTFA: Malmstrom, a	>32 g/kg	1:1 in corn oil	6 @ 2.0 — 64.0 cc/kg	5 rats/ dose	undiluted	6 rabbits	0	undiluted	9 rabbits	mild transient irritation

8	CTFA: Malmstrom, a	>64 cc/kg	undiluted	6 @ 4.0 — 64.0 cc/kg	5 rats/ dose	undiluted	6 rabbits	0.1 no irritation	undiluted	9 rabbits	no damage
9	CTFA: Robinson-Wagner, a	>5.0 g/kg	25% in corn oil	1 @ 5.0 g/kg	10 rats/ dose	undiluted	6 rabbits	0.38 mild irritant	undiluted	9 rabbits	no damage
10	CTFA: Croda, a	>20.0 g/kg	25% in corn oil	5 @ 1.25 — 20 g/kg	5 rats/ dose	undiluted	6 rabbits	0.71 mild irritant	undiluted	9 rabbits	mild transient irritation

TABLE 7. Acute Animal Toxicity — Lanolin Oil

		Acute Oral				Skin Irritation		Draize Woodard Calvery	Eye Irritation Draize		
Sample Number	Reference	LD50	Conc.	Dosage	Animals	Conc.	Animals	Irritation Index	Conc.	Animals	Comment
1	CTFA: Westbrook, b	>16 ml/ kg	undiluted	1 @ 16 ml/kg	10 rats/ dose	undiluted	3 rabbits	0.5 mild irritant	undiluted	3 rabbits	no irritant
2	CTFA: Croda, b	>20 ml/ kg	undiluted	5 @ 1.25 — 20.0 ml/kg	5 rats/ dose	undiluted	6 rabbits	1.0	undiluted	6 rabbits	mild transient irritant
3	CTFA: Robinson-Wagner, b	>21.5 ml/kg	undiluted	5 @ 1.0 — 21.5 ml/kg	5 rats/ dose	undiluted	6 rabbits	0.17	undiluted	6 rabbits	mild in 1 animal
4	CTFA: Malmstrom, b	46.5 cc/kg	undiluted	5 @ 8.0 — 64.0 cc/kg	5 rats/ dose	undiluted undiluted	3 rabbits 6 rabbits	1.4 mild 0.30 slight	undiluted	9 rabbits	no irritant

TABLE 7. (Continued) Acute Animal Toxicity — Lanolin Oil

5	CTFA: Malmstrom, b	24.8 g/kg	propylene glycol vehicle	7 @ 2.0 — 32.0 g/kg	5 rats/ dose	undiluted	6 rabbits	0.13 slight	undiluted	9 rabbits	irritant to unwashed eye
6	CTFA: R.I.T.A.	>10 ml/ kg	undiluted	1 @ 10 ml/kg	10 rats/ dose	10% in mineral oil	6 rabbits	0	undiluted	9 rabbits	not irritating

TABLE 8. Acute Animal Toxicity — Lanolin Wax

		Acute Oral				Skin Irritation		Draize Woodward Calvery	Eye Irritation Draize		
Sample Number	Reference	LD50	Conc.	Dosage	Animals	Conc.	Animals	Irritation Index	Conc.	Animals	Comment
1	CTFA: Malmstrom, c	48-64 cc/kg	1:1 in corn oil	6 @ 4.0— 64.0 cc/kg	5 rats/ dose	undiluted	6 rabbits	0.28 mild irritant	undiluted	9 rabbits	no damage
2	CTFA: Malmstrom, c	>42.7 g/kg	66% in corn oil	6 @ 2.0— 64 cc/kg	5 rats/ dose	undiluted	6 rabbits	0	undiluted	9 rabbits	no damage
3	CTFA: Robinson-Wagner, c	>32 g/kg	1:1 in corn oil	6 @ 2.0— 64 cc/kg	5 rats/ dose	undiluted	3 rabbits	0	undiluted	6 rabbits	no damage
4	CTFA: Amerchol , a	• • •	• • •	• • •	• • •	undiluted	3 rabbits	0.67 mild irritant	• • •	• • •	• • •

TABLE 9. Acute Animal Toxicity — Lanolin Acid

		Acute Oral				Skin Irritation		Draize Woodward Calvery	Eye Irritation Draize		
Sample Number	Reference	LD50	Conc.	Dosage	Animals	Conc.	Animals	Irritation Index	Conc.	Animals	Comment
1	CTFA: Westbrook, c	• • •	• • •	• • •	• • •	undiluted	6 rabbits	2.2 moderately irritating	undiluted	6 rabbits	moderately severe irritant
2	CTFA: Amerchol , b	>10 ml/kg	undiluted	5 @ 2.5—40.0 ml/kg	2 rats/dose	undiluted	6 rabbits	1.60 mild irritant	undiluted	6 rabbits	mild transient irritant
3	CTFA: Amerchol , b	>20 ml/kg <40 ml/kg	undiluted	5 @ 2.5—40.0 ml/kg	2 rats/dose	undiluted	6 rabbits	0.78 slight irritant	20% in mineral oil	6 rabbits	non-irritating
4	CTFA: Malmstrom, d	56.5 cc/kg	undiluted	7 @ 4.0—80.0 cc/kg	5 rats/dose	undiluted	6 rabbits	1.05 mild irritant	undiluted	9 rabbits	minimal irritant
5	CTFA: Croda, c	>5 g/kg	undiluted	1 @ 5 g/kg	10 rats/dose	undiluted	6 rabbits	2 moderate irritant	undiluted	6 rabbits	moderately severe irritant

TABLE10 Acute Animal Toxicity — Lanolin Alcohol

		Acute Oral				Skin Irritation		Draize Woodard Calvery	Eye Irritation Draize		
Sample Number	Reference	LD50	Conc.	Dosage	Animals	Conc.	Animals	Irritation Index	Conc.	Animals	Comment
1	CTFA: Westbrook, d	>16 g/kg	40 % in arachis oil	1 @ 16 g/kg	10 rats/dose	• • •	• • •	• • •	• • •	• • •	• • •
2	CTFA: Westbrook, d	• • •	• • •	• • •	• • •	undiluted	3 rabbits	0	undiluted	3 rabbits	very slight irritant
3	CTFA: Robinson-Wagner, d	27 g/kg	propylene glycol vehicle	8 @ 1.0—32.0 g/kg	5 rats/dose	undiluted	6 rabbits	0	undiluted	6 rabbits	no irritation
4	CTFA: Croda, d	>20.0 ml/kg	50% in mineral oil w/ 5% propylene glycol	5 @ 1.25—20.0 ml/kg	5 rats/dose	50% in mineral oil	6 rabbits	1.5 mild irritant	50% in mineral oil	6 rabbits	mild transient irritant
5	CTFA: Malmstrom, e	12.1 mg/kg	2 mg/cc corn oil w/5% propylene glycol	6 @ 8.0—64.0 cc/kg	5 rats/dose	undiluted	6 rabbits	1.5 mild irritant	undiluted	9 rabbits	no damage
6	CTFA: Malmstrom, e	23.3 mg/kg	2 mg/cc of corn oil	5 @ 16.0—64.0 cc/kg	5 rats/dose	undiluted	6 rabbits	1.05 mild irritant	undiluted	9 rabbits	no damage
7	CTFA: Malmstrom, e	>42.7 g/kg	66% in corn oil	6 @ 2.0—64.0 cc/kg	5 rats/dose	undiluted	6 rabbits	0	undiluted	9 rabbits	no damage

8	CTFA: Malmstrom, e	>32 g/kg	50% in corn oil	6 @ 2.0—64.0 cc/kg	5 rats/dose	undiluted	6 rabbits	0	undiluted	9 rabbits	no damage
9	CTFA: Malmstrom, e	21.1g/kg	propylene glycol vehicle	7 @ 2.0—32.0 g/kg	5 rats/dose	undiluted	6 rabbits	0	undiluted	9 rabbits	no damage
10	CTFA: Malmstrom, e	21.3 g/kg	1:2 w/v in corn oil	6 @ 2.0—64.0 cc/kg	5 rats/dose	• • •	• • •	• • •	• • •	• • •	• • •
11	CTFA: Malmstrom, e	21.3 cc/kg	1:2 w/v in corn oil	6 @ 2.0—64.0 cc/kg	5 rats/dose	• • •	• • •	• • •	• • •	• • •	• • •

TABLE11 Acute Animal Toxicity — Acetylated Lanolin

		Acute Oral				Skin Irritation		Draize Woodard Calvery	Eye Irritation Draize		
Sample Number	Reference	LD50	Conc.	Dosage	Animals	Conc.	Animals	Irritation Index	Conc.	Animals	Comment
1	CTFA: Westbrook, e	>16 g/kg	undiluted	1 @ 16 g/kg	10 rats/dose	undiluted	6 rabbits	0.3 mild irritant	undiluted	8 rabbits	marginal irritant
2	CTFA: Croda, e	>15 ml/kg	50% in oil	1 @ 15 ml/kg	20 mice/dose	undiluted	3 rabbits	0	undiluted	3 rabbits	no irritation
3	CTFA: Malmstrom, f	>64 cc/kg	undiluted	6 @ 4.0—64.0 cc/kg	5 rats/dose	undiluted	6 rabbits	0.5 mild irritant	undiluted	9 rabbits	no irritation
4	CTFA: Amerchol , f	>10 ml/kg	undiluted	5 @ 2.5—40.0 ml/kg	2 rats/dose	undiluted	6 rabbits	Avg. 1.62 mild irritant	undiluted	6 rabbits	mild transient irritation

TABLE12 Acute Animal Toxicity — Acetylated Lanolin Alcohol

		Acute Oral				Skin Irritation		Draize Woodard Calvery	Eye Irritation Draize		
Sample Number	Reference	LD50	Conc.	Dosage	Animals	Conc.	Animals	Irritation Index	Conc.	Animals	Comment
1	CTFA: Malmstrom, g	64 cc/kg	undiluted	6 @ 4.0—64.0 cc/kg	5 rats/dose	undiluted	6 rabbits	0	undiluted	9 rabbits	no irritation
2	CTFA: Amerchol , d	40.0 ml/kg	undiluted	5 @ 2.5—40 ml/kg	2 rats/dose	undiluted	6 rabbits	1.3 mild irritant	undiluted	6 rabbits	mild transient irritant
3	CTFA: Westbrook, f	16 g/kg	40% in arachis oil	1 @ 16 g/kg	10 rats/dose	undiluted	6 rabbits	2.3 mod. irritant	undiluted	6 rabbits	not an irritant
4	CTFA: Westbrook, g	16 ml/kg	undiluted	1 @ 16 ml/kg	10 rats/dose	undiluted	6 rabbits	2.1 mod. irritant	undiluted	8 rabbits	marginal irritant
5	CTFA: Croda, f	40 g/kg	undiluted	5 @ 2.5—40.0 g/kg	5 rats/dose	undiluted	3 rabbits	0	undiluted	3 rabbits	not an irritant

TABLE13 Acute Animal Toxicity — Hydrogenated Lanolin

		Acute Oral				Skin Irritation		Draize Woodard Calvery	Eye Irritation Draize		
Sample Number	Reference	LD50	Conc.	Dosage	Animals	Conc.	Animals	Irritation Index	Conc.	Animals	Comment
1	CTFA: Malmstrom, h	>64.0 cc/kg	undiluted	6 @ 4.0—64 occ/kg	5 rats/dose	undiluted	6 rabbits	0.1 mild irritant	undiluted	9 rabbits	no damage
2	CTFA: Malmstrom, h	>42.7 g/kg	66% in corn oil	6 @ 2.0—64 occ/kg	5 rats/dose	undiluted	6 rabbits	0	undiluted	9 rabbits	no damage
3	CTFA: Croda, g	>5 g/kg	undiluted	1 @ 5 g/kg	10 rats/dose	undiluted	6 rabbits	0.6 mild irritant	undiluted	6 rabbits	no damage
4	CTFA: R.I.T.A.	8.12 g/kg	25% in propylene glycol	2 @ 5 & 10g/kg	5 rats/dose	undiluted	6 rabbits	0	50% aqueous paste	9 rabbits	no irritation

TABLE14 Acute Animal Toxicity — Hydroxylated Lanolin

		Acute Oral				Skin Irritation		Draize Woodard	Eye Irritation Draize		
Sample Number	Reference	LD50	Conc.	Dosage	Animals	Conc.	Animals	Irritation Index	Conc.	Animals	Comment
1	CTFA: Avon	2.0 g/kg	undiluted	2 @ 1.0—2.0 g/kg	5 rats/dose	undiluted	9 rabbits	0	undiluted	6 rabbits	mild transient irritation
2	CTFA: Amerchol , e	>10 ml/kg	undiluted	5 @ 2.5—40.0 ml/kg	2 rats/dose	• • •	• • •	• • •	undiluted	3 rabbits	no irritation

Clinical Assessment of Safety

General Assessment No scientific reports of adverse reactions among persons occupationally exposed during production or use of Lanolin over a 50-year period have been reported (Table 15) (CTFA: Westbrook, a). Similarly there have been no reported adverse experiences in 22, 22, 25, 30, 6 and 14 years of use by workers or customers for Lanolin Oil (CTFA: Westbrook, b), Lanolin Wax (CTFA: Westbrook, h), Lanolin Acid (CTFA: Westbrook, c), Lanolin Alcohol (CTFA: Westbrook, d), Acetylated Lanolin (CTFA: Westbrook, e), and Acetylated Lanolin Alcohol (CTFA: Westbrook, f,g), respectively.

Skin Irritation Numerous patch tests were conducted on volunteers with Lanolin and related cosmetic ingredients. These studies are summarized in Table 15. Undiluted Lanolin showed no evidence of primary irritation or sensitization in over 250 subjects (CTFA: Malmstrom, a; CTFA: Croda, a). Lanolin Oil has been skin tested in more than 300 volunteers without adverse reactions (CTFA: Croda, b; CTFA: Malmstrom, b). Undiluted Lanolin Wax showed extremely low irritation potential and no evidence of sensitization in over 200 subjects (CTFA: Malmstrom, c). Of the 115 subjects exposed topically to Lanolin Acid, three showed increased reaction not considered sensitization and one showed sensitization (CTFA: Westbrook, c; CTFA: Amerchol, b; CTFA: Croda, c). There were no adverse effects noted when 50 volunteers were exposed to undiluted Lanolin Alcohol in a repeated insult patch test (CTFA: Croda, d). Questionable evidence of fatiguing was found in 2 of 53 subjects exposed to Acetylated Lanolin (CTFA: Amerchol, c). Acetylated Lanolin Alcohol caused an extremely low level of irritation in over 60 individuals (CTFA: Malmstrom, g; CTFA: Amerchol, d). In a repeated insult test on 50 subjects, undiluted Hydrogenated Lanolin presented no suggestions of irritation, fatiguing, or sensitization (CTFA: Croda, g). There were no visible skin changes observed in 53 volunteers exposed to Hydroxylated Lanolin (CTFA: Amerchol, e).

Skin Sensitization Over the years of its use, Lanolin has been observed to produce allergic or hypersensitivity reactions. The first reports of Lanolin skin sensitization were published in 1930 (Ramirez and Eller, 1930). Since then, numerous reports of Lanolin allergy have been published, several of which will be elaborated upon below. The incidence of hypersensitivity among persons exposed has been a matter of great uncertainty (Anonymous, 1971; Clark *et al.*, 1977; Clark, 1975; DeBeukelaar, 1968; Epstein 1972; Fisher *et al.*, 1971; Hannuksela *et al.*, 1976; Schorr, 1974, 1975; Taub, 1976; Wilson, 1973).

Clark (1975) has summarized three large European retrospective studies of dermatology patients with Lanolin Alcohol hypersensitivity with a reported incidence of 0.70, 2.38, and 1.82%. Using numerous assumptions, the incidence in the general population was estimated to be no more than 9.7 cases per million people.

Epstein (1972) and Breit and Bandmann (1973) suggested for detection of Lanolin allergy the use of 30% wool wax alcohol in petrolatum as the testing agent for Lanolin materials in patch testing. With this Lanolin fraction, Lanolin

sensitivity was successfully identified. It was noted that addition of salicylic acid to the Lanolin fraction produced false-positive reactions (Epstein, 1972).

Peter *et al.*, (1969) concluded from his studies that the greatest allergenic reaction is given by C_{14}-C_{16} Lanolin Alcohols.

A European study group noted that the incidence of hypersensitivity to topical medicaments was 14% (560/4000) in clinic patients with eczema. Positive test reactions were reported for neomycin (4%), wool alcohols (3%), iodochlorohydroxyquin (2%), parabens (2%), and chlorquianaldol (1%). The difference between these total values of 12%, and the overall total of 14% was not stated (Bandman *et al.*, 1972).

The North American Contact Dermatitis Group has issued a series of reports on results of diagnostic patch testing of dermatitis patients using a standard array of test substances. Out of 1200 patients tested over an 18-month period ending in June 1972, wool wax alcohols (30% in petrolatum) ranked eighth in frequency of reaction with 3% of the patients reacting (North American Contact Dermatitis Group, 1973). In the subsequent two-year testing period, wool wax alcohol ranked eleventh, again experiencing a 3% reaction rate out of 3165 patients tested (North American Contact Dermatitis Group, 1975). A preliminary report of a more recent testing period (July 1, 1975—June 30, 1976) showed wool alcohol ranking thirteenth with a reaction incidence of 2.9% of 900-2000 patients tested (Rudner, 1977). An unpublished tabulation of 1976-1977 data from the groups shows a sensitivity index of 2% for wool alcohol and 1% for 100% hydrous Lanolin (North American Contact Dermatitis Group, 1976-77).

Clark *et al.*, (1977) demonstrated in Lanolin-sensitive patients that the removal of free fatty Lanolin Alcohols and detergents reduced the incidence of detectable hypersensitivity by 96%. An anonymous submission suggests that parabens, alkyl esters of p-hydroxybenzoic acid, cosmetic preservatives, may increase or be responsible for Lanolin hypersensitivity (Anonymous, 1971; DeBeukelaar, 1968).

Estimates of the extent of hypersensitivity vary apparently according to the type of provocative patch test applied or according to the populations tested. Salicylic acid as a keratolytic agent has been used to increase the sensitivity to Lanolin in patch testing systems with differing results according to the type of Lanolin material used (Lanolin esters or alcohols). It has even been suggested that autoxidation products may contribute to the allergenicity of Lanolin Alcohols (Stutsman, 1977; DeBeukelaar, 1968).

Photosensitivity Two product formulations, each containing 0.75% Lanolin Acid, 3.0% Lanolin Alcohol, and 0.5% Hydroxylated Lanolin, were tested for phototoxicity on 20 human subjects and for photosensitization on 25 human subjects. There was no evidence of either phototoxicity or photosensitivity (CTFA Task Force).

TABLE 15. Clinical Adverse Reactions — Clinical Trials

Ingredient/ Brand Number	Reference	Human Response: Test	No. of Subjects	No. of Applications	Concentration	Incubation Period	Final Challenge	Comment
Lanolin								
1	CTFA: Westbrook, a	• • •	• • •	• • •	• • •	• • •	• • •	no reported adverse experiences in 50 yrs of use by workers or customers
2	CTFA: Malmstrom, a	Draize	200	10, 3x's/wk	undiluted	duration not given	yes	no evidence of sensitization
3	CTFA: Croda, a	repeated insult patches	50	every other day for 10 applications	undiluted	10-14 days	yes	no evidence of primary irritation, fatiguing or sensitization
Lanolin Oil								
1	CTFA: Westbrook, b	• • •	• • •	• • •	• • •	• • •	• • •	no reported adverse experiences in 22 yrs of use by workers or customers
2	CTFA: Croda, b	repeated insult patches	50	every other day for 10 applications	undiluted	10-14 days	yes	no evidence of fatiguing, primary irritation or sensitization
3	CTFA: Malmstrom, b	21-day cumulative irritancy assay	8	daily for 21 days	undiluted	• • •	• • •	extremely low irritancy potential
4	CTFA: Malmstrom, b	repeated insult	50	daily for 15 days	undiluted	21 days	yes	no evidence of irritancy, fatiguing or sensitization
5	CTFA: Malmstrom, b	Draize	200	10, 3x's/wk	undiluted	duration not given	yes	no evidence of sensitization
Lanolin Acid								
1	CTFA: Westbrook, c	applied to skin	12	single	undiluted	3 wks	yes	3 subjects showed increased reactions not considered sensitization

2	CTFA: Westbrook, c	• • •	• • •	• • •	• • •	• • •	• • •	no reported adverse experiences in 25 yrs of use by workers or customers
3	CTFA: Amerchol , b	induction	53	4x's/wk for 3 wks	100 & 20-80% in petrolatum	18 days	yes	nothing observed in 53 subjects
4	CTFA: Croda, c	repeated insult patches	50	every other day for 10 applications	undiluted	10-14 days	yes	fatiguing and sensitization in 1 subject
Lanolin Alcohol								
1	CTFA: Westbrook, d	• • •	• • •	• • •	• • •	• • •	• • •	no reported adverse experiences in 30 yrs of use by workers or customers
2	CTFA: Croda, d	repeated insult patches	50	every other day for 10 applications	undiluted	10-14 days	yes	no evidence of primary irritation, fatiguing, or sensitization
Acetylated Lanolin								
1	CTFA: Westbrook, e	• • •	• • •	• • •	• • •	• • •	• • •	no reported adverse experience 6 yrs of use by workers or customers
2	CTFA: Amerchol , d	induction	53	4x's/wk for 3 wks	100 & 20-80% in petrolatum	18 days	yes	questionable evidence of fatiguing in 2 subjects
Acetylated Lanolin Alcohol								
1	CTFA: Malmstrom, g	21-day cumulative irritancy assay	8	daily for 21 days	undiluted	• • •	• • •	extremely low irritancy potential
2	CTFA: Amerchol , d	induction	53	4x's/wk for 3 wks	10-50% in petrolatum	18 days	yes	evidence of fatiguing in 3 subjects
3	CTFA: Westbrook, f	• • •	• • •	• • •	• • •	• • •	• • •	no reported adverse experiences in 7 yrs of use by workers or customers
4	CTFA: Westbrook, g	• • •	• • •	• • •	• • •	• • •	• • •	no reported adverse experiences in 14 yrs of use by workers or customers

Table 15 (continued). Clinical Adverse Reactions — Clinical Trials

Hydrogenated Lanolin								
1	CTFA: Croda, g	repeated insults	50	every other day for 10 applications	undiluted	10-14 days	yes	no evidence of fatiguing, irritation or sensitization
Hydroxylated Lanolin								
1	CTFA: Amerchol , e	induction	53	4x's/wk for 3 wks	100 & 20-80% in petrolatum	18 days	yes	no visible skin damage
Lanolin Wax								
1	CTFA: Malmstrom, c	21-day cumulative irritancy assay	8	daily for 21 days	undiluted	• • •	• • •	extremely low irritancy potential
2	CTFA: Malmstrom, c	Draize	200	10,3 times/ week	undiluted	not specified	yes	no evidence of sensitization
3	CTFA:	• • •	• • •	• • •	• • •	• • •	• • •	no reported adverse experiences in 22 yrs of use by workers or customers

Comedone Formation (Acnegenic Effect) Kligman and Mills (1972) and Fulton *et al.*, (1976) have studied the acnegenic properties of cosmetics including those containing Lanolin and Lanolin related materials. Their papers described the comedogenic effects of these ingredients. Other ingredients in cosmetics that were indicated as comedogenic included petrolatum, certain vegetable oils, butyl stearate, lauryl alcohol, oleic acid, isopropyl myristate, and sodium lauryl sulfate.

Effect on the Eyes Fraunfelder *et al.*, (1973) attempted to determine whether Lanolin-containing ophthalmic materials, applied topically, could be incorporated into the cornea. It is their conclusion, following a series of provocative animal tests, that no Lanolin-containing ointment was trapped in the cornea unless the surface of the cornea was directly and repeatedly disrupted and abraded. These findings further substantiate the animal toxicity data reported previously in Tables 6-14.

SUMMARY

The results of tests on animals and humans with Acetylated Lanolin, its related cosmetic ingredients, and with numerous cosmetic formulations containing these materials attest to the safety of these ingredients as presently used.

These ingredients, as a group, are used extensively in cosmetics as well as in many other consumer products, and there has been ample opportunity for a large proportion of the population to be exposed to some of these materials. The acute toxicity of these materials is low, and the animal tests for skin sensitization are negative. However, extensive clinical experience indicates that there is a low incidence of sensitivity to these materials among exposed persons. This appears to be mainly due to the Lanolin Alcohols. There was no evidence of photosensitization induced by these ingredients. Comedogenic effects from cosmetics incorporating Lanolin and related materials have been reported.

The safety assessment of these ingredients rests on the information at hand and on the considerable usage in various concentrations in a variety of cosmetic formulations. Additional biological assessment of these ingredients might reasonably be expected to include more extended studies in the areas of percutaneous absorption, cutaneous hypersensitivity, chronic toxicity, and mutagenicity.

CONCLUSIONS

Based on the available animal data and human experience, the Panel concludes that Lanolin and related Lanolin materials described herein are safe for topical application to humans in the present practice of use and concentration.

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CTFA.: Malmstrom Chemicals., e Lanolin Alcohol[1].

CTFA.: Malmstrom Chemicals., f Acetylated Lanolin[1].

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[1]Available upon request. Administrator, Cosmetic Ingredient Review, Suite 212, 1133 15th St., NW, Washington, DC 20005.

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Cosmetic Ingredient Review
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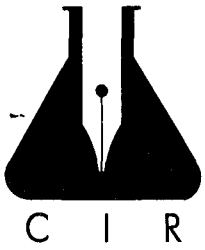

January 10, 2003

Memorandum

To: CIR Expert Panel Members and Liaisons

From. F. Alan Andersen, PhD
Director, CIR

Subject: Re-review of Acetylated Lanolin Alcohol and related compounds

In 1980, the CIR Expert Panel issued a final safety assessment stating that: "based on the available animal data and human experience, it is concluded that lanolin and related lanolin materials described in the report are safe for topical application to humans in the present practice of use and concentration."

Attached is the original 1980 report on Acetylated Lanolin Alcohol and related compounds and a reference list was generated of new information. The "relevant" articles are briefly summarized as appropriate. I noted with some disappointment that the 1953 Sulzberger study on patch test results using lanolin (J. Invest Dermatol 20:33-43) was not included in the original CIR safety assessment! See the 1994 Steel reference.

The Panel should determine if the original conclusion is still valid in light of the new data. If it is not, an amendment should be initiated. If the conclusion is still valid, then the panel can decide to not reopen this report.

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Re-review on the Final Report of The Safety Assessment for Acetylated Lanolin Alcohol and Related Compounds

INTRODUCTION

In 1980 CIR Expert Panel issued a final report stating "Based on the available animal data and human experience, it is concluded that lanolin and related lanolin materials described in the report are safe for topical application to humans in the present practice of use and concentration." The list of ingredients included:

Lanolin	Acetylated Lanolin
Lanolin Oil	Acetylated Lanolin Alcohol
Lanolin Wax	Hydrogenated Lanolin
Lanolin Acid	Hydroxylated Lanolin
Lanolin Alcohol	

The relevant CAS numbers are: Acetylated Lanolin (CAS No. 61788-48-5), Acetylated Lanolin Alcohol (CAS No. 61788-49-6), Hydrogenated Lanolin (CAS No. 8031-44-5), Hydroxylated Lanolin (CAS No. 68424-66-8), Lanolin (anhydrous) (8006-54-0), Lanolin Acid (68424-43-1), Lanolin Alcohol (8027-33-6), Lanolin Oil (8038-43-5;70321-63-0) and Lanolin Wax (68201-49-0).

In the first group of re-reviewed safety assessments in June, 2001, the CIR Expert Panel considered the 1979 Isopropyl Lanolin safety assessment and reached the conclusion to not reopen the report.

Lanolin is the refined derivative of the unctuous fat-like sebaceous secretion of sheep. It consists of highly complex mixture of esters of high molecular weight aliphatic, steroids or triterpenoid alcohols and fatty acids. Acetylated Lanolin is the acetylated ester of Lanolin (q.v.). Acetylated Lanolin Alcohol is the acetyl ester of Lanolin Alcohol (q.v.). Hydrogenated Lanolin is the end product of controlled hydrogenation of Lanolin (q.v.). Hydroxylated Lanolin is the product obtained by controlled hydroxylation of Lanolin (q.v.). Lanolin Acid is a mixture of organic acids obtained from the hydrolysis of

Lanolin (q.v.). Lanolin Alcohol is a mixture of organic alcohols obtained from the hydrolysis of Lanolin (q.v.). Lanolin Oil is the liquid fraction obtained by physical means from whole Lanolin. Lanolin Wax is the semisolid fraction obtained by physical means from whole Lanolin (Pepe et al., 2002).

USE

Lanolin and Lanolin Alcohol functions as an emulsion stabilizer agent. Lanolin, Acetylated Lanolin, Acetylated Lanolin Alcohol, Hydrogenated Lanolin, Lanolin Oil, Lanolin Alcohol and Lanolin Wax functions as a hair conditioning agent. Lanolin, Acetylated Lanolin, Acetylated Lanolin Alcohol, Lanolin Oil and Lanolin Wax functions as a skin-conditioning agents-emollient. Lanolin functions as a skin protectant agent. Lanolin functions as a surfactant-emulsifying agent. Acetylated Lanolin, Acetylated Lanolin Alcohol and Hydrogenated Lanolin functions as a skin-conditioning agent-occlusive. Hydrogenated Lanolin functions as a fragrance ingredient. Hydroxylated Lanolin, Lanolin Wax and Lanolin Alcohol functions as a binder. Hydroxylated Lanolin functions as a skin-conditioning agent-miscellaneous. Lanolin Alcohol and Lanolin Wax functions as a viscosity increasing agents-nonaqueous. Lanolin Acid functions as a surfactant-cleansing agent. Lanolin is an active ingredient is OTC drug products as well (Pepe et al., 2002).

SCOPE AND EXTENT OF USE IN COSMETICS

Data from the 1980 report on frequency of use and concentration of use (circa 1976) is provided in Table 1, along with current frequency of use and total products in each category as provided by the FDA (FDA, 2002). The FDA product categories in the 1980 safety assessment were broad in several cases. For example, we do not know the breakout among the nine current makeup categories that corresponds to the 1980 designation of “makeup preparations.” The broad 1980 categories are noted by an *.

Table 1 Product Formulation Data

Product Category (Number of Formulations in Category - FDA, 2002)	Number of Formulations Containing Ingredient (FDA, 1976)	Historical Concentration of Use (%) (FDA, 1976)	Current Number of Formulations (FDA, 2002)	Current Concentration of Use (%) (CTFA, 2002)
		Acetylated Lanolin		
Baby Lotions, Oils, Powders, and Creams (60)	2	>0 1-1	1	
Bath Oils, Tablets, and Salts (143)	2	>1-5	-	
Eye Lotion (25)	-	-	1	
Eye Makeup Preparations*	5	>0 1-50	-	
Other Eye Makeup Preparations (152)	-	-	5	
Colognes and Toilet Waters (215)	4	>0 1-1	-	
Hair Conditioner (651)	-	-	1	
Hair Preparations (non-coloring)*	3	>0 1-5	-	
Face Powders (305)	-	-	2	
Foundations (324)	-	-	3	
Lipstick (962)	-	-	33	
Other Makeup Preparations (201)	-	-	3	
Makeup preparations*	57	>0 1-50	-	
Shaving Preparations*	6	≤0 1-1		
Skin Cleansing (775)	-	-	14	
Face and Neck (exc shave) (310)	-	-	6	
Body and Hand (exc shave) (840)	-	-	20	
Moisturizing (905)	-	-	35	
Night (200)	-	-	23	
Paste Masks/mud packs (271)	-	-	4	
Other Skin Care Preparations (725)	-	-	8	
Skin Care Preparations*	50	>0 1-25	-	
Suntan Gels, Creams and Liquids (131)	-	-	4	
Total Acetylated Lanolin	**127**		**151**	
		Acetylated Lanolin Alcohol		
Baby Lotions, Oils, Powders, and Creams (60)	-	-	2	
Other Bath Preparations (196)	-	-	1	
Bath Preparations*	74	>1-5	-	
Eye Shadow (576)	-	-	17	
Eye Lotion (25)	-	-	1	
Mascara (195)	-	-	4	
Other Eye Makeup Preparations (152)	-	-	11	
Eye Makeup Preparations*	31	>0 1-10	-	
Colognes and Toilet Waters (684)	16	>0 1-25	5	
Powders (273)	-	-	6	
Other Fragrance Preparations (173)	-	-	3	
Hair Conditioners (651)	-	-	1	
Hair Sprays (aerosol fixatives) (275)	-	-	4	

Product Category (Number of Formulations in Category - FDA, 2002)	Number of Formulations Containing Ingredient (FDA, 1976)	Historical Concentration of Use (%) (FDA, 1976)	Current Number of Formulations (FDA, 2002)	Current Concentration of Use (%) (CTFA, 2002)
		Acetylated Lanolin Alcohol - continued		
Hair Straighteners (63)	-	-	3	
Shampoos (non-coloring) (884)	-	-	1	
Hair Tonics, Dressings, etc (598)	-	-	6	
Other Hair Preparations (277)	-	-	3	
Hair Preparations (non-coloring)*	4	>0 1-5	-	
Other Hair Coloring Preparations (55)	-	-	1	
Blushers (all types) (245)	-	-	9	
Face Powders (305)	-	-	10	
Foundations (324)	-	-	9	
Lipstick (962)	-	-	100	
Makeup Bases (141)	-	-	8	
Rouges (28)	-	-	1	
Other Makeup Preparations (201)	-	-	8	
Makeup Bases (141)	133	>0 1-25	-	
Nail Polish and Enamel Removers (36)	-	-	2	
Manicuring Preparations*	2	≤0 1-5	-	
Bath Soaps and Detergents (421)	-	-	4	
Other Personal Cleanliness Products (308)	-	-	2	
Aftershave Lotion (231)	-	-	2	
Shaving Cream (134)	-	-	3	
Cleansing (775)	-	-	10	
Face and Neck (exc shave) (310)	-	-	4	
Body and Hand (exc shave) (840)	-	-	53	
Moisturizing (905)	-	-	33	
Night (200)	-	-	5	
Paste Masks (mud packs) (271)	-	-	3	
Skin Fresheners (184)	-	-	2	
Other Skin Care Preparations (725)	-	-	14	
Skin Care Preparations*	105	>0 1-50	-	
Suntan Gels, Creams, and Liquids (131)	-	-	6	
Suntan and Sunscreen Preparations*	11	>0 1-50	-	
Total Acetylated Lanolin Alcohol	**376**		**251**	
		Hydrogenated Lanolin		
Eyeliner (548)	-	-	2	
Mascara (195)	-	-	5	
Other Eye Makeup Preparations (152)	-	-	1	
Eye Makeup Preparations*	1	>5-10	-	
Colognes and Toilet Waters (684)	1	>1-5	-	
Other Fragrance Preparations (152)	-	-	1	
Hair Conditioners (651)	-	-	1	

Product Category (Number of Formulations in Category - FDA, 2002)	Number of Formulations Containing Ingredient (FDA, 1976)	Historical Concentration of Use (%) (FDA, 1976)	Current Number of Formulations (FDA, 2002)	Current Concentration of Use (%) (CTFA, 2002)
		Hydrogenated Lanolin - continued		
Rinses (non-coloring) (42)	-	-	1	
Hair Tonics, Dressings, etc (598)	-	-	1	
Foundations (324)	-	-	2	
Lipstick (926)	-	-	30	
Makeup Bases (141)	-	-	1	
Other Makeup Preparations (201)	-	-	1	
Makeup Preparations*	58	>1-25	-	
Nail Creams and Lotions (15)	-	-	1	
Manicuring Preparations*	1	>1-5	-	
Deodorant (underarms) (247)	-	-	1	
Cleansing (775)	-	-	4	
Other Shaving Preparations (63)	-	-	-	
Shaving Preparations*	15	>0 1-1	-	
Face and Neck (exc shaving) (310)	-	-	4	
Body and Hand (exc shaving) (840)	-	-	25	
Moisturizing (905)	-	-	16	
Night (200)	-	-	3	
Paste Masks (mud packs) (271)	-	-	1	
Skin Fresheners (184)	-	-	1	
Other Skin Care Preparations (725)	-	-	4	
Skin Care Preparations*	15	>0 1-10	-	
Suntan Gels, Creams, and Liquids (131)	-	-	3	
Other Suntan Preparations (38)	-	-	2	
Suntan and Sunscreen Preparations*	4	>0 1-5	-	
Total Hydrogenated Lanolin	**95**		**111**	
		Hydroxylated Lanolin		
Eyebrow Pencil (102)	-	-	3	
Eyeliner (548)	-	-	73	
Eye Shadow (576)	-	-	7	
Mascara (195)	-	-	10	
Other Eye Makeup Preparations (152)	-	-	3	
Blushers (all types) (245)	-	-	2	
Face Powders (305)	-	-	3	
Foundations (324)	-	-	2	
Lipstick (962)	-	-	18	
Makeup Bases (141)	-	-	2	
Makeup Fixatives (20)	-	-	1	
Other Makeup Preparations (201)	-	-	1	
Makeup preparations*	7	>5-25	-	
Cleansing (775)	-	-	2	

Product Category (Number of Formulations in Category - FDA, 2002)	Number of Formulations Containing Ingredient (FDA, 1976)	Historical Concentration of Use (%) (FDA, 1976)	Current Number of Formulations (FDA, 2002)	Current Concentration of Use (%) (CTFA, 2002)
		Hydroxylated Lanolin - continued		
Body Hand (exc shaving) (840)	-	-	2	
Moisturizing (905)	-	-	6	
Night (200)	-	-	3	
Skin Care Preparations*	5	>0 1-5	-	
Suntan Gels, Creams, and Liquids	-	-	1	
Total Hydroxylated Lanolin	**12**		**141**	
		Lanolin		
Baby Lotions, Oils, Powders, and Creams (60)	-	-	3	
Bath Oils, Tablets, and Salts (143)	-	-	1	
Other Bath Products (196)	-	-	1	
Eyebrow Pencil (102)	-	-	16	
Eyeliner (548)	-	-	6	
Eye Shadow (576)	-	-	11	
Mascara (195)	-	-	3	
Other Eye Makeup Preparations (152)	-	-	7	
Sachets (28)	-	-	9	
Other Fragrance Preparation (173)	-	-	3	
Hair Conditioners (651)	-	-	30	
Hair Sprays (aerosol fixatives) (275)	-	-	1	
Hair Straightener (63)	-	-	7	
Permanent Waves (207)	-	-	2	
Shampoos (non-coloring) (884)	-	-	5	
Hair Tonics, Dressings, etc (598)	-	-	52	
Wave Sets (53)	-	-	1	
Other Hair Preparations (277)	-	-	1	
Other Hair Coloring Preparations (55)	-	-	2	
Blusher (all types) (245)	-	-	30	
Face Powders (305)	-	-	9	
Foundations (324)	-	-	17	
Lipstick (926)	-	-	126	
Makeup Bases (141)	-	-	5	
Rouges (28)	-	-	4	
Other Makeup Preparations (201)	-	-	10	
Cuticle Softeners (19)	-	-	6	
Nail Creams and Lotions (15)	-	-	1	
Bath Soaps and Detergents (421)	-	-	9	
Deodorants (underarm) (247)	-	-	1	
Other Personal Cleanliness Products (308)	-	-	6	
Aftershave Lotion (231)	-	-	2	
Shaving Cream (134)	-	-	9	

Product Category (Number of Formulations in Category - FDA, 2002)	Number of Formulations Containing Ingredient (FDA, 1976)	Historical Concentration of Use (%) (FDA, 1976)	Current Number of Formulations (FDA, 2002)	Current Concentration of Use (%) (CTFA, 2002)
		Lanolin - continued		
Cleansing (775)	-	-	35	
Depilatories (34)	-	-	2	
Face and Neck (exc shaving) (310)	-	-	19	
Body and Hand (exc shaving) (840)	-	-	68	
Moisturizing (905)	-	-	41	
Night (200)	-	-	23	
Paste Masks (mud packs) (271)	-	-	10	
Other Skin Care Preparations (725)	-	-	40	
Suntan Gels, Creams, and Liquids (131)	-	-	8	
Indoor Tanning Preparations (71)	-	-	5	
Total Lanolin	-		**639**	
		Lanolin Acid		
Eyeliner (548)	-	-	3	
Eye Shadow (576)	-	-	4	
Mascara (195)	-	-	13	
Other Eye Makeup Preparations (152)	-	-	1	
Eye Makeup Preparations*	23	>0 1-10	-	
Hair Conditioners (651)	-	-	4	
Hair Straighteners (63)	-	-	3	
Hair Preparations (non-coloring)*	2	>1-5	-	
Other Hair Coloring Preparations (55)	-	-	1	
Foundations (324)	-	-	2	
Lipstick (962)	-	-	2	
Other Makeup Preparations (201)	-	-	1	
Makeup preparations*	13	>0 1-10	-	
Manicuring preparations*	2	>1-5	-	
Shaving Cream (134)	-	-	3	
Shaving Preparations*	1	>0 1-1	-	
Moisturizing (905)	-	-	4	
Night (200)	-	-	1	
Other Skin Care Preparations (725)	-	-	1	
Skin Care Preparations*	10	>0 1-10	-	
Suntan Gels, Creams, and Liquids (131)	-	-	1	
Total Lanolin Acid	**51**		**44**	
		Lanolin Alcohols		
Baby Lotions, Oils, Powders, and Creams (60)	2	>0 1-5	2	
Bath Oils, Tablets, and Salts (143)	-	-	7	
Bath Preparations*	28	>0 1-10	-	
Eyebrow Pencil (102)	-	-	1	
Eyeliner (548)	-	-	1	

Product Category (Number of Formulations in Category - FDA, 2002)	Number of Formulations Containing Ingredient (FDA, 1976)	Historical Concentration of Use (%) (FDA, 1976)	Current Number of Formulations (FDA, 2002)	Current Concentration of Use (%) (CTFA, 2002)
	Lanolin Alcohols - continued			
Eye Shadow (576)	-	-	27	
Eye makeup Remover (100)	-	-	3	
Mascara (195)	-	-	1	
Other Eye Makeup Preparations (152)	-	-	7	
Eye Makeup Preparations*	120	>0.1-25	-	
Colognes and Toilet Waters (684)	13	>0 1-25	-	
Other Fragrance Preparations (173)	-	-	5	
Hair Conditioners (651)	-	-	8	
Hair Sprays (aerosol fixatives) (275)	-	-	1	
Hair Tonics, Dressings, etc (598)	-	-	2	
Other Hair Preparations (277)	-	-	3	
Hair Preparations (non-coloring)*	15	≤0 1-25	-	
Other Hair Coloring Preparations (55)	-	-	1	
Hair Coloring Preparations*	4	>0 1-1	-	
Blushers (all types) (245)	-	-	16	
Face Powders (305)	-	-	7	
Foundations (324)	-	-	28	
Lipstick (962)	-	-	18	
Makeup Bases (141)	-	-	22	
Makeup Fixatives (20)	-	-	4	
Other Makeup Preparations (201)	-	-	7	
Makeup Preparations*	422	≤0.1-25	-	
Cuticle Softeners (19)	-	-	1	
Bath Soap and Detergents (421)	-	-	3	
Feminine Deodorants (4)	-	-	2	
Other Personal Cleanliness Products (308)	-	-	1	
Personal Cleanliness*	6	≤0 1-5	-	
Aftershave Lotions (231)	-	-	3	
Shaving Cream (134)	-	-	6	
Other Shaving Preparation Products (63)	-	-	6	
Shaving Preparation*	7	>0.1-5	-	
Cleansing (775)	-	-	10	
Depilatories (34)	-	-	1	
Face and Neck (exc shaving) (310)	-	-	9	
Body and Hand (exc shaving) (840)	-	-	52	
Moisturizing (905)	-	-	40	
Night (200)	-	-	19	
Paste Masks (mud packs)	-	-	7	
Other Skin Care Preparations (725)	-	-	10	
Skin Care Preparations*	115	>0.1->50	-	
Suntan Gels, Creams, and Liquids (131)	-	-	12	

Product Category (Number of Formulations in Category - FDA, 2002)	Number of Formulations Containing Ingredient (FDA, 1976)	Historical Concentration of Use (%) (FDA, 1976)	Current Number of Formulations (FDA, 2002)	Current Concentration of Use (%) (CTFA, 2002)
		Lanolin Alcohols - continued		
Indoor Tanning Preparations (71)	-	-	2	
Other Suntan Preparations (38)	-	-	3	
Suntan and Sunscreen Preparations*	6	>0.1-5	-	
Total Lanolin Alcohols	**738**		**337**	
		Lanolin Oil		
Baby Lotions, Oils, Powders and Creams (60)	6	>0 1-5	1	
Bath Oils, Tablets, and Salts (143)	-	-	9	
Bubble Baths (215)	-	-	1	
Other Bath Preparations (196)	-	-	1	
Bath Preparations*	44	≤0 1-25	-	
Eyebrow Pencil (102)	-	-	2	
Eyeliner (548)	-	-	8	
Eye Shadow (576)	-	-	55	
Eye Makeup Remover (100)	-	-	1	
Mascara (195)	-	-	1	
Other Eye Makeup Preparations (152)	-	-	5	
Eye Makeup Preparations*	135	≤0 1-50	-	
Powders (273)	-	-	1	
Other Fragrance Preparations (152)	-	-	4	
Colognes and Toilet Waters*	9	>0 1-5	-	
Hair Conditioners (651)	-	-	5	
Permanent Waves (207)	-	-	1	
Shampoo (non-coloring) (884)	-	-	4	
Hair Bleaches (120)	-	-	11	
Hair Preparations (non-coloring)*	17	≤0 1-5	-	
Hair Colors Sprays (aerosol) (5)	-	-	1	
Hair Coloring Preparations*	9	≤0 1-5	-	
Blushers (all types) (245)	-	-	11	
Face Powders (305)	-	-	12	
Foundations (324)	-	-	10	
Lipstick (962)	-	-	226	
Makeup Bases (141)	-	-	10	
Makeup Fixatives (20)	-	-	1	
Other Makeup Preparations (201)	-	-	8	
Makeup preparations*	887	>0 1->50	-	
Basecoats and Undercoats (44)	-	-	2	
Cuticle Softeners (19)	-	-	2	
Nail Creams and Lotions (15)	-	-	1	
Other Manicuring Preparations (55)	-	-	1	
Manicuring Preparations*	10	>0 1-50	-	
Bath Soaps and Detergents (421)	-	-	9	

Product Category (Number of Formulations in Category - FDA, 2002)	Number of Formulations Containing Ingredient (FDA, 1976)	Historical Concentration of Use (%) (FDA, 1976)	Current Number of Formulations (FDA, 2002)	Current Concentration of Use (%) (CTFA, 2002)
		Lanolin Oil - continued		
Deodorants (underarms) (247)	-	-	1	
Personal Cleanliness*	3	>1-5	-	
Shaving Cream (134)	-	-	4	
Shaving Preparations*	2	>0 1-5	-	
Cleansing (775)	-	-	12	
Face and Neck (exc shaving) (310)	-	-	4	
Body and Hands (exc shaving) (840)	-	-	27	
Moisturizing (905)			37	
Night (200)	-	-	6	
Paste Mask (mud packs) (271)	-	-	1	
Other Skin Care Preparations (725)	-	-	14	
Skin Care Preparations*	218	≤0 1-50	-	
Suntan Gels, Creams, and Liquids (131)	-	-	6	
Indoor Tanning Preparations (71)	-	-	1	
Other Suntan Preparations (38)	-	-	4	
Suntan and Sunscreen Preparations*	16	>0 1-10	-	
Total Lanolin Oil	**1256**		**532**	
		Lanolin Wax		
Eyeliner (548)	-	-	4	
Eye Shadow (576)	-	-	1	
Mascara (195)	-	-	6	
Eye Makeup Preparations*	41	>0 1-25	-	
*Colognes and Toilet Waters**	11	>1-25	-	
Tonics, Dressings, and Other Hair Groom (598)	-	-	4	
Hair Preparations*	3	>0 1-1	-	
Blushers (all types) (245)	-	-	2	
Face Powders (305)	-	-	1	
Foundations (324)	-	-	2	
Lipsticks (962)	-	-	56	
Other Makeup Preparations (201)	-	-	1	
Makeup Preparations*	69	≤0 1-50	-	
*Manicuring Preparations**	1	>1-5	-	
Shaving Preparations*	1	>1-5	-	
Cleansing (775)	-	-	2	
Body and Hand (exc shaving) (840)	-	-	3	
Moisturizing (905)	-	-	6	
Night (200)	-	-	2	
Paste Masks (mud packs) (271)	-	-	1	
Other Skin Care Preparations (725)	-	-	4	
Skin Care Preparations*	9	>0 1-5	-	

Product Category (Number of Formulations in Category - FDA, 2002)	Number of Formulations Containing Ingredient (FDA, 1976)	Historical Concentration of Use (%) (FDA, 1976)	Current Number of Formulations (FDA, 2002)	Current Concentration of Use (%) (CTFA, 2002)
		Lanolin Wax - continued		
Suntan Gels, Creams, and Liquids (131)	-	-	1	
Other Suntan Preparations (38)	-	-	1	
Suntan and Sunscreen Preparations*	2	>10-25	-	
Total Lanolin Wax	**157**		**97**	
		Lanolin, anhydrous		
Baby Lotions, Oils, Powders, etc (60)	9	>0 1-10	-	
Bath Preparations*	4	>0 1-5	-	
Other Eye Makeup Preparations (152)	-	-	1	
Eye Makeup Preparations*	243	≤0 1->50	-	
Powders (273)	-	-	1	
Colognes and Toilet Water*	37	>0 1-10	-	
Hair Conditioners (651)	-	-	3	
Shampoos (non-coloring) (884)	-	-	4	
Hair Tonics, Dressings, etc (598)	-	-	17	
Wave Sets (53)	-	-	1	
Hair Preparations (non-coloring)*	137	≤0 1-50	-	
Other Hair Coloring Preparations (55)	-	-	6	
Hair Coloring Preparations*	7	>0.1->50	-	
Blushers (all types) (245)	-	-	1	
Lipstick (962)	-	-	7	
Other Makeup Preparations (201)	-	-	2	
Makeup Preparations*	1314	≤0 1->50	-	
Manicuring Preparations*	18	>0 1-50	-	
Bath Soaps and Detergents (421)	-	-	2	
Deodorants (underarms) (247)	-	-	3	
Other Personal Cleanliness Products (308)	-	-	1	
Personal Cleanliness*	23	>0 1-5	-	
Shaving Cream (134)	-	-	2	
Shaving Preparations*	31	≤0 1-5	-	
Cleansing (775)	-	-	13	
Depilatories (34)	-	-	1	
Face and Neck (exc shaving) (310)	-	-	7	
Body and Hand (exc shaving) (840)	-	-	20	
Moisturizing (905)	-	-	16	
Night (200)	-	-	9	
Paste Masks (mud packs) (271)	-	-	2	
Other Skin Care Preparations (725)	-	-	11	
Skin Care Preparations*	531	≤0 1->50	-	
Suntan Gels, Creams, and Liquids (131)	-	-	3	
Indoor Tanning Preparations (71)	-	-	2	
Other Suntan Preparations (38)	-	-	1	
Suntan and Sunscreen Preparations*	31	>0 1-50	-	
Total Lanolin, anhydrous	**2384**		**135**	

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~~Lanolin Acid~~
~~Lanolin Alcohol~~
~~Lanolin Wax~~
~~Laureth-4 and -23~~
~~Microcrystalline Wax~~
~~Montan Wax~~
~~Myrtistyl Myristate~~
~~Myristyl Stearate~~
~~Octyl Palmitate~~
~~Octyl Stearate~~
~~Ozokerite~~
~~Paraffin~~
~~PEG-3, -7, -8, -9, -10, -12, -14, and -17 Dimethicone~~
~~PEG-2, -6, -8, -12, -20, -32, -40, -50, -100, and -150 Stearate~~
~~PEG/PPG-3/10, -4/12, -6/11, -8/14, -14/4, -15/15, -16/2, -17/18, -18/18, -19/19, -20/6, -20/15, -20/23, -20/29, -22/23, -22/24, -23/6, -25/25, and -27/27 Dimethicone~~
~~Polyamino Sugar Condensate~~
~~Polybutene~~
~~Polyquaternium-11~~
~~Potassium Cocyl Hydrolyzed Collagen (formerly Potassium-Coco-Hydrolyzed Animal Protein)~~
~~Propane~~
~~Propylene Glycol Stearate and Propylene Glycol Stearate SE~~
~~Prunus Amygdalus Dulcis Oil (formerly Sweet Almond Oil)~~
~~Prunus Amygdalus Dulcis Seed Meal (formerly Almond Meal)~~
~~Rhus Succedanea Fruit Wax~~
~~Sodium Laureth Sulfate~~
~~Sodium Lauryl Sulfate~~
~~Sweet Almond Oil~~
~~Synthetic Beeswax~~
~~Synthetic Wax~~
~~TEA-Cocoyl Hydrolyzed Collagen (formerly TEA-Coco-Hydrolyzed Animal Protein)~~
~~VA/Crotonates Copolymer (formerly VA/CA Copolymer~~)

ACETYLATED LANOLIN, ACETYLATED LANOLIN ALCOHOL, HYDROGENATED LANOLIN, HYDROXYLATED LANOLIN, LANOLIN (ANHYDROUS), LANOLIN ACID, LANOLIN ALCOHOL, LANOLIN OIL, AND LANOLIN WAX

A safety assessment of Acetylated Lanolin, Acetylated Lanolin Alcohol, Hydrogenated Lanolin, Hydroxylated Lanolin, Lanolin (anhydrous), Lanolin Acid, Lanolin Alcohol, Lanolin Oil, and Lanolin Wax was published in 1980 in which the CIR Expert Panel concluded that these ingredients are safe for topical application to humans in the then present practice of use and concentration (Elder 1980). The Panel reviewed new studies (listed at the end of this section), along with updated information regarding types and concentrations of use. The Panel determined to not reopen this safety assessment.

CIR Expert Panel acknowledged that there are current uses of lanolin compounds that may include aerosols. The effects of inhaled aerosols depend on the specific chemical species, the concentration, the duration of exposure, and site of deposition within the respiratory system. Particle size is the most important factor affecting the location of deposition (Jensen and O'Brien 1993). The mean aerodynamic diameter of pump hair spray particles is $\geq 80\ \mu$ and the diameter of anhydrous spray particles is 60 to 80 μ. Typically, less than 1% are below 10 μ, which is the upper limit for respirable particles (Bower 1999). Based on the particle size, lanolin and related compounds would not be respirable in formulation.

The panel also noted that animal derived products may contain residues present in the plant material ingested by the animal. Manufacturers are reminded that cosmetic products containing plant or animal derived ingredients should be formulated to limit the presence of pesticide/heavy metal residues as follows: lead $\leq$10 ppm, arsenic $\leq$3 ppm, mercury $\leq$1 ppm, total PCB/pesticide contamination $\leq$40 ppm with $\leq$10 ppm for any specific residue (Andersen 1998). In addition, the CIR Expert Panel has recently stressed that animal-derived ingredients must be free of detectible pathogens and/or infectious agents (e.g., prions). Suppliers and users of these ingredients should assure that these ingredients are risk-free. Tests to assure the absence of a pathogenic agent in the ingredients, or controls to assure deviation from pathogen-free sources are two approaches that should be considered.

Data from the 1980 report on frequency of use and concentration of use (circa 1976) is provided in Table 1 along with current frequency and concentration of use and total products in each category as provided by the Food and Drug Administration (FDA) and Cosmetic, Toiletry, and Fragrance Association (CTFA) (FDA 2002; CTFA 2003). Although the total number of products containing lanolin and related compounds has decreased since 1980 (5196 in 1980 versus 2438 in 2002), there has been an increase in the variety of product categories containing these chemicals. In the 1980 report, the highest concentrations of these ingredients were in makeup and eye makeup preparations, skin care, suntan and sunscreen preparations, manicuring products, noncoloring hair preparations, and hair-coloring preparations. In 2003, lipsticks and rouges have the highest use concentrations.

Acetylated Lanolin. Acetylated lanolin is the acetylated ester of lanolin (q.v.) and is used as hair conditioning agent and skin conditioning agent, both emollient and occlusive. It was used in 127 cosmetic products in 1976, with the highest concentration range of >0.1% to 50% in eye and other make-up preparations. Currently Acetylated lanolin is used in 151 products at a maximum use concentration of 7% in makeup foundations. Table 1 provides the available use information.

Acetylated Lanolin Alcohol is the acetyl ester of Lanolin Alcohol (q.v.) and is primarily used as a hair conditioning agent and skin-conditioning agent—emollient and occlusive. It was used in 376 cosmetic products in 1976, with the highest concentration

TABLE 1
Historical and current cosmetic product uses and concentrations for Acetylated Lanolin, Acetylated Lanolin Alcohol, Hydrogenated Lanolin, Hydroxylated Lanolin, Lanolin (anhydrous), Lanolin Acid, Lanolin Alcohol, Lanolin Oil, and Lanolin Wax

Product category	1976 uses (Elder 1980)	2002 uses (FDA 2002)	1976 concentrations (Elder 1980) (%)	2003 concentrations (CTFA 2003) (%)
	Acetylated Lanolin			
Baby lotions, oils, powders, and creams	2	1	>0.1–1	3
Bath oils, tablets, and salts	2	—	>1–5	—
Eye lotion	—	1	—	0.6
Eye makeup (other)	5	5	>0.1–50	0.1
Bath soaps and detergents	—	—	—	1
Colognes and toilet waters	4	—	>0.1–1	—
Hair conditioners	3	1	>0.1–5	—
Face powders	—	2	—	0.2–0.3
Foundations	—	3	—	3–7
Lipsticks	—	33	—	5
Makeup (other)	57	3	>0.1–50	0.5–3
Shaving cream		—		—
Shaving soap	6*	—	≤0.1–1*	—
Skin-cleansing creams, lotions, liquids, and pads	—	14	—	0.1
Face and neck skin care preparations	—*	6	—*	1
Body and hand skin care preparations		20		0.5–2
Moisturizers	—	35	—	1
Night skin care preparations	—	23	—	4
Paste masks (mud packs)	—	4	—	1
Skin care preparations (other)	50	8	>0.1–25	3
Suntan gels, creams, and liquids	—	4	—	—
Total uses/ranges for Acetylated Lanolin	127	151	≤0.1–50	0.2–7
	Acetylated Lanolin Alcohol			
Baby lotions, oils, powders, and creams	—	2	—	0.01–16
Bath oils, tablets, and salts		—		—
Bubble baths		—		—
Bath capsules	74*	—	>1–5*	—
Bath preparations (other)		—		—
Eye shadow		17		0.9
Eye lotions		1		—
Mascara		4		0.002
Eyebrow pencils	31*	—	>0.1–10*	0.1
Eyeliners		—		0.4
Eye makeup (other)		11		—
Colognes and toilet waters	16	5	>0.1–25	0.07
Powders	—	6	—	0.01
Fragrance preparations (other)	—	3	—	0.1–0.4
Hair conditioners	—	1	—	—
Hair sprays (aerosol fixatives)	—	4	—	0.01
Hair straighteners	—	3	—	—
Shampoos (noncoloring)	—	1	—	0.02
Hair tonics, dressings, etc.	—	6	—	0.01
Hair preparations (other)	4	3	>0.1–5	—
Hair-coloring preparations (other)	—	1	—	—

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TABLE 1

Historical and current cosmetic product uses and concentrations for Acetylated Lanolin, Acetylated Lanolin Alcohol, Hydrogenated Lanolin, Hydroxylated Lanolin, Lanolin (anhydrous), Lanolin Acid, Lanolin Alcohol, Lanolin Oil, and Lanolin Wax *(Continued)*

Product category	1976 uses (Elder 1980)	2002 uses (FDA 2002)	1976 concentrations (Elder 1980) (%)	2003 concentrations (CTFA 2003) (%)
Blushers (all types)	—	9	—	0.3–0.8
Face powders	—	10	—	0.01–2
Foundations	—	9	—	1–2
Lipstick	—	100	—	2–3
Makeup bases	133	8	>0.1–25	—
Rouges	—	1	—	—
Makeup (other)	—	8	—	0.1–3
Nail polish and enamel removers		2		0.01
Cuticle softeners	2*	—	≤0.1–5*	0.1
Nail polish and enamel removers		—		0.02
Bath soaps and detergents	—	4	—	0.4
Personal cleanliness products (other)	—	2	—	0.1
Aftershave lotion	—	2	—	—
Shaving cream	—	3	—	0.02
Skin-cleansing creams, lotions, liquids, etc.		10		<1
Face and neck skin care preparations		4		0.2–3
Body and hand skin care preparations		53		0.1–6
Moisturizers	105*	33	>0.1–50*	0.5–5
Night skin care preparations		5		0.1
Paste masks (mud packs)		3		0.01
Skin fresheners		2		—
Skin care preparations (other)		14		0.01–0.4
Suntan gels, creams, and liquids	11	6	>0.1–50	—
Total uses/ranges for Acetylated Lanolin Alcohol	376	251	≤0.1–50	0.01–16
	Hydrogenated Lanolin			
Eyeliner		2		1
Mascara	1*	5	>5–10*	—
Eye makeup (other)		1		7–10
Colognes and toilet waters	1	—	>1–5	—
Fragrance preparations (other)	—	1	—	—
Hair conditioners	—	1	—	0.5
Hair dyes and colors	—	—	—	1
Rinses (noncoloring)	—	1	—	—
Hair tonics, dressings, etc.	—	1	—	—
Foundations		2		—
Lipstick		30		3–9
Makeup bases	58*	1	>1–25*	—
Makeup (other)		1		—
Nail creams and lotions	1	1	>1–5	—
Underarm deodorants	—	1	—	—
Skin-cleansing creams, lotions, liquids, etc.	—	4	—	—
Shaving preparations (other)	15	—	>0.1–1	—
Face and neck skin care preparations		4		10
Body and hand skin care preparations		25		2
Moisturizers		16		—

(Continued on next page)

TABLE 1
Historical and current cosmetic product uses and concentrations for Acetylated Lanolin, Acetylated Lanolin Alcohol, Hydrogenated Lanolin, Hydroxylated Lanolin, Lanolin (anhydrous), Lanolin Acid, Lanolin Alcohol, Lanolin Oil, and Lanolin Wax *(Continued)*

Product category	1976 uses (Elder 1980)	2002 uses (FDA 2002)	1976 concentrations (Elder 1980) (%)	2003 concentrations (CTFA 2003) (%)
Night skin care preparations	15*	3	>0.1–10*	—
Paste masks (mud packs)		1		—
Skin fresheners		1		—
Skin care preparations (other)		4		2
Suntan gels, creams, and liquids	4	3	>0.1–5	2
Suntan preparations (other)		2		—
Total uses/ranges for Hydrogenated Lanolin	95	111	>0.1–10	0.5–10
Hydroxylated Lanolin				
Baby products (other)	—	—	—	2
Eyebrow pencils	—	3	—	—
Eyeliner	—	73	—	5–10
Eye shadow	—	7	—	3–10
Mascara	—	10	—	1
Eye makeup (other)	—	3	—	2–11
Blushers (all types)		2		3
Face powders		3		2
Foundations		2		2
Lipstick		18		0.5–28
Makeup bases	7*	2	>5–25*	—
Makeup fixatives		1		—
Leg and body paints		—		10
Makeup (other)		1		4
Skin-cleansing creams, lotions, liquids, etc.		2		—
Body and hand skin care preparations	5*	2	>0.1–5*	—
Moisturizers		6		—
Night skin care preparations		3		—
Suntan gels, creams, and liquids	—	1	—	—
Total uses/ranges for Hydroxylated Lanolin	12	141	>0.1–25	0.5–28
Lanolin				
Baby lotions, oils, powders, and creams	9	3	>0.1–10	0.2–4
Bath oils, tablets, and salts		1		—
Bath products (other)	4*	1	>0.1–5*	—
Eyebrow pencils		16		6–7
Eyeliner		6		10–32
Eye shadow		11		5–9
Mascara	243*	3	≤0.1–>50*	0.1–12
Eye makeup preparations (other)		8		5
Colognes and toilet waters	37	—	>0.1–10	—
Powders	—	1	—	—
Sachets	—	9	—	—
Fragrance preparations (other)	—	3	—	—
Hair conditioners		33		0.2–10
Hair sprays (aerosol fixatives)		1		0.001
Hair straighteners		7		0.3
Permanent waves	137*	2	≤0.1–50*	—

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TABLE 1
Historical and current cosmetic product uses and concentrations for Acetylated Lanolin, Acetylated Lanolin Alcohol, Hydrogenated Lanolin, Hydroxylated Lanolin, Lanolin (anhydrous), Lanolin Acid, Lanolin Alcohol, Lanolin Oil, and Lanolin Wax *(Continued)*

Product category	1976 uses (Elder 1980)	2002 uses (FDA 2002)	1976 concentrations (Elder 1980) (%)	2003 concentrations (CTFA 2003) (%)
Shampoos (noncoloring)		9		0.5
Hair tonics, dressings, etc.		69		0.5–19
Wave sets		2		4
Hair preparations (other noncoloring)		1		5
Hair-coloring preparations (other)	7	8	>1–50	0.4
Blusher (all types)		31		2–9
Face powders		9		1–5
Foundations		17		2–9
Lipsticks	1314*	133	≤0.1–>50*	1–33
Makeup bases		5		0.4–5
Rouges		4		5
Makeup (other)		12		10–17
Cuticle softeners		6		20
Nail creams and lotions	18*	1	>1–50*	0.3–3
Nail polish and enamel		—		15
Bath soaps and detergents		11		0.01–4
Underarm deodorants	23*	4	>0.1–5*	0.2
Personal cleanliness products (other)		7		—
Aftershave lotion	—	2	—	0.5
Shaving cream	31	11	≤0.1–5*	0.5–2
Skin-cleansing creams, lotions, liquids, etc.		48		0.1–3
Depilatories		3		—
Face and neck skin care preparations		26		2–4
Body and hand skin care preparations		88		2–37
Moisturizers	531*	56	≤0.1–>50*	0.2–11
Night skin care preparations		32		0.5–10
Paste masks (mud packs)		12		16
Skin care preparations (other)		51		22
Suntan gels, creams, and liquids		11		—
Indoor tanning preparations	31*	7	>0.1–50*	2
Suntan preparations (other)		1		—
Total uses/ranges for Lanolin	2384	774	≤0.1–>50	0.001–37
		Lanolin Acid		
Eyeliner		3		—
Eye shadow		4		—
Mascara	23*	13	>0.1–10*	3
Eye makeup (other)		1		—
Hair conditioners		4		—
Hair straighteners	2*	3	>1–5*	—
Hair-coloring preparations (other)	—	1	—	—
Foundations		2		—
Lipsticks	13*	2	>0.1–10*	-
Makeup (other)		1		—
Nail care preparations	2	—	>1–5	—
Shaving cream	1	3	>0.1–1	—

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TABLE 1
Historical and current cosmetic product uses and concentrations for Acetylated Lanolin, Acetylated Lanolin Alcohol, Hydrogenated Lanolin, Hydroxylated Lanolin, Lanolin (anhydrous), Lanolin Acid, Lanolin Alcohol, Lanolin Oil, and Lanolin Wax *(Continued)*

Product category	1976 uses (Elder 1980)	2002 uses (FDA 2002)	1976 concentrations (Elder 1980) (%)	2003 concentrations (CTFA 2003) (%)
Moisturizers		4		—
Night skin care preparations	10*	1	>0.1–10*	—
Skin care preparations (other)		1		1
Suntan gels, creams, and liquids	—	1	—	—
Total uses/ranges for Lanolin Acid	51	44	>0.1–10	1–3
Lanolin Alcohol				
Baby lotions, oils, powders, and creams	2	2	>0.1–5	—
Bath oils, tablets, and salts	28	7	>0.1–10	—
Eyebrow pencils		1		—
Eyeliner		1		—
Eye shadow		27		—
Eye makeup remover	120*	3	>0.1–25*	—
Mascara		1		—
Eye makeup (other)		7		—
Colognes and toilet waters	13	—	>0.1–25	—
Fragrance preparations (other)	—	5	—	—
Hair conditioners		8		—
Hair sprays (aerosol fixatives)	15*	1	≤0.1–25*	—
Hair tonics, dressings, etc.		2		—
Hair preparations (other)		3		—
Hair-coloring preparations (other)	4	1	>0.1–1	4
Blushers (all types)		16		—
Face powders		7		—
Foundations		28		—
Lipsticks	422*	18	≤0.1–25*	—
Makeup bases		22		—
Makeup fixatives		4		—
Makeup (other)		7		—
Cuticle softeners	—	1	—	—
Bath soaps and detergents		3		—
Feminine deodorants	6*	2	≤0.1–5*	—
Other personal cleanliness products		1		—
Aftershave lotions		3		—
Shaving cream	7*	6	>0.1–5*	—
Shaving preparation products (other)		6		—
Skin-cleansing creams, lotions, liquids, etc.		10		—
Depilatories		1		—
Face and neck skin care preparations		9		—
Body and hand skin care preparations		52		0.6
Moisturizers	115*	40	>0.1–>50*	—
Night skin care preparations		19		—
Paste masks (mud packs)		7		—
Skin care preparations (other)		10		—
Suntan gels, creams, and liquids		12		—
Indoor tanning preparations	6*	2	>0.1–5*	—

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TABLE 1
Historical and current cosmetic product uses and concentrations for Acetylated Lanolin, Acetylated Lanolin Alcohol, Hydrogenated Lanolin, Hydroxylated Lanolin, Lanolin (anhydrous), Lanolin Acid, Lanolin Alcohol, Lanolin Oil, and Lanolin Wax *(Continued)*

Product category	1976 uses (Elder 1980)	2002 uses (FDA 2002)	1976 concentrations (Elder 1980) (%)	2003 concentrations (CTFA 2003) (%)
Suntan preparations (other)		3		—
Total uses/ranges for Lanolin Alcohols	738	337	≤0.1–>50	0.6–4
Lanolin Oil				
Baby lotions, oils, powders, and creams	6	1	>0.1–5	1
Bath oils, tablets, and salts		9		0.1
Bubble baths	44*	1	≤0.1–25*	—
Bath preparations (other)		1		3
Eyebrow pencils		2		1
Eyeliner		8		2–10
Eye shadow		55		3–6
Eye makeup remover	135*	1	≤0.1–50*	—
Mascara		1		1–3
Eye makeup (other)		5		6
Powders (273)	—	1	—	—
Colognes and toilet waters	9		>0.1–5	
Fragrance preparations	—	4	—	—
Hair conditioners		5		0.4–2
Permanent waves	17*	1	≤0.1–5*	1
Shampoo (noncoloring)		4		0.3
Tonics, dressings, and other hair-grooming aids		—		0.5–2
Hair bleaches	9*	11	≤0.1–5*	—
Hair color sprays (aerosol)		1		0.8
Blushers (all types)		11		2–12
Face powders		12		2
Foundations		10		0.7–2
Lipsticks	887*	226	>0.1–>50*	3–65
Makeup bases		10		0.4
Makeup fixatives		1		—
Makeup (other)		8		20–45
Nail basecoats and undercoats		2		—
Cuticle softeners		2		2
Nail creams and lotions	10*	1	>0.1–50*	5
Nail care preparations (other)		1		3–25
Bath soaps and detergents	3*	9	>1–5*	—
Underarm deodorants		1		—
Shaving cream	2	4	>0.1–5	2
Skin-cleansing creams, lotions, liquids, etc.		12		3
Face and neck skin care preparations		4		3
Body and hand skin care preparations		27		
Moisturizers	218*	37	≤0.1–50*	2
Night skin care preparations		6		1
Paste mask (mud packs)		1		18
Skin care preparations (other)		14		10
Suntan gels, creams, and liquids		6		8
Indoor tanning preparations	16*	1	>0.1–10*	—

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TABLE 1
Historical and current cosmetic product uses and concentrations for Acetylated Lanolin, Acetylated Lanolin Alcohol, Hydrogenated Lanolin, Hydroxylated Lanolin, Lanolin (anhydrous), Lanolin Acid, Lanolin Alcohol, Lanolin Oil, and Lanolin Wax *(Continued)*

Product category	1976 uses (Elder 1980)	2002 uses (FDA 2002)	1976 concentrations (Elder 1980) (%)	2003 concentrations (CTFA 2003) (%)
Other suntan preparations		4		1
Total uses/ranges for Lanolin Oil	1256	532	≤0.1–50	0.1–65
		Lanolin Wax		
Eyeliner		4		4
Eye shadow	41*	1	>0.1–25*	4
Mascara		6		2
Colognes and toilet waters	11		>1–25	
Hair tonics, dressings, etc.	3	4	>0.1–1	—
Blushers (all types)		2		4
Face powders		1		—
Foundations	69*	2	≤0.1–50*	4
Lipsticks		56		20–23
Makeup preparations (other)		1		0.5
Manicuring preparations	1	—	>1–5	—
Shaving preparations	1	—	>1–5	—
Skin-cleansing creams, lotions, liquids, etc.		2		—
Body and hand skin care preparations		3		0.5
Moisturizers		6		—
Night skin care preparations	9*	2	>0.1–5*	—
Paste masks (mud packs)		1		—
Skin care preparations (other)		4		—
Suntan gels, creams, and liquids	2*	1	>10–25*	—
Suntan preparations (other)		1		—
Total uses/ranges for Lanolin Wax	157	97	≤0.1–50*	0.5–25

*In the original safety assessment, information on frequency of use and concentration of use was provided only as a function of broad product categories, e.g., baby products, skin care preparations, etc.

range of >0.1% to 50% in skin care and suntan and sunscreen preparations. Currently Acetylated Lanolin Alcohol is used in 251 products at a maximum use concentration of 16% in baby lotions, oils, etc. Table 1 provides the available use information.

Hydrogenated Lanolin is the end product of controlled hydrogenation of Lanolin (q.v.) which is used as a fragrance ingredient, hair conditioning agent, and skin-conditioning agent—occlusive. It was used in 95 cosmetic products in 1976, with the highest concentration range of >1% to 25% in makeup preparations. Currently Hydrogenated Lanolin is used in 111 products at a maximum use concentration of 10% in face and neck skin care preparations. Table 1 provides the available use information.

Hydroxylated Lanolin is the product obtained by controlled hydroxylation of Lanolin (q.v.) and is used as a binder and skin-conditioning agent—miscellaneous. It was used in 12 cosmetic products in 1976, with the highest concentration range of >5% to 25% in makeup preparations. Currently Hydroxylated lanolin is used in 141 products at a maximum use concentration of 28% in lipsticks. Table 1 provides the available use information.

Lanolin is the refined derivative of the fat-like sebaceous secretion of sheep. It consists of a highly complex mixture of esters of high-molecular-weight aliphatic, steroids or triterpenoid alcohols, and fatty acids. Lanolin functions as an emulsion-stabilizer agent, hair-conditioning agent, skin-conditioning agent, and skin-protectant agent. Lanolin is an active ingredient is over-the-counter (OTC) drug products as well. In 1976 there were 2384 uses (as Lanolin-anhydrous) at a maximum concentration of >50% in several product categories. Currently, Lanolin (as Lanolin and Lanolin-anhydrous) is used in 774 products at a maximum use concentration of 37% in body and hand skin care preparations. Table 1 provides the available use information.

Lanolin Acid is a mixture of organic acids obtained from the hydrolysis of Lanolin (q.v.) and functions as a surfactant-cleansing agent. It was used in 51 cosmetic products in 1976, with the highest concentration range of >1% to 10% in eye

makeup, makeup and skin care preparations. Currently Lanolin Acid is used in 44 products at a maximum use concentration of 3% in mascara. Table 1 provides the available use information.

Lanolin Alcohols are a mixture of organic alcohols obtained from the hydrolysis of Lanolin (q.v.). These are used as emulsion stabilizer agent, hair conditioning agent, binder, and nonaqueous viscosity increasing agents. These were used in 738 cosmetic products in 1976, with the highest concentration range of >0.1% to 50% in skin care preparations. Currently Lanolin Alcohols are used in 337 products at a maximum use concentration of 4% in hair coloring preparations (other). Table 1 provides the available use information.

Lanolin Oil is the liquid fraction obtained by physical means from whole Lanolin which is used as skin-conditioning agent-emollient and hair conditioning agent. It was used in 1256 cosmetic products in 1976, with the highest concentration range of >0.1% to >50% in makeup preparations. Currently Lanolin oil is used in 532 products at a maximum use concentration of 65% in lipsticks. Table 1 provides the available use information.

Lanolin Wax is the semisolid fraction obtained by physical means from whole Lanolin (Pepe et al. 2002). It is used as hair conditioning agent, skin-conditioning agents—emollient, nonaqueous viscosity-increasing agents, and binder. It was used in 157 cosmetic products in 1976, with the highest concentration range of ≤0.1% to 50% in makeup preparations. Currently Lanolin Wax is used in 97 products at a maximum use concentration of 23% in lipsticks. Table 1 provides the available use information.

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~~BENZOPHENONE AND BENZOPHENONE-1, -2, -3, -4, -5, -6, -7, -8, -9, -10, -11, AND -12~~

~~A safety assessment of Benzophenone-1, -3, -4, -5, -9, and -11 was published in 1983 with the conclusion "safe for topical application to humans in the present practices of use and~~

Concentration of Use by FDA Product Category – Lanolin Ingredients

Acetylated Lanolin	Hydroxylated Lanolin	Lanolin Alcohol
Acetylated Lanolin Alcohol	Lanolin	Lanolin Oil
Hydrogenated Lanolin	Lanolin Acid	Lanolin Wax

Ingredient	Product Category	Maximum Concentration of Use
Acetylated Lanolin	Lipstick	7.5-8%
Acetylated Lanolin Alcohol	Eyeliners	0.38%
Acetylated Lanolin Alcohol	Eye shadows	6.3%
Acetylated Lanolin Alcohol	Colognes and toilet waters	0.02%
Acetylated Lanolin Alcohol	Perfumes	0.07%
Acetylated Lanolin Alcohol	Lipstick	1.1%
Acetylated Lanolin Alcohol	Rouges	0.6%
Acetylated Lanolin Alcohol	Cuticle softeners	0.25%
Acetylated Lanolin Alcohol	Nail polish and enamel removers	0.61%
Acetylated Lanolin Alcohol	Body and hand products Not spray	0.1%
Hydrogenated Lanolin	Eye shadows	10.2%
Hydroxylated Lanolin	Eyeliners	10.8%
Hydroxylated Lanolin	Eye shadows	17.5%
Hydroxylated Lanolin	Mascaras	3.5%
Hydroxylated Lanolin	Other eye makeup preparations	11.1%
Lanolin	Baby lotions, oils, and creams	0.2%
Lanolin	Eyebrow pencils	4.4%
Lanolin	Eyeliners	32%
Lanolin	Eye shadows	0.018-9%
Lanolin	Hair conditioners	0.9-10%
Lanolin	Hair sprays Aerosol	1.6%
Lanolin	Tonics, dressings, and other hair grooming aids	0.5-15%
Lanolin	Hair dyes and colors	0.91%
Lanolin	Hair rinses (coloring)	0.5%
Lanolin	Blushers	9%
Lanolin	Face powders	0.0099%
Lanolin	Lipstick	1.3-20.7%
Lanolin	Makeup bases	0.4-6%
Lanolin	Cuticle softeners	1%
Lanolin	Nail creams and lotions	40%
Lanolin	Bath soaps and detergents	0.48%
Lanolin	Body and hand products Not spray	7%
Lanolin	Moisturizing products Not spray	0.5-18%
Lanolin Acid	Hair conditioners	0.04%
Lanolin Acid	Shampoos (noncoloring)	0.05%

Lanolin Acid	Tonics, dressings, and other hair grooming aids Not spray	0.04%
Lanolin Alcohol	Baby lotions, oils, and creams	0.2%
Lanolin Alcohol	Eye shadows	0.8%
Lanolin Alcohol	Eye lotions	0.04%
Lanolin Alcohol	Blushers	0.3%
Lanolin Alcohol	Face powders	0.3%
Lanolin Alcohol	Lipstick	0.36%
Lanolin Alcohol	Other manicuring preparations	5%
Lanolin Alcohol	Other shaving preparations	0.5%
Lanolin Alcohol	Face and neck products Not spray	0.08%
Lanolin Alcohol	Body and hand products Not spray	0.01-1%
Lanolin Alcohol	Moisturizing products Not spray	0.25%
Lanolin Alcohol	Night products Not spray	0.08%
Lanolin Oil	Eye shadows	11.1%
Lanolin Oil	Tonics, dressings, and other hair grooming aids	1%
Lanolin Oil	Other hair preparations (noncoloring) Not spray	2%
Lanolin Oil	Blushers	0.25%
Lanolin Oil	Face powders	0.25%
Lanolin Oil	Lipstick	14.3-47%
Lanolin Oil	Makeup bases	0.35%
Lanolin Oil	Face and neck products Not spray	1-2%
Lanolin Oil	Body and hand products Not spray	1-2%
Lanolin Oil	Moisturizing products Not spray	1%
Lanolin Oil	Other suntan preparation Not spray	1.1%
Lanolin Wax	Shampoos (noncoloring)	0.4%
Lanolin Wax	Tonics, dressings, and other hair grooming aids	0.6-8%
Lanolin Wax	Other hair preparations (noncoloring)	8.5%
Lanolin Wax	Blushers (all types)	0.5%
Lanolin Wax	Lipstick	3.2%
Lanolin Wax	Makeup bases	0.5%
Lanolin Wax	Face and neck products Not spray	0.5%
Lanolin Wax	Body and hand products Not spray	2%

Information collected in 2022

Table prepared: October 28, 2022