

Lanolin

Demythologised

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Introduction

The history of lanolin is both long and fascinating [1,2,3]. Indeed, one of lanolin's many strengths as an active ingredient lies in its extensive record of safe use in skincare applications. Lanolin was known to, and used by, the ancient Greeks and the famous Greek physician, Discorides, in describing its refinement and use, referred to it as "Oesypos" [4]. The name "Lanolin" is modern by comparison having been coined by Otto Braun and used in his patent of 1882 [5]. It is a contraction of the Latin words "lana" and "oleum" so the literal meaning of "lanolin" is "wool oil".

As a consequence of lanolin's long history, perhaps inevitably, many stories and anecdotes have come to be associated with it. Besides being traceable to the times of Greek mythology, lanolin has also acquired its own mythology over the years. Myths often contain elements of fact and fiction in various proportions and this is also the case with the myths surrounding lanolin.

Primarily, lanolin has always been renowned as an excellent emollient. This long-held reputation could have proved to have been an example of a myth, which contained more fiction than fact as it was largely based on subjective assessment and anecdote. However, skin surface profilometry studies have provided objective evidence and confirmed the emollient effect of lanolin and its derivatives [6,7]. Therefore, lanolin emolliency has been elevated out of the realms of myth. More recently, in addition to noting the chemical similarities between lanolin and human skin lipids [TABLE 1], remarkable physical similarities have been observed. Examination by means of cross polarised light microscopy reveals that lanolin contains multilamellar structures, typical of liquid crystals, which are very similar to those found in human skin lipids.

In contrast to lanolin emolliency, most of the other reputations lanolin has acquired over the years have tended to owe less to fact than to fiction. For instance, it was once widely thought that lanolin stimulates hair growth but, unfortunately, there is no known factual basis for such an idea. Another example is the rather unappealing notion that lanolin is obtained from sewage. Thankfully, this is also untrue but the mistake is understandable once it is realised that, during the heyday of the woollen industry in Bradford, the local sewage works produced large quantities of crude woolgrease, which was used in industrial applications.

Table 1 Comparison between the lipid groups present in human stratum corneum and Lanolin.

Lipid Group	Stratum Corneum	Lanolin
Triglycerides	yes	no
Free fatty acids	yes	yes
Free aliphatic alcohols	no	yes
Free sterols	yes	yes
Ceramides	yes	no
n-Alkanes	yes	yes
Squalene	yes	no
Aliphatic alcohol esters	no	yes
Sterol esters	yes	yes
Cholesterol sulphate	yes	no

The purpose of the present paper is to identify and examine the major contemporary "lanolin myths". It is suggested that the following four areas are commonly misunderstood and each will be addressed in turn:

1. The Animal Cruelty Myth
2. The TSE Risk Myth
3. The Allergy Myth
4. The Poor Public Perception Myth

The Animal Cruelty Myth

In recent times there has been a pronounced move away from the use of "animal derived" ingredients. Lanolin is of ovine origin. That simple statement of fact is enough to cause many to leap to the conclusion that obtaining lanolin must involve animal cruelty! In doing so, they make a serious mistake. The raw material from which lanolin is refined is a by-product of the woollen industry. In the processing of wool, which has been shorn from live sheep, the first step is a washing operation known as woolscouring. The greasy coating is removed from the wool during this operation and is then recovered from the spent scouring liquors as "woolgrease" which can then be refined into lanolin.

Therefore, although lanolin is of ovine origin, it is not, strictly speaking, "animal derived" as it is not obtained from slaughtered animals. Rather, it is obtained from sheep, which are specifically kept in order to continue providing wool. So, considered to be "animal harvested". In this, it is akin to materials such as milk, honey, beeswax and, indeed, wool itself.

The idea that there is an animal cruelty issue associated with lanolin is a myth, which has no foundation.

The TSE Risk Myth

The bovine spongiform encephalopathy (BSE) scare, combined with the fact that lanolin is of ovine origin has proved to be a fertile spawning ground for another modern

lanolin myth. The sudden emergence of BSE and the fact that another spongiform encephalopathy disease, scrapie, is endemic in sheep has caused some to worry that there could be a risk of transmission of Spongiform Encephalopathy agents to humans via lanolin.

BSE was first officially recognised in 1986 [8] and reached epidemic proportions in the UK. In contrast, scrapie was first reported in 1732 [9] and is endemic in many countries e.g. Belgium, Canada, Cyprus, Czech Republic, France, Germany, Ghana, Iceland, Norway, Switzerland, UK, USA [10]. As scrapie was a pre-existent disease, it had been extensively studied. This had two consequences. Firstly, the proposal was made that BSE could have arisen from scrapie infected animal feed. Secondly, when guidelines on minimising the risk of transmission of BSE to humans were issued, they contained numerous references to sheep and scrapie [11, 12]. This all tended to create the impression that sheep, scrapie and, by extension, lanolin might pose a threat to human health. That this is not the case becomes apparent as soon as some pertinent questions are answered.

What is the incidence of scrapie?

The term "endemic" is usually applied to scrapie. Contrary to common misperception, this does not imply a high incidence. It simply means "regularly found". The incidence of scrapie is actually astoundingly low. The data in TABLE 2 shows that only approximately 0.001% of British sheep are reported to be infected with scrapie each year.

Table 2 Incidence of scrapie in UK sheep.

Year	No. of sheep (millions) [13]	No. of cases of scrapie [14]	Incidence of infected sheep (%)
1993	29.5	328	0.0011
1994	29.3	234	0.0008
1995	29.5	254	0.0009

The data presented in TABLE 3 compares the UK incidence of scrapie with that of BSE. This helps to put the extremely low incidence of scrapie into its proper perspective.

Table 3 Number of cases of scrapie and BSE in the UK

Year	Scrapie [14]	BSE [15]
1993	328	35,091
1994	234	24,434
1995	254	14,558
1996	453	7,453

On the basis of this data alone, even if BSE in cattle actually presents a risk to human health, the risk from sheep would be expected to be many times smaller.

Does scrapie transmit to humans?

The jury is still out on BSE as this is a new disease and there are many unknowns associated with it. This is not the case with scrapie. Therefore, the "Guidelines for minimising the risk of transmission of agents causing, spongiform encephalopathies via medicinal products: [12] which were issued by the Commission of the European Communities could include the following statement:

"Human beings must have been naturally exposed to scrapie agent for at least 200 years, but despite extensive epidemiological studies, no sign of transmission to humans has been detected."

Since scrapie does not transfer to humans from ovine materials in general (e.g. widespread eating of lamb and even sheep's eyeballs and brains) it follows that there can be no risk of transmission via topically applied lanolin.

Can scrapie agent be present in lanolin?

The literature and guidelines [11,2] define "Category IV Tissues" as being those tissues in which there is no detectable scrapie infectivity. Wool, from which lanolin is obtained, is a Category 1V Tissue. So, even if the incidence of scrapie was high and it could transfer to humans, there would still be no risk of transmission from lanolin because lanolin does not contain scrapie agent.

So, the notion that there is a risk of TSE transmission via lanolin is another lanolin myth, which has no factual basis.

The origin of the lanolin allergy myth.

The lanolin allergy myth stems from the misinterpretation of the results of a perfectly sound dermatological study, which was published by Sulzberger et al in 1953 [19]. In this study, 1048 dermatological patients were tested with lanolin and only 12 positive responses were observed (i.e. 1.15%). The authors stressed that, as all of the subjects had been suffering from proved or presumptive allergic dermatoses, they were "predisposed to acquire multiple specific sensitisations of the skin to eczematous allergens". The same paper also reported that no reactions had been observed in a group of 120 "normal" subjects.

This paper really confirmed the safety of lanolin as it indicated that almost 99% of dermatitis patients were not allergic to lanolin. Unfortunately, the results came to be misinterpreted and the observed incidence of 1.15% was erroneously taken to apply to the general population [20]. The misunderstanding led to many people, including some dermatologists, becoming "psychologically" sensitised to lanolin. Consequently, when the EEC Cosmetics Directive (76/768) was issued in 1976 it included a requirement that products containing lanolin should be labelled accordingly. Reason eventually revealed and the requirement was subsequently repealed (82/368/EEC). However, misperceptions about lanolin allergy had been reinforced and marketing strategists took full advantage by introducing the "Lanolin Free" slogan.

The incidence of lanolin allergy.

A review of the literature [17] has revealed, perhaps not surprisingly, a paucity of studies into lanolin allergy among ordinary, non-dermatitic populations. Besides Sulzberger's 120 ordinary subjects, Kligman has reported [16] patch testing 943 healthy individuals with three different lanolin allergy diagnostics. He also observed no positive reactions.

The vast majority of the numerous lanolin allergy studies to be found in the literature have been conducted on dermatitis patients and the review [17] revealed that various lanolin allergy diagnostics have been used. The data presented in TABLE 4 summarises the numbers of positive patch test results obtained by using each of the diagnostics. It is evident that, even among dermatitis patients, the incidence of allergy to lanolin is very low, especially when lanolin itself is used as the diagnostic.

Table 4 Summary of patch test data, by diagnostic, for dermatological patients

Diagnostic Subjects	No. of Responses	No. of +ve. Responses	% +ve.
Lanolin	37,675	102	0.27
30% Lan. Alcs. in WSP	36,208	691	1.90
Eucerin	15,721	228	1.45
Amerchol L-101	1,651	95	5.81

One recent study is particularly worth considering [21]. This was a "Fifteen year review of lanolin allergy" based on the records of the prestigious St John's Institute of Dermatology in London between 1982 and 1996. During this period, 24,930 patients had been tested with 30% Lanolin Alcohols in White Soft Paraffin (1.70% positive) and 7,367 had been tested with Eucerin (0.60% positive). These findings led the authors to conclude: "Lanolin is perceived to be a notorious sensitiser by physicians and the public. However, our results show that even among a high-risk population i.e. those with recent or active eczema, there is a relatively low and steady rate of sensitivity to this substance"

The potency of lanolin allergy.

It is evident from TABLE 4 that alternatives to lanolin are often used as diagnostics for lanolin allergy. This is because, besides being an infrequent sensitiser, lanolin is also a very weak sensitiser. Dermatologists have been concerned that if they use lanolin to test for lanolin allergy they might get too many false negatives. Therefore, they use more potent alternatives and probably produce false positives instead [22]. According to Kligman [16]: "lanolin must be classified among the most marginal sensitises in all of clinical medicine".

Lanolin allergy and formulations.

The patch test data to be found in the literature has been produced by using either 100% lanolin or alternative lanolin allergy diagnostics which tend to exaggerate the number of positive responses. In practice, lanolin is usually used in formulations

and typical concentrations are in the 2-10% range. This means that the lanolin allergens are considerably diluted so the incidence of allergy to lanolin in lanolin containing formulations would be expected to be lower than that for lanolin itself.

This has been observed by Cronin [23], who, in her paper entitled "Lanolin Dermatitis", commented on "a surprising absence of cosmetic dermatitis in the majority of women in the varicose eczema group." Likewise, Wolf [24], in his paper entitled "The Lanolin Paradox", stated: "Patients with a allergic contact dermatitis to lanolin in a medication applied to a stasis ulcer can nevertheless, use lanolin containing cosmetics and not experience a reaction." He went on to conclude: "This is not surprising since the concentration of wool fat allergens is very low, probably below the threshold needed for eliciting a skin reaction or positive patch test, even in allergic individuals."

If patients who are lanolin sensitive are unlikely to react to lanolin containing cosmetics, the risk to the general population must be extremely small. This is the view of Kligman [16] who wrote: "In a healthy population encountering lanolin in the normal way, the incidence of lanolin allergy is vanishingly small."

Hypoallergenic lanolin

Although the incidence of lanolin allergy among the general population and from cosmetic formulations is extremely low, another eminent American dermatologist, Professor Maibach, made the following astute observation [25]: "The dermatitis patient who cannot tolerate lanolin is at serious disadvantage." Alongside the assertion that lanolin is beneficial in the treatment of dermatitis patients is the recognition that some such patients might not be able to tolerate the high level of lanolin that would maximise the benefit. Therefore, there is a need for a grade of lanolin, which is hypoallergenic.

Such a grade, known as Medilan, has been developed. Clinical trials were conducted in four European hospitals on 149 lanolin sensitive patients and only one positive patch test was observed [26]. This represents a reduction in positive responses, which is in excess of 99%. So, Medilan is hypoallergenic in the true sense of the word.

The Poor Public Perception Myth

Many marketers seem to be very ready to assume that the public has a poor perception of lanolin. However, this conjecture should not be left unchallenged. The fact is that, not so long ago, lanolin seemed to be ubiquitous and highly desirable, Michael Flanders captured something of this in his witty introduction to the Flanders and Swan stage show entitled "At the Drop of a Hat". He said: "Need I introduce at the piano, the well known pianist, composer, linguist: also contains lanolin: Donald Swan."

Since then, of course, many marketers have jumped aboard the "Lanolin Free" products. If there is a poor public perception of lanolin, it is more likely to be due to adverse marketing hype than any substantive issue. However, lanolin continues to be used in vast quantities. In 1979, the Cosmetic Ingredient Review (CIR) identified over 5,000 formulations, which contained lanolin or its derivatives [27]. Even as recently as 1996, it was reported that 2,967 of the cosmetic formulations registered with the FDA contained lanolin or its derivatives [28].

Despite the adverse marketing slogans, it seems that the public does not actually have a poor perception of lanolin at all. The results of a consumer survey commissioned by Rohm and Haas Company [29], though primarily intended to determine the level of consumer knowledge of and concerns about preservatives, nonetheless, provides some interesting evidence which suggest that most consumers do not have concerns about lanolin.

In this survey, a total of 2,000 women were interviewed in five major European countries (France, Germany, Italy, Spain and UK). The results revealed that 53.4% of those interviewed often or always read the labels on cosmetic products and the 35.7% said that there are ingredients, which they do not like to see in the products they buy. When asked to state, without any prompting, which specific ingredients they did not like to see, only four (three in France and one in UK) mentioned lanolin [30]. Therefore, only 0.2% of those interviewed expressed concern about lanolin as a cosmetic ingredient.

It is to be concluded that the idea that the public has a poor perception of lanolin is a modern marketing myth and that the marketers really ought to follow the excellent advice of Professor Kligman [16] who said: "Lanolin is a marvellous material. We should begin to emphasise the benefits; not the risks. The latter are miniscule, the former a still unfolding promise."

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