INTRODUCTION

Vaseline has a long history in cosmetic and pharmaceutical products. It was discovered during the late 1850’s and has since been marketed to the public for an array of uses. Vaseline is also known under the names mineral jelly, petroleum jelly, vaselinum flavum, white/yellow soft paraffin and others.

What is vaseline? From the chemical point of view it is a purified mixture of saturated non-polar long-chain liquid and solid hydrocarbons having the general formula C₁₅H₃₂. It is a semi-solid, amorphous, white, translucent colloid in which a solid wax forms the external phase and a liquid oil forms the internal phase. This composition accounts for its most appreciated qualities – physiological and chemical inertness and stability, as well as a plastic and soft texture that makes it an ideal structure-forming excipient in ointments.

Thanks to this neutral character, absence of taste and odour, it is the number one vehicle for active substances in the pharmaceutical industry. Bearing testimony to this property is the fact that whereas distilled water is routinely used as a vehicle for water soluble substances in allergic contact patch testing, vaseline is similarly used as the vehicle for oil soluble test substances.

That is why vaseline is widely used in such delicate applications as an emollient for non-adherent sterile wound dressings, ophthalmic preparations, as a constituent in dermatological anhydrous ointments and hydrophobic creams and even as a laxative product for oral application.

Among the other attributes of vaselines that make their use in topical applications advantageous, are its moisturising efficiency, water barrier property, water repellence and resistance to being washed off by water. The hydrating properties of vaselines set a standard against which other moisturizers are compared. Thanks to its good oil-holding capacity vaseline prevents leakage or sweating of oils. Thus, it can replace cerasin and ozokerite, where their high melting point is not desirable.

In cosmetic products, vaseline is a central component of many products like barrier creams, body lotions, hair care products, baby care products, hand and skin creams, lip-care sticks and foot creams, to name a few. Most of us use it for chapped lips, dry skin, and as a make-up remover and moisturizer.

SAFETY AND STABILITY

Safety has always been most important when dealing with cosmetic products and pharmaceutical drugs. On the one hand, petroleum jelly has a long history of safe and effective use and is generally considered to be a non-irritant and non-toxic material. On the other hand, isolated cases of allergic hypersensitivity reactions to petroleum jelly have been reported in scientific literature (1-6). So what are the concerns about the safety of petroleum jellies in cosmetics?

Indeed in its pure form, petroleum jelly is one of the safest and well-studied raw materials, but its varied and unregulated manufacturing procedures and refining level can strongly influence the purity of the product.

Let’s take a look at the way the vaselines are produced. There are three main types of vaselines: natural, artificial, and synthetic (1-3):

- Natural petroleum jelly is obtained from the purification of petroleum to remove odours and modify the colour. White and yellow petrolatums are both natural petrolatums. The purification process is extended further in white petrolatum than in yellow petrolatum, so that practically all of the former’s yellow colour is removed. The product obtained has the INCI name “petrolatum” and CAS number 8009-03-08.
Artificial petroleum jelly is a mixture of natural hydrocarbons: microcrystalline wax, paraffin and refined mineral oils. Careful selection of ingredients produces the best results for various applications. Aiglon has been producing its vaselines by this method for more than 30 years. This practice helps us to formulate tailor-made products with desired melting point, viscosity, consistency, oil absorption capacity, fibre length and last, but not the least, texture, gloss and skin feel. Also, our selection of refined pharmaceutical ingredients allows a product that offers all guarantees of purity and safety to the final consumer.

Finally, synthetic petrolatum is made from synthetic hydrocarbons obtained by carbon monoxide hydrogenation. In cosmetic and pharmaceutical products mainly the first two type of vaselines are used – natural and artificial. Impurities that might influence safety and stability of petroleum jelly are: polycyclic aromatic hydrocarbons and other unsaturated hydrocarbons.

Polycyclic Aromatic Hydrocarbons
Polycyclic aromatic hydrocarbons (PAHs), also known as poly-aromatic hydrocarbons or polynuclear aromatic hydrocarbons, are chemical compounds that consist of fused aromatic rings and do not contain heteroatoms or carry substituents. As a pollutant, they are of concern because some compounds have been identified as Carcinogenic, Mutagenic, and toxic for Reproduction (CMR) (8).

Also, the PAHs appear to be an allergenic component of petroleum jelly (1-3) and after analysis of the allergenic fraction of yellow petrolatum the most likely allergens were determined to be Phenanthrene derivatives (2).

As the quantity of these impurities is largely a function of the source of petroleum jelly and the production process, it appears that there is often a marked variation in allergenicity between brands of petrolatum produced by different manufacturers (2). Thus, because of the extension of the purification process, white petroleum jelly contains fewer sensitizing impurities than yellow (2).

Unsaturated Hydrocarbons
The second group of impurities that might potentially be present are unsaturated hydrocarbons, which tend to oxidise on exposure to light and oxygen and to interact with certain acids and alkalis. This results in numerous negative effects:

- Loss of neutral character – neutral character is one of the most appreciated qualities of petroleum jelly that is usually taken for granted and makes it a vehicle of choice for sensitive cosmetic and pharmaceutical ingredients. Exposed to oxidation processes in formulation, the active substance is less protected and its activity might strongly decrease during the storage period. Moreover, the oxidation products initiate a chain of uncontrolled reactions in the final formulation that might result in worst case in formation of new allergens – the so-called “compound allergy”. Therefore it is essential to control the unsaturation level of petroleum jelly to ensure its chemically neutral behaviour in formulation and upon application.

- Reduced shelf life – oxidation results in discolouration of petroleum jelly and produces an unpleasant odour. That is why it is essential to minimize the presence of unsaturated substances resulting from the production process and to control this parameter with suitable test methods.

REGULATORY ISSUES AND PURITY CONTROL OF PETROLEUM JELLY: A CONTROVERSIAL SITUATION

There is no doubt that particular attention should be paid to the verification of impurities so as to keep them at an acceptable minimum level.

In the USA petroleum jelly for food packaging or drugs has to meet the impurity restrictions for PAHs (21 CFR 178, 21 CFR 172.880) required by the Food and Drug Administration. But surprisingly no requirement for refinement applies for the use of petroleum jellies in personal care.

The cosmetic industry controls the purity of its own products, as there are no federal standards for ingredients purity. While it seems likely that some manufacturers buy petroleum jellies certified by a non-governmental organization called United States Pharmacopoeia, it is equally likely that many do not. Consumers and government officials have no way of knowing.

In Europe petroleum jellies for the pharmaceutical industry should conform to requirements of European Pharmacopoeia. As far as cosmetic manufacturers are concerned, they must ensure that any cosmetic product launched on the market fulfills the requirements of EU Cosmetic Directive (76/768/EEC), which lists the substances authorized or banned for use in cosmetic products. Its second and third annexes list substances that must not be used owing to their toxicity, and substances that can be used only in specified circumstances. Thus category 2 carcinogens are not allowed for use in cosmetic products.

Products with the INCI name “petrolatum” fall under this category, as, since 2004, they are listed as a probable human carcinogen (Category 2) in the European Union’s Dangerous Substances Directive with the following sentence – Note N: “The classification as a carcinogen need not apply if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen”. This classification is due to potential PAH presence in petroleum jelly. That means that over and above the compliance to the European Pharmacopoeia, suppliers of “petrolatums” have to give absolute assurance that their product is not a carcinogen. According to the interpretation of COLIPA (European Cosmetic, Toiletry and Perfumery Association) there are two possibilities to achieve this objective:

- First option: “The supplier will guarantee that the full refining history of the raw materials for the production of Petrolatum is known”. COLIPA suggests that suppliers might include the following statement in the Certificate of Analysis: “It is hereby guaranteed that the product is produced from substances that are not carcinogens according to the Dangerous Substances Directive and of which the full refining history is known.” This suggestion leaves many questions unanswered as there is no clear explanation about how exactly refining history should be proved.

- Second option: “If the product has been manufactured of components from substances from the two non-carcinogenic groups “Highly Refined Base Oils” and “Paraffin and Hydrocarbon Waxes” the supplier may apply for a new INCI-name for its trade name material as a mixture, instead of the single ingredient Petrolatum” (9).

This is the case of Aiglon’s vaselines, which are not considered as “petrolatums” as they are produced by blending three pharmaceutical quality raw materials each having their own CAS number and INCI:

- Paraffin CAS No. 8002-74-2
- Microcrystalline Waxy CAS No. 64742-60-7
- Mineral Oil CAS No. 8042-47-5

Thanks to this our products are not concerned by the European Union’s Dangerous Substances Directive and by REACH legislation.

Besides the ambiguous situation of petrolatums listed as potential carcinogens, European Cosmetic Directive does not fix restrictions for impurities for PAHs. Suppliers of petroleum jellies offer cosmetic manufacturers petroleum jellies that conform to EP pharmacopoeia.

Let’s take a closer look at the requirements of the Pharmacopoeia regarding purity standards for petroleum jellies. Until 2003, quality control for petroleum jelly used in the pharmaceutical industry was regulated by Pharmacopoeias specific to each European country, such as BP (British Pharmacopoeia), DAB (German Pharmacopoeia), Codex (French Pharmacopoeia) and others.

French Pharmacopoeia Codex was at that time much stricter than all other pharmacopoeias in terms of the allowed...
impurities level in petroleum jellies, particularly on the unsaturated substances (Test of carbonisable substances by absorbance measured at a determinate wavelength – Vaseline is treated by 95% sulphuric acid; after formation of the sultonates, they are quantified by UV spectrophotometry; the unsaturation level is measured by optical density). Due to these test requirements most of BP, USP, DAB vaselines could not pass purity tests; requested by the Codex monograph.

Within the context of the European Union, in order to standardise the specifications, the European Pharmacopoeia has been drawn up and since July 2003 replaced Pharmacopoeias of each European country. Surprisingly its requirements are much less strict than those of Codex – the test on unsaturated matter figures nowhere and the maximum allowed level of PAHs is increased up to 300 ppm!

According to tests performed by Aiglon, the unsaturation level of non-Codex vaselines (EP, USP) is in average five times higher than that of Codex vaselines. From that point of view it seems logical that the competent authorities have warned to mention in the product definition that EP Vaselines are not recommended for oral use. This restriction does not appear in the French Codex monograph and today only Codex vaselines are officially allowed for oral use.

**VASELINE AND THE “GREEN REVOLUTION”**

Vaseline is one of the best characterized and clinically tested ingredients. However ingredients of mineral origin have been widely criticized in the last few years, mainly because they didn’t fit into the new trend of “natural” cosmetics that started a while back, but got some momentum in the mid to late nineties.

No universally recognized definition exists for a natural cosmetic product. Many dictionaries tend to have similar definitions of the term “natural”. In general it means “existing in, produced by, or derived from nature”. Crude oil and its components – including mineral wax and mineral oil – exist in nature, so they are natural by definition. It is also known that hydrocarbons of paraffinic structure exist naturally in human skin (9). Vaseline is as natural as natural can get! While it is 100% natural and was used long before the idea of the chemical industry was conceived, it is not “Green”. Despite its usefulness in many cosmetics, petroleum derivatives are frequently thought of as undesirable ingredients. Customers nowadays read cosmetic labels and an ingredient with the INCI name “petrolatum” is more and more often in the “no go” zone. Cosmetic consumers’ forums abound with messages where “petrolatum” is mentioned as a carcinogen and placed on a cosmetic ingredients “black list”.

In view of this situation, Aiglon’s French vaselines offer competitive advantages for cosmetic manufacturers, as they enable the use of all petroleum jellies’ advantages without having “petrolatum” mentioned on the label. In addition to this, Aiglon developed two synthetic-based vaselines without mineral oil as an answer to “Mineral Oil-Free” concepts.

**LAST, BUT NOT THE LEAST: TEXTURE AND SENSORY PROPERTIES**

In cosmetic and pharmaceutical applications, texture is an important attribute that is sensed by the hands, lips, skin, hair and scalp. It encompasses the product’s feel, such as the hardness of lipstick or spreadability of pharmaceutical ointment. It also encompasses that product’s effectiveness, such as the ability of emollient to impart gloss to lips or hair. Texture affects rheological properties involved in processing and handling, and influences buying habits and consumer acceptance of products.

For example ductility is an important textural property of vaseline; it is the ability of the material to form filaments on extension – different vaseline grades behave differently in manufacturing processes such as extrusion, filling, and also when a consumer removes a sample from container.

The method of fabrication by mixing allows the fine-tuning of the crystalline structure of vaseline and produces a variety of vaseline grades with a wide range of properties, including sensorial parameters such as unctuousness, gloss, fibrous structure, absorption and spreadability. The texture of premium quality vaselines can be evaluated at the micro-level: when viewed under a microscope at a magnification of 200, only small needle-like crystals can be seen. There are no granular or coarse crystals.

What is the first idea that crosses one’s mind when vaseline is mentioned? Most people would imagine an inelegant, greasy product which is incapable of providing a soft, cushiony skin feel and a silky, powder after-feel.

A production method by mixing allows us to go far above “classic” vaselines – we are able to produce high-gloss products having a soft, cushiony skin feel and a silky, powder after-feel. Thanks to their excellent spreadability and low tack they can be used as emollients for elegant cosmetic and pharmaceutical application!

**CONCLUSION**

The safety of cosmetics is regulated in Europe by the 1986 EU Cosmetic Directive, but proof of it remains the responsibility of cosmetic manufacturers or their distributors. That is why, taking consumer safety as the overriding objective, cosmetic manufacturers often fix for themselves internal ingredient purity standards that exceed by far the requirements laid down in the legislation. Despite the fact that European Pharmacopoeia has set lower purity standards for petroleum jellies since 2003, today many cosmetic producers continue to choose products that meet the requirements of French Pharmacopoeia Codex.

Aiglon has been specialized for decades in manufacturing of Codex petroleum jellies. We intend to continue with these high standards to maintain maximal safety guarantees and offer our customers pure, stable and impeccably white products. We emphasize the fact that all our products are produced from highly refined raw materials and do not fall under the category of “petrolatums”, hence they are not considered by European Directive of Dangerous Substances.

Petroleum jelly has a long history of safe and effective use. Despite a “green” trend and a move to plant-based cosmetics, vaselines are still being used in pharmaceutical products treating the very worst of skin conditions, and in cosmetic products for such diverse applications as face and body moisturisers, shaving products, bath products, shampoos and deodorants. Fashion comes and goes, but as formulators continue to develop new products, petroleum jelly will attract their attention time and time again, as it is an incomparable ingredient in view of stability, barrier function and texture.

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