The purity that makes the difference

Petroleum Jellies
Petroleum Jelly

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Unknowingly, everyone uses petroleum jelly daily.

Though it has existed for over one hundred years, petroleum jelly is still poorly known. Yet it is very much present in cosmetic and pharmaceutical products.

The aim of this brochure is to reveal its multiple characteristics and the different manufacturing procedures.

The Aiglon group is a petroleum jelly specialist; principally manufacturing Codex petroleum jellies which are the world’s purest.

Petroleum jelly is present in many cosmetic products: face and body creams, hair removal creams, body lotions, lipstick, deodorant, make-up remover…

Well-known medications also contain petroleum jelly: creams and ointments for treating burns, dermatitis, urticaea, skin irritations, rashes, chapping, moisturisers, ophthalmic ointments, gauzes… The only petroleum jellies authorised for oral use, Aiglon petroleum jellies are a base for ingested laxatives. Petroleum jelly is also used in veterinary treatments: salves, vaccines…

Other types of petroleum jellies are used in modelling clays, candles, polishes and other technical products…

Multiple uses

Excipient: the carrier for active ingredients

Petroleum jelly is the n°1 excipient in pharmaceutical creams and ointments. Its chemical inertness and neutrality are essential. Petroleum jelly respects the therapeutic characteristics (active ingredients) of medications. Its stability and its immutability guarantee the preservation and the constancy of these active ingredients.

Active ingredient: petroleum jelly in itself has protective, healing and moisturising attributes

It is used in the treatment of dry skins, skin disorders, and the acceleration of wound healing…

Emollient: petroleum jelly softens the skin

Its softening characteristic is important for preventing dehydration (moisturising creams for example). It is the reference for moisturising.

Lubricant: highly valued by sportsmen and women

For boxing, rugby, and all contact sports, it is healing and relaxing. It is often used by masseurs.

A pleasant texture

For cosmetics, where petroleum jelly is in direct contact with the skin, hands and lips, the texture is essential. It improves the visual aspect, the floccosity, the touch, the spreadability of the product, and also the capacity to add shine to hair or lips.
1. **Codex petroleum jellies are the purest in the world**

   The purity of petroleum jellies is defined by pharmacopoeias. In 2003, the pharmacopoeias of different European countries were standardised. However, the requirement level of the French Codex Pharmacopoeia is substantially higher than the current European Pharmacopoeia. The Codex petroleum jellies manufactured by Aiglon maintain this level of quality. The actual test results are significantly higher than the standards in force (US Pharmacopoeia, European Pharmacopoeia...).

   Read the tests results page 28

2. **They have no impact on the formation of blackheads**

   A clinical study showed that Aiglon petroleum jellies are non-comedogenic (do not cause comedones or blackheads).

   Read the non-comedogenic test page 33

3. **They have natural cosmetic virtues**

   Test results show that Aiglon petroleum jellies have inherent cosmetic qualities. Volunteers reported that their skin was thoroughly moisturised (90.5%), soft and supple (80.3%), smooth and elastic (71.4%).

   Explanation: petroleum jelly is the renowned reference for moisturising, and it is commonly accepted that good moisturisation is a defence against wrinkles, skin sagging and premature aging.

4. **They are neutral and unalterable**

   Petroleum jelly has the consistency and creaminess of fats of vegetal or animal origin, but has the considerable advantage over these as being absolutely stable, neutral and unalterable. It does not go rancid and is odourless and tasteless.

   The opposition between a “good natural” and a “bad chemical” or between a “natural product” and a “synthetic product” is unfounded.

   NB: Perfectly tolerated on the skin, petroleum jellies are abundantly present in cosmetic formulations in a wide variety of concentrations ranging from 1 to 95%. In contrast, for cosmetic formulations that are vegetal oil based, often allergenic and comedogenic, it is recommended not to exceed the threshold of 5% of vegetal oil in the formula.

5. **They retain their moisturising capacity for a long time**

   Unlike vegetal and mineral oils, petroleum jelly retains its moisturising capacity even in emulsions. A study was done on three water-in-oil emulsions made respectively from petroleum jelly, paraffin oil and sweet almond oil.

   It was shown that in the emulsions based on paraffin oil and sweet almond oil there was important water loss during the first thirty minutes, whereas for petroleum jelly-based emulsions the water loss is minimal or almost inexistent.

6. **They are not “petrolatum”**

   Petroleum jellies obtained from blending highly hydrogenated products, as is the case for Aiglon petroleum jellies, are not “petrolatum.” Their high degree of refinement confers an unequalled purity.

   Aiglon petroleum jellies, being a blend, are defined by three INCI names: “Paraffinum Liquidum,” “Cera Microcristallina” and “Paraffin.” In contrast to “petrolatum,” Aiglon petroleum jellies do not appear in the CMR (carcinogenic, mutagenic and toxic for reproduction) product list of the Cosmetics Directive, nor do they appear in the CLP regulation (Classification, Labelling and Packaging).

The petroleum jellies made by Aiglon are of unequalled purity, with specific characteristics recognised by specialists, the market and consumers.
Aiglon’s dexterity

Aiglon mainly produces petroleum jellies that comply with the French Codex Pharmacopoeia requirements. Codex is a standard whose requirements are highly superior to all the other pharmacopoeias, including the European Pharmacopoeia.

Unmatched purity and stability

Aiglon’s petroleum jellies have superior purity and stability as Aiglon uses only pharmaceutical raw materials that have been severely hydrogenated (mineral oils, microcrystalline waxes and paraffin). The test for determining carbonisable substances, which measures the percentage of the undesirable unsaturated substances, only exists in the French Codex Pharmacopoeia. Only Codex petroleum jellies are authorised for an oral use.

The mastery of petroleum jelly quality

The flexibility of the choice of raw materials allows a control of the highest precision of the physical qualities essential to petroleum jelly:

- the physical characteristics: the drop melting point (temperature at which the petroleum jelly becomes liquid), the viscosity, the consistency, the capacity to absorb oil, etc.
- their texture and their sensorial qualities: fibrosity, spreadability, creaminess, shininess, adherence...

Aiglon innovates

The latest major invention (registered patent): since 2013 Aiglon manufactures mineral-oil-free petroleum jelly.

In the same way that the quality of a wine depends on the quality of the grapes, the type of soil, the geographic situation and the countless production methods, the quality of petroleum jellies, their texture, and above all, their purity, can vary considerably depending on the raw materials used, the different production methods, and the system of quality management.

Conception - Production

The petroleum jellies are manufactured with three components: oil, wax, paraffin.

Aiglon petroleum jellies are made from an intimate blend of these ingredients, which make it possible to obtain the purest petroleum jellies.

Aiglon’s “dexterity” consists of:

- Identifying with the customer, the type of petroleum jelly needed, and for what purpose
- Composing the most ideal petroleum jelly formula:
  - Selecting the components: multitude of oils, waxes, and paraffin exist, all with different performances
  - Determining the proportions of each component
- Defining the conditions of mixing: temperature, centrifuge velocity, duration of blending, etc.

Aiglon, a dedicated specialist of petroleum jelly, is able to manufacture from a few kilos to dozens of tons.
Petroleum jelly is a special case in the raw material category for pharmaceutical use. It often plays the role of a neutral excipient in creams and ointments, but also has the role of active ingredient (API) with its protective, healing, and moisturising attributes.

A specialisation in pharmaceutical and cosmetic markets

Unlike other manufacturers of petroleum jellies with varied fields of application, AIGLON has chosen to specialise in pharmaceutical and cosmetic applications. Consideration of the purity of Aiglon petroleum jellies, customers commonly describe them as active ingredients in their marketing authorisation files. The GMP certification was the logical step for Aiglon.

GMP, a guarantee of security

Manufacturing of all drugs is subject to a marketing authorisation. The use of petroleum jelly as an active ingredient (API) requires the pharmaceutical laboratories to declare the manufacturers name in the marketing authorisation application.

ISO 9001: 2008

CE marking

The Aiglon group meets the criteria of quality in all departments, whether this is purchasing, order processing, production, analysis or expeditions. All the raw materials and finished products are identified, analysed according to written procedures and monitored by quality trained staff.

GMP Certification

Manufacturing of the APIs which compose the drugs is, in itself, subject to obtaining GMP certification. The European Good Manufacturing Practice Part II for active substances for pharmaceutical use – issued by the regulatory authorities.

GMP implies hygiene practices and organisation at all levels. Their implementation requires significant financial and human resources from the company.

European GMP Part II certification: superior to all other GMP certifications

The European GMP Part II certification is the only enforceable regulatory referential for inspections of pharmaceutical establishments by the competent authorities. Other ‘good manufacturing practice’ alternative references, created by membership organisations, are much less restrictive and do not give the right to sell petroleum jellies as APIs.

ISO 9001: 2008

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In France, the competent authority is ANSM (National Agency for the Security of Medicines and Health Products), previously AFSSAPS (French Agency for the Sanitary Security of Health Products). This agency delivers the GMP certificate and conducts regular inspections to validate the certification. Today, AIGLON is the only manufacturer of petroleum jelly with the European GMP Part II certification for APIs.
The Aiglon Group

The French petroleum jelly specialist

The Aiglon group is the only French specialist for the manufacturing of petroleum jellies and waxes, gels, oils and technical products. The high technicality and constant research for innovation has earned world renown. The quality standards are situated above the requirements of the main market standards.
The permanent investment efforts and the high level of the research team make Aiglon a leading company in its sector, resolutely turned towards the future.
The group consists of four companies: Aiglon and Synteal for petroleum jellies, oils and gels, Dioveva for vegetal materials, Civetea for industrial waxes.

Petroleum jelly, leading product
Petroleum jelly is a well used ingredient in the pharmaceutical and cosmetic industries. Aiglon, the only manufacturer in France, offers the widest range of petroleum jellies on the market.

A successful diversification
Though petroleum jelly remains the primary business, the group also manufactures and commercialises paraffin, wax, gels, oils and different technical products.

Pharmacology and cosmetology, key sectors
Aiglon sells its products to the largest French and international companies of pharmacy and cosmetology.

A lasting family business, in constant development
The Aiglon group is a constantly growing family business, armed for the future.

The president, Jean-Jacques Puyoo, has built up a management team that combines members of the family with professionals of the industry.

A winning strategy of external growth and investment
To consolidate the growth of the Aiglon group across all markets, Jean-Jacques Puyoo continues with financial investments, and relies on a skilled and versatile team who undertakes and meets challenges.

A high quality service
The quality of service is unmatched:
- Anticipation and analysis of customer needs
- High quality technicality
- Help for implementation, customised supply chain
- Tailor-made solutions
- Quality monitoring, after-sales...

20% of sales are achieved in export
The success story of a family group

Since the takeover of the company in 1974, Jean-Jacques Puyoo has advanced Aiglon and turned it into an industrial company of international renown. Extremely solid and totally independent financially, Aiglon regularly invests in new equipment and knows how to anticipate market trends.

1901
Creation of Raffinerie de Corps Gras « AIGLON » in Aubervilliers. The company was quickly on the forefront for manufacturing oils, greases and petroleum jellies for various applications (cars, industrial motors, electric industry, textile industry, cement, printing, small metallurgy, pharmaceutical and veterinary products...). In 1921 Aiglon became « La Raffinerie de Corps Gras de l'Aiglon S.A. (S.A.R.C.G.A.) »

1974
The Puyoo family takes over the company. At the time a Spanish teacher in Dax high school, in 1963 Jean-Jacques Puyoo decided to follow in the footsteps of his father who was the co-founder of the HAFA group (motor oils). He created Paneurafric/Redex (automobile products), directed the HAFA oils and bought S.A.R.C.G.A. in 1970. Assisted by his wife Monique (deceased in 2009), he boosted the petroleum jelly activity, manufactured according to the requirements of the French Codex Pharmacopeia, much stricter than the other Pharmacopoeias (EP, BP, USP, DAB...). In 1986 the company added the brand Roxchimie to its range.

1990
Construction of Aiglon’s new factory in Precy-sur-Oise. Rapidly expanding, the company outgrew the site in Aubervilliers and moved to Precy-sur-Oise. With a ground surface of 35 000m² for 12 000m² covered surface, this site allowed for more growth.

1992-1995
Jean-Jacques Puyoo gave up the brands HAFA, Redex and Sels-Schmeder, and merged the enterprises Paneurafric and Roxchimie with S.A.R.C.G.A. This entity took the name Aiglon S.A.

1997
Aiglon obtained its first certification ISO 9002-94.

2003
Aiglon created its first sister company, Synteal, following the takeover of the petroleum jelly activity of the Group Total-Elf. Certification ISO 9001:2000 The Aiglon/Synteal group became the only manufacturer of petroleum jellies in France. Their Codex quality is recognised all over the world by the pharmaceutical and cosmetic industries.

2006
Aiglon created its second sister company, Civeta. This followed the takeover of the civil engineering technical waxes from the Total Group.

2008
The Aiglon group obtained GMP certification (Good Manufacturing Practice).

2009
The group built a new manufacturing line and modernised the laboratory. The production capacity increased to 20 000 tonnes allowing a guarantee of flexibility and security of supply. At the same time, the old laboratory and petroleum jelly unit were completely renovated. The entire operation represented an investment of 4 M€.

2010

2011
GMP certificate renewed.

2013
1 million euros invested in the factory.

2014
Acquisition of Biopress, producer of Bio vegetal oils.

The future
The future of the Aiglon group focuses around two strategic priority axes: acquisitions in France, and reinforcement of international development.

Puyoo Prize
An endowment fund with the prize
Jean-Jacques and Monique Puyoo, who assisted Jean-Jacques Puyoo for more than 40 years, will reward a special talent in the pharmacology and cosmetic fields.

Jean-Jacques Puyoo, founding president of Aiglon

Monique Puyoo

2003
12
The laboratory: innovation and research

After more than one hundred years in this so specific profession, Aiglon has acquired an incomparable expertise and know-how.

Two chemical engineers are in charge of the laboratory

The laboratory is equipped with scientific material at the cutting edge of technology: gas phase chromatograph coupled with a mass spectrometer, Brookfield viscometer, capillary viscometers, automatic densimeter, penetrometer, Mettler drop melting point, UV spectrophotometer, IR spectrophotometer…

The laboratory’s activity is organised around two complementary axes:

Assurance and quality control

The laboratory assures quality control and traceability all through the production procedure, according to the GMP standards.

Research and Development

Aiglon’s scientific team is developing the largest petroleum jelly range on the market. More than 50 standard products are available from "classic" grades to emollients with a melting texture that spreads easily and adds a feeling of comfort and softness.

This large range of petroleum jellies is consistent with their multiple applications: a lip balm does not require the same petroleum jelly as a pharmaceutical ointment or a massage cream.

Always attentive to customers’ wishes, the Aiglon teams innovate and create new textures: made-to-measure petroleum jellies, a range of transparent gelifiers (Transgels), waxes for special applications.

If you dream of a personalised product just for you, Aiglon will fulfil this.
Advanced production equipment

In the last few years, Aiglon has invested 4 million Euros in renovating the old production unit and installing two new production units.

Each production unit is entirely automated. Stocking the raw materials in molten form significantly shortens the production time and improves the final aspect of the product. The capacity of the 5 pharmaceutical petroleum jelly blenders offers a large choice of batches from 2 to 20 tonnes.

The products are available in various packaging, from 2 kg boxes to 20 tonne bulk tankers, or the intermediary 175kg drums.

Storage figures

The site occupies 35000 m² ground space, of which 12000 m² is covered factory space. The storage capacities for the raw materials and finished products guarantee a large flexibility for delivery and supply.
The Aiglon team

The members of the Aiglon team put all their resources at the service of customers. They speak French, English, Russian, Portuguese, Spanish… The reliability and consistency of the teams at all levels guarantee the perfection of the supply chain and the service.

To meet all customer needs, the Aiglon group has implemented a service able to satisfy within the best delays:

- price enquiries,
- delivery terms and availability,
- analysis or test requests in close relation with the laboratory technical service.

The Aiglon group is a family business. To lead the companies, Jean-Jacques Puyoo, founding president, relies on a senior management team from his family and also on Philippe Conti, who brings with him his experience acquired in large international groups.

The Aiglon team comprises employees from five different nationalities.
An international team flexible and adaptable

Sales administration
A team devoted to customer service
contact@aiglon.eu

Quality department
A quality team experienced with all the requirement for the strictest certifications
christophe.bourqui@aiglon.eu

The laboratory
Dr Rachida Francis
rachida.francis@aiglon.eu
Dr Sylvie Paulus
sylvie.paulus@aiglon.eu

Factory supervisors
Dominique Fromentin
Thierry Lenoble
Petroleum jelly, an ingredient with unique qualities

Known for over 100 years, petroleum jelly occupies an enormous space in the range of pharmaceutical and cosmetic ingredients. Its chemical nature and colloidal microstructure define its multiple qualities as well as its uses, such as:

Neutral excipient
In the same way as water is used as an inert vehicle for hydrophilic active substances in skin allergy tests (patch), petroleum jelly is commonly used to vehicle lipophilic active substances for many applications.

Inertia being one of the most sought qualities for excipients, they must be as neutral as possible with regard to fragile active ingredients like hormones, vitamins, antibiotics, perfumes, colourings, etc. It is fundamental to note that an excipient, also known as a “vehicle” or an “adjuvant”, can significantly modify the activity of an active ingredient and the shelf life of the formulation; it is therefore often necessary to repeat clinical trials after changing an excipient.

Petroleum jelly is inert, and thus totally compatible, whatever the active substance used. Petroleum jelly-based ointments are recognised as the best releasing systems in terms of efficiency.

For example, the efficiency of topical steroids can be increased by the application of an occlusive film created by an ointment. In fact, skin under occlusion becomes more permeable and the active ingredients are able to penetrate better.

A little chemistry…
From a chemical point of view, petroleum jelly is a purified mixture of long-chained saturated hydrocarbons (also known as alkanes or paraffin), solids and liquids of general formula (CnH2n+2). They are mainly obtained from refining petrol. Our first lessons of organic chemistry taught us the designation “paraffin” from the Latin “parum affinis”, signifying “little affinity”, with reference to their low reactivity.

This chemical and physiological inertness makes petroleum jelly an ideal vehicle for protecting delicate active ingredients, for creating ointments for sensitive skin, or for formulating products with an acid or alkaline pH (such as depilatory creams, hair dyes, creams with high doses of alpha hydroxyl acids for dermatological treatments).

Structuring agent
Consistency factor
Due to its semi-solid consistency, petroleum jelly can be used as an ideal structuring agent for hydrophobic ointments. The microstructure of the petroleum jelly is an amorphous colloidal gel in which the continuous phase is made up from solid wax containing oil in dispersion. The wax absorbs oil just as gelatine absorbs water.

Because of this capacity, petroleum jelly can also function as an anti-exudation agent for oil by replacing cerezen or oozene. This plastic and semi-solid structure grants petroleum jellies their pasty consistency, their smoothness, their delicate fibrous texture and their lubricating characteristics.

According to its specifications such as fibre length, viscosity, drop melting point or its capacity to absorb oil, petroleum jelly can be used as a regulator of consistency or a stabiliser for emulsions.

Active ingredient:
protection, healing, moisturising
Pure petroleum jelly is sold by pharmacies for treating cuts, burns, rashes, damaged feet, cracked lips, babies’ nappy rash and protection against cold. The main function of all these treatments is to cover and protect the skin from thermal, bacterial and chemical aggressions.

Petroleum jelly is impermeable to air and water; its capacity for protecting cuts and burns prevents germs from entering the wound and keeps the wound soft by preventing the evaporation of humidity.

Moisturising characteristics
By reducing the trans-epidermal water loss by more than 98%, petroleum jelly is an excellent occlusive moisturiser of reference. It creates an inert hydrophobic barrier on the surface of the skin, blocks the trans-epidermal water loss and traps the water under the skin.

Due to its excellent moisturising powers, many dermatologists use petroleum jelly for treating problem skins such as dryness or squamas. Petroleum jelly accelerates the recovery of the normal properties of the skin barrier, in the case of injured skin. This is its purpose in the composition of creams prescribed for dry skin, psoriasis, atopic dermatitis, hyperkeratosis and xeroderma…

Emollient
Due to its softening ability, petroleum jelly is the ultimate emollient; its non-sensitising and highly occlusive properties are effective against trans-epidermal water loss. Its role is to remain on the exterior of the skin; therefore it is very useful in cosmetic protection creams, make-ups, sun care and ethnic hair care products.

Petroleum jellies can, for example, be chosen for their stringiness (capacity of the product to stretch into fibres more or less long). The choice of the fibres depends on its use: for a massage cream or for brilliantine, short fibred petroleum jellies are preferred since they are less sticky and melt easily.

Lubricant
Due to its excellent lubricating properties, petroleum jelly is also used in athletics care. Boxers apply it to soften the skin and thus prevent it creasing and tearing from hits. Its greasy consistency makes the punches “slide”. Rugby men use it for the same reason, but also, to protect their ears and faces from friction in the scrums. Its excellent “sliding” factor facilitates all kinds of massages.

Contrary to popular belief, it is not advisable to use it as a gynaecological lubricant with condoms as it is not compatible with latex.
Petroleum jelly in closer detail

Petroleum jelly is a subtle balance of liquid and solid hydrocarbons.

The crystalline structure of the substances in its composition is one of the basic qualitative elements. The role of the amorphous solid hydrocarbons is, in fact, to retain in a sufficiently dense fibrous mesh, oily hydrocarbons of a generally high molecular weight (see photos below).

Structure of petroleum jellies seen through a microscope

![Petroleum jelly of high pharmaceutical standard, homogeneous structure, without any sweating.](image1)

![Petroleum jelly of standard pharmaceutical quality with sweating rare, but possible.](image2)

![Petroleum jelly with loose structure unstable.](image3)

![Industrial petroleum jelly, various structures.](image4)

The resulting substance can be likened to a thick two-phase colloidal gel.

The stability of the whole is obtained by the choice of perfectly adapted microcrystalline structures which act as a stabilising agent the same way as an emulsifying agent acts in water/oil emulsions for example.

Various structures in infinite quantity

The composition of highly refined constituents and their physical properties vary considerably according to the origin of the raw material and the refining methods. The solid or liquid elements of the hydrocarbons may contain 16 to 60 carbon atoms with significantly different molecular weights; therefore, the possible structures are extremely varied and their number practically infinite.

It is this extreme complexity which gives petroleum jellies their quality, their unique aspect, theirunctuousness, their delicate fibrous texture along with all their other, very specific properties, so much appreciated by formulators.

Petroleum jelly of high pharmaceutical standard, homogeneous structure, without any sweating.

Petroleum jelly of standard pharmaceutical quality with sweating rare, but possible.

Petroleum jelly with loose structure unstable.

Industrial petroleum jelly, various structures.

French Codex Pharmacopoeia, an unrivalled purity

The purity criteria for raw materials or preparations used in manufacturing medicinal products for human and veterinary use, and the analytical methods to be used to ensure their control, are defined by the Pharmacopoeia monographs.

The pharmacopoeias are regulatory monographs

These are national regulatory monographs, such as the French Pharmacopoeia – Ph. FRX (10th edition), the British Pharmacopoeia – BP, the German Pharmacopoeia – DAB, or international, such as the International Pharmacopoeia (Ph. Int) published at a global level by WHO, and the European Pharmacopoeia (EP).

The European Pharmacopoeia, today at its 8th edition, was created in 1964 within the Council of Europe, with the aim of unifying the characteristics and the quality of pharmaceutical substances and preparations. The progressive replacement of national monographs by European monographs was the starting point for the free movement of medicines in Europe.

Concerning the quality requirement of petroleum jellies in Europe, it is to be remembered that until 2003 it was supervised by national pharmacopoeias.

Codex petroleum jellies are not petrolatum

Petroleum jellies obtained from blending three principle high purity materials are not petrolatum.

According to the requirements of the International Nomenclature of Cosmetic Ingredients which lists and assigns the INCI names of cosmetic ingredients, there are two possible designations depending on the manufacturing method of the petroleum jelly:

- if the product is manufactured by blending paraffin oil, wax and mineral paraffin, then the INCI name of the mixture is composed of all the INCI names of the ingredients (Paraffinum Liquidum (and) Cera Microcristallina (and) Paraffin).

- if the product is manufactured by directly refining the crude oil or its derivatives, its INCI name is “petrolatum”.

The INCI designation of the AIGLON petroleum jellies is “Paraffinum Liquidum (and) Cera Microcristallina (and) Paraffin”. These three INCI references are not included in the CMR (cancerogenous, mutagenous and toxic for reproduction) product list of the Cosmetics Directive nor in the CLP (classification, labelling and packaging) regulations. Petrolatum figures in this list.
The French Codex Pharmacopoeia is considerably more demanding than the others in relation to the following purities:
- the test for PAH (Polycyclic Aromatic Hydrocarbons), the most stringent worldwide.
- the test for carbonisable materials, which enables to detect the presence or absence of unsaturated substances. No other pharmacopoeia contains a similar test.

Because of these stringent requirements, petroleum jellies complying with EP, BP, USP, DAB pharmacopoeias do not meet the requirements of Codex.

In contrast, Codex petroleum jellies comply with all the existing pharmacopoeias. As part of the European standardisation of the different pharmacopoeias, a European Pharmacopoeia (EP) for white petroleum jellies was implemented in July 2003. Regrettably, the methods retained in this monograph for controlling the PAH are considerably more lax than those of the French Codex Pharmacopoeia. Moreover, the test for carbonisable materials does not even exist, although it is essential in the purity requirements for pharmaceutical white oils (paraffinum liquidum).

The requirements of the Aiglon Codex petroleum jellies are superior to the European Pharmacopoeia


Carbonisable materials: a criterion directly related to the stability and efficiency of petroleum based finished products.

To demonstrate the superiority of the Codex requirements in relation to the European Pharmacopoeia, it is necessary to explain the PAH methods of analysis with their advantages and their flaws, and then an illustration of the difference between these two pharmacopoeias with the analysis of three petroleum jellies made according to two different methods.

PAH analysis methods
To quantify hydrocarbons in general, and PAH in particular, the analyst has a wide range of means for measuring the PAH count with more or less precision. Can be cited, for example:
- evaluate the total PAH count (comparison with a defined threshold or in relation to a witness control).
- quantify the components by fraction according to the number of cycles or the presence of heteroatom (such as sulphur or nitrogen).
- obtain the individual count of each PAH sought.
- associate methods of quantitative and qualitative separation so as to isolate and identify the PAH.

Generally, the choice should be guided by the relevance of the information obtained in regards to the nature of the sample and the purpose of the analysis.

To detect and quantify PAH, analysts have analytical techniques of spectroscopy or chromatography, and combinations hereof, for example the chromatography in gas phase coupled with mass spectrometry or the chromatography in gas phase coupled with a UV spectrophotometer.

Whilst being sensitive and precise, the chromatographic methods are time consuming and require sophisticated equipment, as well as control samples (samples of the pure substances investigated). Presumably, this is the reason why they are not described by the pharmacopoeias as routine analyses.

The UV spectrophotometry
The UV spectrophotometry is the quantitative and qualitative analytic method which consists of measuring the absorbance or the optical density of a given chemical substance in solution. It assesses all the PAH in the sample. This technique, rapid and simple but not very precise, is the method prescribed by the pharmacopoeias which impose the PAH analysis, such as the French Codex Pharmacopoeia and the European Pharmacopoeia (the American USP does not require a PAH test).

Thus, the PAH presence is measured by the UV absorbance (optical density) at intervals of wavelength defined by each pharmacopoeia. In the Codex monograph, the measured optical density values must not pass a defined threshold, whereas the European Pharmacopoeia test provides for comparison with a control sample.

Whatever the chosen method of analysis, the sample of petroleum jelly must first be placed in a solution or stable suspension. And it is notably the way in which the solution to be analysed is prepared, that distinguishes the Codex test from the EP test.

The preparation of the sample affects the results of the analysis

How can the way in which the sample is prepared have a direct influence on the analysis results?

The PAH fraction is a complex mixture of molecules whose molecular weight and polarities differ greatly. Consequently, their solubility varies significantly depending on the solvents used. In the Codex test, the sample preparation consists of dissolving 0.100g of petroleum jelly in 200ml of hexane. This way, all the PAH present in the petroleum jelly remain in the sample. As for the EP test, 1g of petroleum jelly is dissolved in hexane, then the PAH are extracted by dimethyl sulphoxide (DMSO), a good, though not universal solvent: the DMSO extraction procedure is selective for the least polar PAH such as highly alkylated molecules.

Using this extraction method, only the PAH extracted by the DMSO are detected, whereas other PAH that remain trapped in the hexane, are not detected. Observation of graphs (fig. 1 – fig. 2) the difference between the three curves is a perfect illustration of the selective PAH extraction by DMSO. As the PAH in each product can vary considerably depending on the origin, their distribution between the hexane and the DMSO also varies considerably.

On the other hand, the sample prepared without extraction, according to the Codex monograph, preserves all the PAH. This method is therefore more representative.

Analysis of the results of 3 petroleum jelly samples: A, B and C (Codex)

The petroleum jelly A - (USP petrolatum) does not pass the European Pharmacopoeia test (fig. 1), but is far from conforming to the much stricter Codex test (fig. 2). This study has been confirmed by an independent laboratory by the Grimmer test. This method, based on chromatography, is amongst the most advanced and the most accurate, and can measure the absolute content of 16 adverse PAH. According to the results, the count for these 16 PAH for petroleum jelly B, is 31.2 ppm, whereas for the Aiglon Codex petroleum jellies this count is at the level of 1.5 ppm, in other words, 20 times less; and this is well below the threshold of the official tolerance.

USP petroleum jelly can be of very poor quality. Indeed, the USP imposes no test for detecting the PAH.

The petroleum jelly B – (EP, BP, USP petrolatum) easily passes the very tolerant European Pharmacopoeia test (fig. 1), but is far from conforming to the much stricter Codex test (fig. 2). This study has been confirmed by an independent laboratory by the Grimmer test. This method, based on chromatography, is amongst the most advanced and the most accurate, and can measure the absolute content of 16 adverse PAH. According to the results, the count for these 16 PAH for petroleum jelly B, is 31.2 ppm, whereas for the Aiglon Codex petroleum jellies this count is at the level of 1.5 ppm, in other words, 20 times less; and this is well below the threshold of the official tolerance.

The petroleum jelly C – (BP, USP petrolatum) easily passes the very tolerant European Pharmacopoeia test (fig. 1), but is far from conforming to the much stricter Codex test (fig. 2). This study has been confirmed by an independent laboratory by the Grimmer test. This method, based on chromatography, is amongst the most advanced and the most accurate, and can measure the absolute content of 16 adverse PAH. According to the results, the count for these 16 PAH for petroleum jelly B, is 31.2 ppm, whereas for the Aiglon Codex petroleum jellies this count is at the level of 1.5 ppm, in other words, 20 times less; and this is well below the threshold of the official tolerance.
These two diagrams show the guarantee of security provided by the Codex petroleum jellies

**PAH European Pharmacopoeia test – Fig. 1**

This test quantifies the hydrocarbons. It shows whether the petroleum jellies conform to the European Pharmacopoeia (red). This diagram shows that Aiglon Codex petroleum jellies (curve C) are, by far, the most noble. The USP petroleum jelly (curve A) does not pass the test of the European Pharmacopoeia and yet, it complies with the American Pharmacopoeia norms. The petroleum jelly B is within the norms. This test is not truly significant of the quality of petroleum jelly due to its low threshold.

**Absorbance test; Codex 10th edition - Fig. 2**

To know the true quality of petroleum jellies, only this absorbance test is significant. It meets the Codex Pharmacopoeia quality which is much stricter than the European Pharmacopoeia. This test shows that only the Aiglon Codex petroleum jellies pass this test, truly representative of their superiority.

Petroleum jelly, a non-comedogenic ingredient

In addition to these 16 PAH, there are hundreds of other polycyclic aromatic molecules. Consequently, the quantity of PAH really present in the sample of petroleum jelly B is actually much higher than 31.2 ppm. When referring to the high tolerance of the European Pharmacopoeia, it is conceivable that a petroleum jelly containing twice the PAH count of petroleum jelly B has every chance of still conforming.

Obviously, Codex petroleum jellies represent more guarantees of security for consumers, in comparison with those which are controlled uniquely according to the European Pharmacopoeia. From this point of view, it is logical that the competent authorities added to the monograph of the EP description of the product that it is not suitable for oral use. On the contrary, the French Codex Pharmacopoeia mentions that the petroleum jelly “described in this monograph is particularly suitable for oral use”.

Since its inception, Aiglon, the sole manufacturer of petroleum jellies in France, specialises in manufacturing Codex petroleum jellies to offer its customers products of impeccable purity and whiteness with maximum safety guarantees.

In addition to the green trend, a number of cosmetic excipients which have been used for centuries have seen their reputation battered. Regarding petroleum jelly, the misconception concerning its potential comedogenicity is well ingrained in most minds and sometimes even misleading to specialists. In the face of a thorough data based examination, this myth does not hold up.

Glycerine-free, silicone-free, petroleum derivatives-free. The suffix “free” is increasingly found on cosmetic labels. This is mostly in response to marketing issues: to generate irrational or groundless fears in order to propose reassuring products. What’s important in this “fear marketing” is not the actual danger, but the perception one has of it.

Because of its greasy texture, petroleum jellies are often wrongly accused of impeding the good evacuation of sebum, thus causing the formation of comedones. Such false allegations are spread through the murky waters of Internet – web portals, blogs, and forums. And yet, scientific studies have demonstrated the non-comedogenicity of highly refined petroleum jellies, whilst conversely, a number of vegetable oils have been incriminated [1,2]. For scientists, there is no correlation between a greasy consistency and the capacity for causing acne [3]. For instance, isopropyl myristate, a non-greasy emollient, is highly comedogenic [1].

To understand the link between cosmetic ingredients and acne, it’s useful to recall the conjuncture of three events necessary for the occurrence of acne (see diagram):

1) **Seborrhea**. This is excessive secretion and a qualitative change of the sebum by
Codex petroleum jellies have no influence on the formation of black heads

2) Keratinisation disorders. Concomitants are dead cells produced in excess and abnormally adherent to one another, forming a plug of keratin lamellae that holds the sebum produced upstream in the canal and the follicle. This phenomenon called keratinisation disorders is the cause of comedones (blackheads) or closed spherical microcysts (white heads). Mainly determined by endogenous factors, it can also be triggered by medicines, cosmetics, toxic substances, tobacco or sunlight.

3) Development of inflammatory lesions. The trapped sebum exerts a pressure on the walls of the follicle and can penetrate surrounding tissue. Its decomposition by bacteria that live naturally in the follicles, e.g. propionibacterium acnes, is a major factor in the inflammatory phase from which acne pimples originate.

Among these stages, only retention hyperkeratosis may be due to exogenous factors. Thus, in the absence of comedogenic properties, it is the ability to induce keratinisation disorders that is sought, hence the development of the test on the rabbit ear, that easily develops folliculitise keratosis. Unrelated to the physical properties [3], the comedogenic potential is influenced by three main factors: the presence of impurities, the chemical nature of substances, and the ability to penetrate the skin.

The presence of carcinogenic impurities

The link between carcinogenic and comedogenic properties has been demonstrated by Kligman. They started from the assumption that the formation of a comedo involved disturbances in the differentiation of epidermal cells which are also a necessary step in the evolution of skin cancer. They highlighted a very strong comedogenic effect of several carcinogenic agents including polycyclic aromatic hydrocarbons (PAH): benzo(a)pyrene, methylbenz(a)anthracene, dimethylbenz(a)anthracene. These substances are particularly responsible for oil pimples that engineers happened to develop when in contact with technical mineral greases which used to be rich in PAH. Coal tar, which is also rich in PAH, is very comedogenic even when diluted to 5% [1]. Isolated cases of acne, or allergic reactions associated with high levels of PAH in poor petroleum quality have been reported [5,6,7]. It is recalled that these impurities are inherent not only to petroleum derivatives (petrogenic PAHs), but also to some vegetable oils (grape seed, coconut, pomace) and their derivatives, e.g. vitamin E. These are PAH of pyrogenic origin. They form, sometimes in large quantities (2000 mg/kg in coconut oil before refining) when seeds are dried over a naked flame. A strict control of impurities in cosmetics seems obvious. Surprisingly, unlike food and drug regulations, the European Cosmetic Directive tolerates the presence of these carcinogenic impurities without explicitly setting their limits.

Petroleum jellies chemical structure

Composed of saturated long chain hydrocarbons, petroleum jelly is chemically and biologically neutral: its low biodegradability, though often criticized, preserves it from decomposition by the microflora of the skin. It is used in medicines for sensitive skins and in skin tests as a neutral carrier for oil-soluble substances. Conversely, comedogenic properties of many lipids of biological origin, including human sebum [11] and many vegetable oils (soybean, sesame, avocado, coconut, grape, peach kernels, sweet almond, corn, cotton, cocoa butter...) [12,29], are determined by their molecular structure. Two mechanisms are involved:

1) The decomposition of triglyceride under the effects of the lipases of the skin's microflora with the formation of irritant and pro-inflammatory comedogenic free fatty acids [10]. These properties start from compounds in C10, reaching a peak in C12 and C14, decrease in C16 and C18, to become completely absent in C20. The potential for irritation and comedogenicity proved to be independent properties. Fatty acids in C3 and C5 are highly irritating and non-comedogenic, while C16 and C18 are comedogenic and non irritating [11]. Unsaturated fatty acids, abundant in the sebum of women with an excess of large pores, are responsible for keratinisation disorders [12,13].

2) The oxidation of unsaturated molecules, with the formation of peroxides, feeding hyperkeratosis and inflammation [14,18]. Thus squalene and acid peroxides induce fairly large

For the purity of petroleum jelly, cosmetic manufacturers, who are fully responsible for the safety of their products, turn to other standards, including national and international pharmacopoeias.

Being the most stringent regarding the content of PAH, the French Pharmacopoeia Codex guarantees maximum safety for consumers. And better still, it is the only one to set limits for unsaturated substances. Thus, according to results of an independent laboratory [8], measuring the content in 22 PAH, the rate for a petroleum jelly complying with the French Pharmacopoeia Codex (Aiglon, France) is lower than 1.5 ppm and for two other brands compliant with the European Pharmacopoeia is equal to 31 ppm and 48 ppm. The purity of the Aiglon petroleum jelly is due to the manufacturing method which consists in mixing mineral oil, microcrystalline waxes and highly refined paraffin. Thus, unlike “petrolatum”, which is obtained through direct refining of crude oil, they have the INCI denomination “Paraffinum Liquidum (and) Cera Microcrystallina (and) Paraffin”.

The three factors responsible for acne

Seborrhoea
Keratinisation disorders
Development of inflammatory lesions

Three features of Codex petroleum jellies

Never CMR
Absolute purity of Codex petroleum jellies
Very specific qualities

Three features of non-Codex petroleum jellies

CMR (carcinogenic, mutagenic and toxic for reproduction) molecules not excluded
Insufficient purity requirements
Very standard qualities
comedones and their size is correlated with the concentration of peroxides [15,17]. In addition, for a number of unsaturated substances, including oleic, linoleic, linolenic, undexylenic, malic acids and squalene, sensitization properties have been demonstrated recently [19] according to the protocol LLNA (Local Lymph Node Assay) a preferred test of the Reach Regulation [20] during the registration of chemical substances.

Skin penetration
A number of substances known for their ability to alter the skin barrier, e.g. some fatty acids, derived esters (isopropyl linleate, isopropyl myristate, isopropyl palmitate, decyl oleate, etc.) and even vitamin E, are highly comedogenic [1,21].

Unlike medicines, for a cosmetic product trans-epidermal absorption should be minimized. The bulk of doubts and accusations on cosmetic components stem from the fact that they are likely to enter skin through the skin barrier. Perfectly compliant with the legal definition of a cosmetic product, petroleum jelly does not penetrate the skin [22]. Paradoxically, pseudo-scientific critiques cite this as a proof of their uselessness. Yet, the excellent moisturizing, protective and healing properties of petroleum jelly have been long proven through decades of research [23,24,25].

Let’s stop comparing good “organic” to poor «mineral» or natural products versus “synthetic.” Today the situation is paradoxical. The use of so called “natural” or “organic” cosmetics is constantly growing. At the same time, the skin sensitivity to external influence is increasing. From this trend flourish dermo-cosmetic products, originally designed for people with sensitive or intolerant skin. Petroleum jellies, which are perfectly tolerated by the skin, are abundantly present in their formulations in a broad range of concentrations from 1 to 100%, whereas for comedogenic ingredients, including many vegetable oils, it is usually recommended to not exceed the threshold of 5% in cosmetic formulations [1]. Moreover, petroleum jelly is similar to living cells: long chain hydrocarbons are found in the protective layer of leaves and fruits, in beeswax, and even in human skin [26,27,28]. Petroleum jellies are actually responsible for the waxy sensation perceived by touch when we rub an apple for instance. Thanks to its unique qualities, petroleum jelly finds a place of its own in cosmetic products, including luxury brands.

**Non-comedogenicity test**

**Aim of the study**
To verify the absence of comedogenicity and skin acceptability of Codex petroleum jellies under dermatological controls.

**Protocol**
21 female volunteers (aged 22-61) with combination-type facial skin. Application of white Codex Petroleum Jelly Syntadex 87042 DI. Treatment each evening for 28 consecutive days.

**Verification of the absence of comedogenic potential**
At the start and at the end of the products trial period: visual examination of the experimental area and count of comedons on the three skin regions defined by the dermatologist. Questioning of volunteers.

**Skin acceptability**
Examination of the experimental region (face) by the dermatologist and questioning of the volunteers before and after the 28 consecutive days of use. Analysis of any eventual discomfort reported by the volunteers directly to the dermatologist or in their daily written reports.

The cosmetic qualities and perceived efficacy were assessed at the end of the study using a self-assessment target questionnaire.

**Results and conclusions**
- The results of the study demonstrated the absence of the potential comedogenicity of the White Codex Petroleum Jelly Syntadex 87042 DI.
- Moreover, during the study, the number of comedones in most volunteers significantly decreased. Possible explanation it is known...
that the oxidation of unsaturated lipids is one of the major factors for causing blackheads. Petroleum jelly forms a film that probably protects unsaturated lipids of sebum from oxidation. The Syntadex 87042 \(\text{DI petroleum jelly} \) was selected for the study because of its pleasant texture. Indeed, used 100% pure, most of the volunteers noted the absence of discomfort (87.5%) and its easy application (81%).

Petroleum jelly is very well tolerated by the skin: the absence of irritation was reported by 100% of the volunteers.

**Last, but not least**, the evaluation results of the cosmetic qualities of Codex petroleum jelly compare favourably with luxury beauty products. The volunteers reported that the skin was more hydrated (90.5%), more soft and supple (90.5%) and more smooth and elastic (71.4%). Explanation petroleum jelly is recognised as the golden standard of moisturising and it is widely accepted that good moisturising is a bulwark against wrinkles and sagging skin.

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Pharmacopoeia compilations

European Pharmacopoeia Paraffin, White Soft

Vaselium album - 07/2009 : 1799

DEFINITION
Purified and wholly or nearly decolourized mixture of semi-solid hydrocarbons, obtained from petroleum. It may contain a suitable antioxidant. White soft paraffin described in this monograph is not suitable for oral use.

CHARACTERS
Appearance: white or almost white, translucent, soft unctuous mass, slightly fluorescent in daylight when melted. Solubility: practically insoluble in water, slightly soluble in methylene chloride, practically insoluble in ethanol at 96 per cent and in glycerol.

IDENTIFICATION
First identification: A, B, D. Second identification: A, C, D.

A. The drop point is between 35°C and 70°C and does not differ by more than 5°C from the value stated on the label, according to method (2.2.17) with the following modification to fill the cup: heat the substance to be examined at a temperature not exceeding 80°C with stirring to ensure uniformity. Warm the metal cup at a temperature not exceeding 80°C in an oven, remove it from the oven, place on a clean plate or ceramic tile and place it in a water-bath at 24°C to 26°C for 30 - 40 mm. Level the surface of the sample with a single stroke of a knife or razor blade, avoiding compression of the sample.

B. Melt 2 g and when a homogeneous phase is obtained, add 2 ml of water R and 0.2 ml of 0.05 M iodine. Shake. Allow to cool. The solid upper layer is violet-pink or brown.

D. Appearance (see tests).

TESTS
Appearance
The substance is white. Melt 12 g on a water-bath. The melted mass is not more intensely coloured than a mixture of 1 volume of yellow paraffin on a plate of sodium chloride R. The solution is colourless. Not more than 0.5 ml of 0.01 M sodium hydroxide is required to change the colour of the indicator to red.

Consistency (2.9.9) - 60 to 300 Polycyclic aromatic hydrocarbons
Use reagents for ultraviolet spectrophotometry. Dissolve 1.0 g in 50 ml of hexane R which has been previously shaken twice with 10 ml of dimethyl sulphoxide R. Transfer the solution to a 125 ml separating funnel with un lubricated ground-glass parts (stopper, stopcock). Add 20 ml of dimethyl sulphoxide R. Shake vigorously for 1 min and allow to stand until 2 clear layers are formed. Transfer the lower layer to a second separating funnel. Repeat the extraction with a further 20 ml of dimethyl sulphoxide R. Shake vigorously the combined lower layers with 20 ml of hexane R for 1 min. Allow to stand until 2 clear layers are formed. Separate the lower layer and dilute to 50.0 ml with dimethyl sulphoxide R. Measure the absorbance (2.2.25) over the range 260 nm to 420 nm using a path length of 4 cm and dimethyl sulphoxide solution R as compensation liquid. At no wavelength in the range 260 nm to 420 nm does the absorbance of the sample exceed that of the reference solution at 278 nm.

Sulphuric ashes (2.4.14)
Maximum 0.05 per cent, determined on 2.0 g

European Pharmacopoeia Paraffin, Yellow Soft

Vaselium flavum - 07/2008 : 1554

DEFINITION
Yellow soft paraffin is a purified mixture of semi-solid hydrocarbons, obtained from petroleum. It may contain a suitable antioxidant.

CHARACTERS
Appearance (see tests).

TESTS
Appearance
The substance is yellow. Melt 12 g on a water-bath. The melted mass is not more intensely coloured than a mixture of 7.6 volumes of yellow primary solution and 2.4 volumes of red primary solution (2.2.2, Method II).

Acidity or alkali
To 10 g of yellow soft paraffin, add 20 ml of boiling water R and shake vigorously for 1 min. Allow to cool and decant. To 10 ml of the aqueous layer add 0.1 ml of phenolphthalein solution R. The solution is colourless. Not more than 0.5 ml of 0.01 M sodium hydroxide is required to change the colour of the indicator to red.

Consistency (2.9.9)
The consistency is 100 to 300.
Polycyclic aromatic hydrocarbons
Use reagents for ultraviolet absorption spectrophotometry. Dissolve 1.0 g in 50 ml of hexane R which has been previously shaken twice with one-fifth its volume of dimethyl sulphoxide R. Transfer the solution to a 125 ml separating funnel with un lubricated groundglass parts (stopper, stopcock). Add 20 ml of dimethyl sul phoxide R. Shake vigorously for 1 min and allow to stand until two clear layers are formed. Transfer the lower layer to a second separating funnel. Repeat the extraction with a further 20 ml of dimethyl sulphoxide R. Shake vigorously the combined lower layers with 20 ml of hexane R for 1 min. Allow to stand until two clear layers are formed. Separate the lower layer and dilute to 50.0 ml with dimethyl sulphoxide R. Measure the absorbance (2.2.25) between 260 nm and 420 nm using a path length of 4 cm and using as the compensation liquid the clear lower layer obtained by vigorously shaking 10 ml of dimethyl sulphoxide R with 25 ml of hexane R for 1 min. Prepare a 9.0 mg/l reference solution of naphthalene R in dimethyl sulphoxide R and measure the absorbance of this solution at the maximum at 278 nm using a path length of 4 cm and using dimethyl sulphoxide R as the compensation liquid. At no wavelength in the range of 260 nm to 420 nm does the absorbance of the test solution exceed that of the reference solution at 278 nm.

Sulphuric ashes (2.4.14)
Not more than 0.05 per cent, determined on 2.0 g.

STORAGE
Store protected from light.

LABELLING
The label states the nominal drop point.

French Pharmacopoeia Codex
White Petroleum Jelly (Codex*) 2004

DEFINITION
White Soft Paraffin is a mixture of purified hydrocarbons obtained from heavy fractions of some petroleum. White Soft Paraffin described in this monograph is particularly suitable for oral use.

CHARACTERISTICS
Aspect
Soft unctuous mass, of variable consistency according to the uses it is intended for, of whitish colour, translucent in fine layers, slightly fluorescent in daylight when melted. Solubility: insoluble in water, When melted, White Soft Paraffin is soluble, in all proportions, in methylene chloride. White Soft Paraffin, when allowed to cool can show a slight deposit. F: 36 °C to 60 °C. White Soft Paraffin is more or less fibrous. It is practically anhydrous.

IDENTIFICATION
A. Spectrophotometry absorption by infrared (2.2.24)
The spectrum obtained shows maximum absorption at 2950 cm⁻¹, 2920 cm⁻¹, 2850 cm⁻¹, 1460 cm⁻¹, 1375 cm⁻¹, 725 cm⁻¹ and 715 cm⁻¹. To measure, it is necessary to realize a film on the halide plate surface in a way that the transmission measured at 2915 cm⁻¹ was about 5 %. Preparation: the substance spread out as a film on a halide plate.

B. Melt 2 g of White Soft Paraffin and when an uniform phase is obtained, add 2 ml of water and 0.2 ml of 0.1 M iodine. Heat until two liquid layers are formed. Shake. Allow to cool, the solid upper layer is violet-pink.

TESTS
Homogeneity
When kept during 1 hour at a temperature of 20°C below its melting point, White Soft Paraffin remains homogenous.

Acidity
To 10 g of White Soft Paraffin add 20 ml of boiling R water, shake vigorously for 1 minute, cool, allow to separate. To 10 ml of the aqueous layer add 0.1 ml of phenolphthalein solution R. The solution is colourless and not more than 0.1 ml of 0.1 M sodium hydroxide is required to change the colour of the solution to pink.

Carbonisable substances
To a graduated test tube introduce 0.5 g of White Soft Paraffin. Add 20.0 ml of sulphuric acid R. Maintain in a water-bath during 10 min. shaking for 5 sec. every 2 min. Cool and transfer the tube content to a perfectly dry separating funnel. Allow to stand during 10 min. Collect the lower layer, filter if necessary on fritted glass (4). Examine the solution over the range 400 nm to 450 nm (2.2.25) using sulphuric acid R as a compensation liquid. Absorbance does not exceed 0.40.

Absorbance (2.2.25)
- Maximum of 0.20 examined from 250 nm to 275 nm.
- Maximum of 0.05 examined from 300 nm to 350 nm.

Saponification number (2.5.6).
Maximum of 2, tested on 2.00 g of White Soft Paraffin.

Sulphated ashes (2.4.14)
Not more than 0.03%, tested on 4.0 g of White Soft Paraffin.

* French Pharmacopoeia Codex Issue NR 11
White Soft Paraffin Vaselineum album

**DEFINITION**
White Soft Paraffin is a mixture of purified, bleached, for the most part saturated hydrocarbons.

**CHARACTERS**
White colour or greenish glint, pasty substance, practically odourless and slightly fluorescent in daylight.

**PURITY TEST**
Colour
Melted on a water-bath, White Soft Paraffin is not more intensely coloured (V.6.2 Method II) than a mixture of 1 volume of yellow primary solution and 9 volumes of 1 per cent solution of hydrochloric acid RN.

Acidity or alkalinity
To 5 ml of White Soft Paraffin on a water-bath add 20 ml of water at 90-95°C and shake vigorously for 1 minute. Shake vigorously the aqueous layer which should not change the colour to red after 0.1 ml of phenolphthalein solution R1 has been added. Not more than 0.5 ml of 0.01 N sodium hydroxide is required to change the colour of the indicator to red.

Congelation temperature at rotary thermometer (V.6.12 N1): 38 to 56°C

Polycyclic aromatic hydrocarbons
Introduce 1.0 g previously dissolved in 25 ml of hexane for spectrophotometry RN (1) into a 100 ml separating funnel with un lubricated ground-glass parts (stopper, stopcock). Add 5 ml of dimethyl sulphoxide R for spectrophotometry. Shake vigorously for 1 minute and allow to stand until two clear layers are formed. Transfer the lower layer to a second separating funnel. Add 2 ml of hexane RN (1) for spectrophotometry and shake vigorously for 1 minute. Allow to stand until two clear layers are formed. The absorption (V.6.19) of the lower layer is measured between 260 nm and 420 nm using as a compensation liquid the inferior liquid layer obtained by vigorously shaking for 1 minute 5.0 ml of dimethyl sulphoxide R for spectrophotometry with 25 ml fo hexane for spectrophotometry RN (1). The cloudy compensation liquid can be withdrawn either by centrifuging or by heating of the solution at max. 40°C. At no wavelength in the range 350 to 400 nm does the absorbance of the solution exceed 0.05 ; 0.32 between 270 and 279 nm ; 0.27 between 280 and 289 nm, 0.24 between 290 and 299 nm and 0.21 between 300 and 310 nm.

High polymer additives
Spread out regularly 3 to 5 g of White Soft Paraffin inside of hands. No thread should be detached when you clap the hands.

Sulphuric acid resistance
Introduce 5 ml of liquid White Soft Paraffin and 5 ml of sulphuric acid 90% RN in a test tube (description in Heavy Paraffin) and heat during 10 minutes on a water-bath at 70 +/-1°C. After 5.6 and 8.8 min draw the tube from the bath and shake vigorously 3 times in the longitudinal direction of the tube for 3 seconds. At latest 5 minutes after the heating is stopped, White Soft Paraffin and the sulphuric acid are so well separated that the colour comparison is possible. At the light, the sulphuric acid layer is not more intensely coloured (V.6.2 Method I) than a mixture of 0.5 ml of blue primary solution, 1.5 ml of red primary solution, 3.0 ml of yellow primary solution.

Ashes (V.3.2.16)
Determined on 2.0 g not more than 0.05%.

**STORAGE**
Protect from light.

**LABELLING**
Oil index following the method V5.1 N1 can be mentioned on the container.

**REMARK**
Use White Soft Paraffin if no other Soft Paraffin is recommended. White Soft Paraffins with a congeiling temperature of 60°C can also be used in a manufacture of special medicines at the condition that all other characters are respected.

(1) Before using the hexane for spectrophotometry RN, shake 1/5 of its volume of dimethyl sulphoxide R for spectrophotometry.

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**German Pharmacopoeia D.A.B. 10**

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**British Pharmacopoeia B.P. 2001**

White Soft Paraffin

**DEFINITION**
White Soft Paraffin is a semi-solid mixture of hydrocarbons obtained from petroleum and bleached.

**CHARACTERS**
A white, translucent, soft unctuous mass, retaining these characteristics on storage and when melted and allowed to cool without stirring; not more than slightly fluorescent by daylight, even when melted; odourless when rubbed on the skin. Practically insoluble in water, soluble in chloroform, in ether and in petroleum spirit (boiling range, 40° to 60°), the solutions sometimes showing a slight opalescence; practically insoluble in ethanol (96%).

Acidity or alkalinity
To 10 g add 20 ml of boiling water; shake vigorously for 1 minute, cool, allow to separate and filter the aqueous layer. To 10 ml of the filtrate add 0.1 ml of phenolphthalein solution. The solution is colourless and not more than 0.1 ml of 0.1 M sodium hydroxide is required to change the colour of the solution to pink.

Light absorption
Absorbance of a 0.05 % w/v solution in 2,2,4-trimethylpentane at 290 nm, not more than 0.5, Appendix II B.

Drop point
42° to 60°, when determined by the following method and using an Ubbelohde apparatus complying with British Standard 894:1956 (Specification for Ubbelohde apparatus for flow and drop points).

Heat the substance being examined, with stirring, to 118° to 122°, to ensure uniformity, and then cool to 103° to 107°.

Warm the metal cup to 103° to 107° in an oven, remove it from the oven, place on a clean plate or ceramic tile and allowed to cool without stirring; not more than 0.05 °C per minute. The temperature at which the first drop of melted liquid falls from the metal cup is regarded as the drop point of the substance. Carry out not fewer than three determinations, each time with a fresh sample of the substance being examined.

The difference between the readings must not exceed 3°. The mean of three readings is taken as the drop point of the substance.

Polycyclic aromatic hydrocarbons
To 1.0 g of the substance being examined in a separating funnel add 50 ml of hexane and shake to dissolve, warming gently if necessary. Shake the solution with 20 ml of dimethyl sulphoxide for 1 minute, allow to stand until two clear layers are produced and transfer the lower layer to a second separating funnel. Repeat the extraction with a further 20 ml of dimethyl sulphoxide. Add 20 ml of hexane to the combined extracts, shake for 1 minute, allow to stand until two clear layers are produced, discard the upper layer and dilute the washed, lower layer to 50 ml with dimethyl sulphoxide (solution A).

Measure the light absorption of a 4 cm layer of solution A in the range 265 nm to 420 nm, Appendix II B, using in the reference cell the clear lower layer obtained by shaking 10 ml of dimethyl sulphoxide with 25 ml of hexane for 1 minute. Measure the absorbance of a 4 cm layer of solution containing 6.0 µg per ml of naphthalene in dimethyl sulphoxide at 278 nm, Appendix II B, using dimethyl sulphoxide in the reference cell.

The absorbance of solution A at all wavelengths in the range 265 to 420 nm is not more than that of the naphthalene solution at 278 nm.

Foreign organic matter
Heat 1 g until fumes appear. No acrid odour is evolved.

Sulphuric ashes
Not more than 0.1 %, Appendix IX A.

**STORAGE**
White Soft Paraffin should be protected from light.
American Pharmacopoeia U.S.P. XXIV

Petrolatum

**DEFINITION**

Petrolatum is a purified mixture of semisolid hydrocarbons obtained from petroleum. It may contain a suitable stabilizer.

**Packaging and storage**

Preserve in well-closed containers. Labelling – Label it to indicate the name and proportion of any added stabilizer.

**Color**

Melt about 10 g on a steam bath, and pour about 5 ml of the liquid into a clear glass 15 - X 150-mm test tube, keeping the petrolatum melted. The petrolatum is not darker than a solution made by mixing 3.8 ml of ferric chloride CS and 1.2 ml of cobaltous chloride CS in a similar tube, the comparison of the two being made in reflected light against a white background, the petrolatum tube being held directly against the background at such an angle that there is no fluorescence.

**Specific gravity (841)**

Between 0.815 and 0.880 at 60°.

**Melting range, class III (741)**

Petrolatum to a temperature of 82 +/- 2.5°, pour between 38° and 60°.

**Packaging and storage**

Ground up to a fine powder, store in airtight containers.

**Test for consistency**

Place the required number of containers in the test, place the container on the penetrometer table, and lower the cone until the tip just touches the top surface of the test substance at a spot 25 mm to 36 mm from the edge of the container. Adjust the zero setting and quickly release the plunger, then hold it free for 5 seconds. Secure the plunger, and read the total penetration from the scale. Make three or more trials, each so spaced that there is no overlapping of the areas of penetration. Where the penetration exceeds 20 mm, use a separate container of the test substance for each trial. Read the penetration to the nearest 0.1 mm. Calculate the average of the three or more readings, and conduct further trials to a total of 10 if the individual results differ from the average by more than +/- 3% of the final average of the trials is not less than 10.0 mm and not more than 30.0 mm, indicating a consistency value between 100 and 300.

**Acidity or alkalinity**

If the addition of phenolphthalein TS in the test for Alkalinity produces no pink color, add 0.1 ml of methyl orange TS: no red or pink color is produced.

**Alkalinity**

Introduce 35 g into a suitable beaker, add 100 ml of boiling water, cover, and place on a stirring hot plate maintained at the boiling point of water. After 5 minutes, allow the phases to separate. Draw off the separated water into a casserole, wash the petrolatum further with two 50-ml portions of boiling water, and add the washings to the casserole. To the pooled washings add 1 drop of phenolphthalein TS, and boil – the solution does not acquire a pink color.

**Residue on ignition (281)**

Heat 2 g in an open porcelain or platinum dish over a Bunsen flame: it volatilizes without emitting an acid odor and on ignition yields not more than 0.1 % of residue.

**Organic acids**

Weigh 20.0 g add 100 ml of a 1 in 2 mixture of neutralized alcohol and water, agitate thoroughly, and heat to boiling. Add 1 ml of phenolphthalein TS, and titrate rapidly with 0.1 N sodium hydroxide VS, with vigorous agitation to the production of a sharp pink endpoint, noting the color change in the alcohol-water-layer: not more than 400 μl of 0.100 N sodium hydroxide is required.

**Fixed oils, fats and rosin**

Digest 10 g with 50 ml of 0.1 N sodium hydroxide at 100° for 30 minutes. Separate the water layer, and add 5 ml of 5% sulfuric acid: no oil or solid matter separates.

**European Pharmacopoeia**

Liquid Paraffin (Paraffinum Liquidum)

**DEFINITION**

Liquid paraffin is a purified mixture of liquid saturated hydrocarbons obtained from petroleum.

**CHARACTERS**

Oily liquid, colourless, transparent, free from fluorescence in daylight, practically insoluble in water, sparingly soluble in ethanol at 96 per cent, soluble in hydrocarbons.

**IDENTIFICATION**

First identification: A, C.

Second identification: B, C.

A. Examine the liquid paraffin by absorption spectrophotometry in infrared (2.2.24), in comparison with the reference spectre of solid paraffin of European pharmacopoeia.

B. In a glass tube, boil cautiously 1 ml of liquid paraffin and 1 ml of sodium hydroxide 0.1 M. Shake during about 30 s. Cool at room temperature. The two phases are separated. Add 0.1 ml phenolphthalein R to the aqueous phase. The solution colour becomes red.

C. The liquid paraffin is conform to viscosity test (see test).

**TESTS**

**Acidity or alkalinity**

To 10 ml add 20 ml of boiling R water and shake vigorously for 1 min. Separate the aqueous layer and filter. To 10 ml of the filtrate, add 0.1 ml of phenolphthalein solution R. The solution is colourless. Not more than 0.1 ml of 0.1 M sodium hydroxide is required to change the colour to pink.

**Relative density. (2.2.5)**

0.827 to 0.890

**Viscosity. (2.2.9)**

110 mPa.s to 230 mPa.s

**Polycyclic aromatic hydrocarbons**

Use solvents for spectrophotometry. Introduce 25.0 ml of liquid paraffin into a 125 ml separating funnel with unlubricated ground joint-glass parts (stopper, stopcock). Add 25 ml of hexane R preliminary cleaned by shaking with 2 times the fifth of its volume of dimethyl sulphoxide R. Mix and add 5.0 ml of dimethyl sulphoxide R. Shake vigorously for 1 min. and allow to stand until the two clear layers are formed. Transfer the lower layer to a second separating funnel. Add 2 ml of hexane R and shake the mixture vigorously. Allow to stand until the two clear layers are formed. Separate the lower layer and measure its absorbance (2.2.25) over the range 260 nm to 420 λ using compensation liquid the clear lower layer obtained by vigorously shaking 5.0 ml of dimethyl sulphoxide R with 25 ml of hexane R. Prepare a reference solution in trimethylpentane R containing 7.0 mg of napththalene R per litre and measure the absorbance of that solution at the maximum at 275 nm using trimethylpentane R as compensation liquid. At no wavelength in the range 260 nm to 420 nm does the absorbance of the test solution exceed one-third that of the reference solution at 275 nm.
**Light Liquid Paraffin (Paraffinium Perliquidum) 01/2008: 0240**

**DEFINITION**
Light liquid paraffin is a purified mixture of liquid saturated hydrocarbons obtained from petrol.

**CHARACTERS**
Oily liquid, colourless, transparent, free from fluorescence in daylight, practically insoluble in water, sparingly soluble in ethanol at 96 per cent, soluble in hydrocarbons.

**IDENTIFICATION**
First identification: A.C. Second identification: B.C.

**A.** Examine the light liquid paraffin by absorption spectrophotometry in infrared (2.2.24), in comparison with the reference spectrum of solid paraffin of European pharmacopoeia.

**B.** In a glass tube, bring cautiously to the boil 1 ml of liquid paraffin and 1 ml of sodium hydroxide 0.1 M. Shake during about 30 s. Cool at room temperature. The two phases are separated. Add 0.1 ml phenolphthalein R to the aqueous phase. The solution colour becomes red.

**TESTS**
Light liquid paraffin complies with tests of the monograph Liquid Paraffin (0239) with the following modifications:

- **Relative density:** (2.2.5) 0.810 to 0.875
- **Viscosity:** (2.2.9) 25 mPa.s to 80 mPa.s

**STORAGE**
Store protected from light.

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**F.D.A. Regulation**

**PETROLATUM**

**Some synonyms**
Petroleum jelly; Vaseline; White petrolatum; White petroleum jelly; White paraffin; Yellow petrolatum.

**Current CAS number**
8009-03-8

**Other CAS number(s)**
8027-32-5; 8038-17-3; 8040-67-7; 8044-44-8; 8044-45-9; 8044-46-0; 8057-56-5; 8063-27-2

**Empirical formula**
Unknwon.

**Use Hydrocarbons that may be used in combination**

<table>
<thead>
<tr>
<th>Use Hydrocarbons that may be used in combination</th>
<th>Limitation (exclusive of all petrolatum with petrolatum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In bakery products; as release agent and lubricant</td>
<td>With white mineral oil, not to exceed 0.15% of bakery product.</td>
</tr>
<tr>
<td>In confectionery: as release agent and as sealing and polishing agent</td>
<td>Not to exceed 0.2% of confectionery</td>
</tr>
<tr>
<td>In dehydrated fruits and vegetables; as release agent</td>
<td>Not to exceed 0.02% of dehydrated fruits and vegetables.</td>
</tr>
<tr>
<td>In eggs white solids; as release agent</td>
<td>Not to exceed 0.1% of egg white solids.</td>
</tr>
<tr>
<td>On raw fruits and vegetables; as protective coating</td>
<td>In an amount not to exceed good manufacturing practice.</td>
</tr>
<tr>
<td>In best sugar and yeast; as defoaming agent</td>
<td>As described in § 173.340 of this chapter.</td>
</tr>
</tbody>
</table>

**Regulatory Citations**

<table>
<thead>
<tr>
<th>Citation number / CFR part</th>
<th>Food category</th>
<th>Permitted functionality</th>
<th>Use limits</th>
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<td>21 CFR 172.880</td>
<td>Food additives permitted for direct addition to food for human consumption. Subpart I – Multipurpose additives</td>
<td>See above</td>
<td>See above</td>
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<tr>
<td>21 CFR 173.720</td>
<td>Food additives permitted in food and drinking water of animals. Petrolatum.</td>
<td>See above</td>
<td>See above</td>
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</table>
MINERAL OIL, WHITE

Some synonyms
Liquid paraffin; Paraffin oil; White mineral oil; White oils.

Current CAS number
8012-95-1

Other CAS number(s)
8015-59-6; 8033-89-4; 8038-04-8; 8039-14-3; 8039-75-6; 8043-78-5; 37231-69-9; 37232-05-6; 37232-06-7; 37232-07-8; 39290-23-8; 39355-35-6; 39464-77-2; 39464-78-3; 50935-85-8; 50935-95-0; 51004-58-1; 52012-27-8; 52012-28-9; 53028-74-3; 58391-38-1; 58615-80-8; 85-8; 50935-95-0; 51004-58-1; 52012-27-8; 52012-28-9; 53028-74-3; 58391-38-1; 58615-80-8; 85-8; 50935-95-0; 51004-58-1; 52012-27-8; 52012-28-9; 53028-74-3; 58391-38-1; 58615-80-8; 85-8; 50935-95-0; 51004-58-1; 52012-27-8; 52012-28-9; 53028-74-3; 58391-38-1; 58615-80-8; 85-8; 50935-95-0; 51004-58-1; 52012-27-8; 52012-28-9; 53028-74-3; 58391-38-1; 58615-80-8; 85-8; 50935-95-0; 51004-58-1; 52012-27-8; 52012-28-9; 53028-74-3; 58391-38-1; 58615-80-8; 85-8; 50935-95-0; 51004-58-1; 52012-27-8; 52012-28-9; 53028-74-3; 58391-38-1; 58615-80-8; 85-8.

Description
A mixture of refined liquid hydrocarbons, essentially paraffinic and naphthenic in nature, obtained from petroleum. It occurs as a colorless, transparent, oily liquid, free or nearly free from fluorescence. It is odorless and tasteless when cold, and develops not more than a faint odor of petroleum when heated. It is insoluble in water and in an alcohol, is soluble in volatile oils, and is miscible with most fixed oils, but not with castor oil. It may contain any antioxidant permitted in food by the U.S. Food and Drug Administration, but not with castor oil. It may contain any antioxidant permitted in food by the U.S. Food and Drug Administration, but not with castor oil.

Purity
Not available.

Specifications
Ready carbonizable substances: Passes test. Specific gravity: Not less than that stated, or within the range claimed by the vendor. Ultraviolet absorbance (polynuclear hydrocarbons) passes test. Viscosity: Not less than that stated, or within the range claimed by the vendor.

Functional use in foods
Binder, defoaming agent, antioxidant, fermentation aid, lubricant, release agent.

Regulatory notes
§ 172.878 White mineral oil may be safely used in food in accordance with the following conditions:
(a) White mineral oil is a mixture of liquid hydrocarbons, essentially paraffinic and naphthenic in nature obtained from petroleum, it is refined to meet the following specifications: (1) It meets the test requirements of the USP XXI for readily carbonizable substances. (2) It meets the test requirements of USP XVII for sulfur compounds. (3) It meets the specifications of the … (ADAC)…
(b) White mineral oil may contain any antioxidant permitted in food by regulations… in an amount no greater than that required to produce its intended effect. (c) White mineral oil is used or intended for use as follows.


Use Limitation
In frozen meat, as a component of hot-melt coating. Not to exceed 0.09% of meat.
As a protective seal on brine used in the curing of pickles. In an amount not to exceed good manufacturing practice.
In molding starch used in the manufacture of confectionery. Not to exceed 0.3% in the molding starch.
As a release agent, binder and lubricant in the manufacture of the yeast. Not to exceed 0.15% of yeast.
As an antiaging agent in sorbic acid for food use. Not to exceed 0.25% in the sorbic acid.
As release agent and as sealing and polishing agent in the manufacture of confectionery. Not to exceed 0.02% of confectionery.
As a dust control agent for wheat, corn, soybean, barley, rye, rye, oats and sorghum. Applied at a level of no more than 0.07% by weight of grain.

Use
As a release agent, binder and lubricant in or on capsules or tablets containing concentrates of flavouring spices, condiments, and nutrients intended for addition to food, excluding confectionary.
As a release agent, binder, and lubricant in or on capsules and tablets containing food for special dietary use.
As a fluid on fermentation fluids in the manufacture of vingear and wine to prevent or retard access of air, evaporation, and wild yeast contamination during fermentation.
As a deaerator in food. In accordance with 21 CFR 173-340.
In bakery products, as a release agent and lubricant.
In dehydrated fruits and vegetables, as a release agent.
In egg white solids, as a release agent.
On raw fruits and vegetables, as a protective coating.

Limitation
Not to exceed 0.6% of the capsule or tablet.
Not to exceed 0.6% of the capsule or tablet.
In any amount not to exceed food manufacturing practice.
In accordance with 21 CFR 173-340.
Not to exceed 0.15% of bakery product.
Not to exceed 0.02% of dehydrated fruits and vegetables.
Not to exceed 0.1% in egg white solids.
In an amount not to exceed good manufacturing practice.

Other uses:
- In dehydrated fruits and vegetables, as a release agent. Not to exceed 0.02% of dehydrated fruits and vegetables.
- In egg white solids, as a release agent. Not to exceed 0.1% in egg white solids.
- On raw fruits and vegetables, as a protective coating. In an amount not to exceed good manufacturing practice.

For the removal of water from substances intended as ingredients of animal feeds. (c) The quantity of mineral oil used in animal feed shall not exceed 3.0% in mineral supplements, nor shall it exceed 0.06% of the total ration when present in feed or feed concentrates.

Citation number / CFR part
21 CFR 172.878 Food additives permitted for direct addition to food for human consumption. Subpart I – Multipurpose additives
21 CFR 175.230 indirect food additives: Adhesives and components of coatings. Subpart C - Substances for use as components of coatings. Hot-melt stripable food coatings
21 CFR 178-3620 Indirect food additives: adjuvants production aids and sanitizers. Subpart D – Certain adjuvants and production aids. Lubricants with accidental food contact
21 CFR 573.680 Food additives permitted in food and drinking water of animals. Mineral oil