Oleogel DAC Pionier® PLW
A new oil for application in cosmetic and pharmacy

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Pionier® PLW

Hydrophobic Base Gel DAC

A new Oil gel for application in cosmetic and pharmacy

We wish to present you a new oil-gel called Pionier® PLW® developed by Hansen & Rosenthal for applications in cosmetic and pharmaceutical products.

The qualitative formulation of an oil-gel composed of paraffinum liquidum and polyethylene was published for the first time in the 9th edition of the German Pharmacopoeia (DAB), chapter “Monographies” under the rubric “Hydrophobic Gels”.

In this connection we would like to alter slightly the title of this presentation. The gelatinization of paraffin oil using polyethylene or polyethylene wax is already well known and has been practised for a long time. In so far as an oil-gel does not present something totally new, products produced by simple dissolution of polyethylene wax in hot paraffin oil and subsequent cooling down by the surrounding air are useful ointment bases, but they only possess to a lesser extend, if any, the special properties, which are going to be presented here. To obtain the extraordinary properties of Pionier® PLW it is only necessary to have carefully selection of raw materials applying different structure-related criteria, but also to generate a special crystal matrix of the melted polyethylene. This, together with a reduction of the solid content to a minimum, is obtained by applying an extremely precise temperature control to a large scale process. Such a large scale process involving precise temperature control is a major technological breakthrough achieved by Hansen & Rosenthal KG.

70% of the production of the product is consumed by the cosmetic industry. Here, Pionier® PLW is used primarily in the cold-production of emulsions as well as in the development of products with problems of stability at high temperature.

The remaining 30% is used in the pharmaceutical industry. Here, the high purity and sterility are appreciated in the production of preparations to be applied to wounds and mucus, but above all for the possibility of nearly unlimited combination with emulsion destroying agents and problematical substances (e.g. antirheumatic gel), whilst preserving viscosity stability in a temperature range from minus degrees up to 60 or 70 degrees Celsius.

Due to these properties Pionier® PLW displaces in the pharmaceutical field the common petrolatum, which is used in pharmacy as a carrier for solid or hydrophobic active agents as well as in skin protection creams and lotions. The direct comparison to petrolatum shows clearly these advantages.

These advantages will now be briefly discussed. Many of these points were published in October 1988’s issue of the German magazine “Pharmazeutische Zeitschrift”.

Rapid Liberation of Active Substances

The extraordinary crystal structure of the oil-gel allows a liberation rate of the contained active substances comparable to that of water containing ointment and emulsions.
In a test, 2% salicylic acid was included as conserving substance in petrolatum, PIONIER® PLW, and in the so-called "hydrous wool-wax-alcohol ointment" (DAB) whilst the liberation was controlled.

This liberation rate was measured using two different methods; a microbiological way based on the inhibition test in agar plates and a chemical way based on the formation of a complex of iron salicylic acid after treatment with an aqueous ferric-chloride solution.

You can see here that the diffusion of the acid to the culture medium was higher in the case of PIONIER® PLW oil-gel, due to the large inhibitive activity. For petrolatum and for the "hydrous wool-wax-alcohol ointment" only little inhibitive activity was noticed and therefore only a little diffusion to the culture medium occurred.

For the chemical determination two grams of the preparation were placed on the interior surface of a rubber stopper of a penicillin flask. 200 ml of the ferric-chloride solution at pH-value of 8 were poured into the flask. The flasks were put into an agitator and after controlled periods of time the formation of the iron-salicylic acid colour complex was measured in each case at 529 nm against the control value.
PIONIER® PLW

Hydrophobic Base Gel DAC

Viscosity Hardly Temperature Dependent

The viscosity of oil-gels, as well as that of petroleum in the solid state is primarily determined by the solid components. However, the viscosity drops dramatically at temperatures near to those of the melting points of these solid components. Due to this the structure of the entire preparation breaks down.

While in the case of petrolatum the viscosity is built up by a mixture of low melting paraffins and waxes, in the PIONIER® Oil-Gel the presence of the plastic polyethylene leads to an extremely high melting point, up to 90°C, almost twice as high as the average value for petrolatum.

You can see here two flow curves of PIONIER® PLW and petrolatum. The viscosity is registered on the Y-axis against the increasing temperature on the X-axis. The measurement was conducted at 5 rpm.

The graph was prepared after stabilization of the measured values in order to avoid the registration of the initial high yield point of petrolatum. The discussing of these two curves makes clear where the resulting advantages for the practical application lie: in comparison to petrolatum, preparations produced using PIONIER® PLW as base can easily be squeezed out of the tube at very winter temperatures, conversely the same viscosity stability is maintained at high temperatures as experienced at the seaside in the summertime. Furthermore only these preparations survive under conditions of high heat strain (e.g. in tropical areas), without loss of stability due to the melting of the ointment base.

This heat stability can be transposed very easily to most emulsion systems of the “water in oil” type: the external phase, the fat phase, determines mostly the structure and the stability of the whole emulsion and it is in this external phase where the PIONIER® PLW is located, which leads to a considerable increase of stability to the emulsion.

Shear Stability

The shear stability is able to predict the viscosity alterations of the product due to mechanical strain, e.g. in the mixer or in the filling machine during the manufacturing process.

In the case of the so-called Newton’s substances the viscosity, that means the resistance of the substance against the mixing power during the manufacturing process is always directly proportional to the force, given by the mixing speed.
This Newtonian behaviour is shown for example by mineral oils or water. However, in the case of the usual ointment bases the viscosity decreases to values lower than theoretical during the mechanical strain leading to structure desintegration. Therefore, they display after mechanical strain an extraordinary low stability which returns after a certain period of rest. This kind of behaviour is called thixotropic or not stable to mechanical strain.

In the case of petrolatum it can be so pronounced that during the process in the ointment mill or in the mixer the preparation becomes liquid. The measurement of the viscosity is in the case of thixotropic substances because the mechanical strain imposed on the sample during the measurement is influencing the viscosity in a direct way. Therefore, the measurement takes place usually in the so called rotational viscometer. This is a spindle which rotates with a certain speed. At the same time an X-Y-plotter registers the power needed to turn the spindle against the resistance of the sample.

In the examples shown in the figure above the speed of the turning spindle has been increased stepwise in two minutes from zero to one hundred revolutions per minute and decreased in similar registered braking power of the products to the spindle is a standard for the viscosity and it is shown on the X-Y axis (here due to comparative reasons slopping downwards).

**Cold or So Called Heatfree Processing**

The basic influence on this approach was the fact that Pionier® PLW can absorb up 50% of essential oils without loosing its jelly-like appearance. If you intend to include water instead of the essential oils, the hydrophobic gel must contain hydrophylic agents.
This can be accomplished by adding a liquid "water in oil" emulsifier to Pionier® PLW.

In the resulting hydrophilic gel you can now include up to the 80% water without any problems at room temperature. For this purpose it is only necessary to have a high-speed stirring machine.

Cold processable "oil in water" emulsions have been on the market for a long time, because it is not a problem to thicken them without heating the external phase, which is, in the case of the "oil in water" emulsions, the water phase.

This external phase forms primarily the structure of the cream and there are a lot of substances for this situation which will form more or less solid gels only by swelling in the water.

For the "water in oil" emulsions the situation is basically different; there was previously no satisfactory possibility to thicken the fat phase at room temperature without losing the homogeneous nature and surface brilliance of the finished cream.

This problem has been solved in an outstanding way with the hydrophilic form of Pionier® PLW: you can judge it by yourself by looking at the sample called Pionier® KWH-Soft, which contains about 75% water.

Let us now further highlight the general advantages of cold processable systems:

- Only a small working area is required for the installation. Normally you need only space for the heating and cooling facilities and for two further vessels, one for heating up the water phase and the other one to heat up the fat phase.

- The total energy cost is very low.

- You have lower maintenance and repair charges.

- Downtime during production is an exception, because the equipment which cause the most disruptions, the heating and cooling facilities, are not in use.

- It is a non-heat sensitive production process for the product; the manufacturing and handling of temperature sensitive substances and active agents becomes a simple reality. Clever marketing people could exploit this property in product promotion. We would like to present this graph to illustrate the heading "Spare Energy". The involved values were measured by the company HOECHST AG and put kindly at our disposition. Here you can see the value of thermal and mechanical energy as well as the time needed to manufacture a typical cream by taking into consideration different kinds of processing. You will find the highest valued for the usual kind of manufacturing that means homogenization of the hot fat phase with the hot water phase and final cold stirring of the emulsion. The so called hot/cold processing (in the middle of the graph) allows in most of the cases the direct absorption of the cold water phase into the running homogenizator. Only the fat phase is hot.
Finally the best conditions are represented in the totally cold processing system, there is no thermal energy input required at all.

We know that these data are not transferable to every system and every machine. However, they clearly show the relative differences for the three production processes.

**High purity**

Pionier® Oil-Gel as well as petrolatum are composed of oil which are fixed by inclusion in a matrix of solid components.

In case of the Oil-Gel Pionier® PLW, the oil component is only white oil called paraffinum liquidum DAB, but for petrolatum, the specification in this pharmacopoeia allows the inclusion of white oil of a technical quality.

The resultant content of aromatics is one of the main reasons why cosmetics sticks and creams manufactured from petrolatum instead of Pionier® PLW turn yellow under the influence of daylight. Furthermore another effect is that the Pionier® Oil-Gel is more tolerated even by the mucus than oil-gels from petrolatum and technical white oils.

Finally, we would like to present three more points that are more or less of a subjective nature, nevertheless, they highlight some further important aspects.

**Light Spreadability**

Unlike petrolatum, Pionier® PLW Oil-Gel can be applied almost without pressure over sensitive and painful skin areas like burns, wounds and inflammations. Please recall the curves of reograms, where it was shown that in the case of Pionier® PLW there is no yield point.

**Attractive Appearance**

The soft Pionier® Oil-Gel presents with its transparent nature clear advantages against the solid white petrolatum which has a very greasy and fatty character.

This fact is very important for OTC medical preparations as well as for the ointment bases in decorative and protective cosmetics where quite often water resistant preparations are needed (e.g. in sun protection, repellents, make-up’s, and protection during work), and where petrolatum bases due to the above mentioned points are not accepted by the consumer.

**Quick absorption**

Because of the low content of solid components, the Pionier® PLW Gel is absorbed more quickly by the skin than petrolatum.
Most beauty cosmetics and dermatological carriers, aside from gels, oils and pastes, have in fact an emulsion as base. An emulsion exists, when a liquid is very thoroughly spread within a second one, in which it usually does not dissolve very well or not at all (most common e.g. water and oil).

Such a spreading can be reached mechanically, only - it does not show stability. Because of the different specific density data the result will be two more or less well separated phases of the two original products.

Nevertheless, such a system can be stabilized, by adding emulsifiers, which influence the surface tension of the liquid. The resulting emulsion remains stable, even after years. Always depending on the chemical composition of the emulsifier used, different types of emulsions can be generated.

The most common types are:

- The W/O (water in oil) type
- The O/W (oil in water) type

As the name already inclines, the W/O type has the watery phase thoroughly spread within the oil phase. The quantitative relation of the phases is of no importance. In a certain quantity of oil ten times as much water, which would be the inner phase in that case, could be spread without any problems. Since the W/O has its water phase spread within the oil, all water particles are surrounded by oil particles. Therefore the surface with which the emulsion exposes itself to the environment is an oily one.

This fact has its advantages as well as its disadvantages, especially when being compared to the, in its structure, opposite type of emulsion. It has to be said that most of the disadvantages depend on the greasier character, the slower penetration of the skin, the lacking cooling down effect.

According to the recent research publications the W/O type is named as the definitely most advantageous type of emulsion.

Generally the following rules ought to be considered:

**O/W Emulsions**

- Almost all lotions
- Preparations for oily skin

**W/O Emulsions**

- Night cream, eye cream, nuturing cream
- Preparations for strained and elderly skin
- Preparations with only little or no conservation at all
Before selecting the type of emulsion you have to choose how you want to offer the preparation: in liquid form (e.g. milk, lotion) or none liquid form (e.g. cream, ointment).

In many cases, this decision is already made by the products later on market name, that often includes established terms, which describe the purpose of application (e.g. cleaning milk, night cream). In any case the product should fulfill the consumer's expectations triggered by that market name.

Following the above mentioned criteria the adequate Hansen & Rosenthal base, which leads to the finally wanted product, should be chosen from table 1.

If more than one base is eligible, table 2 should be helpful, by characterizing the products shortly.
**Pionier® PLW**

**Hydrophobic Base Gel DAC**

**Recipes**

All Hansen & Rosenthal bases plus product data and description as well as frame recipes with manufacturing instructions are listed in the cosmetic and pharmaceutical base products file.

These frame recipes are kept simple deliberately, since they are meant to offer just scaffold for the customer’s own ideas. Water has to be added simply and the resulting emulsion to be conserved. Glycerine takes care of a high stability at low temperature and magnesia sulfate enables the emulsion to remain more stable in heat conditions (the latter applies only to the W/O type).

The Hansen & Rosenthal bases are composed in such a way, that small quantities of further additives are tolerated well by the ideal composition with its originally fixed percentages of water, oil and emulsifier. The stability of the emulsion is not impaired.

On the other hand, larger quantities of additives require an alteration of the frame recipe. Hydrophilic substances do not cause any problems. They are simply exchanged for the same quantity of water in the recipe. The same procedure with lipophilic additives starts out more complicated: The emulsifier and the oil components are already mixed and therefore the oil/emulsifier ratio is fixed.

In order to solve this problem Hansen & Rosenthal offers also splitted bases, which means that the oil component is left out. The remaining part runs as Hansen & Rosenthal emulsifier for composing recipes.

The term “emulsifier” is of course a simplification. As a matter of fact the complete rest of the lipophilic recipe can be described as a mixture of the prime emulsifier, stabilizer, spreading agent and consistence agents.

From now on the process turns out to be the same as the one before with the hydrophilic substances. The cosmetic file delivers the frame recipe belonging to the Hansen & Rosenthal emulsifier. The oily or fatty additive is simply exchanged for the same quantity of the present oily component (e.g. liquid paraffin or oil-gel).

Note that one aspect has to be watched carefully: exchange of high percentages of the oleo-gel Pionier® PLW could mean loss or impairment of special properties of the W/O base. High stability at extreme temperatures or cold processing are reached just by bringing Pionier® PLW into the base.
Hydrophobic Base Gel DAC

“Cold Processing” - What for?

The traditional making of creams and lotions requires commonly the separate heating of both water and oil phase. The two phases are then unified forming an emulsion with the support of more or less fast running mills and homogenizators and the subsequent cold stirring in vacuum.

The heating-up often to more than 80°C is of course not very desirable from an economical point of view. This bears an even greater meaning taking into account the fact that the product has to be cooled down inevitably with the same amount of energy. These are even more disadvantages considering industrial scale production: e.g. for the heating of the water phase a pot of the same size as the ointment mixer is needed since modern preparations do contain more than 80% of water.

Cooling and heating devices would have to be installed, therefore lack of room is a problem that occurs often. Also higher costs because of maintenance, repair and the consequent break in production would have to be taken into account. The common big mixers could be used more effectively, once the long waiting periods of the heating and cooling-down vanished.

Small companies would probably be less affected by these problems, but even for them “Cold Processing” could bring advantages when investing in new machines.

A mixer without the costly double mantling for temperature regulation certainly would be much cheaper. The expensive heating and cooling devices could be renounced of. Last but not least it should be born in mind that consumers have become more able to recognize good quality through constant work with the modern media. A sharp mind could possibly make a good publicity of the fact that “Cold Processing” is indeed preserving the product and active substances very well.

After all you will probably ask yourself why the traditional production method is still commonly in use.

The reason is simply that the outer phase of the emulsion has to be thickened for the build-up of consistence. Substances granting consistence like waxes, fatty alcohols, paraffins, etc, help to carry out the work by being melted with the fatty phase. Afterwards they become solid again but this time thoroughly spread with the emulsion. If, on the other hand, solid substances were simply incorporated at room temperature, the result would be completely different: even after thorough homogenization the new structure and the shiny character of a cream would not be reached, the impression left would always be somewhat “granular”. The objective, therefore, is to reach the most homogeneous outer phase without heating. The result should be a gel-like substance. This is possible with an O/W emulsion since there are a lot of watery-gel producing agents on the market.

This issue causes a lot of difficulties for the dermatologically well proven W/O preparations. Until now the only common solution used to be mixing the oils with substances like mineral silicates which increase the viscosity only because of their huge surface.

Hansen & Rosenthal KG however has developed special emulsifying bases. “Cold Processing” is made possible by using particular polyethylene swollen in liquid paraffin.

Brand name: PIONIER® PLW.

The resulting W/O creams and lotions do have an excellent shiny and evenly structured appearance that is hard to match.
**Pionier® PLW**

**Hydrophobic Base Gel DAC**

Beyond that fact the polyethylene-gel Pionier® PLW has an astonishingly stabilizing effect: the W/O cream is supported by the polyethylene matrix in such a way that temperature of up to 80°C cannot lead to a break-up of the emulsion.

Pionier® PLW is being listed with a monography in the DAC (German Medication Codex) as hydrophobic base gel. This fact simplifies the application of Pionier® PLW as medium for analgesics, preparations against rheumatism and wounds.

**Pionier® PLW - Ointment / Cream Base Hydrophobic**

Pionier® PLW hydrophobic is an extremely homogeneous, gel-like, opalizing and odourless ointment/cream base. Its consistency is vaseline-like, but contrary to this mixture of hydrocarbons it can practically not be influenced by temperatures in the 0 to 70°C range. But as the cream base Pionier® PLW looses its consistency and suppleness at temperatures over 76 to 80°C, it should only be heated to higher temperatures if the hydrophilic form has to be reached by adding emulsifiers.

Production procedures result in a special molecular structure which allows additives to diffuse practically without hindrance and thus permits the direct penetration of the treated skin. Pionier® PLW is absolutely neutral i.e. it is compatible with all pharmaceutics and, therefore, predestined for use in pharmaceutical preparations.

Because of its relative insensitivity towards high and low temperature Pionier® PLW is also an important alternative cream base for cosmetics. We can recommend it either for our customers’ formulas or its hydrophilic form W/O (as Pionier® WWH Soft) and O/W recipes (as Pionier® OEWA) in order to obtain stable, homogeneous creams which do not tend to bleed out (oil) or precipitate water even under extreme conditions (rocking test). The special suppleness of Pionier® PLW allows also its use as a massage cream.

**Clinical Judgement**

The dermatological harmlessness has been proved in a 6 week application test under the guidance of Professor Ippen of Georg August University at Göttingen. The original expertise can be put at your disposal upon request. A sufficiently large quantity of Pionier® PLW was given to a group of 50 persons of both sexes aged from 19 to 63 years. They were instructed to use the product according to the prescription and contact the university clinic at once in case of unwanted skin reactions. After 6 weeks of trial the following results were reported:

The compatibility of Pionier® PLW has been approved without reserve since none of the persons experimented upon showed any objective or subjective skin irritation during the regular use. This proves that also in case of long term application the product will not cause any unwanted reaction of the skin and no significant sensitization has to be expected. There were also no complaints about an irritation of the mucous membrane.
**Pionier® PLW**

**Hydrophobic Base Gel DAC**

**Application**

Ointments, gels, creams and lotions for cosmetical and pharmaceutical purpose.

**Composition**

Paraffinum Liquidum (Ph. Eur.) and Polyethylene (Ph. Eur.)

**Consistency and properties**

Ointment-like, opalizing, with special molecular structure. High diffusion and penetration capacity.

**Typical Physical Properties**

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<td>Microbiological qualification</td>
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**Production procedures**

When producing so called "cold processing preparations" or gels, the Oleogel should not be heated. Only when using Pionier® PLW for your own preparations of hydrophilic character, a clear melt has to be reached at temperatures of approx. 90°C.
PIONIER® PLW Ointment / Cream Base hydrophobic is made of special high quality raw materials and is subject to a special production procedure in order to obtain those properties which are important for the manufacture of medicines.

Although the ointment base has the aspect of petroleum jelly its molecular structure is completely different so that the constituents diffuse practically without hindrance and thus reach an optimum efficiency.

A working temperature of less than 70°C has to be maintained. As the ointment base PIONIER® PLW looses its consistency and suppleness at temperatures over 76 to 80°C, it should be heated only to higher temperatures if the hydrophilic form has to be reached by adding emulsifiers.

Interdependency of Temperature and Viscosity

The Reogram 654 shows that the transverse strain which is analogous to the viscosity, reduces with raising temperatures. This phenomenon is normal although more clearly shown in competing products.

PIONIER® PLW should, therefore, have slight advantages in respect to bleeding and oil figure.

Interdependency of Viscosity and Transverse Strain

With reference to the molecular structure the Reogram 137 F shows an advantageous ratio of viscosity to the transverse strain.
**Advantages against White Petroleum Jelly**

- Shearing stability
- Cold processing e.g. (20°C)
- Higher purity
- Viscosity not dependent on temperature (-25°C / +75°C)
- Easy application without pressure
- Attractive appearance
- Faster migration of incorporated additives

**In W/O - Emulsions (W/O - Cream / Lotion - Oil Base)**

- High stability up to +75°C (dependent on recipe)
- Practically no dependence on temperature
- No separation of oil and water
- High capacity to absorb water up to 80%
- Fast soaking into the skin
- No oily appearance

**Physiologically unobjectionable mucous membrane compatible**

Please ask for test reports!
Pionier® PLW

Hydrophobic Base Gel DAC

**Specification**

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The substance complies with the monograph

“Hydrophobes Basisgel”
(Gelatum basalis hydrophobicum)
of the DAC (Deutscher Arzneimittel Codex)
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