



Ichthyol[®] Pale

Active substance for skin and hair
Safety and efficacy from nature

▶ **ICHTHYOL**



Ichthyol® Pale

Ichthyol-Gesellschaft manufactures unique raw materials from highly sulfuric and organic matter-rich limestone in GMP compliant production under the umbrella term of Ichthyol® substances. Fascinated by the numerous inclusions of prehistoric scale fish in the rock, Greek "Ichthys" was combined with latin "Oleum" to the illustrious name of "Ichthyol®".

Chemically regarded Ichthyol® substances are sulfonated shale oils of highest purity. Their uniquely high content of organically combined sulfur is indispensable for their therapeutic efficacy.

The Ichthyol® substances belong to the best documented active ingredients from nature today. Their multifunctional action profile and their good tolerance are substantiated by clinical and toxicological studies, respectively.

Under the name of Ichthyol® Pale, a pale Ichthyol® substance specially developed for cosmetic application is offered. In hair and skin care the cosmetic agent with the official INCI designation "ICTASOL" has gained importance worldwide because of its broad action profile. Its benefits in control of severe dandruff and skin blemishes could be proven in a variety of clinical studies. Ichthyol® Pale is distinguished by versatile cosmetic formulation possibilities. Manufacture and quality are adapted to the ever-growing legal requirements in order to provide users of our raw material certainty for future utilization.

Convince yourself on the following pages about quality and action mechanisms of a unique raw material.

**Thank you for your interest.
Sincerely yours, Ichthyol-Gesellschaft**



**You can find more information
under www.ichthyol.com**

Advantages at a glance

- Natural origin (from organic matter-rich limestone)
- High purity
- Good tolerance
- Large safety factor
- Broad spectrum of efficacy
- GMP-controlled manufacture
- Reliable processing
- Versatile formulations (water soluble)
- Comprehensive documentation
- REACH registered

Identification

REACH Substance
Identification:
Ichthyolic Acid,
Sodium Salt

TradeMark
Ichthyol® Pale

EC # 215-671-7

CAS # 1340-06-3

INCI: ICTASOL

Former INCI and synonym =
sodium shale oil sulfonate

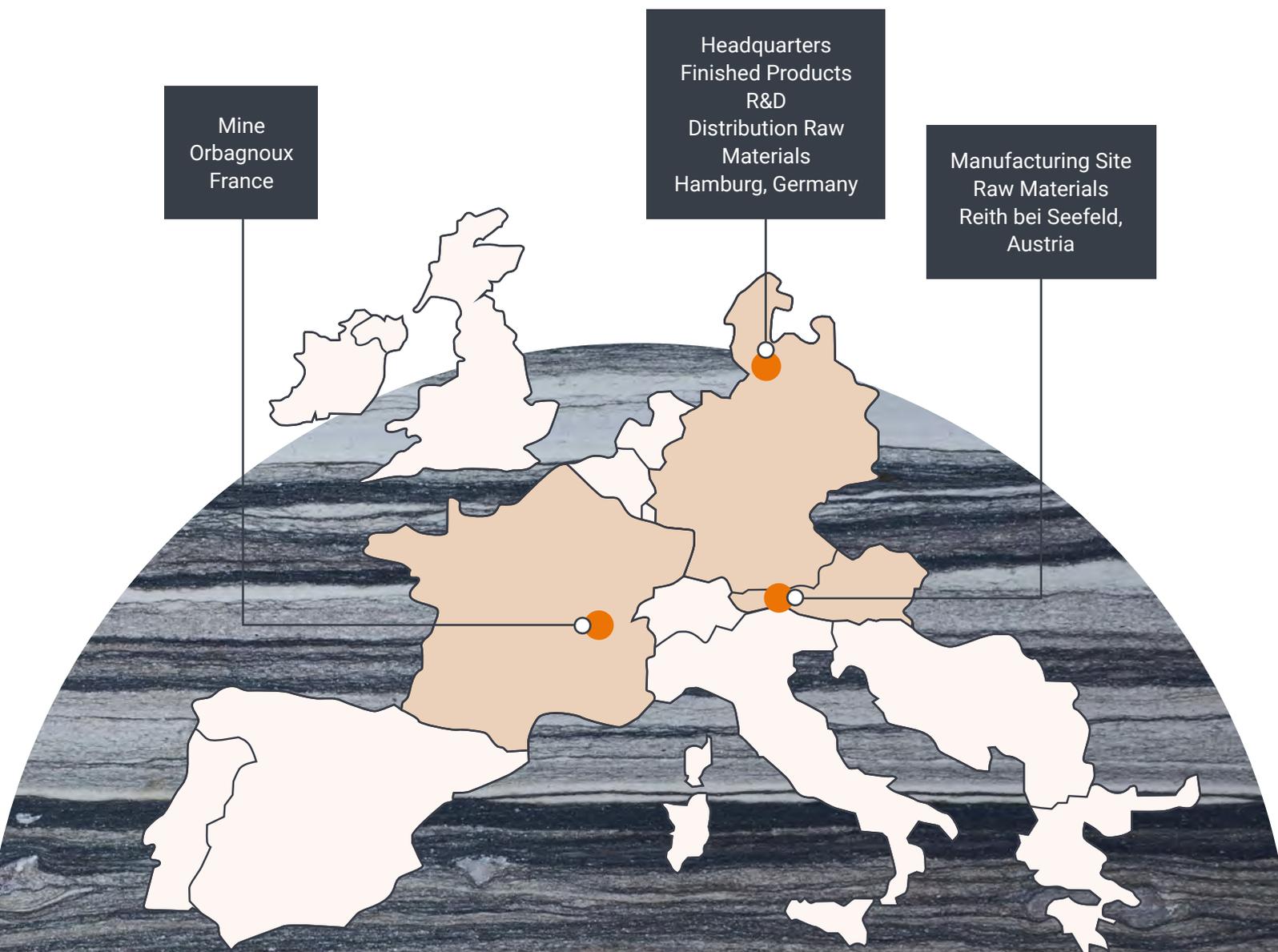
Ichthyol-Gesellschaft: A story to tell

Founded back in 1884, Ichthyol-Gesellschaft today is a renowned address in the dermatological field. For more than 140 years the family-run company has been based mainly on its unique active ingredient **Ichthyol®** that gave the company its name.

Bringing together tradition and progress as well as science and service Ichthyol-Gesellschaft offers comprehensive solutions for dermatological needs. Laboratories, pilot plant capabilities and collaboration with the finest research institutes

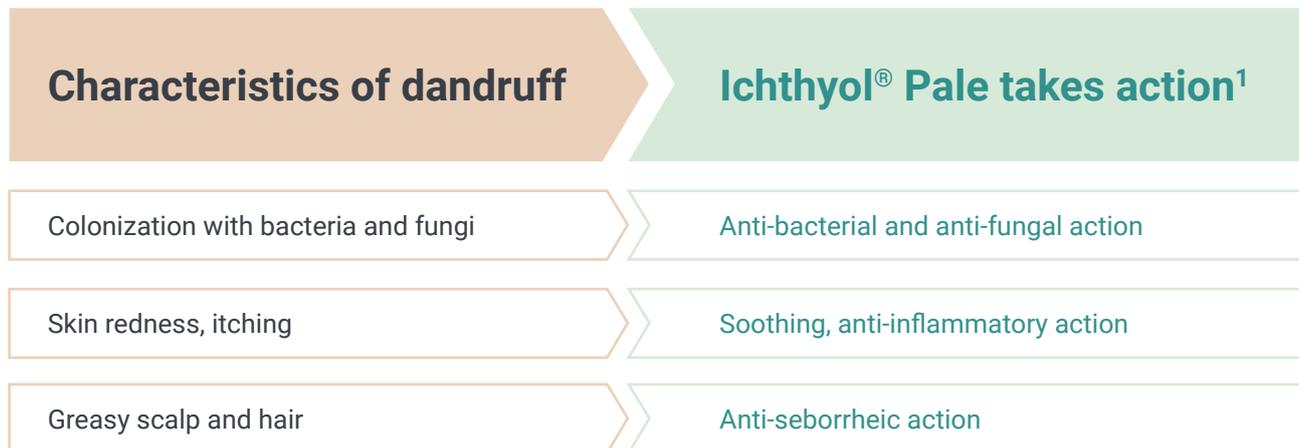
(e.g. Helmholtz and Fraunhofer) give the company extensive possibilities for research and development. From the river Rhone in France via the mountains of Austria to Hamburg, the substance **Ichthyol® Pale** is the result of a multinational cooperation.

The well-tolerated substance of natural origin can be used in hair care products (e.g. for treatment of dandruff) and for skin care as well (e.g. for treatment of blemishes) due to its broad spectrum of efficacy.



Research – Hair Care / Dandruff

A complex condition requires an inspired answer



Ichthylol® Pale: Take advantage of its broad spectrum of efficacy & compatibility with a variety of substances. **Exemplary shampoo formulation:**

Ingredient	Supplier	[%]	INCI
Water		64.1	Aqua
Texapon N 70	BASF	19.0	Sodium Laureth Sulfate
Lamepon S UP	BASF	8.0	Potassium Cocoyl Hydrolyzed Collagen
Glycerox HE	Croda	5.0	PEG-7 Glyceryl Cocoate
Ichthylol® Pale	Ichthylol-Gesellschaft	1.0	ICTASOL
Sodium Chloride		1.0	Sodium Chloride
Euxyl K 712	Schülke & Mayr	0.8	Sodium Benzoate/Potassium Sorbate
Perfume Heliodor*	Grau Aromatics	0.5	Parfum
Sodium Citrate		0.4	Sodium Citrate
Citric Acid		0.2	Citric Acid

¹ Gayko, G.: dealing with dandruff needs integrated approach, Personal Care Magazine, May 2009

Research – Effect/ Dandruff

Comparison with established anti-dandruff agents

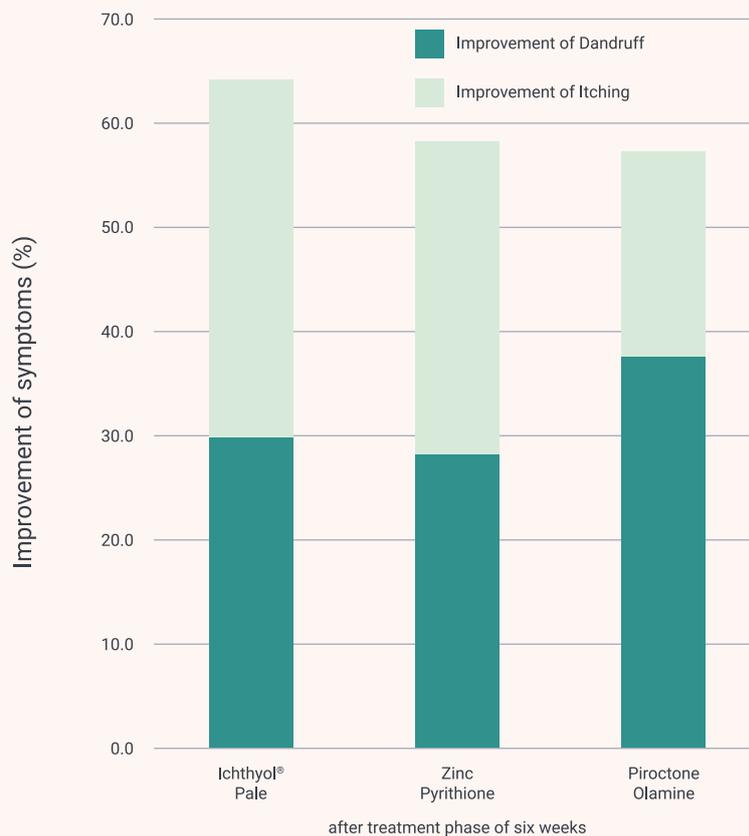


Fig. 1. Excerpt from studies of Ichthyol® Pale vs. Zinc Pyrithione and Piroctone Olamine. Ichthyol® Pale is superior in improving dandruff and itching due to its multifunctionality.

Dandruff is most often accompanied by unpleasant concomitant symptoms as skin redness, itching and greasy scalp and hair. **Ichthyol® Pale** is suitable for an all-embracing treatment.

This could be proved in studies in which it was compared with the well-known synthetic anti-dandruff agents Zinc Pyrithione and Piroctone Olamine².

All findings reflect: **Ichthyol® Pale** is superior due to multifunctionality, good tolerance and long-term safety. Therefore, **Ichthyol® Pale** can be considered as an alternative to obsolete Zinc Pyrithione (ZPT).

Combination with established anti-dandruff agents

In combination shampoos with potent anti-fungal agents, **Ichthyol® Pale** provides valuable additional actions for an exceptional anti-dandruff performance.

Faster and broader effects are observed and symptoms concomitant to dandruff are successfully countered³. **Ichthyol® Pale**, therefore, is used as a booster of efficacy.

² Gayko, G.: Sulfonate d'huile de schiste sodique contre les pellicules - Sodium Shale Oil Sulfonate against dandruff, Parfums Cosmétiques Actualités, No. 170, Avril/Mai 2003

³ Gayko, G. et al.: The use of a pale type of Ichthyol® in cosmetic dermatology, Clinical Dermatology 8 (4), (2006) 243-247

Research – Effect/Dandruff

Comparison with coal tar

Coal Tar, clinically beneficial in the treatment of dandruff without a doubt, is known to contain carcinogens.

On account of safety reasons, therefore, Coal Tar has already been banned from uncontrolled use in cosmetics in the European Union.

It could be proved that a safe, well tolerated and, above all, similarly effective and 'broad spectrum' alternative of natural origin is available with **Ichthyol® Pale** to substitute Coal Tar in dandruff shampoos.⁴

In Europe, this exchange has already been done successfully.

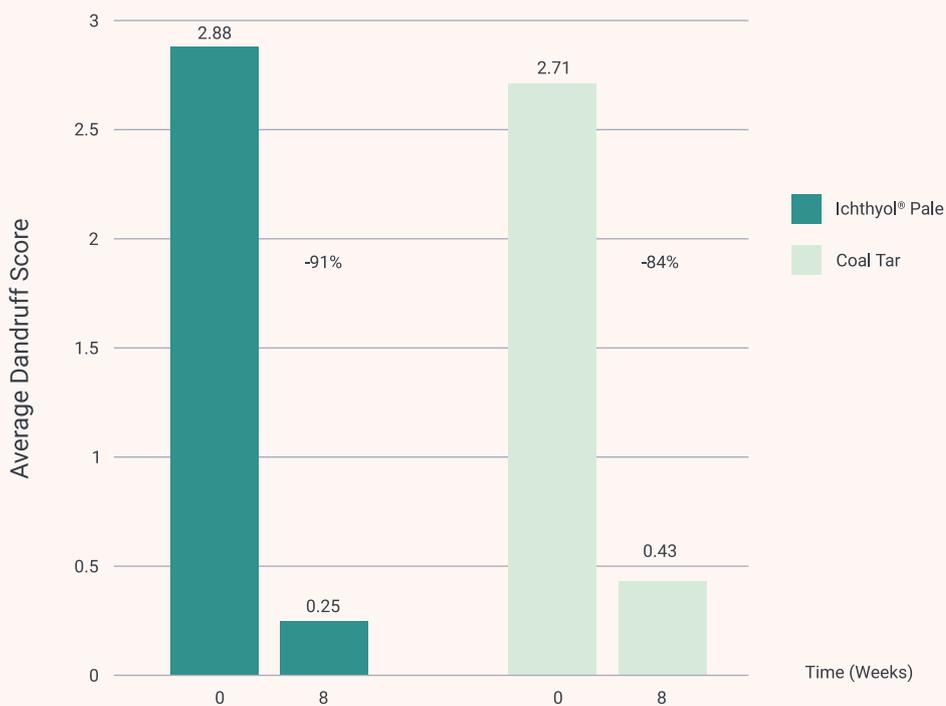


Fig. 2. Excerpt from the comparison study of Ichthyol® Pale vs. Coal Tar: Ichthyol® Pale is as effective as Coal Tar in the reduction of dandruff, however, in contrast to Coal Tar it is safe in long-term treatment.

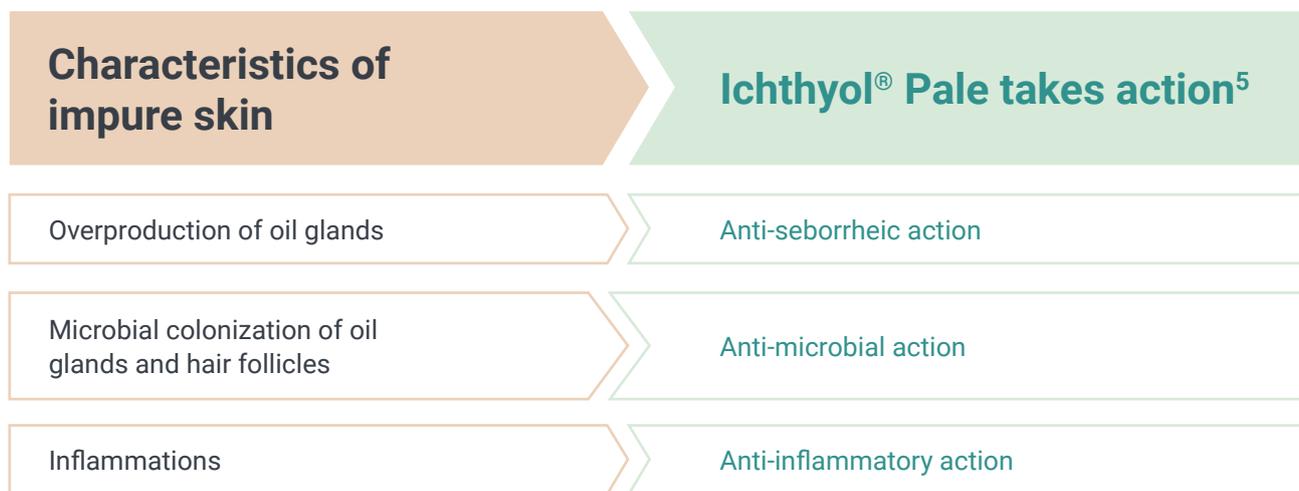
⁴Gayko, G. et al.: Antidandruff Efficacy of Sodium Shale Oil Sulfonate versus Coal Tar, *Cosmetics & Toiletries* 120 (3), (2005) 83-92

Research – Skin blemishes and pimples

When oil glands are out of control ...

Ichthyol® Pale makes no concessions: Threefold action in one ingredient for modern treatment of skin blemishes and pimples. In a study on 101 humans after a treatment period of 6 weeks, great improvements in elimination of skin impurities

could be observed in nearly 80 % of the cases using a cream containing 1 % of **Ichthyol® Pale** (see exemplary formulation below).



Exemplary paste formulation

Ingredient	Supplier	[%]	INCI
Water		25.0	Aqua
Softisan 649	IOI Oleo	15.0	Bis-Diglyceryl Polyacyladipate-2
Petrolatum		13.0	Petrolatum
Zinc Oxide		10.0	Zinc Oxide
Titanium Dioxide		10.0	Titanium Dioxide
Span 80 V	Croda	7.0	Sorbitan Oleate
Monosteol	Gattefosse	7.0	Propylene Glycol Stearate
Propylene Glycol		6.0	Propylene Glycol
Cutina E 24	BASF	3.0	PEG-20-Glyceryl Stearate
Ichthyol® Pale	Ichthyol-Gesellschaft	2.0	ICTASOL
Cera Alba		2.0	Cera Alba

⁵ Reinhard, S. and Warnecke, J., Helles sulfoniertes Schieferöl zur lokalen Behandlung der Acne vulgaris, Der Allgemeinarzt 17, (1995) 182 (engl. translation available)

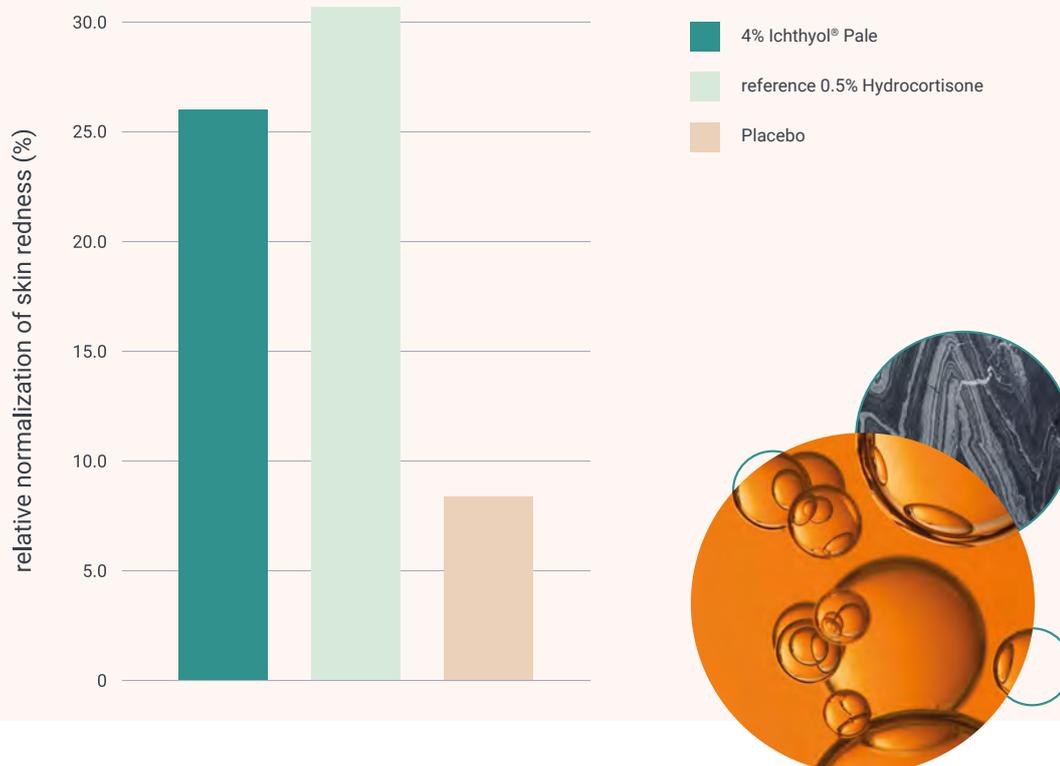
Research – Skin irritations like redness and itching

Inflammatory processes like redness and itching of the skin can be countered excellently by **Ichthyol® Pale**. The anti-inflammatory action was confirmed recently by means of the UVB erythema test.⁶

In the study, a cream with 4 % of **Ichthyol® Pale** was compared with the active ingredient-free vehicle and a reference product containing 0.5 % of hydrocortisone as active substance.

Ichthyol® Pale in a concentration of 4 % exerts an anti-inflammatory action equivalent to 0.5 % hydrocortisone

Comparison of skin colour 24h after UVB-irradiation



⁶ Warnecke, J.: Teerersatzstoffe in der Dermatologie und Kosmetologie, Kosmetische Medizin 19(6), (1999) 332 (engl. translation available)

Research – Effect: Bacteria and fungi

Effect of Ichthyol® Pale

Micro-organism	MIC [%]*	Inhibiting zone Diameter [mm] Aqueous solution of 1% Ichthyol® Pale	Inhibiting zone Diameter [mm] Aqueous solution of 5% Ichthyol® Pale	Growth reduction [log CFU]** Serial dilutions of Ichthyol® Pale in liquid broth
Staphylococcus aureus	0.039	1.0	2.5	6.5
Propionibacterium acnes	0.039			
Malassezia spec.		2.0	11.0	
Candida albicans	0.2 – 5.1			3.0 – 4.9
Dermatophytes (e.g. Microsporum canis, Trichophyton spec.)	0.05 – 0.1			4.9 – 5.1

*MIC / Minimum inhibitory concentration

**log CFU / logarithm of colony forming units (log CFU > 3 = strong growth reduction and anti-microbial efficacy)

Ichthyol® Pale exhibits anti-microbial action in all micro-organisms relevant in cosmetically significant skin conditions

The anti-bacterial and anti-fungal actions of **Ichthyol® Pale**, expressed by the minimal inhibitory concentration (MIC), inhibiting zone diameters and

logarithmic growth inhibition (log CFU), were determined in dilution and plate diffusion test as well as microplate-laser-nephelometry.^{7,8,9,10}

⁷ Leimbeck, R. and Sonnenschein, B.: Determination of the minimal inhibitory concentration (MIC) towards test strains of different species (1992), unpublished report.

⁸ Listemann, H. et al.: Anti-mycotic activity of sulfonated shale oil. Drug Research 43(II), 7 (1992), 784-788.

⁹ Grimm, V. et al.: Investigations on the anti-microbial action of pale sodium bituminosulfonate, Biennial Meeting of the German Dermatological Society, Berlin, May 1st-5th. (2001), Poster No.: P201.

¹⁰ Wiegand, C. et al.: Assessment of the antimicrobial activity of sodium bituminosulfonate against bacteria, yeast and dermatophytes in vitro, 52nd Scientific Conference of the German speaking Mycological Society (DMyKG) e.V., Innsbruck, September 6th-8th (2018), Poster No.: 61 (S1).

On the safe side Ichthyol® Pale is well tolerated

Research – Safety evaluation

The good tolerance of **Ichthyol® Pale** has been verified in numerous toxicological studies.

Ichthyol® Pale showed itself to be well-tolerated both in short-term as well as long-term administration. There was no evidence of any teratogenic, mutagenic or cancerogenic properties.¹¹

With hair shampoo (rinse-off) and body lotion (leave-on) as formulation examples, safety factors clearly above the required minimum value of 100 result for **Ichthyol® Pale**.

The safety of a raw material such as **Ichthyol® Pale** is best illustrated by calculating the „margin of safety“.

Formulation	Safety Factor (required: ≥ 100)
Shampoo (rinse off)	230769 (5 % Ichthyol® Pale in shampoo)
Body Lotion (leave on)	2885 (1 % Ichthyol® Pale in Body Lotion) 577 (5 % Ichthyol® Pale in Body Lotion)

Ichthyol® Pale can, therefore, be classified as a safe substance in accordance with the European Regulation on Cosmetic Products.



¹¹ Cholcha, W. et al.: Experimental Studies on the Tolerance of Pale Sulfonated Shale Oil Following Local and Systemic Application, *Arzneim.-Forsch./Drug Res.* 44(I), 2 (1994) 170

Research – Differentiation from tars

There are still some reports in the scientific literature in which sulfonated shale oils from organic matter-rich limestone, such as **Ichthyol® Pale**, are grouped

with tars because of their related efficacy and characteristic odor. This classification, however, is wrong.

Ichthyol® Pale and tars differ in terms of:

Ichthyol® Pale	Coal Tar
From nature Raw material: organic matter rich limestone Processing temperature: starting from 300°C up to below 480°C	From nature Raw material: coal Processing temperature: about 1000 °C
Rich in sulfur (11-13.5 %)	Low in sulfur (< 1 %)
Water-soluble	Non-water-soluble
Surface-active	Non-surface-active
High purity (< 0.1 ppb BaP*)	Severely PAH-contaminated (> 5,000,000 ppb BaP*)
Non-mutagenic, Non-carcinogenic	Evidence of mutagenicity and carcinogenicity

*BaP: benzo[a]pyrene

The high purity of **Ichthyol® Pale** is confirmed by PAH analyses. It can be demonstrated with gas chromatography/mass spectrometry that **Ichthyol® Pale** is virtually free from polycyclic aromatic hydrocarbons (regularly less than 0.01 ppb benzo[a]pyrene). These findings coincide with the good tolerance of **Ichthyol® Pale**.

In addition, if one considers the active ingredient concentration to be applied, i.e. 0.5 - 5 %, this means that the content of benzo[a]pyrene as leading substance is below the analytical detection limit in the finished cosmetic product.

Manufacture – Origin and GMP-controlled manufacture

Organic matter-rich limestone

Ichthyol® Pale has an extremely interesting history of development.

In geoscientific terms, its origin goes back to deposits of microscopically small algae (phytoplankton) in a special lagoon milieu in the alpine region of the mesozoic era.

Under certain conditions, large quantities of organically combined sulfur could be formed in the biomass during biological (anaerobic) degradation of the marine phytoplankton by sulfate reducing bacteria.

By diagenetic processes, the periodic deposits developed into finely stratified sedimentary rocks (organic matter-rich limestone) that contain the marine biomass in a solidified form today.

The extraction of suitable organic matter-rich limestone from deposits inside the mountain and the further manufacture of **Ichthyol® Pale** are very complex and technically challenging. At the end of geological processes qualitatively appropriate, highly sulfuric deposits of limestone are hidden hardly accessible inside the mountains and have to be exploited in a complicated system of underground chambers. In the dry distillation process following underground mining the organic matter-rich limestone is gently heated under exclusion of air.

Thereby, biomass present in the rock is decomposed only to such an extent that it can be converted from a solid into a liquid form. The resulting oil is distinguished by a high content of organically combined sulfur (up to 15%) which is unequalled world-wide.

Distillative refinement

The obtained oil is purified before undergoing further processing. A distillation treatment is carried out in order to remove finely distributed solid particles and high molecular substances (e.g. polycyclic aromatic hydrocarbons, PAH). Thereby, one obtains a special, low-boiling oil fraction.

Ichthyol® Pale

The low-boiling oil fraction is allowed to react with concentrated sulfuric acid in a gentle sulfonation reaction and is then neutralized with sodium hydroxide solution. The non-polar oil is thereby converted into the water-soluble and surface-active **Ichthyol® Pale**.

Quality Assurance

To constantly obtain a good quality of **Ichthyol® Pale**, it is absolutely necessary to carry out the manufacturing process under exactly defined and controlled conditions in accordance with the Guidelines for Good Manufacturing Practice, GMP.

Our manufacturing site is regularly inspected by health authorities. A corresponding GMP-Certificate is available.

Ichthyol®
Pale





Further information is available from
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