



CERTIFICATE OF ANALYSIS
ICHTHAMMOL¹ PH. EUR. (BP)

ÖSTERREICHISCHE
ICHTHYOL GESELLSCHAFT m.b.H.
nunmehr KG

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Description: ICHTHAMMOL[®] PH. EUR. 8 (including BP)

Manufacture in accordance with the EU Guidelines for Good Manufacturing Practice (GMP), certificate available complying with article 46f of Directive 2001/83/EC and 50f of Directive 2001/82/EC (as amended) concerning Good Manufacturing Practice of active substances for medicinal products for human and veterinary use

Manufacture in complete compliance with the European Pharmacopoeia

Certificate of Suitability (Certificate No. R1-CEP 2001-274-Rev 01)

Registration for application in veterinary medicine according to Council Regulation [EEC] 2377/90 (unrestricted application in all mammalian food producing species including milk according to EMEA Summary Report)

product free from Genetically Modified Organisms (GMO) and residual solvents
product not from animal origin and not from plant origin².

Order No.: **2016-5415**

Barrel No.: **A.C.E.F. SPA 1 - 24**

Batch size: **6.200 kg**

Batch No.: **4/16**

Gross Weight: **1.296 kg**

Net Weight: **1.200 kg**

Manufacturing date: **MAY 2016** Release date: **02.06.2016** Expiry Date: **APRIL 2022**

Manufacturer:

Österreichische Ichthyol Gesellschaft m.b.H.
Nunmehr KG
6103 Reith bei Seefeld, Maxhüttenweg 4, Austria
Phone: +43 5212 2204
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1. Obligatory specifications

Check of identification

- A. Formation of a resinous precipitate.
The precipitate is partly soluble in ether..... **corresponds**
- B. 2 mL of solution A, obtained in identification test A, gives the reaction of ammonium salts and salts of volatile bases..... **corresponds**
- C. Gas evolved turns lead acetate paper R brown or black.
The filtrate gives reaction (a) of sulfates..... **corresponds**

Check of purity

test	specification	result
Acidity or alkalinity	requirement of hydrochloric acid or sodium hydroxide solution	corresponds
Relative Density*	1.040 - 1.085	1.062/20°
Sulphated ash	max. 0.3 %	< 0.3%

¹ ICHTHAMMOL is a trademark owned by ÖSTERREICHISCHE ICHTHYOL (see address details above)

² According to CAS Registry information and European (British) as well as United States Pharmacopoeia definition ICHTHAMMOL in the first step is obtained by the destructive distillation of certain bituminous schists. Plant (vegetable oil) origin of ICHTHAMMOL is not in line with any definition of the substance.



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Obligatory specifications (continued)

Assay

Content	specification	result
Dry matter	50.0 - 56.0 %	51.7%
Total ammonia**	4.5 - 7.0 %	4.8%
Organically combined sulphur**	min. 10.5 %	15.5%
Sulphur in the form of sulphate***	max. 20.0 %	16.4%

* determined on a mixture of equal volumes of the substance to be examined and water

** with reference to the dried substance, *** with reference to the total sulphur content

2. Non-obligatory characters

(according to Ph.Eur. 1.3 statements given under the side-heading characteristics (properties) are no analytical norm and not to be regarded as official requirements)

Consistency and colour	dense, blackish-brown liquid
Miscibility with water.....	in all proportions, partly colloidal
Miscibility with glycerol.....	miscible (observed for 24 hours)
Solubility in ethanol, ether, fatty oils and in liquid paraffin.....	slightly soluble
Mixtures with wool fat and soft paraffin.....	homogeneous

Test for residual Polycyclic Aromatic Hydrocarbons according to the European Directorate for the Quality of Medicines – Certificate No. R1-CEP 2001-274-Rev 01

benzo[a]pyrene	< 0.05 ppm	corresponds
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Additional specifications (beyond Ph. Eur.)

pH	DGF standard methods (DGF Einheitsmethoden) Tenside (surfactants) H-III 1 (92) ; 1 g/100 ml** 6.0 – 7.5	6.7
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Manufacturer's remarks concerning storage and handling

Storage: tightly closed. Long time storage³ not exceeding 25°C.

Remarks: Improper storage may result in separation of an oily phase.

The appearance of an oily phase on the surface of Ichthammol has no negative effect on the product. It is recommended to stir the container before use.

Date: 05.09.2016

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³ Six months or more.