ÖSTERREICHISCHE ICHTHYOL
GESELLSCHAFT m.b.H. & Co. KG

CERTIFICATE OF ANALYSIS

Ichthammol[1] Ph. Eur. 10

Description: Ichthammol® Ph. Eur. 10

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 origin**[2].

Batch No.: **0071020415Ö8/20** Batch size: **5400 kg**
Gross weight: **54 kg** Net weight: **50 kg**
Manufacturing date: **10/2020** Release date: **2020-12-07** Expiry date: **09/2026**

Manufacturer: Österreichische Ichthyol Gesellschaft m.b.H. & Co KG
6103 Reith bei Seefeld, Maxhüttenweg 4a, Austria
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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	1.051
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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Ichthammol® Ph. Eur. 10
Batch No. 0071020415Ö8/20

Obligatory specifications (continued)

Assay

Content	specification	result
Dry matter	50.0 - 56.0 %	51.7 %
Total ammonia**	4.5 - 7.0 %	5.2 %
Organically combined sulphur**	min. 10.5 %	15.6 %
Sulphur in the form of sulphate***	max. 20.0 %	16.2 %

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

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	0.012 ppm

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	7.0

Manufacturer's remarks concerning storage and handling

Storage: tightly closed. Long time storage[3] 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.

ÖSTERREICHISCHE ICHTHYOL
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Date: 2020-12-07

Quality Control

[3] Six months or more.