

**Certification of Substances Department**

**Certificate of suitability  
No. R1-CEP 2001-274 - Rev 02**

1 *Name of the substance:*

2 **ICHTHAMMOL**

3 *Name of holder:*

4 **ÖSTERREICHISCHE ICHTHYOL GESELLSCHAFT M.B.H. & CO. KG**

5 Maxhüttenweg 4a

6 Austria-A-6103 Reith bei Seefeld

7 *Site(s) of production:*

8 **SEE ANNEX 1**

9 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**  
10 **R1-CEP 2001-274 - REV 01**

11 After examination of the information provided on the manufacturing method and subsequent  
12 processes (including purification) for this substance on the site(s) of production listed in annex, we  
13 certify that the quality of the substance is suitably controlled by the current version of the  
14 monograph **ICHTHAMMOL** no. 917 of the European Pharmacopoeia, current edition including  
15 supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical  
16 procedure(s) given in annex.

17 – Test for residual Polycyclic Aromatic Hydrocarbons (Annex 2)  
18 Benzo[a]pyrene not more than 0.05 ppm

19 In the last steps of the synthesis water is used as solvent.

20 A risk management summary for elemental impurities has been provided. (Annex 3)

21 – Test for elemental impurities by ICP-MS (Annex 4)  
22 Arsenic not more than 8 ppm

23 The holder of the certificate has declared the absence of use of material of human or animal  
24 origin in the manufacturing of the substance.

25 The submitted dossier must be updated after any significant change that may alter the quality,  
26 safety or efficacy of the substance.