

Section A1 Applicant

Annex Point IIA1

- 1.1 Applicant
 [REDACTED]
 PelGar International Ltd,
 Unit 13, Newman Lane, Alton,
 Hampshire GU34 2QR, UK
 [REDACTED]
 [REDACTED]
 Email: [REDACTED]
 PelGar address has changed to
 [REDACTED]
 ACTIVA s.r.l.
 Via Feltre 32
 20132 MILANO
 Italy
 Telephone: [REDACTED]
 Fax: [REDACTED]
 Email: [REDACTED]
- 1.2 Manufacturer of Active Substance (if different)
 1) Name: XXXXX
 Address: XXXXX
 2) Name: XXXXX
 Address: XXXXX
- 1.3 Manufacturer of Product(s) (if different)
 Name XXXXX
 Address XXXXX
 1) Product 1

Section A2 Identity of Active Substance

Subsection (Annex Point)

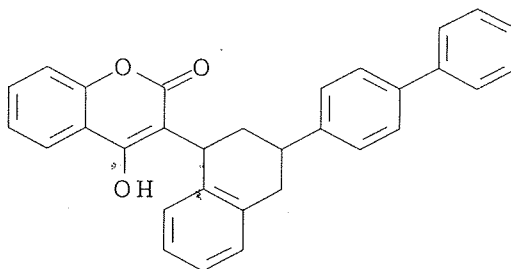
Official use only

- 2.1 Common name (IIA2.1) Difenacoum
- 2.2 Chemical name (IIA2.2) 3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin
- 2.3 Manufacturer's development code number(s) (IIA2.3) None
- 2.4 CAS No and EC numbers (IIA2.4)
- 2.4.1 CAS-No 56073-07-5
- 2.4.2 EC-No 259-978-4
- 2.4.3 Other RTECS: GN4934500
- 2.5 Molecular and structural formula, molecular mass (IIA2.5)
- 2.5.1 Molecular formula C₃₁H₂₄O₃

Section A2

Identity of Active Substance

2.5.2 Structural formula



- 2.5.3 Molecular mass 444.5
- 2.6 Method of manufacture of the active substance (IIA2.1) The method of manufacture of the active substance is commercially sensitive as this knowledge provides a competitive advantage. Please see Annex Confidential Data and Information.
- 2.7 Specification of the purity of the active substance, as appropriate (IIA2.7) The purity specification could be used to identify the synthesis pathway and the method of manufacture. This information is therefore also commercially sensitive. Please see Annex Confidential Data and Information.
- 2.8 Identity of impurities and additives, as appropriate (IIA2.8) Please see separate standard format IIA2.8 in Annex Confidential Data and Information.
- 2.8.1 Isomeric composition Please see Annex Confidential Data and Information.
- 2.9 The origin of the natural active substance Not relevant

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	7.1.2008
Materials and methods	-
Results and discussion	-
Conclusion	-
Reliability	0 (Not an experimental study)
Acceptability	Acceptable
Remarks	2.7: Minimum purity of 5 samples was 99.54% w/w. Purity cannot be confidential information.
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>
Results and discussion	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	