

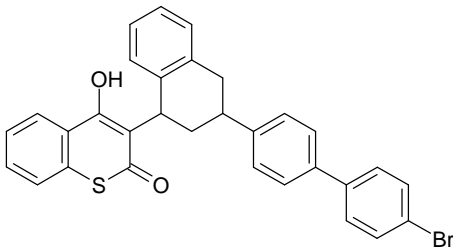
Section A2

Identity of Active Substance

Subsection

(Annex Point)

Official
use only

2.1	Common name (IIA2.1)	Difethialone
2.2	Chemical name (IIA2.2)	2H-1-Benzothiopyran-2-one, 3-[3-(4'-bromo[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy- (CAS) 3-((1RS,3RS;1RS,3SR)-3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxy-1-benzothin-2-one (IUPAC) Note: The CAS name used in Commission regulation no. 2032/2003 to identify difethialone was 3-[3-(4'-bromo[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxybenzothiopyran-2-one (these names refer to the same active substance).
2.3	Manufacturer's development code number(s) (IIA2.3)	LM-2219
2.4	CAS No and EC numbers (IIA2.4)	
2.4.1	CAS-No	104653-34-1
2.4.2	EC-No	None assigned
2.4.3	Other	CIPAC No. 549
2.5	Molecular and structural formula, molecular mass (IIA2.5)	
2.5.1	Molecular formula	$C_{31}H_{23}BrO_2S$
2.5.2	Structural formula	
2.5.3	Molecular mass	539.495 g/mol
2.6	Method of manufacture of the active substance (IIA2.1)	The method of manufacture is confidential to LiphaTech S.A.S. and is presented in the confidential document.

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2.7	Specification of the purity of the active substance, as appropriate (IIA2.7)	g/kg	g/l	% w/w	% v/v	x	
				>97.6			
	Specification of purity is based on the organic purity value. This incorporates the combined concentrations of both diastereoisomers in the analysis of representative batches (references: IIA2.7/01, XXXXXX XXXX and IIA2.8.9/02, XXXXXX XXXX. Note – these are confidential reports). Both diastereoisomers are considered as active substance.						
2.8	Identity of impurities and additives, as appropriate (IIA2.8)	See separate standard format.					
2.8.1	Isomeric composition	Isomeric composition is confidential to LiphaTech S.A.S. and is presented in the confidential attachment.					
2.9	The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)	Not relevant.					

Evaluation by Competent Authorities	
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EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	14 September 2005, revised 29 December 2006
Materials and methods	-
Conclusion	-
Reliability	-
Acceptability	Acceptable.
Remarks	<p>Full study report is given in the confidential document and is found to be acceptable without any comments.</p> <p>New 5 batch analyzes submitted after change of active substances manufacturing plant</p> <p>Comment (2.6): The method of manufacturing, after change of production site in 2005 is considered to be the same as before 2005</p> <p>Comment (2.7): The specification of the a.s. after change of production site in 2005 is considered to be the same as before 2005.</p>