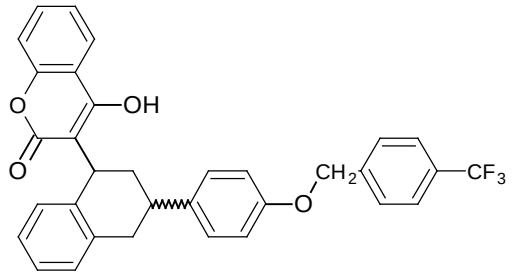
Section A2 Identity of Active Substance

Annex Point IIA2

			Official use only
		Reference for Sections 2.1 to 2.5: **A2/01:** Txxxx Mxxxx (2001) Description of BAS 322 I (Flocoumafen). Bxxxx Axxxx Rxxxx, Pxxxx, Nxxxx, Uxxxx, Report No. APBR 1188, July 30, 2001 (unpublished).	
2.1	**Common name (IIA2.1)**	Flocoumafen	
2.2	**Chemical name (IIA2.2)**	CA: 4-hydroxy-3-[1,2,3,4-tetrahydro-3-[4-[[4-(trifluoromethyl)phenyl]methoxy]phenyl]-1-naphtalenyl]-2H-1-benzopyran-2-one	X
2.3	**Manufacturer's development code number(s) (IIA2.3)**	BAS 322 I (BASF) Development codes of former manufacturers include: WL 108366 (Sxxxx Rxxxx Lxxxx, Sxxxx Lxxxx) DSC 60300 R (Dxxxx Sxxxx Cxxxx Gxxxx) CL183540 (Cxxxx)	
2.4	**CAS No and EC numbers (IIA2.4)**		
2.4.1	CAS-No	90035-08-8	
2.4.2	EC-No	Not assigned	X
2.4.3	Other	CIPAC-No.: 453	
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**		
2.5.1	Molecular formula	$C_{33}H_{25}F_3O_4$	
2.5.2	Structural formula		
2.5.3	Molecular mass	542.6 g/mol	
2.6	**Method of manufacture of the active substance (IIA2.6)**	The information on the method of manufacture is considered to be a trade secret of BASF and therefore claimed to be CONFIDENTIAL. Thus, the manufacturing process is summarised in Appendix 1 to Document III-A (confidential information).	

Section A2 Identity of Active Substance

Annex Point IIA2

			Official use only
2.7	**Specification of the purity of the active substance, as appropriate (IIA2.7)**	> 95.5 % w/w Since the original document allocated to this data requirement is considered to contain commercially sensitive information, thus being a trade secret of BASF, further information is provided in Appendix 1 to Document III-A (confidential information). **Reference A2.7/01:** Bxxxx Wxxxx, Sxxxx Bxxxx (2001) Flocoumafen technical (CL 183540; STORM) – Technical active ingredient specification. Bxxxx Cxxxx, Report No. 2110.2, March 20, 2001 (unpublished). This reference is provided in a separate file to Document IV-A (confidential information).	
2.8	**Identity of impurities and additives, as appropriate (IIA2.8)**	The information on the identity of impurities is considered to be a trade secret of BASF and therefore claimed to be CONFIDENTIAL. Thus, the corresponding data, summarised in the separate standard format for Section A2.8, are given in Appendix 1 to Document III-A (confidential information). Information on the isomeric composition is given under 2.8.1 below.	
2.8.1	Isomeric composition	Technical flocoumafen consists of a mixture of cis/trans-isomers (see section 2.6). The technical specification demands a content of cis-flocoumafen in the range of 50–80 %. In an analysis of five batches from the current manufacturer of the active substance, the cis/trans-ratios ranged between 61/39 and 56/44. Both isomers exhibit the intended biocidal effect.	X
2.9	**The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)**	Not applicable Neither the active substance nor any of the precursors are of natural origin.	

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	

	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	20 September 2005
Materials and Methods	(2.2) The IUPAC name is: 4-hydroxy-3-[(1*RS*,3*RS*;1*RS*,3*SR*)-1,2,3,4-tetrahydro-3-[4-(4-trifluoromethylbenzyloxy)phenyl]-1-naphthyl]coumarin The CA name is: 4-hydroxy-3-[1,2,3,4-tetrahydro-3-[4-[[4-(trifluoromethyl)phenyl]methoxy]phenyl]-1-naphtalenyl]-2H-1-benzopyran-2-one (2.4.2) The ELINCS no is 421-960-0 (2.8.1) As indicated by the notifier, specifications demand a cis content of 50-80%. This range is not in agreement with the ISO publication of the common name flocoumafen. However, the ISO publication will be amended to reflect the proposed specification of 50-80% cis- and 20-50% trans- isomers.
Results and discussion	No comments.
Conclusion	No comments.
Reliability	1
Acceptability	Acceptable.
Remarks	None.

	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Subsection		Official use only
2.10.1 Human exposure towards active substance	*The following form requests information about occupational exposure towards the active substances based on Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC.* *Further information of the Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances (short title: TGD for Risk Assessment for New and Existing Substances) was taken into account.* *The detailed structure supports the company to avoid further requests for the required data.*	

2.10.1.1 Production

2.10.1.1.1 Likely tonnage to be placed on the market per year [IIA V.5.8]	[***Note:*** *This field is taken from section IIA V.5.8 and must be filled in only in this chapter. This option will be available only in the electronic form*]	
Produced	☒	
Imported	☐	
Quantity lower	xxxx	
Quantity upper	xxxx	
Unit (Quantity)	kg	
Year		
Remarks / further specifications	An average of xxxx kg every 2 years was produced over the last 4 years	
2.10.1.1.2 Description of process		
Temperature of process	Reference A2.10.1/01: Pxxxx Fxxxx (1998): Mode opératoire - fabrication du flocoumafène. Mxxxx Lxxxx sxxxx Mxxxx, Fxxxx, Report no.: 1053-1, June 17, 1998 (unpublished). Remark: The orignal reference is claimed to be confidential. 84 °C	
Pressure of process	Atmospheric	
Use pattern	Closed reactor	
Type of process	Discontinuous	
Batch size	xxxx t/batch, an average of xxxx working hours are needed per batch	

Throughput	Not applicable
Further description of process	A mixture of tetralol ether, 4-hydroxycoumarin and 4-toluenesulphonic acid in dichloroethane is refluxed at 82–84 °C for 12 hours with azeotropic removal of water. Following washing of the solution with sodium carbonate and water, dichloroethane is removed by first atmospheric, and finally reduced pressure distillation. Methanol is added to the residue and the slurry is allowed to cool. The product is filtered and dried to give Flocoumafen as a fine off-white product.
Remarks / further specifications	None

2.10.1.1.3 Workplace description	Bagging, sampling and weighing operations. One worker at a time.
Pattern of control	*In the following section describe the actual used pattern of control.*
Engineering controls	Dedicated plant with spill containment tank, air treatment (dust collectors equipped with absolute filters), closed equipments, dedicated storage warehouse.
Administrative procedures	Specific training of users, ISO 14001 certification, waste management, quality assurance system, medical follow-up of users, written SOPs including safety instructions, dust collectors annual performance qualification.
Personal protective equipment	Protective gloves, safety glasses, single use protective coveralls, powered air purifying respirators
Remarks / further specifications	

2.10.1.1.4 Exposure		X
2.10.1.1.4.1 Task	Bagging, sampling and weighing. These tasks are simultaneously performed. ***Note:*** *If more than one task is indicated fill in the fields of inhalation and dermal exposure for each task. Please use the field below "Further Task?" (end of 2.10.1.1.4.1.2) which support your fill in procedure.*	
2.10.1.1.4.1.1 Inhalationexposure	No data available	X
Description of method		
Frequency of task(s)		
Duration of task(s)		
Form during handling		
Year(s) of measurement		
Number of measurements		
Type of measurements		
Exposure concentration		
Typical case		
Reasonable worst case		
Remarks		
2.10.1.1.4.1.2 Dermal exposure	No data available	X
Description of method		
Frequency of task		
Duration of task		
Form during handling		
Exposed parts of the body		
	(Reference: Risk assessment for occupational dermal exposure to chemicals, RISKOFDERM. Contract QLK4-CT-1999-01107, Part 1)	
Year(s) of measurement		
Number of measurements		
Type of measurements		
	Note: *personal sampling is appropriate*	
Exposure concentration		
Typical case		
Reasonable worst case		
Remarks		
Further Task?	☐	

2.10.1.2 Intended uses

2.10.1.2.1 Use of active substance for the formulation of biocidal product

2.10.1.2.1.1 Likely tonnage to be placed on the market per year [IIA V.5.8]	See Section A5.8. [***Note:*** *this information is taken from section IIA V.5.8 and must be filled in only in the actual chapter. This option will be available only in the electronic form*]
Produced	☒
Imported	☐
Quantity lower	xxxx
Quantity upper	xxxx
Unit (Quantity)	tonne
Year	2003
Remarks / further specifications	

2.10.1.2.1.2 Description of process

Temperature of process	Ambient
Pressure of process	xxxx lb/ in^2 ≡ xxxx exp +xxxx Pa
Use pattern	Daily
Type of process	Compaction
Batch size	xxxx kg
Throughput	xxxx kg/h
Further description of process	Compaction
Package details	Bulk
Site inventory	BEPEX Compactor
Storage information	Bulk bags
Concentration of marketed formulation	0.005 % (w/w)
Remarks / further specifications	Apprearance, size of block, hardness of block

2.10.1.2.1.3
Workplace description

Pattern of control	*In the following section describe the actual used pattern of control.*
Engineering controls	LEV at control points
Administrative procedures	ISO9001:2000 and works instructions
Personal protective equipment	Coverall and safety shoes
Remarks / further specifications	None

2.10.1.2.1.4 Exposure		
2.10.1.2.1.4.1 Task		x
	Note: *If more than one task is indicated fill in the fields of inhalation and dermal exposure for each task. Please use the field below "Further Task?" (end of 2.10.1.2.1.4.2) which support your fill in procedure.*	
2.10.1.2.1.4.1.1 Inhalation exposure		
Description of method	Compaction	
Frequency of task(s)	Daily	
Duration of task(s)	8 h	
Form during handling	Solid	
Year(s) of measurement	2003	
Number of measurements	12	
Type of measurements	Blood prothrombin time	
Exposure concentration	No exposure shown	
Typical case		
Reasonable worst case		
Remarks	Blood prothrombin time monitoring of production operatives is a means of indirect measurement of exposure.	**X**
2.10.1.2.1.4.1.2 Dermal exposure		
Description of method	Compaction	
Frequency of task(s)	Daily	
Duration of task(s)	8 h	
Form during handling	Solid	
Exposed parts of the body	Hands, face	
	(Reference: Risk assessment for occupational dermal exposure to chemicals, RISKOFDERM. Contract QLK4-CT-1999-01107, Part 1)	
Year(s) of measurement	2003	
Number of measurements	12	
Type of measurements	Blood prothrombin time	
	Note: *personal sampling is appropriate*	
Exposure concentration	No exposure shown	
Typical case		
Reasonable worst case		
Remarks	Blood prothrombin time monitoring of production operatives is a means of indirect measurement of exposure.	**X**

Further Task? ☐

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE (*)	
Date	24 May, 2005
Materials and Methods	na
Results and discussion	na
Conclusion	na
Reliability	na
Acceptability	na
Remarks	(2.10.1.1.4) It should be clarified whether or not worker exposure can occur during production of the a.i. (2.10.1.1.4.1) Exposure estimates for production required, if within the scope of Directive 98/8/EC. Due to current TM discussions on this issue, no further calculations were made by the RMS. (2.10.1.1.4.1.2) see (2.10.1.1.4.1) (2.10.1.2.1.4) Tasks to be described (2.10.1.2.1.4.1.1) Blood prothrombine time is not an exposure measurement but should be regarded as a health check. Further exposure calculations on formulation of the biocidal product required if within the scope of Directive 98/8/EC. (2.10.1.2.1.4.1.2) see (2.10.1.2.1.4.1.1)
COMMENTS FROM ...	
Date **Materials and Methods** **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	

Section A2.10 Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L 154, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Annex Point IIA2.10

Subsection			Official use only
2.10.1	Human exposure towards active substance		
2.10.1.1	*Production*	See separate standard format (A2.10.1)	
2.10.1.2	*Intended use(s)*	Human exposure during use is considered to be product-related. Thus, exposure estimates are provided in Document III-B, Section 6.6 (Information related to the exposure of the biocidal product).	
2.10.2	Environmental exposure towards active substance		
2.10.2.1	*Production*		
	(i) Releases into water	None	
	(ii) Releases into air	None	
	(iii) Waste disposal	Organic solvents used during synthesis and cleaning either disposed of as chlorinated waste or submitted to controlled incineration.	
2.10.2.2	*Intended use(s)*	PT 14 (Rodenticides), pest control in and around buildings	
	Affected compartments:	Mackay model: Reference **A2.10.2/01**: Sxxxx Txxxx (2003) Estimation of distribution in the environment of Flocoumafen. Exxxx Cxxxx Gxxxx, Hxxxx, Gxxxx, Report No. BAS-031117-01, November 17, 2003 (unpublished).	
	Water	0.0836	
	Sediment	2.1691	
	Air	0.0654	X
	Soil	97.6086	
	Predicted concentration in the affected compartments	Predicted environmental concentrations are provided at Document II-B level.	
	Water	See Document II-B	X
	Sediment	See Document II-B	X
	Air	See Document II-B	X
	Soil	See Document II-B	X

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	

	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	21 April 2005
Materials and Methods	No comments.
Results and discussion	(2.10.2.2) Affected compartments. The vapour pressure of Flocoumafen is $<10^{-3}$ Pa. Model calculations were performed with a value of 10^{-3} Pa. Hence, the results for distribution into air can be considered worst-case. (2.10.2.2) Predicted concentrations in the affected compartments. The PEC values were recalculated by the RMS based on the relevant emission scenario document for rodenticides and revised use data. Results are given in Doc II-B.
Conclusion	The results of Mackay level I environmental distribution model vs 2.02 are: compartment: Distribution (%) Air: 0.0654 Water: 0.0836 Soil: 97.6086 Sediment: 2.1691
Reliability	1 (Mackay model). 3 (Doc II-B calculations).
Acceptability	Acceptable.
Remarks	-

	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	