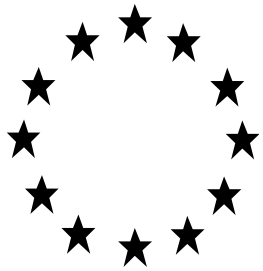
Directive 98/8/EC concerning the placing biocidal products on the market

Inclusion of active substances in Annex I or IA to Directive 98/8/EC

Assessment Report



Flocoumafen

Product-type 14 (Rodenticide)

15 May 2009

Annex I – the Netherlands

Flocoumafen (PT 14)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 15 May 2009 in view of its inclusion in Annex I to Directive 98/8/EC

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of Flocoumafen as product-type 14 (rodenticide), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Flocoumafen (CAS no. 90035-08-8) was notified as an existing active substance, by BASF Agro B.V. Wädenswil Branch , hereafter referred to as the applicant, in product-type 14.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 7(1) of that Regulation, the Netherlands was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for Flocoumafen as an active substance in Product Type 14 was 28 March 2004, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 26 March 2004, the Netherlands competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 27 June 2004.

On 4 October 2007, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 8 October 2007. The competent authority report included a recommendation for the inclusion of Flocoumafen in Annex I to the Directive for product-type 14.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 12 November 2007. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

1 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

2 Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.

On the basis of the final competent authority report, the Commission proposed the inclusion of Flocoumafen in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 15 May 2009.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 15 May 2009.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include Flocoumafen in Annex I to Directive 98/8/EC for product-type 14. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in product-type 14 that contain Flocoumafen. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website[3], shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Directive 98/8/EC, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Overall conclusion in the context of Directive 98/8/EC

The overall conclusion from the evaluation is that it may be expected that there are products containing Flocoumafen for the product-type 14, which will fulfil the requirements laid down in Article 5 of Directive 98/8/EC. This conclusion is however subject to:

i. compliance with the particular requirements in the following sections of this assessment report,

ii. the implementation of the provisions of Article 5(1) of Directive 98/8/EC, and

iii. the common principles laid down in Annex VI to Directive 98/8/EC.

Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond

3 http://ec.europa.eu/comm/environment/biocides/index.htm

those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Identity of the active substance
The CAS no. of flocoumafen used in this CA-report is 90035-08-8.
The EC no. of flocoumafen used in this CA-report is 421-960-0.

The minimum purity of flocoumafen is 95.5% w/w (50% to 80% cis- and 20% to 50% trans-isomers).

> *Note:* the ISO published common name of flocoumafen will be amended accordingly because the name flocoumafen is currently restricted to 40-60%/60%-40% cis/trans-isomer mixtures.

There are no (eco)toxicologically relevant impurities.

Physical and chemical properties of the active substance
Flocoumafen is a coumarin anticoagulant rodenticide. It consists of a mixture of cis- and trans-isomers. Flocoumafen is a solid substance with a melting range of 166-168ºC and a vapour pressure of $<1 \times 10^{-3}$ Pa at 20°C. Flocoumafen is stable up to 250°C. The substance has no explosive and oxidising properties and is neither flammable nor auto-flammable. Flocoumafen is very slightly soluble (0.0024 mg/L, pH 4) to moderately soluble (14.0 mg/L, pH 9) in water. It has a pKa of 4.5 and the log(Kow) is 5.11 (pH 9), 6.12 (pH 7) and >6.12 (pH 4). Flocoumafen is stable to hydrolysis.

Flocoumafen does not exhibit any particularly hazardous physical-chemical properties: The substance is thermally stable, not “highly flammable”, does not show explosive and/or oxidising properties, and can be stored in commercially available packaging material. Corrosiveness to any type of containers and apparatus has not been observed. In conclusion, users are not considered to be at risk due to the physical-chemical properties of flocoumafen.

Analysis of active substance as manufactured

The submitted methods fulfilled the validation criteria as outlined in SANCO/3030/99 rev. 4 and is considered suitable for the determination of the active substance flocoumafen and impurities in flocoumafen technical grade material.

The submitted methods fulfilled the validation criteria as outlined in SANCO/825/00 rev. 6 (except for the lack of validation data of the confirmatory method for soil) and are considered

suitable for the determination of flocoumafen in soil, surface, ground- and drinking water, urine, blood and liver.

A method for the determination of flocoumafen in air is not required due to low volatility and the intended uses (block baits) (limited exposure).

An acceptable LC-MS/MS analytical method for determination of flocoumafen residues in cucumber, wheat, meat, oil seed rape and lemon was provided.

2.1.2. Intended Uses and Efficacy

Product type and field of use envisaged

Main group 3: pest control

Product type 14: rodenticide

Flocoumafen is intended to be used for the control of commensal rodents in and around buildings, animal housings, or food stores.

Intended Users

Trained professionals, non-trained professionals, non-professionals

Function

Rodenticide (Anticoagulant)

Application

The applicant intended the products (Wax blocks) to be deployed close to rodent nesting and feeding sites at protected baiting points, e.g. using commercially available tamper-resistant bait containers, small pieces of piping, active rat and mouse holes, and other places to be covered by slates, boards or similar suitable material.

For rats, 2–3 bait blocks (40–60 g) are placed per bait point, with bait points placed 5–10 m apart. For mice, one single bait block (20 g) is placed per bait point; with bait points placed approx. 2 m apart. Application of the pulse-baiting technique is recommended: appropriate amounts of bait are deployed in areas with rodent infestations, as specified above. Bait is checked every 7 days and uneaten bait is removed at the end of the campaign (21 days). An additional visit on day 3 may be included as an option. Inclusion of this date into the baiting scheme may vary per country.

Occurrence of resistance

No incidences of resistance towards flocoumafen are known.

Humaneness

The use of flocoumafen as a rodenticide could cause suffering of vertebrate target organisms. The use of anti-coagulant rodenticides to control the rodent population in the European Union is necessary as at present comparable less painful alternative biocidal substances or biocidal products or even non-biocidal alternatives are not available. Rodent control is needed to prevent disease transmission, contamination of food and feeding stuffs and structural damage. A comparative assessment is not in the scope of this report, but should be performed when possible alternatives have been evaluated and all data are available.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling

The following classification and labelling is proposed for flocoumafen:

Hazard symbol(s): T+, N

Indication of danger: very toxic, dangerous for the environment

Risk phrases: R 26/27/28, 48/23/24/25, 50/53, 61*

Safety phrases: S 53-45-60-61

* Based on read-across from Warfarin

Specific concentration limits will be proposed by the C&L group, as the LD50 values for acute effects and the effects for repeated exposure with flocoumafen are far below the criteria used for classification.

Above classification and labelling deviates from the current classification and labelling of flocoumafen according to the 28th adaptation of Directive 67/548/EEC:

Risk phrases: R 26/27/28, 48/23/24/25, 50/53

Safety phrases: S (1/2), 28, 36/37/39, 45

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

Hazard assessment flocoumafen is a 4-hydroxycoumarin derivate with an anticoagulant action. Flocoumafen inhibits the vitamin K1-epoxide cycle, thereby interrupting the supply of vitamin K1 necessary for producing blood clotting factor precursors.

Toxicokinetics

After single low (0.14 mg/kg) oral administration of ^{14}C-flocoumafen, total absorption amount to 69% in males and 75% in females, based on radio label found in urine, tissues (liver, skin and kidneys) and cage wash. After single high (14 mg/kg) oral administration of ^{14}C-flocoumafen, total absorption amount to 17% of the administered dose based on the radio label found in urine, liver and cage wash.

Based on physical chemical properties of flocoumafen, a dermal absorption (default) value of 10% was considered for risk assessment purposes. A 4% value is also proposed based on comparable molecular mass and log Pow of the other similar second generation anticoagulants. In conclusion, both the 4% as well as the 10% value would be used in the first tier of a tiered approach.

Within 7 days after administration of a single low dose (0.14 mg/kg), males and females excreted 0.35-0.45% and 26.16-23.07% of the administered dose in urine and faeces, respectively. Male rats that had received a high dose (14 mg/kg) of coumarin-U-^{14}C-labelled or trifluoromethyl-phenyl-U-14C-labelled flocoumafen excreted 0.6-6.1% and 63.2-71.0% of the administered dose within 72 hours.

Flocoumafen accumulates in tissues after dermal and oral administration. Flocoumafen is extensively distributed, with highest tissue levels in liver. The order of tissue concentrations was liver > kidneys > skin > muscle > fat > blood. The calculated half-life of flocoumafen in liver was 215 days. Radioactivity levels in tissues and organs of males were very similar to those in females.

In samples of faeces and liver, mainly the unchanged parent compound was identified. Bile did not contain flocoumafen. In urine no parent compound was identified, but polar metabolites.

The main routes of biotransformation were represented by phase I reactions oxidising all ring systems of flocoumafen. Conjugation of flocoumafen was observed with glucuronic acid. Cleavage of the benzyl ether bridge played a minor role in metabolism of flocoumafen, but explained the urine metabolites detected at low quantities. There is much accumulation in the liver and no metabolism of flocoumafen in the liver leading to bile excretion and subsequently metabolites in faeces.

Acute toxicity

Flocoumafen is very toxic if swallowed, in contact with skin and by inhalation. Flocoumafen is not a skin irritant, not an eye irritant and not a skin sensitizer.

Repeated dose toxicity

In the available repeated dose toxicity studies, flocoumafen induced effects on the coagulation systems, including increased (activated) prothrombine times and haemorrhages in various organs.

In a 28-day oral toxicity study, a NOAEL of 0.0025 mg/kg bw/day is established, based on increased APTT and increased levels of plasma protein, alkaline phosphatase and cholesterol.

In a 90-day oral toxicity study, a NOAEL of 0.0025 mg/kg bw/day is established, based on haemorrhages in lymph nodes.

Genotoxicity

Flocoumafen is considered to be non-genotoxic.

Reproductive toxicity

In rabbits a NOAEL for maternal effects was established at 0.002 mg/kg bw/day, based on abortions and clinical signs. A NOAEL for developmental effects was set at > 0.004 mg/kg bw/day, since no toxicological significant effects were observed in foetuses. In rats a NOAEL of 0.02 mg/kg bw/day was established for maternal effects, based on haemorrhages and mortality. As no toxicological significant effects were observed in foetuses, the NOAEL for developmental effects was set at >0.004 mg/kg bw/day. There is a provisional decision for all anticoagulants rodenticides to be regarded as if they cause developmental toxicity in humans (cat. 2) or known to cause developmental toxicity in humans (cat. 1)

2.2.1.1. Risk assessment

The human health risk characterisation is performed using both the MOE and A(O)EL approach. For both approaches the most relevant NOAEL is chosen.

A risk index of < 1 is considered safe using a safety factor of 300 for acute, subacute and chronic exposure.

For acute, subacute and chronic exposure a MOE of 300 is considered safe, based on a factor 10 for interspecies differences, 10 for intraspecies differences and 3 for severe “teratogenic” effects based on read across from warfarin.

The risk characterisations are performed with 10% dermal absorption (worst case) as well as 4% dermal absorption.

Table 2-1 Risk characterisation for direct and indirect exposure using Storm BB

Workplace operation	**PPE**	**Exposure path**	**Total systemic dose (mg/kg w/d)**	**Risk index Exposure/AEL**	**MOE NOAEL/ Exposure**
Trained and non-trained professionals					
Pest control operator Using 10% dermal	None	Dermal, oral	$2.3*10^{-4}$	27.7	10.8

absorption					
		Only dermal	$13*10^{-5}$	15.7	19.2
Pest control operator Using 4% dermal absorption	None	Dermal, oral	$1.5*10^{-4}$	18.1	16.7
		Only dermal	$5.2*10^{-5}$	6.3	48.1
Pest control operator Using 10% dermal absorption	Protective gloves	Dermal	$13*10^{-6}$	1.6	192.3
Pest control operator Using 4% dermal absorption	Protective gloves	Dermal	$5.2*10^{-6}$	0.6	480.8
Non-trained professional	None	Dermal, oral	$*10^{-6}$		
		Only dermal	$13.3*10^{-6}$	1.6	188.0
Non-trained professional Using 4% dermal absorption		Dermal, oral	$14.7*10^{-6}$	1.8	170.1
		Only dermal	$4.9*10^{-6}$	0.6	510.2
	Protective gloves	Only dermal	$4.9*10^{-7}$	0.06	>>300
Non-professional users					
Non-professional Using 10% dermal absorption	None	Dermal, oral	$6.0*10^{-6}$	0.72	417
		Only dermal	$3.3*10^{-6}$	0.40	758
Using 4% dermal absorption		Dermal, oral	$4.1*10^{-6}$	0.49	610
		Only dermal	$1.4*10^{-6}$	0.17	1786
Indirect exposure of the general public after use of Storm BB					
Handling dead rodents Based on exposure data 10% DA	None	Dermal	$8.3*10^{-8}$	0.01	>>300
4% DA			$3.3*10^{-8}$	<0.01	>>300
Based on default values 10% DA			$8.3*10^{-5}$	12.4	24
4% DA			$3.3*10^{-5}$	4.9	76
Mouthing of poison bait	None	Oral	$3.8*10^{-5}$ (0.01 g) 0.019 (5 g)	5.7 2836	53 0.13

Conclusion: Based on the risk characterisation for trained professionals with protective gloves and non-trained professionals, safe uses for primary exposure to Storm BB are calculated, either by the AEL or MOE approach.

Safe uses for the non-trained professionals are calculated using the dermal absorption percentage of 4% not taken into account oral exposure. Furthermore, non-trained professionals using gloves have an acceptable risk.

Although it is questionable whether non-trained professionals can be expected to wear gloves and to handle these gloves correctly, the risk for the non-trained professionals is acceptable, taking into account the negligible oral exposure and reduced dermal exposure due to risk mitigation measures, especially in the post-application phase to prevent disease transmission by rodents to man. Furthermore, the oral exposure was based on 10% of the entire hand exposure, leading to a clear worst case (not a reasonable) calculated exposure value (10% is normally used for children licking their hands). A safe use results from the assumption that 3% or less of the amount rubbed from the hands may get into contact with the mouth.

It is expected that the use of flocoumafen as wax blocks (Storm BB) will not lead to unacceptable risk for the general public. A risk has been identified for infants sensitive and not sensitive for the bittering agent accidentally ingesting bait. For infants all necessary risk mitigation measures have to be applied.

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and distribution in the environment

The active substance: Flocoumafen

In the atmosphere, flocoumafen has the potential for rapid photo-oxidative degradation.

Biodegradation

Biodegradation of flocoumafen in an aquatic environment has been investigated under aerobic and anaerobic conditions. Flocoumafen is not readily biodegradable and does not degrade under anaerobic conditions. The degradation rate of flocoumafen in soil was rather low (average mean degradation half life of flocoumafen ± 213 days at 20 ºC). Mineralization rate and extent of non extractable radioactivity (NER) strongly depended on soil type. In a test with 4 soils, recovery varied from 85.6 – 102.4%. Mineralization ranged between 2.5 - 15.6% after 120 days of incubation. The extractable radioactivity was nearly exclusively due to the parent compound, while NER ranged from 8.3 – 47.4%.

Abiotic degradation

Flocoumafen has been shown to be hydrolytically stable under environmentally relevant conditions (DT_{50} > 1 year). Flocoumafen was found to be susceptible to photo-transformation in water (DT_{50} = 1.67 d). Transformation products (>10%) could be identified partially as 4-hydroxy-3-[3-(4-hydroxyphenyl)-1,2,3,4-tetrahydro-1-naphthyl]coumarin and 4-(Trifluoromethyl)-benzoic acid.

Distribution/Mobility

Due to the low vapour pressure, flocoumafen is not expected to partition to the atmosphere to a relevant extent. Should it be present in air, it is expected to be quickly degraded by photooxidation (DT_{50} = 0.085d).

The available data on distribution indicate that flocoumafen will adsorb to environmental compartments containing organic matter like soil, sediment and sewage sludge and that leaching will be negligible.

Bioaccumulation

Measurements of aquatic and terrestrial bioaccumulation of flocoumafen have not been performed. Therefore the bioconcentration factors for fish and earthworm have been calculated according to the TGD, showing a high potential for bioaccumulation:

BCF_{fish} = 36,134 l/kg

$BCF_{earthworm}$ = 15,820 l/kg

2.2.2.2. Effects assessment

Aquatic compartment

Lowest acute toxicity data are for fish, Daphnia and algae are a 96 h LC_{50} of 0.07 mg/L, a 48 h EC_{50} of 0.18 mg/L and a 72 h E_bC_{50} of >18.2 mg/L, respectivelly. The fish *Oncorhynchus mykiss* was considered the most sensitive species. The PNEC is derived by dividing the lowest LC_{50} (0.07 mg/L) by an assessment factor of 1000, resulting in a
$PNEC_{aquatic} = 7.0 \times 10^{-5}$ mg/L

Sediment

Studies in which the test organisms were exposed to flocoumafen via spiked sediment are not available. Therefore, the $PNEC_{sediment}$ was derived from the PNECwater using the equilibrium partitioning method, lowered by a factor 10 to compensate for the log Pow >5, resulting in a
$PNEC_{sediment}$ of 0.0155 µg/kg ww.

Sewage treatment plant (STP)

The effect of flocoumafen on aerobic biological sewage treatment processes was assessed by determining inhibition of respiration of the micro-organisms present in activated sludge following three hour contact. The NOEC was greater than 4 mg/l, the highest concentration applied, which exceeds the limit of solubility of flocoumafen in water (0.114 mg/L). According to the TGD, the PNEC for micro-organisms in a STP is derived by dividing the NOEC (4.0 mg/L) from a respiration inhibition test (OECD 209) by a factor of 10, resulting in a **PNECmicro-organisms (STP) = 0.4 mg/L**. It is alternatively proposed to use the maximum solubility as PNEC, which results in a PNECmicro-organisms (STP) = 0.114 mg/L. The RMS prefers to use the PNEC on basis of the NOEC micro-organisms, considering that exposure of micro-organisms will be both from the soluble and adsorbed fraction. As there is no consensus as to what PNEC to use for the risk assessment, both values are included.

Terrestrial compartment

Soil non-target micro- and macro-organisms:

A soil microbial inhibition test, acute and chronic studies with earthworms and short- and long-term plant terrestrial growth test were not submitted. These studies are required when bait is used outdoors. Estimation of $PNEC_{soil}$ was performed following the same principle as with sediment dwellers (by the equilibrium partitioning method), using EUSES 2.0 in the course of estimating predicted environmental concentrations. It should be emphasised that in line with the TGD (page 117) the PNECsoil is lowered by a factor of 10, as flocoumafen has a log Pow > 5. The resulting predicted no-effect concentration is given as

$PNEC_{soil}$ = 0.0126 mg/kg wet weight

Air compartment

No direct emissions to air are expected from the use of flocoumafen in bait boxes as rodenticides. Therefore no data for the air compartment was available, and the PNEC was not calculated.

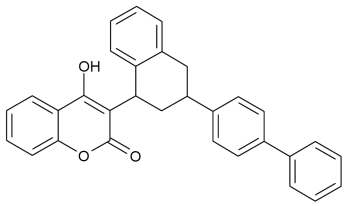
Primary and secondary poisoning

Birds

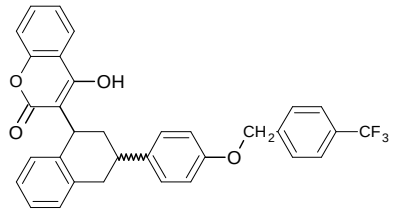
Anas platyrhynchos was the most sensitive species in 5-day dietary toxicity tests (LC_{50} 12 ppm). The lowest single dose LD_{50} value for this species is 24 mg/kg bw.

An avian reproduction study with difenacoum has been carried out at low exposure concentrations. Since no long-term data for flocoumafen is available the study with difenacoum is used as the basis for a read-across from difenacoum to flocoumafen. Difenacoum is structurally closely related to flocoumafen and is an anti-vitamin K anticoagulant rodenticide with a similar mode of action.

Difenacoum:



Flocoumafen:



Few other avian toxicity endpoints are available for difenacoum, but the short-term dietary LC50 obtained with mallard ducks was 18.9 mg difenacoum/kg diet. Based on comparison of the acute toxicity of difenacoum and flocoumafen an assessment factor of 1.6 was derived.

It should be noticed that for derivation of the extrapolation factor the results of high quality flocoumafen studies were used as compared with low quality difenacoum studies. Furthermore it is questionable that a relationship between substances on basis of acute data and chronic data is equal. Therefore the RMS has reservations as related to the use of this extrapolation factor. For consistency reasons, however, the extrapolation factor of 1.6 is used in the assessment to calculate the chronic NOEC birds for flocoumafen from the reproduction study with difenacoum. The need for an avian reproduction study with flocoumafen is waived. Based on the study with difenacoum and applying an assessment factor of 1.6 for flocoumafen the NOEC>0.063 mg a.i./kg diet and NOEL>0.0075 mg a.i./kg bw/d is derived. Adding an assessment factor of 30 prescribed by the TGD, the avian dietary predicted no-effect concentration PNECs on basis of food and body weight are given as

$PNEC_{oral,birds}$ = >0.0021 mg/kg diet

$PNEC_{oral,birds}$ = >0.00025 mg/kg bw/day

Wild mammals:

Effects on mammalian wildlife are usually evaluated by means of rat/mouse data generated in the framework of human health effects assessment. In addition to acute toxicity data (lowest LD50 in laboratory rat 0.13 mg/kg bw), a NOEC from a 90-day toxicity study in rat is available (0.05 mg/kg diet, equivalent to 0.0025 mg/kg bw/day). In addition, the toxicology dossier provides a NOAEL in rat of 0.05 mg/kg diet (equivalent to 0.0025 mg/kg bw/day) from a 28-day toxicity study in rat. A two-generation study in rat is not available, but the performance of

this study was considered to be undesirable for reasons of animal welfare. The PNEC is derived by dividing the NOEC by an assessment factor of 90, resulting in

$PNEC_{oral,mammal}$ = 0.00056 mg/kg diet

$PNEC_{oral,mammal}$ = 0.000028 mg/kg bw/day

2.2.2.3. PBT assessment

Flocoumafen fulfils the criteria for (very) Persistence, Toxicity and (very) Bioaccumulation in fish.

Flocoumafen is considered to be very persistent in water and sediment. Based on the calculated high BCF values flocoumafen is considered to be very bioaccumulative. Flocoumafen is considered very toxic in water and sediment and therefore flocoumafen can be considered a potential PBT/vPvB substance.

In 2008 the PBT working group evaluated second generation anticoagulant rodenticides. The working group concluded the following: “There is not enough information available to finally be able to clarify the B-criterion. However, for the substance flocoumafen the screening B-criterion is fulfilled as the log Pow is above 4.5. Formally BCF testing with fish would be required in order to be able to clarify if flocoumafen meets the B-criterion. However, this test might be technically difficult to conduct as flocoumafen is highly toxic to fish. Furthermore, second generation anticoagulant substances are designed to accumulate in the liver of target rodents and it can be assumed that they also accumulate in the livers of non-target mammals and birds. This is confirmed by the fact that all of the second generation anticoagulant substances are found in wildlife. However, as the exposure situation is not known and no criteria exist for bioaccumulation via the terrestrial food chain these findings are merely an indication that flocoumafen may have B-properties on a level which is indicted by the aquatic B-criterion. It is concluded that flocoumafen should be considered a potential PBT as uncertainties with regard to the B-criterion could not be clarified at the moment.”

This indicates that the substance cannot be included in Annex I unless releases to the environment can be effectively prevented, as is laid down in the TNsG on Annex I inclusion.

As is decided at the CA meeting of March 2007 (ENV B.3/PC D(2007) - 21/03/2007) the following restriction must be included in the directions for use:

In view of the fact that the active substance is a potential PBT/vPvB substance, flocoumafen is a candidate for a comparative risk assessment and appropriate risk mitigation measures must be taken to protect the environment (see paragraph 3.3).

2.2.2.4. Exposure assessment

The EU risk assessment procedure for biocides should consider the full lifecycle of the product including: manufacture, formulation, professional and private uses, and service life and

disposal. The potential impact on all relevant environmental compartments should be considered. During production of the active substance and formulation of the product it is considered that release of the active substance into the environment (water, air or via waste disposal) will be negligible due to the control measures undertaken.

Exposure is related to the application and use phase.

Aquatic compartment (incl. sediment and STP)

Exposure of the aquatic compartment and the STP in the application, use and waste phase of the product (wax block) for the scenario 'in and around buildings' is considered negligible (according to ESD). It should be noted that the use in sewers was not evaluated.

Atmosphere

Due to the very low vapour pressure ($\leq 10^{-3}$ Pa at 50°C) and Henry's law constant (7.43×10^{-8} Pa·m^3/mol), flocoumafen is not expected to partition to the atmosphere to any relevant extent. In addition, the degradation rate of photochemical reactions of flocoumafen with hydroxyl and ozone radicals was estimated to be 1.5 and 2.0 h, respectively, hence any volatilised flocoumafen may be expected to be quickly degraded by photo-oxidation. Thus exposure of the atmosphere is highly unlikely.

Terrestrial compartment

The terrestrial compartment may be exposed to flocoumafen via degradation of uncollected residual bait (e.g., spills during application and carried by rodents), rodent carcasses and poisoned rodent faeces/urine. In view of the envisaged use patterns (in and around buildings), exposure resulting from these sources is localised around the bait points (55 m^2 per bait point for indirect releases and 0.09 m^2 per bait point for direct releases, as decided in ESD PT14). The scenario 'in and around buildings' considers that there is no emission to the STP, therefore exposure due to sludge from a STP that is spread on agricultural soil is considered not relevant.

Primary and secondary poisoning

An exposure assessment for the food chain rodenticide/bait → (rodent) → bait- or rodent-eating mammal or bird is presented below together with the risk assessment for this scenario.

Secondary poisoning as a result of consumption of contaminated fish

Emission to surface water and the STP, and hence exposure due to secondary poisoning via the aquatic food chain, can be assumed to be negligible.

Secondary poisoning as a result of consumption of contaminated earthworms

A secondary poisoning risk assessment for the terrestrial food chain is conducted according to the TGD. The food-chain soil → earthworm → worm-eating birds or mammals is assessed, using as a worst case, typical case on basis of indirect release and on basis of 50 % of the maximum PECsoil (direct plus indirect release) from the scenario "in and around buildings", for calculations. This results in a PECoral,predator = Cearthworm of 0.003, 0.008 and 0.039 mg/kg, for typical case (indirect release), realistic worst case, and derived from 50 % of the maximum PECsoil (combined direct and indirect release), respectively.

2.2.2.5. Risk characterisation

There are no direct and indirect releases of flocoumafen to air, STP and surface water anticipated for the intended use (wax block, in and around buildings). No further risk assessment is performed on these compartments.

Terrestrial compartment

The PEC/PNEC ratio for direct and indirect contamination of soil resulting from the use phase of flocoumafen as a rodenticide in and around buildings is 0.7 and therefore acceptable. It should be noted that the notifier also included in the intended use "application of bait to active rat and mouse holes". These application methods will cause an increased emission to soil, but are not part of the Emission Scenario " in and around buildings" and therefore not assessed.

Risk characterisation for the secondary poisoning assessment via the terrestrial food chain

The food-chain soil → earthworm → worm-eating birds or mammals is assessed here. For PNECoral derivation see section above effect assessment on primary and secondary poisoning.

PECoral,predator = Cearthworm = 0.039, 0.008 and 0.003 mg/kg diet

PNECoral, bird = >0.0021 mg/kg diet

PNECoral, mammal = 0.00056 mg/kg diet

PEC/PNEC bird = **<19, <3.8** and <**1.4**

PEC/PNEC mammal = **69.6, 14.3 and 5.4**

The risk is considered to be high (PEC/PNEC >1) for birds and mammals.

Primary and secondary poisoning

Non-target vertebrates may be exposed to the active substance either directly by ingestion of exposed bait (primary poisoning) or indirectly by ingestion of the carcasses of target rodents that contain residues of the active substance (secondary poisoning). For the scenario “in and around buildings” a primary and secondary poisoning assessment is carried out as non-target mammals and birds may be both exposed to bait and to poisoned rodents.

Primary poisoning of non-target organisms eating bait

For primary poisoning a quantitative risk assessment is carried out for Tier 1and for the long-term exposure assessment at Tier 2. For secondary poisoning a quantitative risk assessment is carried out for the long-term exposure assessment at Tier 1 and 2. This is in accordance with the Addendum relevant to Biocides to the TGD on Risk Assessment on PNECoral derivation for the primary and secondary poisoning assessment of anticoagulant rodenticides (European Commission; Directorate - General Environment, 2006).

Tier I short term risk assessment, quantitative

As an absolute worst case the risk at this tier is quantified as the ratio between the concentration of flocoumafen in food and the PNECoral. It is assumed that non-target animals have direct access to an unlimited amount of formulated product. Bait blocks contain 50 mg/kg flocoumafen and hence the PECoral is 50 mg/kg food. The PNECoral for birds is 2.1 µg/kg food, the PNECoral (mammal) is 0.56 µg/kg food. The PEC/PNEC values are rounded values. There are many uncertainties related to the calculation of PEC/PNEC values. Moreover, the PEC/PNEC values are very high.

Birds: PEC/PNEC ≈ 24,000

Mammals: PEC/PNEC ≈ 89,000

This conservative approach clearly highlights a “high” risk to birds and non-target mammals if flocoumafen containing products are freely consumed.

Tier 2 long-term risk assessment

At Tier 2 long-term a refinement of the acute exposure is made by assessing the amount of food (as bait blocks from one bait point ingested by non target animals after 5 meals. The step 1 worst case exposure estimates were based on an avoidance factor (AV) of 1 (no avoidance), and a fraction of diet obtained in the treated area (PT) of 1 and no elimination (EL). The Tier 2

worst exposure estimates were based on AV=0.9 instead of 1, PT=0.8 instead of 1 and EL=0.7 or 0.3 instead of 1. From table 2.4-5 can be seen that PEC/PNEC ratios are very high.

At Tier 2 the worst-case PEC/PNEC ratio for birds at step 1 is about 98,480 (sparrow) and about 297,000 for mammals (dog).

At step 2 the ratio for birds is about 70,880 (sparrow) and about 214,000 for mammals (dog).

Tier 3 field monitoring data

The notifier claims that, when Storm BB is applied according to submitted directions for use, i.e., in tamper-resistant bait stations, rat burrow entrances or under equivalent cover, access of non-target organisms to the bait is sufficiently excluded, and therefore estimated daily uptake rates should be negligible for non-target species. They refer to During field trials, where flocoumafen bait was placed according to the submitted directions for use, or at a higher rate, and conclude that no evidence of primary poisoning hazards to non-target organisms was found. This suggests that when the submitted directions for use are followed, primary poisoning hazards are minimised. From the field tests can be derived that birds are able to enter bait boxes and that non-target rodents, such as house mouse, wood mouse and vole fed extensively on the bait and the analysed specimens contained flocoumafen residues.

Secondary poisoning of non-target animals eating contaminated rodents

Rodents targeted by baiting campaigns are likely to roam outdoors and within the hunting ranges of predatory birds and mammals. A potential for secondary poisoning of birds and mammals therefore exists.

The long-term assessment at Tier 1 compares the concentration in the rodent immediately after a last meal on day 5 with the PNEC. It is assumed that non-target animals consume 50 % of their daily intake on poisoned rodents.

The worst-case PEC/PNEC ratios at Tier 1 are about <3,300 for birds and 12,500 for mammals.

At Tier 2 the PECoral is the concentration in the non-target animal after a single day of exposure to poisoned rodents. It is assumed that non-target animals consume 50% of their daily intake on poisoned rodents.

The worst-case PEC/PNEC ratio for birds at Tier 2 is about <10,440 (kestrel) and 97,000 for mammals (weasel).

The values for secondary poisoning represent only a single day of exposure. However, poisoned rodents are likely to be available for at least several days during a rodenticide treatment and a predator could therefore be exposed over several days. Therefore, these values do not necessarily represent a realistic worst case.

Tier 3: field monitoring data

A secondary hazard was identified in field trials in UK at 10 farms which employed an exaggerated baiting scheme (saturation baiting): flocoumafen residues were detected in one barn owl, one cat and one stoat found dead. Also slight primary hazards was found to birds as there were 4 observations of birds entering bait boxes and one observation of a bird pecking at the bait. However, no blue-dyed bird faeces were found. A clear primary hazard was identified in non-target rodents (house mouse, wood mouse and vole) with 60 carcasses containing flocoumafen residues. Trials at 6 other farms in UK using the proposed minimal baiting scheme (3 pulses of 2 blocks per baiting point) however produced no evidence of a secondary hazard. A primary hazard was found for non-target rodents (house mouse, wood mouse and vole) with 12 carcasses. No primary hazard to non-rodents and birds was not identified at any farm.

In the study using saturation baiting, average flocoumafen residues in rat carcasses (0.6 mg/kg bw) were found comparable with the normal case scenario (fraction treated bait in rodent's diet = 20%). For non-target rodents average flocoumafen residues were even higher, comparable with the intermediate case (fraction treated bait in rodent's diet = 50%). In the study using restricted baiting average flocoumafen residues in rat and mouse carcasses (1.1-3.5 mg/kg bw) were ca. a factor 2 lower than the normal case concentrations. It should be noticed that all the flocoumafen residues in both live and dead rodents, exceed the PNECs (>0.0021 and 0.00056 mg/kg diet) for birds and mammals, respectively.

It should be noted that flocoumafen may not have appeared significantly in the data because the use of products containing this active substance is not significant compared to other actives. Therefore, any conclusion made on these data may not be sufficiently robust. The RMS considers that the available field studies can be used as supporting evidence, recognizing that the information on effects to non-target animals is limited.

Conclusion

Calculated risks of primary and secondary poisoning are high. It is recognised, however, that the risk of flocoumafen-poisoning of livestock and household animals as well as of wild seed-eating birds can be reduced to a minimum when the rodenticide is handled with diligence and care (adherence to good baiting practice). Appropriate risk mitigation measures must be taken to protect the environment (see paragraph 3.3).

2.2.3. List of endpoints

In order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles

laid down in Annex VI of that Directive, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

3. DECISION

3.1. Background to the Decision

Flocoumafen has been evaluated as a rodenticide against rats and mice for the use pattern "in and around buildings, animal housings, or food stores.".

Efficacy of the active substance flocoumafen is proven in rats (*R. norvegicus and R. rattus*) and in mice (*M. musculus*) at a concentration of 50 mg/kg (50 ppm, 0,005%). No incidences of resistance towards flocoumafen are known.

It is recognised that anticoagulants like flocoumafen do cause pain in rodents but it is considered that this is not in conflict with the requirements of Article 5.1 of Directive 98/8/EC 'to avoid unnecessary pain and suffering of vertebrates', as long as effective, but comparably less painful alternative biocidal substances or biocidal products or even non-biocidal alternatives are not available

Based on the risk characterisation for trained professionals and non-trained professionals users, safe uses for primary exposure to Storm BB are calculated, either by the MOE approach. For the professionals protective gloves are necessary.

Based on the risk characterisation for non-professional users, a safe use for primary exposure to Storm BB is calculated, by both the AEL and MOE approach.

Based on the risk characterisation for the general public, safe uses for indirect (secondary) exposure to Storm BB are identified, by both the ARfD/AEL and MOE approach. A risk has been identified for infants not sensitive for the bittering agent accidentally ingesting bait (calculations based on the more conservative estimate of 5 g intake). For infants not sensitive for the bittering agent all necessary risk mitigation measures have to be applied.

Because Storm BB is not intended to come into contact with food or feeding stuffs, contamination of food and feeding stuff can be excluded.

For the STP, the aquatic and atmospheric compartment, including groundwater and sediment, no risk is calculated when flocoumafen is used in wax block applications in and around buildings.

For the terrestrial compartment the risk in the application and use phase is acceptable.

Flocoumafen poses an unacceptable risk for primary and secondary poisoning of birds and non-target mammals. The risk for primary poisoning can be reduced by deploying baits so that they cannot be reached by the non-target animals. The risk for secondary poisoning is more difficult to control, as poisoned rodents may be available for predators for several days after intake of flocoumafen. The use of flocoumafen inside the buildings may reduce the secondary poisoning risk, but does not exclude it as the exposed rodents may move out of the building. The

secondary poisoning can be excluded only in fully enclosed spaces where rodents cannot move to outdoor areas or to areas where predators may have access. When using flocoumafen as a rodenticide all possible measures have to be taken in order to minimize secondary poisoning of the non-target animals. The mitigation measures are presented in paragraph 3.3. according to the instructions so that the risk for secondary poisoning is minimised.

Flocoumafen is considered as a potential PBT and vPvB substance and such substances should not be included in Annex I unless releases to the environment can be effectively prevented. The direct releases of flocoumafen to the environment can be minimized when the product is used according to the specific restrictions described in paragraph 3.3. The representative products in the risk assessment were wax blocks. Risks associated with other type of formulations have not been evaluated. The risk assessment has been done for products containing 50 mg flocoumafen /kg product, and higher concentrations should not be allowed in authorized products.

According to the Annex I inclusion criteria referred to in Article 10 of the Directive and TNsG on Annex I inclusion, flocoumafen should not be included in Annex I. However, in the decision making also benefits of using the active substance in the biocidal products have to be considered (Paragraph 96 in Annex VI of the Directive). Rodent control is needed to prevent disease transmission, contamination of food and feedingstuffs, structural damage and social abhorrence. Currently anticoagulants are the dominating substances in rodent control. Fourteen rodenticides are included in the review programme of the existing biocidal substances, and nine of these substances are anticoagulants, two are gases and three are nonanticoagulants.

It is concluded that flocoumafen is needed as a rodenticide for human hygiene and public health reasons. It enables effective control of the target rodents and it can be used against rats and mice which are resistant to the first generation anticoagulants such as warfarin and coumatetralyl. In this exceptional case the benefit should take precedence over the risks and flocoumafen should be included in Annex I.

Flocoumafen is suggested as a candidate for the comparative assessment due to the potential PBT and vPvB properties, unacceptable risk for secondary poisoning of the non-target vertebrates and risk for secondary exposure of humans. A more detailed risk benefit analysis should be made as a part of the comparative assessment when more information is available on alternative substances.

3.2. Decision regarding Inclusion in Annex I

The substance Flocoumafen shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type 14 (Rodenticide), subject to the following specific provisions:

In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second

subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorisations are subject to the following conditions:

1. The nominal concentration of the active substance in the products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised.

2. Products shall contain an aversive agent and, where appropriate, a dye.

3. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.Elements to be taken into account by Member States when authorising products

3.3. Elements to be taken into account by Member States when authorising products

1. The applicant has not applied for a usage of flocoumafen in open areas, e.g. on waste dumps nor in sewers. As a consequence, this type of use has not been evaluated. If the use of flocoumafen in open areas and/or sewers is applied for at product authorisation stage at national level, a full risk evaluation of , this type of use of the substance has to be performed at that stage and the assessment report should be amended accordingly.

2. In this CA report no assessment for the application of bait to active rat and mouse holes has been made because this is not available in the Emission Scenario “in and around buildings”. Therefore the use of the application of bait to active rat and mouse holes, in and around buildings has to be assessed at product authorisation stage at a national level.

3. In view of the facts that the active substance is a potential PBT and vPvB substance and that the calculated risks of primary poisoning are high, appropriate risk mitigation measures must be taken to protect the environment. It is recognised, however, that the risk of flocoumafen-poisoning of livestock and household animals as well as of wild birds can be reduced to a minimum when the rodenticide is handled with diligence and care (adherence to good baiting practice). The following restrictions must be taken into account:

    a. Bait must be placed using specially designed bait boxes, inaccessible to children and non-target animals, or in case any other bait covers are used, it must be explicitly stated that these other covers must be tamper proof and heavy enough to avoid displacement by non-target organisms.

    b. Blocks must be secured in such a way that they cannot be dragged away.

c. The duration of the control operation must be as short as possible, and, depending on the reduction of the population, observations on activity of rats and mice during the control operation are necessary.

d. During the control operation pets are not allowed free movement at or around the places where the pest control takes place.

e. During the control operation, at and around the campaign location, active searches must be made at frequent intervals, at least as often as when baits are checked and/or replenished, for missing bait blocks, spilled bait, dead rat and mice and other dead animals. Dispose of dead rodents in accordance with local requirements. An accurate record must be kept of the number of bait blocks applied and disappeared from the bait points.

f. During the control operation, at and around the campaign location all inactive rodent holes should be closed, after removal of spilled bait, dead rat and mice and other dead animals.

g. At the end of the control operation all bait blocks must be removed and an active search must be made for missing bait blocks, spilled bait, dead rat and mice and other dead animals not only on the soil surface, but also in rat and mouse holes and in places that are difficult to access.

h. The restriction of products to professionals or trained professionals only, should be considered.

3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the inclusion of Flocoumafen in Annex I to Directive 98/8/EC.

The following studies or information should be submitted when applying for authorisation of the biocidal product for the first time after Annex I inclusion of flocoumafen.

1. The composition of the product was not always clear. At product authorisation palatability tests should be conducted with the product under consideration.

2. Palatability tests should be conducted with the product under consideration after the maximum storage period, for all rodents claimed in the intended use. The methods used to identify the effects of product aging on palatability and efficacy must be worked out in greater detail. In the present reports the tests were only done with male mice (no rats) and there were no details on the Standard Operating Procedure.

3. No palatability, choice- or field tests with the roof or black rat, *Rattus rattus,* were provided. In some EU countries a test with *R. rattus* has to be provided when the general claim is “for use against rats”.

4. Field data using bait boxes and secured bait will be needed at the product authorisation stage.

5. A scientific statement justifying the validity of the test result of the pellet bait formulation Storm RB (reference B7.6.1/01) for Storm BB, taking into consideration the difference in composition between the test material and Storm BB.

6. An extensive validation of the analytical methods used in field trials B7.8.7.1/04, B7.8.7.1/05, B7.8.7.1/06, B7.8.7.1/08 and B7.8.7.2.

3.5. Updating this Assessment Report

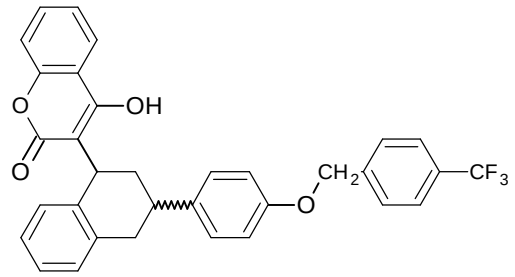
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of Flocoumafen in Annex I to the Directive.

APPENDIX I: LIST OF ENDPOINTS

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Common Name)	Flocoumafen *
Product-type	Rodenticide

Identity (Annex IIA, point II.)

Chemical name (IUPAC)	4-hydroxy-3-[(1*RS*,3*RS*;1*RS*,3*RS*)-1,2,3,4-tetrahydro-3-[4-(4-trifluoromethylbenzyloxy)phenyl]-1-naphthyl]coumarin
Chemical name (CA)	4-hydroxy-3-[1,2,3,4-tetrahydro-3-[4-[[4-(trifluoromethyl)phenyl]methoxy]phenyl]-1-naphtalenyl]-2H-1-benzopyran-2-one
CAS No	90035-08-8
EC No	421-960-0 (ELINCS)
Other substance No.	CIPAC No.: 453
Minimum purity of the active substance as manufactured (g/kg or g/l)	Minimum purity 95.5% w/w (50% to 80% cis- and 20% to 50% trans- isomers) *
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None identified.
Molecular formula	$C_{33}H_{25}F_3O_4$
Molecular mass	542.6 g/mol
Structural formula	

** the ISO published common name of flocoumafen will be amended to 50%-80%/20%-50% cis/trans- isomers because the name flocoumafen is currently restricted to 40-60%/60%-40% cis/trans-isomer mixtures.*

Physical and chemical properties (Annex IIA, point III., unless otherwise indicated)

Melting point (state purity)	166.1–168.2 °C (Purity: 99.4 %)
Boiling point (state purity)	Decomposes before boiling (Purity 99.4%)
Temperature of decomposition	~280 °C
Appearance (state purity)	White, fine crystalline solid (Purity: 99.4 %) TGAI: White, fine crystalline solid (Purity 98.6%)
Relative density (state purity)	1.40 (Purity: 99.4 %)
Surface tension	Not required in view of water solubility < 1 mg/l
Vapour pressure (in Pa, state temperature)	$< 1 \times 10^{-3}$ Pa at 20, 25 and 50 °C
Henry's law constant (Pa m^3 mol^{-1})	< 3.871 Pa × m^3/mol
Solubility in water (g/l or mg/l, state temperature)	pH 4: 0.0024 mg/l (T = 20 °C) pH 7: 0.114 mg/l (T = 20 °C) pH 9: 14.0 mg/l (T = 20 °C)
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	**Solvent [g/l; 20°C]** Methanol 14.1 Toluene 31.3 n-Octanol 17.4
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	Not relevant
Partition coefficient (log Pow) (state temperature)	pH 4: >6.12 (20°C) pH 7: 6.12 (20°C) pH 9: 5.11 (20°C)
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	pH 4: DT_{50} > 1 yr (estimate based on 5-day study at T = 50 °C) pH 7: DT_{50} > 1 yr (estimate based on 5-day study at T = 50 °C) pH 9: DT_{50} > 1 yr (estimate based on 5-day study at T = 50 °C)
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	pK_a = 4.5
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	ε_{311} = 14162 l × mol^{-1} × cm^{-1} (water, pH 6.8)
Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	$t_{½E}$ = 1.67 d
Quantum yield of direct phototransformation in water at □ > 290 nm (point VII.7.6.2.2)	8.90 x 10^{-4}
Flammability	Not flammable. No self-ignition of the test substance was observed up to 400 °C.
Explosive properties	Not explosive.
Oxidizing properties	No oxidizing properties.

Classification and proposed labelling (Annex IIA, point IX.)

with regard to physical/chemical data	Not required.
with regard to toxicological data	R26/27/28 (Very toxic by inhalation, in contact with skin and if swallowed) R48/23/24/25 (Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed) R61 (May cause harm to the unborn child)
with regard to fate and behaviour data	Not required.
with regard to ecotoxicological data	N (Dangerous for the environment) R50 (Very toxic to aquatic organisms) R53 (May cause long-term adverse effects in the aquatic environment)

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	Dissolution in hexane/dichloromethane/acetic acid 70/30/0.5 (v/v/v). Normal-phase HPLC-UV (235 nm).
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	Dissolution in acetonitrile/dioxane/0.1% phosphoric acid. C18-reversed-phase HPLC-UV (215 nm).

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	Extraction with MeOH/water followed by partitioning against n-hexane. Clean-up on NH2 Bond Elut column. C18-reversed-phase HPLC-Fluorescence (Ex = 310 nm, Em = 390 nm). LOQ = 1 µg/kg.
Air (principle of method and LOQ) (Annex IIA, point 4.2)	Not required.
Water (principle of method and LOQ) (Annex IIA, point 4.2)	Extraction with hexane. Reversed-phase LC-MS. LOQ = 0.05 µg/L. (Method validated for surface water and groundwater).
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	Urine: SPE, no further clean-up. Blood: acetontrile extraction, no further clean-up. Liver: extraction with dichloromethane/acetone followed by Bond-Elut CN-U clean-up. Reversed-phase LC-MS, LOQ = 5 µg/L (blood, urine), 5 µg/kg (liver).
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	LC-MS/MS method for the determination of flocoumafen residues in cucumber, wheat, oil seed rape and lemonLOQ = 0.01 mg/kg (all matrices)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	LC-MS/MS method for the determination of flocoumafen residues in meat (beef).LOQ = 0.01 mg/kg

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, point 6.2)

Rate and extent of oral absorption:	69-74% at 0.14 mg/kg bw based on radiolabel recovered from urine, tissues (liver, skin and kidneys) and cage wash. 17% at 14 mg/kg bw based on radiolabel recovered from urine, liver and cage wash.
Rate and extent of dermal absorption:	10% based on physical chemical properties. 4% tier based on comparable molecular mass and log Pow of the other similar second generation anticoagulants
Distribution:	Extensively distributed, with highest tissue levels in liver which is the target organ.
Potential for accumulation:	Yes, half life of flocoumafen in liver 215 days.
Rate and extent of excretion:	Low dose: 0.35-0.45% in urine and 26.16-23.07 faeces in 7 days. High dose: 0.6-6.1% in urine and 63.2-71.0% in faeces in 72 hours.
Toxicologically significant metabolite	None

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	0.13-0.5 mg/kg (R28)
Rat LD_{50} dermal	0.43-1.14 mg/kg (R27)
Rat LC_{50} inhalation	0.0006-0.007 mg/l (R26)
Skin irritation	Testing not possible due to labelling R27. 1% solution in PEG not skin irritating.
Eye irritation	Non-irritant.
Skin sensitization (test method used and result)	Non-sensitizer.

Repeated dose toxicity (Annex IIA, point 6.3)

Species/ target / critical effect	Rat, prothrombin time prolongation and haemorrhaging.
Lowest relevant oral NOAEL / LOAEL	Rat, 90-d, 0.05 mg/kg food (0.0025 mg/kg bw/day) (R48/25)
Lowest relevant dermal NOAEL / LOAEL	No data available, no data required (R48/24).
Lowest relevant inhalation NOAEL / LOAEL	No data available, no data required (R48/23).

Genotoxicity (Annex IIA, point 6.6)	No genotoxic potential, in *in vitro* and *in vivo* genotoxicity studies.

Carcinogenicity (Annex IIA, point 6.4)

Species/type of tumour	No data available, no data required.

lowest dose with tumours	No data available, no data required.

Reproductive toxicity (Annex IIA, point 6.8)

Species/ Reproduction target / critical effect	No data available, no data required.
Lowest relevant reproductive NOAEL / LOAEL	No data available, no data required .
Species/Developmental target / critical effect	Rabbit, abortion due to bleeding. No developmental or teratogenic effects (R61 based on read-across from warfarin).
Lowest relevant developmental NOAEL / LOAEL	>0.004 mg/kg bw/day in rabbit NOAEL maternal toxicity in rabbit 0.002 mg/kg bw/day NOAEL maternal toxicity in rat 0.02 mg/kg bw/day

Neurotoxicity / Delayed neurotoxicity (Annex IIIA, point VI.1)

Species/ target/critical effect	No data available, no data required.
Lowest relevant developmental NOAEL / LOAEL.	No data available, no data required.

Other toxicological studies (Annex IIIA, VI/XI)

No data available, no data required.

Medical data (Annex IIA, point 6.9)

No evidence of toxicological concern from medical surveillance of manufacturing plant personnel

Summary (Annex IIA, point 6.10)	Value	Study	Safety factor
ADI (if residues in food or feed)	No allocated, not necessary.		
AEL (Operator/Worker Exposure)	$8.3*10^{-6}$ mg/kg bw/day	90-days, rat	300
Chronic / long-term			
Sub-acute / medium term	$8.3*10^{-6}$ mg/kg bw/day	28-days, rat	300
Drinking water limit	No allocated, not necessary.		
Acute rAEL	$6.7*10^{-6}$ mg/kg bw/day .	Teratogenicity study, rabbits	300

Summary	Value	Study	Safety factor
Non-professional user			
ADI (acceptable daily intake, external long-term reference dose)	Not applicable		
AEL (acute, medium long term)	$6.7*10^{-6}$ mg/kg bw/day (acute)	Teratogenicity study, rabbits	300
	$8.3*10^{-6}$ mg/kg bw/day	28-days, rat	300

	(medium)		
	$8.3*10^{-6}$ mg/kg bw/day (chronic)	90-days, rat	300
ARfD (acute reference dose)	Not applicable		
Professional user			
Reference value for inhalation (proposed OEL)	-		
Reference value for dermal absorption	10%	Based on physical chemical properties.	
	4%	Based on comparable molecular mass and log Pow of the other similar second generation anticoagulants	

Acceptable exposure scenarios

Professional users	Trained: acceptable for proposed uses with PPE. Non-trained: acceptable for proposed uses
Non-professional users	Acceptable for proposed uses.
Indirect exposure as a result of use	Acceptable for proposed uses (with risk mitigation measures)

Acceptable exposure scenarios (including method of calculation)

Professional users	Trained professionals Exposure scenario: Application + post application - Placing wax bait in rodent burrows and loading of bait boxes with wax bait - Collection of uneaten bait, empty packages and dead animals, disposed of as controlled waste Frequency of daily use: - Loading and placement: The dermal exposure is based on the dislodgeable residue per wax block for securing wax blocks in bait stations for 74.9 exposure events per day (based on EBRC Report). - Clean-up: The dermal exposure is based on the dislodgeable residue per wax block for clean-up and disposal for 74.9 exposure events (based on EBRC Report). Storm BB is a rodenticide product in form of a ready-to-use wax block bait with a mass of 20 g, based on wheat grain containing 0.005% of the active substance

	Level of protection: Gloves For the products used on a repetitive or daily basis, the risk index (exposure/AELmedium or long-term) is 0.6 and the MOE (NOAEL/exposure) 481 for dermal exposure (inhalatory and oral intake is negligible; 4% dermal absorption) derived from exposure study.
	Non-trained professionals Exposure scenario: Application + post application - Placing wax bait in rodent burrows and loading of bait boxes with wax bait - Collection of uneaten bait, empty packages and dead animals, disposed of as controlled waste Frequency of daily use: - Loading and placement: 2 campaigns per year (assuming treatments to be seasonal), 3 to 4 bait placing periods per campaign, 10 bait points per farm, 3 wax blocks per bait point. For the dermal exposure the value of 30 wax blocks handled per day is used. - Clean-up: The dermal exposure is based on the dislodgeable residue per wax block for clean-up and disposal of 30 wax blocks. Storm BB is a rodenticide product in form of a ready-to-use wax block bait with a mass of 20 g, based on wheat grain containing 0.005% of the active substance Level of protection: No Gloves For the products used on a repetitive or daily basis, the risk index (exposure/AELmedium or long-term) is 0.6 and the MOE (NOAEL/exposure) 510 for dermal exposure (inhalatory and oral intake is negligible; 4% dermal absorption) derived from exposure study.
Production of active substance:	-
Formulation of biocidal product	-
Intended uses	
Secondary exposure	-
Non-professional users	Exposure scenario: Application + post application - Placing wax bait in rodent burrows and loading of bait boxes with wax bait Collection of uneaten bait, empty packages and dead animals, disposed of as controlled waste Frequency of daily use: - Loading and placement: 2-4 campaigns per year, 3 to 4 bait placing periods per campaign , 2 bait points per location, 3 max blocks per bait point. For the dermal exposure the value of 6 wax blocks handled per day is used. - Clean-up: The dermal exposure is based on the dislodgeable residue per wax block for clean-up and disposal of 6 wax blocks. Storm BB is a rodenticide product in form of a ready-to-

	use wax block bait with a mass of 20 g, based on wheat grain containing 0.005% of the active substance Level of protection: No Gloves For products used on a single occasion, the risk index (exposure/AELmedium or long-term) is 0.17 and the MOE (NOAEL/exposure) 1786 for dermal exposure (inhalatory and oral intake is negligible; 4% dermal absorption) derived from exposure study.
Indirect exposure as a result of use	Exposure scenario: - Adults in contact with dead rodents. -Infants ingesting 10 mg or 5 g of wax block material. -Systemic Exposure = 3.3 x 10-8 mg/kg/d for adults handling of dead rodents (based on 4% dermal absorption and exposure data). -Systemic Exposure = 3.8 x 10-5 mg/kg/d (Infants ingesting 10 mg), 1.9 x 10-2 mg/kg/d (Infants ingesting 5g).

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water (Annex IIA, point 7.6, IIIA, point XII.2.1, 2.2)

Hydrolysis of active substance and relevant metabolites (DT50) (state pH and temperature)	pH 4: DT50 > 1 yr (estimate based on 5-day study at T = 50 °C)
	pH 7: DT50 > 1 yr (estimate based on 5-day study at T = 50 °C)
	pH 9: DT50 > 1 yr (estimate based on 5-day study at T = 50 °C)
Photolytic/ photo-oxidative degradation of active substance and resulting relevant metabolites	active substance: t½E = 1.67 d (“normal” value in April) ▪ 4-(Trifluoromethyl)-benzoic acid (CAS-No. 455-24-3) ▪ 4-hydroxy-3-[3-(4-hydroxyphenyl)-1,2,3,4-tetrahydro-1-naphthyl]coumarin (no CAS-No. allocated) ▪ Plus two unidentified transformation products
Readily biodegradable (yes/no)	No
Biodegradation in seawater	Not required
Non-extractable residues	Not required
Distribution in water/ sediment systems (active substance)	Not required
Distribution in water/ sediment systems (metabolites)	Not required

Route and rate of degradation in soil (Annex IIIA, point VII.4, XII.1.1, XII.1.4; Annex VI, para. 85)

Mineralization (aerobic)	No reliable mineralization rate can be determined. CO2-formation was max. 15.6%, day 70; and 13.4%, end of study (day 120); determined for trifluoromethylphenyl labelled 14C-flocoumafen
Laboratory studies (range or median, with number of measurements, with regression coefficient)	Geometric mean DT50 = 213 days (range 71-442 days (n=4, 20oC), 4 soils using two labelling positions)
Field studies (state location, range or median with number of measurements)	No reliable data available.
Anaerobic degradation	No degradation under anaerobic conditions
Soil photolysis	Not required
Non-extractable residues	Non-extractable residues: max. 47.4% end of study (120 days)
Relevant metabolites – name and/or code, % of applied a.i. (range and maximum)	The sum of metabolites never exceeded 3.7% for both labels at any sampling date.
Soil accumulation and plateau concentration	No data available

Adsorption/desorption (Annex IIA, point XII.7.7; Annex IIIA, point XII.1.2)

Ka, Kd	Koc = 68510 (cis-isomer) (HPLC method)
Kaoc, Kdoc	Koc = 134858 (trans-isomer) (HPLC method)
pH dependence (yes/no) (if yes type of dependence)	Koc = 101684 (mean) (HPLC method)
	No

Fate and behaviour in air (Annex IIIA, point VII.3, VII.5)

Direct photolysis in air	No data available
Quantum yield of direct photolysis	No data available
Photo-oxidative degradation in air	QSAR estimation: t½ (Ozone) = 2.015 h t½ (OH) = 1.479 h
Volatilization	Not expected; p < 10–3 Pa; H < 3.871 Pa × m3/mol (QSAR estimation: 7.43 x 10-8 Pa x m3/mol)

Monitoring data, if available (Annex VI, para. 44)

Soil (indicate location and type of study)	Not required
Surface water (indicate location and type of study)	Not required
Ground water (indicate location and type of study)	Not required
Air (indicate location and type of study)	Not required

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)
(Annex IIA, point 8.2, Annex IIIA, point 10.2)

Species	Time-scale	Endpoint	Toxicity
Fish			
Oncorhynchus mykiss	96 h	Mortality, LC50	0.07 mg/L
Invertebrates			
Daphnia magna	48 h	Immobility, EC50	0.18 mg/L
Algae			
Pseudokirchneriella subcapitata	72 h	Growth inhibition	EbC50 & ErC50 >18.2 mg/L NOEbC 1.7 mg/L NOErC ≥18.2 mg/L
Microorganisms			
Mixed species activated sludge	3 h	Respiration inhibition	EC50 > 4.0 mg/l NOEC 4.0 mg/L

Effects on earthworms or other soil non-target organisms

Acute toxicity to …. (Annex IIIA, point XIII.3.2)	Not submitted
Reproductive toxicity to… (Annex IIIA, point XIII.3.2)	Not submitted

Effects on soil micro-organisms (Annex IIA, point 7.4)

Nitrogen mineralization	Not submitted
Carbon mineralization	Not submitted

Effects on terrestrial vertebrates

Acute toxicity to mammals (Annex IIIA, point XIII.3.3)	LD_{50} = 0.13 mg/kg bw (oral single dosage, rat)
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	LD50 = 24 mg/kg bw (oral single dosage, *Anas platyrhynchos*)
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	5-day dietary toxicity (*Anas platyrhynchos*): LC50 = 12 mg/kg diet ⇔ 5.6 mg/kg bw/day
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	20 wks reproduction toxicity (*Coturnix japonica*): NOEC>0.063 mg a.i./kg diet, ⇔ NOEL>0.0075 mg a.i./kg bw/d, derived by read-across from a reproductive toxicity study with difenacoum

Effects on honeybees(Annex IIIA, point XIII.3.1)

Acute oral toxicity	Not required

Acute contact toxicity	Not required

Effects on other beneficial arthropods (Annex IIIA, point XIII.3.1)

Acute oral toxicity	Not required
Acute contact toxicity	Not required
Acute toxicity to ……..	Not required

Bioconcentration (Annex IIA, point 7.5)

Bioconcentration factor (BCF)	BCF = 36,134 L/kg (aquatic organisms) BCF = 15,820 kg/kg wwt (earthworms) (Estimates based on log Pow)
Depuration time(DT_{50}) (DT_{90})	No data available
Level of metabolites (%) in organisms accounting for > 10 % of residues	Not required

Chapter 6: Other End Points

none

APPENDIX II: LIST OF INTENDED USES

Serial number	Field of use/ Product type	Application type	Number and timing of application	Waiting periods	Information on recommended variations of the application rate in different locations	Remarks
Wax blocks – In and around buildings	MG03: Pest control. Product type 14.	User category – Professional and Non-professional, Method - Manual application, Application aim – Control, Type of formulation – bait (ready for use).	Against rats: 40–60 g (2-3 blocks) are placed per bait point, with bait points placed 5–10 m apart over area of infestation. Against mice: 20 g (1 block) placed per bait point; with bait points placed approx. 2 m apart. The bait points are visited on a regular basis (for example 1, 3, 7, 14, 21 days) and any consumed or spoilt rodenticide is replenished or replaced.	Not applicable	The application rate of product used is not varied as such but the area treated and the product (i.e. bait type) selected as most appropriate for use is determined depending on the infestation.	--

APPENDIX III: LIST OF STUDIES

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed" column of the table below. For studies marked Yes(i) data protection is claimed under Article 12.1(c) (i), for studies marked Yes(ii) data protection is claimed under Article 12.1(c) (ii). These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

Reference list of studies on the active substance

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.6.4/01	Allen JA, Proudlock RJ, McCaffrey KJ	1986	Genotoxicity studies with WL108366 (rodenticide): in vivo chromosome studies with rat bone marrow cells Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL 85/8610 Not GLP, Not Published	Y (New/First)	BAS
A6.1.1/09	Anonymous	1985	Summary of protocol for determining acute oral LD50 of Flocoumafen (366) for Rattus rattus Sorex Ltd., Agricultural Research Departement, Report No.: FL-411-001 Not GLP, Not Published	Y (New/First)	BAS
A5.7.2/01	Anonymous	2003	Anticoagulant resistance management strategy for pest management professionals, central and local government and other competent users of rodenticides CropLife International, Technical Monograph 2003, Report No.: unnumbered document Not GLP, Published	N	
A6.1.4/04	Anonymous	1983	Acute eye irritation of novel anticoagulants in male rabbits Sorex Ltd., Agricultural Research Departement, Report No.: FL-415-002 Not GLP, Not Published	Y (New/First)	BAS
A6.12.5/01	Anonymous	1984	Shell rodenticide WL108366 - Advice to physicians, medical specialists and poison information centres Shell, Report No.: 74.5279 Not GLP, Not Published	Y (New/First)	BAS
A5.1/01	Anonymous	1987	Storm rodenticide - a user's guide The Shell Guide to Rodent Control, Report No.: FL-120-004 Not GLP, Published	Y (New/First)	
A8.1/01	Anonymous	2002	Safety Data Sheet according to 91/155/EC-Flocoumafen techn. BASF AG, Report No.: 2004/1010401 Not GLP, Not Published	N	BAS
A2.8/01	Anonymous	2004	RTECS search results impurity 1 EBRC Consulting GmbH, Hannover, Germany, Not GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A4.1/02	Anonymous		Determination of Flocoumafen in technical material - liquid chromatographic method Shell Research Ltd., Sittingbourne, UK, Report No.: SAMS 427-1 Not GLP, Not Published	Y (New/First)	BAS
A4.2/02	Anonymous		Determination of residues of WL 108366 in soil - liquid chromatographic method Shell Research Ltd., Sittingbourne, UK, Report No.: SAMS 450-1 Not GLP, Not Published	Y (New/First)	BAS
A2.8/02	Anonymous	2004	PBT-profiler results impurity 1 EBRC Consulting GmbH, Hannover, Germany, Not GLP, Not Published	Y (New/First)	BAS
A5.4/03	Anonymous	1995	Anticoagulant rodenticides WHO, Environmental Health Criteria 175, Report No.: unnumbered document Not GLP, Published	N	
A2.8/03	Anonymous	2004	PBT-profiler results impurity 2 EBRC Consulting GmbH, Hannover, Germany, Not GLP, Not Published	Y (New/First)	BAS
A2.8/04	Anonymous	2004	PBT-profiler results impurity 3 EBRC Consulting GmbH, Hannover, Germany, Not GLP, Not Published	Y (New/First)	BAS
A2.8/05	Anonymous	1992	p-Toluolsulfonsäure, BUA-Stoffbericht 63, Not GLP, Published	N	
A2.8/06	Anonymous	2004	PBT-profiler results impurity 4 EBRC Consulting GmbH, Hannover, Germany, Not GLP, Not Published	Y (New/First)	BAS
A2.8/07	Anonymous	2004	RTECS search results impurity 5 EBRC Consulting GmbH, Hannover, Germany, Not GLP, Not Published	Y (New/First)	BAS
A2.8/08	Anonymous	2004	PBT-profiler results impurity 5 EBRC Consulting GmbH, Hannover, Germany, Not GLP, Not Published	Y (New/First)	BAS
A6.13/13	Anonymous		Storm - advice to veterinarians Shell Agriculture, Report No.: FL-190-002 Not GLP, Not Published	Y (New/First)	BAS
A2.8/09	Anonymous	2004	PBT-profiler results impurity 6 EBRC Consulting GmbH, Hannover, Germany, Not GLP, Not Published	Y (New/First)	BAS
A2.8/10	Anonymous	2004	PBT-profiler results impurity 7 EBRC Consulting GmbH, Hannover, Germany, Not GLP, Not Published	Y (New/First)	BAS
A2.8/11	Anonymous	2004	PBT-profiler results Flocoumafen EBRC Consulting GmbH, Hannover, Germany, Not GLP, Not Published	Y (New/First)	BAS
A6.12.7/01	Anonymous	1987	STORM rodenticide - advice to physicians, medical specialists and poison information centres Shell International Chemical Company Limited, London, UK, Report No.: FL-190-003 Not GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.13/12	Anonymous		The treatment of anticoagulant rodenticide poisoning - Advice to veterinarians Leaflet by consortium of rodenticide manufacturers, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	BAS
A6.8.1/02	Baldwin MK	1988	A study of the effect of WL108366 on the pregnancy of the rabbit Shell Research Ltd., Sittingbourne, UK, Report No.: SLL/144/R Not GLP, Not Published	Y (New/First)	BAS
A6.8.1/05	Baldwin MK	1988	A study of the effect of WL108366 on the pregnancy of the rat Shell Research Ltd., Sittingbourne, UK, Report No.: SLL/143/R Not GLP, Not Published	Y (New/First)	BAS
A7.5.3.1.3/02	Baroch J	2005	Avian reproduction study with Difenacoum in the Japanese quail (Coturnix coturnix japonica). Genesis Laboratories, Inc., Unpublished Wellington, Colorado, USA, Report no. 04012. GLP, Not Published	Y (New/First)	SOREX
A3.15/01	Battersby RV	2004	Explosivity of flocoumafen technical EBRC Consulting GmbH, Hannover, Germany, Report No.: BASF-040112-01 Not GLP, Not Published	Y (New/First)	BAS
A3.16/01	Battersby RV	2004	Oxidising properties of flocoumafen technical EBRC Consulting GmbH, Hannover, Germany, Report No.: BASF-040112-02 Not GLP, Not Published	Y (New/First)	BAS
A2.7/01	Bennett W, Springer B	2001	Flocoumafen technical (CL 183540; STORM) - Technical active ingredient specification BASF Corporation, Report No.: 2110.2 Not GLP, Not Published	Y (New/First)	BAS
A6.13/11	Berny Ph	1998	Clinical trial: evaluation of the efficacy of vitamin K1 in the treatment of poisoning in dogs with Flocoumafen, anticoagulant rodenticide Unité d'Etudes Précliniques, Marcy L'Etoile, France, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	BAS
A6.1.3/02	Blair D	1988	Toxicology of a candidate rodenticide: the acute 4 hour inhalation toxicity of technical concentate containing 0.5% M/M WL108366 Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.87.229 Not GLP, Not Published	Y (New/First)	BAS
A6.1.3/03	Blair D	1984	Toxicology of a candidate rodenticide: The acute 4 hour inhalation toxicity of manufacturing master mix (bait concentrate) containing 0.5% m/m WL108366 Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.84.151 Not GLP, Not Published	Y (New/First)	BAS
A6.6.1/01	Brooks TM, Clare MB, Wiggins DE	1984	Genotoxicity studies with WL108366 (candidate rodenticide) Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.84.160 Not GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.13/06	Burford P, Cope JL, Buist DP, Crook D	1989	An investigative study of the effectiveness of vitamin K, therapy as an antidote to single exposure intoxication by WL108366 Huntingdon Research Centre Ltd., Huntingdon, UK, Report No.: SLL 137/89474 Not GLP, Not Published	Y (New/First)	BAS
A6.13/01	Chesterman H, Burford P, Harling RJ, Heywood R	1984	WL108366 rodenticide - acute oral toxicity in Beagle dogs Huntingdon Research Centre Ltd., Huntingdon, UK, Report No.: SLL 72/84757 Not GLP, Not Published	Y (New/First)	BAS
A6.6.3/01	Clare MG, Wiggins DE	1986	In vitro mutagenicity studies with WL108366 (rodenticide) using cultured chinese hamster V79 cells Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.86.014 Not GLP, Not Published	Y (New/First)	BAS
A6.4.1/01	Clark DG, Esdaile DJ	1989	WL108366: A 90 day feeding study in rats Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.88.147 Not GLP, Not Published	Y (New/First)	BAS
A3.1.1/01	Daum A	2001	Determination of the melting point, the appearance, the thermal stability and the stability in air of BAS 322 I (PAI) BASF AG, Limburgerhof, Germany, Report No.: PCP06480 GLP, Not Published	Y (New/First)	BAS
A3.1.1/02	Daum A	2002	Determination of the melting point and the appearence of Flocoumafen (TGAI) (BAS 322 I, Reg. No. 4060804 identical with CL 183540) BASF AG, Limburgerhof, Germany, Report No.: PCP06579 GLP, Not Published	Y (New/First)	BAS
A3.4/01	Daum A	2003	UV spectra of BAS 322I (Reg.No. 4060804, identical with CL 183540) BASF AG, Limburgerhof, Germany, Report No.: 174136_1 GLP, Not Published	Y (New/First)	BAS
A3.5/01	Daum A	2002	Determination of the solubility in water at 20 C of Flocoumafen (PAI) BASF AG, Limburgerhof, Germany, Report No.: PCP06477 GLP, Not Published	Y (New/First)	BAS
A3.6/01	Daum A	2002	Determination of the dissociation constant of Flocoumafen (PAI) BASF AG, Limburgerhof, Germany, Report No.: PCP06478 GLP, Not Published	Y (New/First)	BAS
A3.7/01	Daum A	2002	Determination of the solubility in organic solvents at 20 C of Flocoumafen (TGAI) BASF AG, Limburgerhof, Germany, Report No.: PCP06479 GLP, Not Published	Y (New/First)	BAS
A3.9/01	Daum A	2002	Determination of the Octanol/Water Partition Coefficient at 20 C of Flocoumafen (PAI) BASF AG, Limburgerhof, Germany, Report No.: PCP06597 GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.1.1.2.1/01	Dengler D	2004	Assessment of the ready biodegradability of Flocoumafen with the closed bottle test Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Öschelbronn, Germany, Report No.: 20031410/01-AACB GLP, Not Published	Y (New/First)	BAS
A7.2.1/02	Derz K	2006	Metabolism of Flocoumafen in soil. Fraunhofer Institute for Molecular Biology and Applied Ecology, Schmallenberg, Germany, Report no. EBR-003/7-90 GLP, Not Published	Y (New/First)	BAS
A4.2/06	Dutton AJ	1994	Development of a method for the analysis of regurgitated raptor pellets for residues of coumarin based rodenticides Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.91.248 Not GLP, Not Published	Y (New/First)	BAS
A6.13/10	Eadsforth CV, Gray A, Huckle KR, Inglesfield C	1993	The dietary toxicity of Flocoumafen to hens: elimination and accumulation following repeated oral administration Pesticide Science 38, 17-25, Report No.: unnumbered document Not GLP, Published	N	
A6.8.1/03	Esdaile DJ	1987	WL108366: A CKA embryotoxicity study in rats Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.86.232 Not GLP, Not Published	Y (New/First)	BAS
A7.5.3.1.2/08	Forbes S	1988	The effect of a repeated oral dose of WL108366 ("Storm") on the liver residue in Japanese quail Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.87.227 Not GLP, Not Published	Y (New/First)	BAS
A6.4.1/02	Forsey JD	1985	An evaluation of the long term sub-acute oral toxicity of WL108366 in wistar rats Sorex Ltd., Agricultural Research Departement, Report No.: FL-425-001 Not GLP, Not Published	Y (New/First)	BAS
A5.7.1/01	Forsey JD	1985	An experimental note on: the acute oral LD50 of WL108366 in hybrid mice Sorex Ltd., Agricultural Research Departement, Report No.: FL-452-005 Not GLP, Not Published	Y (New/First)	BAS
A6.1.4/01	Forsey JD	1983	The acute skin irritation of novel anticoagulants in male rabbits Sorex Ltd., Agricultural Research Departement, Report No.: FL-415-001 Not GLP, Not Published	Y (New/First)	BAS
A3.2/01	Franke J	2001	Vapour pressure Siemens Axiva GmbH & Co. KG, Frankfurt, Germany, Report No.: 20011316.01 GLP, Not Published	Y (New/First)	BAS
A7.5.3.1.2/01	Gallagher SP, Grimes J, Beavers JB, MacGregor J, Ahmed S	2002	Avian dietary toxicity test with BAS 322I (Flocoumafen) in the mallard duck (Anas platyrhynchos) Wildlife International, Ltd, Easton, Maryland, USA, Report No.: 147-217 GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.5.3.1.2/02	Gallagher SP, Grimes J, Beavers JB, MacGregor J, Ahmed S	2002	Avian dietary toxicity test with BAS 322I (Flocoumafen) in the northern bobwhite (Colinus virginianus) Wildlife International, Ltd, Easton, Maryland, USA, Report No.: 147-216 GLP, Not Published	Y (New/First)	BAS
A6.1.1/01	Gardner JR	1989	A comparison of the acute oral toxicity to rats of "Storm", Brodifacoum and 1:1 (M/M) combination of "storm" with Brodifacoum Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.89.045 Not GLP, Not Published	Y (New/First)	BAS
A6.1.1/08	Gill JE	1987	Determination of the acute oral LD50 of Flocoumafen against the ship rat (Rattus rattus) ADAS Tolworth Laboratory, UK, Report No.: FL-411-015 Not GLP, Not Published	Y (New/First)	BAS
A5.3/05	Gill JE	1992	Laboratory evaluation of the toxicity of Flocoumafen as a single-feed rodenticide to seven rodent species Int. Biodet. Biodegr. 30, 65-76, Report No.: unnumbered document Not GLP, Published	N	
A5.7.1/04	Greaves JH	1985	The present status of resistance to anticoagulants Acta Zool. Fennica 173, 159-162, Report No.: unnumbered document Not GLP, Published	N	
A5.7.2/02	Greaves JH	1995	Managing resistance to anticoagulant rodenticides: an appraisal Pesticide Science 43, 79-82, Report No.: unnumbered document Not GLP, Published	N	
A4.2/04	Grützner I	1993	Validation of an analytical method for the determination of residues of Flocoumafen (storm) in water RCC Ltd., Itingen, Switzerland, Report No.: 298315 GLP, Not Published	Y (New/First)	BAS
A6.2/01	Hafemann C	2003	Metabolism of 14C-BAS 322 I in the rat BASF AG, Limburgerhof, Germany, Report No.: 66884 GLP, Not Published	Y (New/First)	BAS
A6.13/04	Hakin B, Rodgers M	1990	The dietary toxicity of WL 108366 to broiler chickens and laying hens Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL 156/891981 Not GLP, Not Published	Y (New/First)	BAS
A6.13/14	Harling RJ, Burford P, Fryer SE, Buist DP, Crook D	1987	WL 108366 palatability/oral toxicity study in beagle dogs Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL 87/861452 Not GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.13/15	Harling RJ, Burford P, Fryer SE:, Buist DP	1987	An investigative study of the palatability of bitrex treated wax blocks and untreated wax blocks to beagle dogs Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL 111-G/861427 Not GLP, Not Published	Y (New/First)	BAS
A4.1/01	Hassink J	2002	Validation of HPLC-method SAMS 427-1 for the determination of Reg. No. 4060804 in technical Flocoumafen BASF AG, Limburgerhof, Germany, Report No.: PCP06560 GLP, Not Published	Y (New/First)	BAS
A4.1/03	Hassink J	2002	Validation of analytical method CFS-CA M 21/1/N: Determination of technical by-products in technical grade Flocoumafen BASF AG, Limburgerhof, Germany, Report No.: PCP06561 GLP, Not Published	Y (New/First)	BAS
A3/01	Hassink, J.	2001	Certificate of analysis (flocoumafen)Lot no. M02 Not GLP, Not Published	N	BAS
A6.2/08	Hawkins DR, Brodie RR, Clarke D, Brindley C	1991	Determination of the residues and the half-life of the rodenticides Brodifacoum, Bromadiolone and Flocoumafen in the livers of rats during 200 days after single oral doses of each at a dose level of 0.2 MG/KG Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: HRC/LPA 158/891590 Not GLP, Not Published	Y (New/First)	BAS
A6.12.5/03	Hemker HC, Devilee PP	1988	Report on the development of a test to detect minimal intoxication with vitamin K antagonists Shell Agriculture Regulatory Affairs Report, Report No.: FL-452-014 Not GLP, Not Published	Y (New/First)	BAS
A7.1.1.1.2/01	Hennecke D	2006	Direct phototransformation of Flocoumafen in water and identity of transformation products. Fraunhofer Institute for Molecular Biology and Applied Ecology, Schmallenberg, Germany, Report no. EBR-003/7-05 GLP, Not Published.	Y (New/First)	BAS
A7.4.1.4/01	Hicks S, Canez V	2002	BAS 322I (Flocoumafen): Activated sludge, respiration inhibition test ABC Laboratories, Columbia, USA, Report No.: 46797 GLP, Not Published	Y (New/First)	BAS
A6.13/05	Huckle KR	1988	Fate of 14C-WL108366 fed to laying hens at a rate of 1 mg and 4 mg per kg per day for 5 days:elimination of radioactivity in excreta and total 14C-residues in eggs and in liver tissue Shell Research. Ltd., Sittingbourne, UK, Report No.: SBRG.87.079 Not GLP, Not Published	Y (New/First)	BAS
A7.5.3.1.3/01	Huckle KR et al	1988	Studies on the fate of Flocoumafen in the Japanese quail Xenobiotica 19, 51-62, Not GLP, Published	N	

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.2/07	Huckle KR et al	1988	Elimination and accumulation of the rodenticide Flocoumafen in rats following repeated oral administration Xenotiotica 18, 1465-1479, Report No.: unnumbered document Not GLP, Published	N	
A6.2/12	Huckle KR, Hutson DH, Logan CJ, Morrison BJ, Warburton PA	1989	The fate of the rodenticide Flocoumafen in the rat: retention and elimination of a single oral dose Pestic. Sci. 25, 297-312, Report No.: unnumbered document Not GLP, Published	N	
A6.2/09	Huckle KR, Morrison J, Warburton PA	1989	The percutaneous fate of the rodenticide Flocoumafen in the rat: role of non-biliary intestinal excretion Xenotiotica 19, 63-74, Report No.: unnumbered document Not GLP, Published	N	
A6.2/13	Huckle KR, Veenstra GE, Owen DE	1991	Metabolic and toxicological studies on the anticoagulant rodenticide, Flocoumafen Arch. Toxicol., Suppl. 14, 160-165, Report No.: unnumbered document Not GLP, Published	N	
A7.5.3.1.2/09	Huckle KR, Warburton PA	1986	WL108366: Absorption, metabolism and disposition in Japanese quail (Coturnix coturnix japonica) following a single dose by intraperiotneal or oral administration Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.85.192 GLP, Not Published	Y (New/First)	BAS
A6.2/02	Huckle KR, Warburton PA	1985	Percutaneous absorption, metabolism and elemination of WL108366 in the rat Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.85.218 Not GLP, Not Published	Y (New/First)	BAS
A6.2/06	Huckle KR, Warburton PA	1986	Elimination, metabolism and disposition of 14C - WL108366 in the Fischer 344 rat following repeated oral administration Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.86.084 Not GLP, Not Published	Y (New/First)	BAS
A6.2/14	Huckle KR, Warburton PA, Logan CJ, Hutson DH	1998	The fate of the anticoagulant rodenticide Flocoumafen in the rat and in quail Shell Research Ltd., Sittingbourne, UK, Report No.: SBB/54/88 Not GLP, Not Published	Y (New/First)	BAS
A6.12.2/01	Ingels M et al.	2002	A prospective study of acute, unintentional, paediatric superwarfarin ingestions managed without decontamination Ann. Emerg. Med. 40, 73-78, Report No.: unnumbered document Not GLP, Published	N	
A6.8.1/04	James P, Jones K, Hughes E, John DM, Parker CA	1989	A study of the effect of WL108366 on the pregnancy of the rat with rearing of F1 offspring (Japanese experiment 2) Huntingdon Research Centre Ltd., Huntingdon, UK, Report No.: SLL 143/881544 Not GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.8.1/01	James P, Jones K, Masters RE	1989	The effect of WL108366 on pregnancy of the rabbit Huntingdon Research Centre Ltd., Huntingdon, UK, Report No.: SLL 144/881513 Not GLP, Not Published	Y (New/First)	BAS
A7.4.1.2/01	Jatzek J	2002	BAS 322 I - Determination of the acute effect on the swimming ability of the water flea Daphnia magna STRAUS BASF, Ludwigshafen, Germany, Report No.: 01/0344/50/2 GLP, Not Published	Y (New/First)	BAS
A7.4.1.3/01	Jatzek J	2002	BAS 322 I - Determination of the inhibitory effect on the cell multiplication of unicellular green algae BASF, Ludwigshafen, Germany, Report No.: 01/0344/60/1 GLP, Not Published	Y (New/First)	BAS
A7.5.3.1.1/06	Jones JR	1983	WL 108366: Acute oral toxicity study in the Japanese quail Hazelton Laboratories Ltd., UK, Report No.: 3511-355/2 Not GLP, Not Published	Y (New/First)	BAS
A3.17/01	Kaltz	2001	Corrosiveness of Flocoumafen BASF AG, Limburgerhof, Germany, Not GLP, Not Published	Y (New/First)	BAS
A6.12.7/02	Kanabar D, Volans G	2002	Accidental superwarfarin poisoning in children - less treatment is better The Lancet 360, 963, Report No.: unnumbered document Not GLP, Published	N	
A4.2/01	Knoch E, Kroker J	1998	Determination of Flocoumafen in soil - validation of the method Institut Fresenius Group, Herten, Germany, Report No.: IF-95/14504-00 GLP, Not Published	Y (New/First)	BAS
A3.11/01	Krips HJ	1996	Determination of the flammability of Flocoumafen, TM NOTOX, 's-Hertogenbosch, NL, Report No.: 165959 GLP, Not Published	Y (New/First)	BAS
A3.11/02	Krips HJ	1996	Determination of the relative self-ignition temperature of Flocoumafen, TM NOTOX, 's-Hertogenbosch, NL, Report No.: 165961 GLP, Not Published	Y (New/First)	BAS
A7.1.1.2.1/02	Lebertz H	1995	Study on the 'ready biodegradability' of technical Flocoumafen according to OECD-test guideline 301 B (CO2 Evolution Test) Institut Fresenius, Taunusstein-Neuhof, Germany, Report No.: IF-95/19438-00 GLP, Not Published	Y (New/First)	BAS
A6.12.3/01	LeQuesne L	2003	Results of Sorex CoaguCheck routine prothrombin times Sorex Product Development Labs, UK, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.5.7.1.1/01	Lund M, Lodal, J	1986	LD 50 trials with the anticoagulant Flocoumafen Danish Pest Infestation Laboratory, Lyngby, Denmark, Report No.: B.651 Not GLP, Not Published	Y (New/First)	BAS
A7.5.3.1.1/01	Mach J, Troup R, Ahmed S	2001	Avian acute oral toxicity test with BAS 322 I (Flocoumafen) in the mallard duck (Anas platyrhynchos) Genesis Laboratories, Inc., Wellington, Colorado, USA, Report No.: 67330 GLP, Not Published	Y (New/First)	BAS
A5.7.1/05	MacNicoll AD	1986	Resistance to 4-Hydroxycoumarin anticoagulants in rodents In National Research Council (ed.), Pesticide Resistance: Strategies and Tactics for Management: 87-99. Washington D.C., National Academy Press, Report No.: unnumbered document Not GLP, Published	N	
A7.3.1/01	Martin CA	2002	BAS 322I (Flocoumafen): Estimation of the photochemical oxidative degradation rate in the atmosphere BASF Agro Research, Ewing, NJ, USA, Report No.: ENV02-009 Not GLP, Not Published	Y (New/First)	BAS
A3.6/02	Martin CA	2001	Flocoumafen (BAS 322 I): Calculation of the Dissociation Constant, pKa BASF Corporation, Princeton, NJ, USA, Report No.: ENV01-022 Not GLP, Not Published	Y (New/First)	BAS
A6.1.3/01	McDonald P, Carter PB	1988	Storm master mix - Acute inhalation toxicity study in mice Inveresk Research International, Musselburgh, Scotland, Report No.: 5330 Not GLP, Not Published	Y (New/First)	BAS
A5.7.1/07	Meehan AP (Ed.)	1984	Rats and Mice - Their biology and control The Rentokil Library, Rentokil Ltd., East Grinstead, UK, Report No.: unnumbered document Not GLP, Published	N	
A6.6.3/02	Meyer AL, Wiggins DE	1985	Genotoxicity studies with WL108366 (rodenticide): in vitro cell transformation studies Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.85.289 Not GLP, Not Published	Y (New/First)	BAS
A6.2/11	Morrison BJ	1987	The effect of Phenobarbitone and Warfarin administration on hepatic 14C-WL108366 residues in fischer 344 rats Shell Research Ltd., Sittingbourne, UK, Report No.: SBRN.87.035 Not GLP, Not Published	Y (New/First)	BAS
A6.12.5/04	Mullins ME, Brands CL, Daya MR	2002	Unintentional paediatric superwarfarin exposures: do we really need a prothrombin time? Pediatrics 105, 402-404, Report No.: unnumbered document Not GLP, Published	N	
A3.2/02	Ohnsorge U	2002	Henry's Law Constant for Flocoumafen BASF AG, Limburgerhof, Germany, Not GLP, Not Published	Y (New/First)	BAS

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A6.1.4/02	Pels Rijcken WR	1996	Acute eye irritation/corrosion study with Flocoumafen technical material in the rabbit NOTOX, 's-Hertogenbosch, NL, Report No.: 173317 GLP, Not Published	Y (New/First)	BAS
A2.10.1/01	Pinteno F	1998	Mode opératoire - fabrication du flocoumafène Merck Lipha S.A., Meyzieu, France, Report No.: 1053-1 Not GLP, Not Published	Y (New/First)	BAS
A5.7.2/03	Prescott CV	2003	A reappraisal of blood clotting response tests for anticoagulant resistance and a proposal for a standardised BCR test methodology CropLife International, Technical Monograph 2003, Report No.: unnumbered document Not GLP, Published	N	
A6.1.2/03	Price JB	1985	Toxicology of rodenticides: The percutaneous toxicity of WL108366 corn oil manufacturing master mix Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.84.227 Not GLP, Not Published	Y (New/First)	BAS
A6.1.1/02	Price JB	1984	Toxicology of rodenticides: the acute and sub-acute oral and acute percutneous toxicity of WL108366 (technical material) in rats Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.84.124 Not GLP, Not Published	Y (New/First)	BAS
A6.1.1/10	Price JB	1984	Toxicology of rodenticides: the acute oral toxicity of WL108366 in mice Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.84.148 Not GLP, Not Published	Y (New/First)	BAS
A6.1.1/11	Price JB	1986	Toxicology of rodenticides: the acute oral toxicity of WL108366 in rabbits and hamsters Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.85.189 Not GLP, Not Published	Y (New/First)	BAS
A6.3.1/01	Price JB	1984	WL108366: a 28 day feeding study in rats Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.84.235 Not GLP, Not Published	Y (New/First)	BAS
A6.3.1/02	Price JB	1984	Toxicology of rodenticides WL108366: a five day range finding feeding study in rats Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.84.279 Not GLP, Not Published	Y (New/First)	BAS
A6.1.2/02	Price JB	1984	Toxicology of rodenticides: the percutaneous toxicity of WL108366 Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.87.230 Not GLP, Not Published	Y (New/First)	BAS
A6.1.2/04	Price JB	1984	Toxicology of rodenticides: The acute percutaneous toxicity of WL108366 bait concentrate Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.84.162 Not GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.1.5/01	Price JB	1986	Toxicology of rodenticides: the skin sensitizing potential of WL108366 Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.86.091 Not GLP, Not Published	Y (New/First)	BAS
A6.13/07	Roberts NL, Cameron DM, Redgrave VA, Crook D	1987	Acute oral toxicity of WL 108366 to goats Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL 89/861037 Not GLP, Not Published	Y (New/First)	BAS
A6.13/08	Roberts NL, Cameron DM, Redgrave VA, Crook D	1987	WL108366 - Acute oral toxicity to sheep Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL 88/861036 Not GLP, Not Published	Y (New/First)	BAS
A6.13/02	Roberts NL, Cameron DM, Street AE	1986	WL108366 - Acute oral toxicity to cats Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL 81/851385 Not GLP, Not Published	Y (New/First)	BAS
A6.13/03	Roberts NL, Cameron DM, Street AE	1985	WL108366 - Acute oral toxicity to pigs Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL/76/851108 Not GLP, Not Published	Y (New/First)	BAS
A7.5.3.1.1/02	Roberts NL, Fairley C, Baldwin MK	1985	The acute oral toxicity of WL108366 to the mallard duck Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL 73BT/8572 GLP, Not Published	Y (New/First)	BAS
A7.5.3.1.1/03	Roberts NL, Fairley C, Baldwin MK	1985	The acute oral toxicity (LD50) of WL 108366 to the mallard duck Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL 67BT/84925 GLP, Not Published	Y (New/First)	BAS
A7.5.3.1.1/04	Roberts NL, Fairley C, Baldwin MK	1984	The acute oral toxicity (LD50) of WL 108366 to the Japanese quail Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL 68BT/84863 GLP, Not Published	Y (New/First)	BAS
A7.5.3.1.2/03	Roberts NL, Fairley C, Baldwin MK	1985	The short-term cumulative dietary toxicity of WL108366 to the Japanese quail Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL 75BT/85111 GLP, Not Published	Y (New/First)	BAS
A7.5.3.1.2/04	Roberts NL, Fairley C, Baldwin MK	1985	The short-term cumulative dietary toxicity of WL108366 to the Japanese quail Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL 70BT/8593 GLP, Not Published	Y (New/First)	BAS
A7.5.3.1.2/05	Roberts NL, Fairley C, Baldwin MK	1985	The short-term cumulative dietary toxicity of WL108366 to the mallard duck Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL 74BT/841259 GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.5.3.1.2/06	Roberts NL, Fairley C, Baldwin MK	1985	The short-term cumulative dietary toxicity of WL108366 to the mallard duck Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL 69BT/841085 GLP, Not Published	Y (New/First)	BAS
A7.5.3.1.2/07	Roberts NL, Fairley C, Baldwin MK	1986	The short-term cumulative dietary toxicity of WL108366 to the house sparrow Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL 79BT/851436 GLP, Not Published	Y (New/First)	BAS
A6.13/09	Roberts NL, Fairley C, Baldwin MK	1985	The short- term comulative dietary toxicity of WL108366 to the domestic chicken Huntingdon Research Centre Ltd., Cambridgeshire, UK, Report No.: SLL 71BT/8592 Not GLP, Not Published	Y (New/First)	BAS
A5.3/03	Rowe FP, Bradfield A, Swinney T	1985	Pen and field trials of a new anticoagulant rodenticide flocoumafen against the house mouse (Mus musculus L.) J. Hyg. 95, 623-627, Report No.: unnumbered document Not GLP, Published	N	
A6.8.2/01	Sangha GK, Bilaspuri GS, Guraya SS	1991	Effects of oral administration of rodenticide Flocoumafen on the rat ovary , Not GLP, Published	N	
A8.4/01	Schenk W	2002	Possible procedures for the decontamination of water from Flocoumafen BASF, Ludwigshafen, Germany, Not GLP, Not Published	Y (New/First)	BAS
A7.1.2.1.2/01	Schwarz H	2004	BAS 322 I - Determination of the ultimate anaerobic biodegradability in the anaerobic biodegradation test BASF, Ludwigshafen, Germany, Report No.: 01/0344/40/1 GLP, Not Published	Y (New/First)	BAS
A7.5.5.1/01	Sendor T	2003	Estimation of the terrestrial bioconcentration factor (BCF) of Flocoumafen EBRC Consulting GmbH, Hannover, Germany, Report No.: BAS-20031107-01 Not GLP, Not Published	Y (New/First)	BAS
A7.4.2/01	Sendor T	2003	Estimation of the bioconcentration factor (BCF) of Flocoumafen EBRC Consulting GmbH, Hannover, Germany, Report No.: unnumbered document Not GLP, Not Published	N	BAS
A2.10.2/01	Sendor T	2003	Estimation of distribution in the environment of Flocoumafen EBRC Consulting GmbH, Hannover, Germany, Report No.: BAS-031117-01 Not GLP, Not Published	Y (New/First)	BAS
A3.2/03	Sendor T	2003	Model calculation of Henry's law constant of Flocoumafen EBRC Consulting GmbH, Hannover, Germany, Report No.: BAS-030801-01 Not GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.5.3.1.1/05	Sharples R	1983	The acute oral toxicity of a series of novel anticoagulants in broiler chick Sorex Ltd., Agricultural Research Departement, Report No.: FL-505-001 Not GLP, Not Published	Y (New/First)	BAS
A6.1.1/03	Sharples R	1983	The acute oral toxicity of WL108366 in New Zealand white rabbits Sorex Ltd., Agricultural Research Departement, Report No.: FL-411-008 Not GLP, Not Published	Y (New/First)	BAS
A6.1.1/04	Sharples R	1983	The acute oral toxicity of WL108366 in Mongolian gerbils Sorex Ltd., Agricultural Research Departement, Report No.: FL-411-009 Not GLP, Not Published	Y (New/First)	BAS
A6.1.1/05	Sharples R	1984	The acute oral toxicity of WL108366 in C57BL/10 mice Sorex Ltd., Agricultural Research Departement, Report No.: FL-411-003 Not GLP, Not Published	Y (New/First)	BAS
A6.1.1/06	Sharples R	1983	The acute oral toxicity of a series of novel anticoagulants in Wistar rats and C57BL/10 mice Sorex Ltd., Agricultural Research Departement, Report No.: FL-411-002 Not GLP, Not Published	Y (New/First)	BAS
A6.1.1/07	Sharples R	1986	The acute oral toxicity of WL108366 in female wistar rats Sorex Ltd., Agricultural Research Departement, Report No.: FL-411-014 Not GLP, Not Published	Y (New/First)	BAS
A6.1.1/12	Sharples R	1983	The acute oral toxicity of a series of novel anticoagulants in Syrian hamsters Sorex Ltd., Agricultural Research Departement, Report No.: FL-411-004 Not GLP, Not Published	Y (New/First)	BAS
A6.1.1/13	Sharples R	1983	The acute oral toxicity of WL108366 in Dunkin-Hartley Guinea pigs Sorex Ltd., Agricultural Research Departement, Report No.: FL-411-006 Not GLP, Not Published	Y (New/First)	BAS
A6.3.1/03	Sharples R	1983	The sub-acute oral toxicity of WL108366 in Wistar rats Shell Research Ltd., Sittingbourne, UK, Report No.: FL-420-001 Not GLP, Not Published	Y (New/First)	BAS
A5.7.1/02	Sharples R	1985	The acute oral toxicity of WL108366 in Cambridge cream mice Sorex Ltd., Agricultural Research Departement, Report No.: FL-452-017 Not GLP, Not Published	Y (New/First)	BAS
A5.7.1/03	Sharples R	1986	The acute oral toxicity of WL108366 in male and female warfarin-resistant Rattus norvegicus Sorex Ltd., Agricultural Research Departement, Report No.: FL-452-022 Not GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.5.6/01	Sharples R	1983	The insecticidal effects of novel anticoagulants against Musca domestica and Blatella germanica Sorex Ltd., Report No.: FL-531-001 Not GLP, Not Published	Y (New/First)	BAS
A5.3/01	Sharples R	1984	The acute oral toxicity of WL108366 in C3H/He mice Sorex Ltd., Agricultural Research Departement, Report No.: FL-452-003 Not GLP, Not Published	Y (New/First)	BAS
A5.3/02	Sharples R	1984	Prothrombin time determination, in rats, for cis- and trans-WL108366 Sorex Ltd., Agricultural Research Departement, Report No.: FL-470-004 Not GLP, Not Published	Y (New/First)	BAS
A5.3/04	Sharples R	1983	Acute feeding of bait containing novel anticoagulants to non-resistant and resistant rats, and non-resistant mice - Bait LC50 determination Sorex Ltd., Agricultural Research Departement, Report No.: FL-452-004 Not GLP, Not Published	Y (New/First)	BAS
A6.2/10	Sharples R	1984	An experimental note on: the release of body residues of WL108366 with phenylbutazone Sorex Ltd., Agricultural Research Departement, Report No.: FL-452-012 Not GLP, Not Published	Y (New/First)	BAS
A7.1.1.1.1/01	Singh M, Trollinger J	2003	Hydrolysis of 14C-BAS 322 I in aqueous media BASF Agro Research, Princeton, NJ, USA, Report No.: 130739 GLP, Not Published	Y (New/First)	BAS
A6.12.2/02	Smolinske SC et al.	1989	Superwarfarin poisoning in children: a prospective study Pediatrics 84 (3), 490-494, Report No.: unnumbered document Not GLP, Published	N	
A7.2.1/01	Standen ME	1985	The degradation of [14C] WL108366 in soil under aerobic laboratory conditions Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.85.067 Not GLP, Not Published	Y (New/First)	BAS
A4.1/04	Stengert I	1996	High performance liquid chromatograohic method to assay for minor components in the technicalo grade of Flocoumafen Cyanamid Forschung GmbH, Schwabenheim, Germany, Report No.: CFS-CA M 21/1/N Not GLP, Not Published	Y (New/First)	BAS
A5.7.1/06	Thijssen HHW	1995	Warfarin-based rodenticides: mode of action and mechanism of resistance Pesticide Science 43, 73-78, Report No.: unnumbered document Not GLP, Published	N	
A2/01	Thomson ML	2001	Description of BAS 322 I (Flocoumafen) BASF Agro Research, Princeton, NJ, USA, Report No.: APBR 1188 Not GLP, Not Published	Y (New/First)	BAS

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A3/02	Thomson, M.L.	1999	Certificate of analysis (flocoumafen) Lot no. AC11303-85 Not GLP, Not Published	N	BAS
A4.3/01	Turnbull G	2005	Validation of analytical methodology to determine rodenticides in food matrices. Central Science Laboratory, Sand Hutton, York, UK, Report no. PGD-180, June 16, 2005 GLP, Not Published	Y (New/First)	BAS
A2.6/01	van Eijk PJSS	1996	Flocoumafen (CL183540) Technical material: product chemistry and manufacturing information on the technical grade material for registration Cyanamid Forschung GmbH, Schwabenheim, Germany, Report No.: CFS 1996-034 Not GLP, Not Published	Y (New/First)	BAS
A6.12.5/02	van Sittert NJ	1987	The selection of laboratory tests for the detection of effects on vitamin K dependent coagulation factors by the rodenticide Flocoumafen Shell, HSE, The Hague, NL, Report No.: HSE 87.002 Not GLP, Not Published	Y (New/First)	BAS
A5.4/02	van Sittert NJ	1990	PIVKA II and prothrombin in the serum of plasma of rabbits after dosing with WL 108366 (Storm) and vitamin K1 therapy Biomedical Laboratory, Shell Pernis, Report No.: FL-452-016 Not GLP, Not Published	Y (New/First)	BAS
A6.12.1/01	van Sittert NJ, Tuinman, CP	1987	Biomedical monitoring of plant workers engaged in Storm - master mix repacking and formulation and in small pack filling of Storm - loose grain bait, Cairo, Egypt, June 1986 Shell, HSE, The Hague, NL, Report No.: HSE 87.004 Not GLP, Not Published	Y (New/First)	BAS
A6.12.1/02	van Sittert NJ, Tuinman, CP	1985	Biomedical monitoring of personnel in Sorex Ltd. (Widness, U.K.) involved in a formulation run with thr rodenticide WL108366 Shell, HSE, The Hague, NL, Report No.: HSE 85.006 Not GLP, Not Published	Y (New/First)	BAS
A6.1.2/01	Veenstra GE	1988	The acute dermal toxicity of storm Sittingbourne Research Centre, Kent, UK, Report No.: SBGR.88.080 Not GLP, Not Published	Y (New/First)	BAS
A6.1.4/03	Veenstra GE	1988	Toxicology of rodenticides: skin and eye irritancy potential of 0.5% Storm manufacturing master mix Sittingbourne Research Centre, Kent, UK, Report No.: SBGR.87.214 Not GLP, Not Published	Y (New/First)	BAS
A5.4/01	Vermeer C, Soute B	1992	Comparison of rodenticide anticoagulant action in vitro and in vivo Department of Biochemistry, University of Limburg, Maastricht, NL, Report No.: FL-130-015 Not GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.2.3.2/01	Wallace BG, Eadsforth CV	1984	The leaching of WL108366 in soil under laboratory conditions Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.84.205 Not GLP, Not Published	Y (New/First)	BAS
A6.2/05	Warburton PA, Huckle KR	1986	WL108366: fate of a single oral dose of (14C)-WL108366 in rats, part III: metabolism Shell Research Ltd., Sittingbourne Research Centre, Sittingbourne, UK, Report No.: SBGR.85.294 Not GLP, Not Published	Y (New/First)	BAS
A6.2/03	Warburton PA, Hutson DH	1985	WL108366: fate of a single oral dose of (14C)-WL108366 in rats, part I: elimination and retention of radioactivity and effect of WL108366 on prothrombin time Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.85.053 Not GLP, Not Published	Y (New/First)	BAS
A6.2/04	Warburton PA, Hutson DH	1985	WL108366: fate of a single oral dose of (14C)-WL108366 in rats, part II Rate of depletion of radioactivity from selected tissues Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.85.177 Not GLP, Not Published	Y (New/First)	BAS
A3.1.1/03	Weaver RC, Camilleri P	1985	Determination of the melting point and differential thermal analysis of the CIS and TRANS isomers of the rodenticide WL108366 Shell Research Ltd., Sittingbourne, UK, Report No.: SBRN.85.283 Not GLP, Not Published	Y (New/First)	BAS
A7.1.3/01	Weissenfeld M	2002	BAS 322 I (flocoumafen): Estimation of the adsorption coefficient (Koc) by HPLC method RCC Ltd., Itingen, Switzerland, Report No.: 835187 GLP, Not Published	Y (New/First)	BAS
A3.1.3/01	Werle H	2001	Determination of the Density of Flocoumafen (reg. no. 4060804, CL# 183540, BAS 322I) according to EC Council Directive 92/69/EEC, A.3 and OECD Guideline No. 109 BioChem GmbH, Karlsruhe, Germany, Report No.: 01 50 40 229 GLP, Not Published	Y (New/First)	BAS
A4.2/03	Xu B, Kukel C	2002	BAS 322 I (Flocoumafen): Validation of method M 3490 for LC/MS determination and LC/MS/MS confirmation of BAS 322 I residues in ground water and surface water BASF Agro Research, Princeton, NJ, USA, Report No.: RES 02-003 GLP, Not Published	Y (New/First)	BAS
A4.2/05	Xu B, Kukel C	2002	BAS 322 I (Flocoumafen): Validation of method M 3508 for LC/MS determination and LC/MS/MS confirmation of BAS 322 I residues in urine, blood and liver BASF Agro Research, Princeton, NJ, USA, Report No.: RES 02-008 GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.4/02	Yan Z	2001	A spectral database for purified active ingredients CL 183540, CL 153080, and CL 153081 BASF Agro Research, Princeton, NJ, USA, Report No.: APBR 1187 GLP, Not Published	Y (New/First)	BAS
A7.4.1.1/01	Zok S	2002	Acute toxicity study on the rainbow trout (Oncorhynchus mykiss) in a semistatic system over 96 hours BASF, Ludwigshafen, Germany, Report No.: 12F0344/015028 GLP, Not Published	Y (New/First)	BAS
A7.4.1.1/02	Zok S	2002	Acute toxicity study on the bluegill sunfish (Lepomis macrochirus) in a semistatic system over 96 hours BASF, Ludwigshafen, Germany, Report No.: 14F0344/015029 GLP, Not Published	Y (New/First)	BAS

Reference list of studies on the product

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B5.2/01	Anonymous	2004	Storm user guide, Not GLP, Published	N	
B5.2/02	Anonymous	2004	Storm rat bait box – instructions, Not GLP, Published	N	
B5.10.2/06	Anonymous	1986	Pen trials to assess the toxicity of storm wax blocks to wild Warfarin-resistant mice (Mus domesticus) MAFF, ADAS Slough Laboratory, UK, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/19	Anonymous	1987	Rodent palatability studies on STORM wax blocks containing 10ppm Bitrex (denatonium benzoate) as a deterrent to ingestion by humans Sorex Ltd., Agricultural Research Departement, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	BAS
B8/01	Anonymous	2003	BASF Safety data sheet. STORM Block Bait BASF Aktiengesellschaft, Ludwigshafen, Germany, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	
B3.7/01	Baker IP	2003	Flocoumafen 0.005% w/w BB: bioassay and chemical and physical stability of formula reference BAS 322 01 I when stored in candidate commercial packaging - 104 week interim report BASF Agro Research, Gosport, UK, Report No.: RLG 4933 GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/19	Barnett EA, HunterK, Fletcher MR, Sharp EA	2000	Pesticide poisoning of animals 1999: Investigations of suspected incidents in the United Kingdom MAFF Publications, London, UK, Report No.: unnumbered document Not GLP, Published	N	

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B6.2/01	Boczon LM	2000	Primary dermal irritation study in albino rabbits with AC 183540 (Flocoumafen) 0.005% block bait (DF 06826) American Cyanamid Company, Princeton, NJ, USA, Report No.: A00-3 GLP, Not Published	Y (New/First)	BAS
B6.2/02	Boczon LM	2000	Primary eye irritation in albino rabbits with AC 183540 (Flocoumafen) 0.005% block bait (DF 06826) American Cyanamid Company, Princeton, NJ, USA, Report No.: A00-4 GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/26	Bosio PG	1986	Residues of WL108366 in rat livers from the UK - 1986 trials - Shell Chemie France, Report No.: BEGR.86.014 Not GLP, Not Published	Y (New/First)	BAS
B6.1.2/01	Bradley D	2000	Dermal LD50 study in albino rats with AC 183540 (Flocoumafen) 0.005% block bait (DF 06826) American Cyanamid Company, Princeton, NJ, USA, Report No.: A99-102 GLP, Not Published	Y (New/First)	BAS
B6.6/04	Chambers JG, Snowdon PJ	2004	Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits Synergy Laboratories Ltd., Thaxted, UK, Report No.: SYN/1302 GLP, Not Published	Y (New/First)	BAS
B7.1/01	Coveney PC, Forbes S	1987	Degradation of WL108366 ("Storm") in rat baits, carcases and faeces in field situations Shell Research Limited, Sittingbourne Research Centre, Sittingbourne, UK, Report No.: SBGR.87.171 Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/08	Dobbs JR	1998	Fungal challenge testing of rat balt pellets British Analytical Control, UK, Report No.: 980030 Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/02	Dutton AJ, Eadsforth, CV	1990	A study to examine the relationship between consumption of (14C) Flocoumafen fed mice by barn owls (tyto alba) and levels of (14C) Flocoumafen in subsequently regurgitated pellets Sittingbourne Research Centre, Kent, UK, Report No.: SBGR.89.232 GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/31	Eadsforth CV	1989	Residues of WL108366 ("Storm") in livers and carcasses from different rodent species following LD50 trials Sittingbourne Research Centre, Kent, UK, Report No.: SBGR.89.011 Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/32	Eadsforth CV	1989	Residue of WL108366 ("Storm") in liver and fat samples from different animals following acute oral toxicity studies Sittingbourne Research Centre, Kent, UK, Report No.: SBGR.88.243 Not GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B7.8.7.2/03	Eadsforth CV, Dutton AJ, Harrison EG	1991	A barn owl feeding study with (14C) Flocoumafen-dosed mice: validation of a non-invasive method of monitoring exposure of barn owls to anticoagulant rodenticides in their prey Pestic Sci. 32, 105-119, Report No.: unnumbered document Not GLP, Published	N	
B7.8.7.1/03	Eadsforth CV, Gray A, Harrison EG	1995	Monitoring the exposure of barn owls to second-generation rodenticides in Southern Eire Pestic. Sci. 47, 225-233, Report No.: unnumbered document Not GLP, Published	N	
B7.8.7.2/18	Fletcher MR, Hunter K, Barnett EA, Sharp EA	1999	Pesticide poisoning of animals 1998: Investigations of suspected incidents in the United Kingdom MAFF Publications, London, UK, Report No.: unnumbered document Not GLP, Published	N	
B7.8.7.2/23	Forbes S	1987	Residues of WL108366 ("Storm") in mouse liver and carcase: Sorex toxicity studies Shell Research Limited, Sittingbourne Research Centre, Sittingbourne, UK, Report No.: SBGR.87.102 Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/25	Forbes S	1987	Residues of WL108366 (Storm) in rodents and non- target animal tissues collected from field trials in the welshpool area, 1986 Shell Research Limited, Sittingbourne Research Centre, Sittingbourne, UK, Report No.: SBGR.87.193 Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/28	Forbes S	1987	Residues of WL108366 ("Storm") in livers of dogs used in HRC palatability/toxicity study SLL/87-G Shell Research Limited, Sittingbourne Research Centre, Sittingbourne, UK, Report No.: SBGR.87.218 Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/33	Forbes S, Coveney PC	1987	Residues of WL108366 ("Storm") in sparrow tissues: HRC toxicity study (SLL.79 BT) Shell Research Limited, Sittingbourne Research Centre, Sittingbourne, UK, Report No.: SBGR.87.104 Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/24	Forbes S, Francis WHP	1987	Residues of WL108366 ("Storm") in rat tissues: Sorex secondary toxicity studies Shell Research Limited, Sittingbourne Research Centre, Sittingbourne, UK, Report No.: SBGR.87.103 Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.1/04	Garforth B	1986	Storm rodenticide: primary and secondary hazards of 50ppm wax block baits to non- target vertebrates: a field study on 3 UK farms, spring 1985 Shell Research Limited, Sittingbourne Research Centre, Sittingbourne, UK, Report No.: SBGR.86.054 Not GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B5.10.2/22	Garforth B, Johnson RA	1987	Performance and safety of the new anticoagulant rodenticide Flocoumafen BCPC MONO, no. 37 Stored Products Pest Control, 115-123, Report No.: unnumbered document Not GLP, Published	N	
B7.8.7.1/05	Garforth BM, Forbes S	1986	Storm rodenticide: primary and secondary hazards of 50ppm wax block baits to non- target vertebrates: a field study on 7 UK farms, winter 1985/86 Shell Research Limited, Sittingbourne Research Centre, Sittingbourne, UK, Report No.: SBGR.86.140 Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/11	Gray A	1991	Flocoumafen (Storm) residues in mice and in owl pellets and livers following an owl feeding study at the institute of terrestrial ecology Sittingbourne Research Centre, Kent, UK, Report No.: SBGR.91.054 GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/04	Gray A, Dutton AJ	1992	A comparative study on the toxicity of Brodifacoum, Difenacoum and Flocoumafen to barn owls, Tyto alba, consumong rodenticide- fed mice Sittingbourne Research Centre, Kent, UK, Report No.: SBTR.92.012 GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/05	Gray A, Eadsforth V, Dutton AJ		Non- invasive method for monitoring the potential exposure of barn owls to second generation rodenticides unpublished manuscript, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/06	Gray A, Eadsforth V, Dutton AJ	1994	Non- invasive method for monitoring the exposure of barn owls to second generation rodenticides Pestic. Sci. 41, 339-343, Report No.: unnumbered document Not GLP, Published	N	
B7.8.7.2/07	Gray A, Eadsforth V, Dutton AJ	1994	The toxicity of three second- generation rodenticides to barn owls Pestic. Sci. 42, 179-184, Report No.: unnumbered document Not GLP, Published	N	
B7.8.7.2/08	Gray A, Eadsforth V, Dutton AJ	1992	Toxicity of second generation rodenticides to barn owls Brit. Crop Protect. Conf. (1992), 781-786, Report No.: unnumbered document Not GLP, Published	N	
B5.10.2/09	Greaves JH, Lazarus AB	1986	Six field trials of 'Storm' Flocoumafen bait blocks for the control of Rattus norvegicus on farms MAFF, Tolworth Laboratory, Tolworth, UK, Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.1/01	Harrison EG, Eadsforth CV, Dutton AJ	1990	Secondary hazard of Storm I: Analysis of barn owl pellets, prey remains and residues of somecoumarin- based rodenticides Sittingbourne Research Centre, Kent, UK, Report No.: SBGR.89.261 GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B7.8.7.2/12	Harrison EG, Eadsforth CV, Vaughan JA	1990	A non-invasive approach for monitoring the exposure of barn owls to rodenticides Brit. Crop Protect. Conf. (1991), 951-955, Report No.: unnumbered document Not GLP, Published	N	
B7.8.7.1/06	Harrison EG, Forbes S	1987	Storm rodenticide (Flocoumafen, WL108366): field trials to assess the hazards to non- target animals arising from the use of a wax block bait with a pulse-baiting regime, in the mid-Wales/Shropshire area, spring 1987 Sittingbourne Research Centre, Kent, UK, Report No.: SBGR.87.178 GLP, Not Published	Y (New/First)	BAS
B7.8.7.1/02	Harrison EG, Pearson N	1991	Secondary hazards of Storm II: a survey of nineteen barn owl sites in Eire in relation to rodenticide use by local landowners Sittingbourne Research Centre, Kent, UK, Report No.: SBGR.90.017 GLP, Not Published	Y (New/First)	BAS
B7.8.7.1/08	Harrison EG, Porter AJ, Forbes S		Development of methods to assess the hazards of a rodenticide to non-target vertebrates Reprint from unknown source, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	BAS
B4.1/02	Hart DA	2000	Method validation of RLA 12580.00 "The HPLC determination of Flocoumafen in rodenticide bait formulations utilising a duel extraction technique" BASF Agro Research, Gosport, UK, Report No.: RLG 4570 GLP, Not Published	Y (New/First)	BAS
B6.3/01	Hoffman GM et al	2000	Dermal sensitization study with AC 183540 (Flocoumafen) 0.005% block bait (DF06826) in guinea pigs- Buehler method (nine inductions) Huntingdon Life Science Ltd., Cambridgeshire, UK, Report No.: 99-0574 GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/13	Joermann G	1998	A review of secondary-poisoning studies with rodenticides Bull. OEPP/EPPO Bull. 28, 157-176, Report No.: unnumbered document Not GLP, Published	N	
B7.6.1/01	Johnson AJ, Ahmed S	1998	Avian oral LD50 test with Flocoumafen (CL 183540) in a 0.005% pellet formulation (RLF 12328) in mallard ducks (Anas platyrhynchos) Huntingdon Life Science Ltd., Cambridgeshire, UK, Report No.: ECO 97-143 GLP, Not Published	Y (New/First)	BAS
B5.10.2/23	Johnson RA	1984	Performance studies with the new anticoagulant rodenticide, Flocoumafen, against mus domesticus and rattus norvegicus Bull. OEPP/EPPO Bull. 18, 481-488, Report No.: unnumbered document Not GLP, Published	N	
B3.6/01	Kaestel R	2003	Odour and density of the formulation BAS 322 01 I BASF AG, Limburgerhof, Germany, Report No.: 174835_1 GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B6.6/03	Keen S	2002	Rodenticides - patterns of use survey Health and Safety Laboratory, Sheffield, UK, Report No.: FSSU/02/03 Not GLP, Not Published	Y (New/First)	BAS
B3.7/03	Kröhl T	2004	Flocoumafen 0.005% w/w BB: bioassay and chemical and physical stability of formula reference BAS 322 01 I when storen in candidate commercial packaging - 156 week final report BASF Agricultural Center, Limburgerhof, Germany, Report No.: 69034/E GLP, Not Published	Y (New/First)	BAS
B5.10.2/15	Latteur G	1996	Evaluation de la perte d'efficacité au cours du viellissement du bloc Storm de 3,6 g, rodenticide à base de 0,005% de Flocoumafene pour lutter contre la souris grise Centre de Recherches Agronomiques Gembloux, Report No.: 938 Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/16	Latteur G	1993	Efficacité du Storm formulé en blocks de 3,6 g. contre le rat brun (Rattus norvegicus L.) Centre de Recherches Agronomiques Gembloux, Report No.: 895 Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/17	Latteur G	1993	Efficacité du Storm formulé en blocks de 16 g. contre le rat brun (Rattus norvegicus L.) Centre de Recherches Agronomiques Gembloux, Report No.: 896 Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/18	Latteur G	1993	Efficacité des blocs Storm de 3,6 g a base de 0,005 % de flocoumafene contre la souris grise (Mus musculus L.) en presence de froment concasse ou de farine d'avoine Centre de Recherches Agronomiques Gembloux, Report No.: 911 Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/10	Lazarus AB	1987	Restricted application of 'Storm' Flocoumafen bait blocks on six farms for the control of Rattus norvegicus MAFF, Tolworth Laboratory, Tolworth, UK, Report No.: SSD 289/86 Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/11	Lazarus AB	1990	A determination of the efficacy of 'Storm' against rat (Rattus norvegicus, Berk.) infestations and an evaluation of the risks of toxicity to non- target vertebrate species MAFF, Tolworth Laboratory, Tolworth, UK, Report No.: C90/0079 Not GLP, Not Published	Y (New/First)	BAS
B6.1.1/01	Lowe CA	2000	Oral LD50 study in albino rats with AC 183540 (Flocoumafen) 0.005% block bait (DF06826) BASF Agro Research, Princeton, NJ, USA, Report No.: A00-17 GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B7.8.7.2/27	McKee J, Gardner JR, Gray A	1991	Range-finding experiment to determine concentrations of Flocoumafen, Difenacoum and Brodifacoum in mice fed on wax block baits Shell Research Limited, Sittingbourne Research Centre, Sittingbourne, UK, Report No.: SBRN.91.003 Not GLP, Not Published	Y (New/First)	BAS
B4.1/01	Moyle J	2003	Method validation of RLA 12671 an HPLC method for the determination of Flocoumafen in rodenticide baits using acid digestion BASF Agro Research, Gosport, UK, Report No.: RLG 4892 GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/10	Newton I, Wyllie I, Gray A, Eadsforth CV	1993	The toxicity of the rodenticide Flocoumafen to barn owls and ist elimination via pellets Pesticide Science 41, 187-193, Report No.: unnumbered document Not GLP, Published	N	
B7.8.7.2/01	Porter AJ	1988	Rodenticide baits: the attractiveness of different colours and formulations to wild birds Sittingbourne Research Centre, Kent, UK, Report No.: SBGR.87.097 GLP, Not Published	Y (New/First)	BAS
B7.8.7.1/07	Porter AJ, Gray A	1993	Storm rodenticide (Flocoumafen, WL108366): field trials to assess the secondary hazard to non-target predators and scavengers from contaminated rodents arising from the use of wax bloc bait for three weeks, with a 7 day pulse-baiting regi Sittingbourne Research Centre, Kent, UK, Report No.: SBGR.91.282 GLP, Not Published	Y (New/First)	BAS
B6.1.1/02	Price JB	1987	Toxicology of rodenticides: The acute oral toxicity of a wax bait formulation of WL108366 ('Storm') Shell Research Limited, Sittingbourne Research Centre, Sittingbourne, UK, Report No.: SBGR.87.072 GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/14	Price JB	1988	WL108366: An overview of a secondary toxicity study in beagle dogs Shell Research Ltd., Sittingbourne, UK, Report No.: SBGR.88.010 Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/03	Redpath CS	1991	Choice feeding (palatability) test on Storm 4g rodenticide bait block, fresh and post 6 month storage at ambient conditions, against male C57BL/10 mice Sorex Ltd., Agricultural Research Departement, Report No.: LR007/91 Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/04	Redpath CS	1992	Choice feeding (palatability) test on storm 4g block bait, fresh and post 6 month storage at ambient conditions, against male C57BL/10 mice Sorex Ltd., Agricultural Research Departement, Report No.: LR069/92 Not GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B5.10.2/13	Redpath CS	1995	Choice feeding (palatability) tests on Storm II block bait, fresh and post 6 month stored at ambient conditions against male BKW mice Sorex Ltd., Agricultural Research Departement, Report No.: LR027/95 Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/14	Redpath CS	1995	Choice feeding (palatability) tests on Storm II block bait, fresh and post 6 month stored at ambient conditions against male Wistar rats Sorex Ltd., Agricultural Research Departement, Report No.: LR026/95 Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/29	Roberts-McIntosh C	1989	Concentrations of WL108366 (Flocoumafen) in liver tissue HRC experiment SLL 112/87472 Bioanalytical Research Ltd., Kent, UK, Report No.: 89/1412/PC GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/30	Roberts-McIntosh C	1989	Concentrations of WL108366 (Flocoumafen) in liver tissue HRC experiment 137/89 Bioanalytical Research Ltd., Kent, UK, Report No.: 89/1364/PC GLP, Not Published	Y (New/First)	BAS
B3.4/01	Schuurman P	1989	Physico-chemical properties of storm block bait Shell Research Limited, Sittingbourne Research Centre, Sittingbourne, UK, Report No.: PML1989-C 13 Not GLP, Not Published	Y (New/First)	BAS
B6.6/01	Sendor T	2004	Estimation of human exposure to Flocoumafen from application of Storm Secure wax blocks EBRC Consulting GmbH, Hannover, Germany, Report No.: BAS-040128-01 Not GLP, Not Published	Y (New/First)	BAS
B7.1/02	Sendor T	2004	Estimation of environmental exposure to Flocoumafen following application of “Storm” wax block bait – EUBEES calculations – EBRC Consulting GmbH, Hannover, Germany, Report No.: BAS-040224-01 Not GLP, Not Published	Y (New/First)	BAS
B7.1/03	Sendor T	2004	Estimation of predicted environmental concentrations of Flocoumafen following application in sewage systems - EUSES report EBRC Consulting GmbH, Hannover, Germany, Report No.: BAS-040224-02 Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/20	Sharples R	1984	The palatability of baits containing cis- or- trans- WL108366 Sorex Ltd., Agricultural Research Departement, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/21	Sharples R	1986	The palatability of Bepex wax blocks containing 50ppm Flocoumafen Sorex Ltd., Agricultural Research Departement, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	BAS

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B5.10.2/24	Sharples R	1985	A WL108366 wax block field trial at the Pit, Linner Farm, Halebank, Cheshire Shell Agriculture Regulatory Affairs, Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/15	Sharples R	1984	To evaluate the potential secondary hazard of WL108366 Sorex Ltd., Agricultural Research Departement, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/16	Sharples R	1984	To evaluate the potential secondary hazard of WL108366: acute studies Sorex Ltd., Agricultural Research Departement, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/17	Sharples R	1985	To evaluate the potential secondary hazard of WL108366 II: Rat to rat studies Sorex Ltd., Agricultural Research Departement, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/05	Sharples R, Chorley C	1987	A choice feeding test of storm rodenticide bait blocks against Rattus norvegicus, wistar strain Sorex Ltd., Agricultural Research Departement, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/12	Sharples R, Chorley C	1987	A choice feeding test of Storm rodenticide bait blocks against mus domesticus C57BL/10 strain Sorex Ltd., Agricultural Research Departement, Report No.: C/S/C57 Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/01	Sharples RL	1986	An experimental note on the median effective dose of 50ppm Flocoumafen wax blocks against wistar rats Sorex Ltd., Agricultural Research Departement, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/02	Sharples RL	1987	A bait LD50 feeding test of Storm rodenticide bait blocks against Rattus norvegicus, wistar strain Sorex Ltd., Agricultural Research Departement, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/22	Shore RF, Birks JDS, Freestone P, Kitchener AC	1996	Second-generation rodenticides and polecats (Mustela putorius) in Britain Second-generation rodenticides and polecats in Britain Environ. Pollution 91, 279-282, Report No.: unnumbered document Not GLP, Published	N	
B6.6/02	Snowdon PJ	2003	Pilot study to determine primary sources of exposure to operators during simulated use of anticoagulant rodenticide baits Synergy Laboratories Ltd., Thaxted, UK, Report No.: SYN/1301 GLP, Not Published	Y (New/First)	BAS

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B5.10.2/07	Thomas KP	1987	An assessment of the infestability of a rodenticide bait by insects and mites MAFF, ADAS Slough Laboratory, UK, Report No.: 750/87 Not GLP, Not Published	Y (New/First)	BAS
B5.10.2/25	Townsend MG	1988	Post-treatment censusing on six farms, six and twelve months after controlling the Rattus norvegicus infestations with "Storm" (Flocoumafen) bait blocks Shell Agriculture Regulatory Affairs, Report No.: SSD 308/86 Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.1/09	Townsend MG	1986	Post- treatment investigations of "Storm" Flocoumafen bait blocks hoarded by Rattus norvegicus MAFF Tolworth Laboratory, Tolworth, UK, Report No.: 307/86 Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/09	Ueckermann, Lutz W, Dutton AJ, Forbes S, Felton JC	1986	The toxicity of the rodenticide Flocoumafen (WL 108366; DSC 60300R) to the common buzzard, Buteo buteo l. Shell, HSE, The Hague, NL, Report No.: HSE 86.004 Not GLP, Not Published	Y (New/First)	BAS
B3.7/02	Walker AF	2002	Comparison of methods for the determination of Flocoumafen in 0.005% w/w rat baits BASF Agro Research, Gosport, UK, Report No.: RLG 4895 Not GLP, Not Published	Y (New/First)	BAS
B7.8.7.2/20	Wyllie I	1995	Potential secondary poisoning of barn owls by rodenticides Pest. Outlook 6, 19-25, Report No.: unnumbered document Not GLP, Published	N	
B7.8.7.2/21	Wyllie I, Newton I, Freestone P	1992	Rodenticide residues in british barn owls unpublished manuscript, Report No.: unnumbered document Not GLP, Not Published	Y (New/First)	BAS