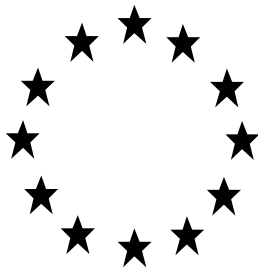
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the eCA)



Storm Ultra

Product type 14

Flocoumafen as included in the Union list of approved active substances

Case Number in R4BP: BC-GJ024217-49

Evaluating Competent Authority: The Netherlands

Date: 7/12/2018

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1 CONCLUSION

The Dutch CA considers the information provided for the intended uses sufficient for the authorisation of the product. Therefore the authorised uses of Storm Ultra will be as a rodenticide against rats and house mice in and around building by the general public and (trained) professionals.

Use(s) appropriate for authorisation	
1	House mice (indoor, general public)
2	Rats (indoor, general public)
3	Rats (outdoor around buildings, general public)
4	House mice (indoor, professionals)
5	Rats (indoor, professionals)
6	House mice and rats (outdoor around buildings, professionals)
7	House mice and rats (indoor, trained professionals)
8	House mice and rats (outdoor around buildings, trained professionals)

Some restrictions in use are necessary to prevent access of children and non-target animals to the product, please refer to the SPC. Prior to renewing the approval of anticoagulant active substances discussions took place at EU-level to harmonise use instructions and risk mitigation measures to the greatest possible extent. As an outcome of these discussions a set of three standard SPCs (Summary of product characteristics) compiling the relevant sentences for the uses that may be authorised for each of the three user categories (general public, professionals and trained professionals) has been produced (for details please refer to document CA-Nov16-Doc.4.1.b – Final). The SPC for Storm Ultra has been provided with the relevant sentences accordingly.

National specific regulations in the Netherlands:

Due to Dutch national specific regulations in the Netherlands, only trained professionals and non-professionals (general public) are allowed to apply rodenticides (no [untrained] professional use). Only trained professionals are allowed to control rats and only trained professionals with additional IPM training are allowed to apply rodenticides outdoors. In addition, the use against house mice is restricted to use in buildings and for both house mice and rats use in covered and protected bait points is not allowed (derogations based on art 37 BPR).

Therefore, in the Netherlands the authorised use of this product will be restricted to the use in buildings against house mice (*Mus musculus*) by the general public, in buildings against house mice (*Mus musculus*) and rats (*Rattus norvegicus* and *Rattus rattus*) by trained professionals, and the use around buildings and food storage locations against rats by trained professionals with additional IPM training. The only application method of the

product in the Netherlands will be in tamper-resistant bait boxes, which will be via pulsed baiting by trained professionals (general public are not permitted to pulse bait).

Use(s) appropriate for authorisation in the Netherlands	
1	House mice (indoor, general public)
2	House mice and rats (indoor, trained professionals)
3	Rats (outdoor around buildings, trained professionals with IPM training)

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier[1]	**Country (if relevant)**
Storm Ultra bait	eCA: NL

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	BASF Nederland B.V.
	Address	Groningensingel 1, 6835 EA, Arnhem, Netherlands
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	BASF Agro B.V., Arnhem (NL) –Freienbach Branch
Address of manufacturer	Huobstrasse 3, 8808 Pfäffikon SZ, Switzerland
Location of manufacturing sites	1) BASF plc, St. Michaels Industrial Estate, Widnes, Cheshire WA8 8TJ, United Kingdom 2) Schirm GmbH, Dieselstraße 8, 85107 Baar-Ebenhausen, Germany

2.1.1.4 Manufacturer(s) of the active substance

Active substance	Flocoumafen
Name of manufacturer	BASF Agro B.V., Arnhem (NL) –Freienbach Branch
Address of manufacturer	Huobstrasse 3, 8808 Pfäffikon SZ, Switzerland
Location of manufacturing sites	Vertellus Specialties UK Ltd., Lower Road, Halebank, Widnes, Cheshire WA8 8NS, United Kingdom

1 Please fill in here the identifying product name from R4BP.

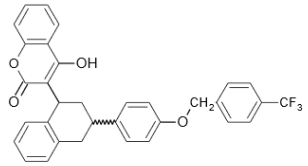
2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Flocoumafen
IUPAC or EC name	4-hydroxy-3-[(1RS,3RS;1RS,3RS)-1,2,3,4-tetrahydro-3- [4-(4-trifluoromethylbenzyloxy) phenyl]-1-naphthyl]coumarin
EC number	421-960-0
CAS number	90035-08-8
Index number in Annex VI of CLP	607-375-00-5
Minimum purity / content	>95.5 % (w/w) (diastereomer ratio: 50-80% (cis) and 20-50% (trans)
Structural formula	

2.1.2.2 Candidate(s) for substitution

The active substance in Storm Ultra, Flocoumafen, is considered a candidate for substitution in accordance with Article 10(1)(a) and 10(1)(e) of Regulation (EU) No 528/2012 according to the BPC opinion for flocoumafen adopted on June 16, 2016 (ECHA/BPC/115/2016).

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Flocoumafen	4-hydroxy-3-[(1RS,3RS;1RS,3RS)-1,2,3,4-tetrahydro-3- [4-(4-trifluoromethylbenzyloxy) phenyl]-1- naphthyl]coumarin	Active substance	90035-08-8	421-960-0	0.0025

For heterogeneous products, an FAO/WHO tolerance of 25% applies to the active substance content.

2.1.2.4 Information on technical equivalence

The active substance contained in the product and the active substance listed in the Union list of approved active substances under Regulation No. 528/2012 are proven to be equivalent. For further details please refer to the confidential "Technical report on equivalence – New Source for Flocoumafen" (Ctgb, Oct 2010), available on S-CIRCABC site (confidential report).

2.1.2.5 Information on the substance(s) of concern

No substances of concern are present.

2.1.2.6 Type of formulation

RB (ready for use bait)

2.1.3 Hazard and precautionary statements

As the concentration flocoumafen (0.0025%) in Storm Ultra is below all specific concentration limits as set by the CLP Regulation for flocoumafen, the product does not need to be classified.

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	-
Hazard statement	-
Labelling	
Signal words	-
Hazard statements	-

Precautionary statements	-
Note	

2.1.4 Authorised use(s)

2.1.4.1 House mice – general public – indoor

Table 1. Use # 1 – House mice – general public – indoor

Product Type	PT 14 - Rodenticides
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	*Mus musculus* (house mice) Juveniles and adults
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Bait products: 15 g - 25 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be 1 - 2 meters.
Category(ies) of users	General public
Pack sizes and packaging material	Pack size:15 g – 100 g Bait blocks (5g/25g) further packed in: • Pre-filled PP tamper resistant bait boxes overpacked in PET/PE re-closable container or re-closable cardboard carton • PP or HDPE or PET or PE buckets with lids and re-closable pots • PP or PE or PET or HDPE lined re-closable container such as a pot, tin or cardboard carton

2.1.4.2 Use-specific instructions for use

The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered. Do not place bait stations near water drainage systems where they can come into

contact with water.

Remove the remaining bait or the bait stations at the end of the treatment period.

2.1.4.3 Use-specific risk mitigation measures

The product information (i.e. label and/or leaflet) shall clearly show that:

-the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only");

-users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations").

Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general instructions for use

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general instructions for use

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general instructions for use

2.1.4.7 Rats – general public – indoor

Table 2. Use # 2 – Rats – general public – indoor

Product Type	PT 14 - Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including	*Rattus norvegicus* (brown rat)

development stage)	*Rattus rattus* (black or roof rat) Juveniles and adults
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Bait products: 50 g - 75 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be 5 - 10 meters.
Category(ies) of users	General public
Pack sizes and packaging material	Pack size: 50 g – 300 g Bait blocks (5g/25g) further packed in: • Pre-filled PP tamper resistant bait boxes overpacked in PET/PE re-closable container or re-closable cardboard carton • PP or HDPE or PET or PE buckets with lids and re-closable pots • PP or PE or PET or HDPE lined re-closable container such as a pot, tin or cardboard carton

2.1.4.8 Use-specific instructions for use

The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.

Do not place bait stations near water drainage systems where they can come into contact with water

Remove the remaining bait or the bait stations at the end of the treatment period.

2.1.4.9 Use-specific risk mitigation measures

The product information (i.e. label and/or leaflet) shall clearly show that:

-the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only");

-users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations").

Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user

should seek advice from the product supplier or call a pest control service. Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.

2.1.4.10 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general instructions for use

2.1.4.11 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general instructions for use

2.1.4.12 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general instructions for use

2.1.4.13 Rats – general public – outdoor around buildings

Table 3. Use # 3 – Rats – general public – outdoor around buildings

Product Type	PT 14 – Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat) Juveniles and adults
Field of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Bait products: 50 g - 75 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be 5 - 10 meters.
Category(ies) of users	General public
Pack sizes and packaging material	Pack size: 50 g – 300 g Bait blocks (5g/25g) further packed in: • Pre-filled PP tamper resistant bait boxes overpacked in PET/PE re-closable container or re-closable cardboard carton • PP or HDPE or PET or PE buckets with lids and re-closable

	pots • PP or PE or PET or HDPE lined re-closable container such as a pot, tin or cardboard carton

2.1.4.14 Use-specific instructions for use

Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding

Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.

The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.

Do not place bait stations near water drainage systems or close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) where they can come into contact with water.Remove the remaining bait or the bait stations at the end of the treatment period.

2.1.4.15 Use-specific risk mitigation measures

The product information (i.e. label and/or leaflet) shall clearly show that:

-the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only");

-users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations").

Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.

2.1.4.16 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general instructions for use

2.1.4.17 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general instructions for use

2.1.4.18 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general instructions for use

2.1.4.19 House mice – professionals – indoor

Table 4. Use # 4 – House mice – professionals – indoor

Product Type	PT 14 – Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) Juveniles and adults
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	15 g - 25 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be 1 - 2 meters.
Category(ies) of users	Professionals
Pack sizes and packaging material	Pack size: 3 kg – 10 kg Bait blocks (5g/25g) further packed in: • PP or HDPE or PET or PE buckets with lids and re-closable pots • PP or PE or PET or HDPE lined re-closable container such as a pot, tin or cardboard carton

2.1.4.20 Use-specific instructions for use

The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. [When available] Follow any additional instructions provided by the relevant code of best practice. Remove the remaining bait or the bait stations at the end of the treatment period.

2.1.4.21 Use-specific risk mitigation measures

See general instructions for use

2.1.4.22 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.1.4.23 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general instructions for use

2.1.4.24 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general instructions for use

2.1.4.25 Rats – professionals– indoor

Table 5. Use # 5 – Rats – professionals– indoor

Product Type	PT 14 - Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat) Juveniles and adults
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	50 g - 75 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be 5 - 10 meters.
Category(ies) of users	Professionals
Pack sizes and packaging material	Pack size: 3 kg – 10 kg Bait blocks (5g/25g) further packed in: • PP or HDPE or PET or PE buckets with lids and re-closable

	pots • PP or PE or PET or HDPE lined re-closable container such as a pot, tin or cardboard carton

2.1.4.26 Use-specific instructions for use

The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

[When available] Follow any additional instructions provided by the relevant code of best practice.

Remove the remaining bait or the bait stations at the end of the treatment period.

2.1.4.27 Use-specific risk mitigation measures

See general instructions for use

2.1.4.28 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.1.4.29 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general instructions for use

2.1.4.30 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general instructions for use

2.1.4.31 House mice and rats – professionals – outdoor around buildings

Table 6. Use # 6 – House mice and rats – professionals – outdoor around buildings

Product Type	PT 14 - Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides

Target organism (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat) Juveniles and adults
Field of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Mice: 15 g - 25 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be 1 - 2 meters. Rats: 50 g - 75 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be 5 - 10 meters.
Category(ies) of users	Professionals
Pack sizes and packaging material	Pack size: 3 kg – 10 kg Bait blocks (5g/25g) further packed in: • PP or HDPE or PET or PE buckets with lids and re-closable pots • PP or PE or PET or HDPE lined re-closable container such as a pot, tin or cardboard carton

2.1.4.32 Use-specific instructions for use

Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.

The bait stations should be visited [for mice - at least every 2 to 3 days at] [for rats - only 5 to 7 days after] the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.

[When available] Follow any additional instructions provided by the relevant code of best practice.

Remove the remaining bait or the bait stations at the end of the treatment period.

2.1.4.33 Use-specific risk mitigation measures

Do not apply this product directly in the burrows.

2.1.4.34 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

2.1.4.35 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general instructions for use

2.1.4.36 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general instructions for use

2.1.4.37 House mice and rats – trained professionals – indoor

Table 7. Use # 7 – House mice and rats – trained professionals – indoor

Product Type	PT 14 – Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat) Juveniles and adults
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations Covered and protected baiting points
Application rate(s) and frequency	Pulsed Baiting. Mice: 15 g - 25 g of bait per baiting point.

	Rats: 50 g - 75 g of bait per baiting point.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Pack size: 3 kg – 10 kg Bait blocks (5g/25g) further packed in: • PP or HDPE or PET or PE buckets with lids and re-closable pots • PP or PE or PET or HDPE lined re-closable container such as a pot, tin or cardboard carton

2.1.4.38 Use-specific instructions for use

Replace eaten bait only after 3 days and then at maximum 7 days intervals. Collect any spilled bait and dead rodents.

The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.

[When available] Follow the specific instructions provided by the applicable code of good practice at national level.

[When available] Follow any additional instructions provided by the relevant code of best practice.

Remove the remaining product at the end of treatment period.

2.1.4.39 Use-specific risk mitigation measures

Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].

Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.

To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

2.1.4.40 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.1.4.41 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general instructions for use

2.1.4.42 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general instructions for use

2.1.4.43 Mice and rats – trained professionals – outdoor around buildings

Table 8. Use # 8 – Mice and rats – trained professionals – outdoor around buildings

Product Type	PT 14 - Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat) *Rattus rattus* (black or roof rat) Juveniles and adults
Field of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations. Covered and protected baiting points. Direct application of ready-to-use bait into the burrow.
Application rate(s) and frequency	Pulsed Baiting. Mice: 15 g - 25 g of bait per baiting point. Rats: 50 g - 75 g of bait per baiting point. 50 g - 75 g of bait per burrow

Category(ies) of users	Trained professionals
Pack sizes and packaging material	Pack size: 3 kg – 10 kg Bait blocks (5g/25g) further packed in: • PP or HDPE or PET or PE buckets with lids and re-closable pots • PP or PE or PET or HDPE lined re-closable container such as a pot, tin or cardboard carton

2.1.4.44 Use-specific instructions for use

Replace eaten bait only after 3 days and then at maximum 7 days intervals. Collect any spilled bait and dead rodents.

The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice. For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

Baits must be placed to minimise the exposure to non-target species and children.

Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.

[When available] Follow the specific instructions provided by the applicable code of good practice at national level.

Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding.

Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.

Remove the remaining product at the end of treatment period.

[When available] Follow any additional instructions provided by the relevant code of best practice.

2.1.4.45 Use-specific risk mitigation measures

Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].

Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.

To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

2.1.4.46 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

2.1.4.47 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general instructions for use

2.1.4.48 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general instructions for use

2.1.5 General directions for use

2.1.5.1 Instructions for use

Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.

Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.

The product should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).

Where possible, bait stations must be fixed to the ground or other structures.

Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.

Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.

When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

Professionals and trained professionals:

Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.

The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.

Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 5.3 for the information to be shown on the label).

[If national policy or legislation require it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

Bait should be secured so that it cannot be dragged away from the bait station.

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

If bait uptake is low relative to the apparent size of the infestation, consider the

replacement of bait stations to further places and the possibility to change to another bait formulation.

If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodents so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.

2.1.5.2 Risk mitigation measures

Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.

Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

Dispose dead rodents in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.

Professionals and Trained professionals:

Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].

Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

Professionals only:

To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week). [Where relevant, specify if more frequent or daily inspection is required].

The product information (i.e. label and/or leaflet) shall clearly show that:
-the product shall not be supplied to the general public (e.g. "for professionals only");
-the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only");

-users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations").

Do not wash the bait stations with water between applications.

Trained professionals only:

The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only").

Do not use in areas where resistance to the active substance can be suspected.

Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.

Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.

Antidote: Vitamin K1 administered by medical/veterinary personnel only.

In case of:
- Dermal exposure, wash skin with water and then with water and soap.
- Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eye lids open at least 10 minutes.
- Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label [insert country specific information. Contact a veterinary surgeon in case of ingestion by a pet [insert country specific information].

Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre [insert national phone number]".

Hazardous to wildlife.

2.1.5.4 Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose uneaten bait and the packaging in accordance with local requirements [The method of disposal shall be described specifically in the national

SPC and be reflected on the product label].

Use of gloves is recommended.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.
Store in places prevented from the access of children, birds, pets and farm animals.

Shelf life: 2 years.

2.1.6 Other information

Because of their delayed mode of action, anticoagulant rodenticides take from 4 to 10 days to be effective after consumption of the bait. Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them. This product contains a bittering agent and a dye.

2.1.7 Packaging of the biocidal product

Block weights are 25 g and 5 g. The 25 g block is ca. 4.0 x 4.5 x 2.0 cm (w x l x h) and the 5 g block is ca. 2.5 x 3.0 x 15 cm (w x l x h). Loose blocks (no foil) are packaged in the primary packages as given in the packaging specification below.

Type of packaging)*	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Professional and trained professional					
PP or HDPE or PET or PE buckets with lids and re-closable pots	3 to 10 kg	PP or HDPE or PET or PE	lid: PP or PE or HDPE or PET	Professional or Trained professional	Yes
PP or PE or PET or HDPE lined re-closable container such as a pot, tin or cardboard carton	3 to 10 kg	PP or HDPE or PET or PE or tin or cardboard	lid: PP or PE or PET or HDPE or tin, or reclosable cardboard carton	Professional or Trained professional	Yes
General public (non-professional)					
Pre-filled PP bait boxes)* overpacked in PET/PE re-closable container or re-closable cardboard carton	25 g to 300 g	PP, PET/PE or LDPE lined cardboard	reclosable: PP, PET/PE or LDPE lined cardboard	General public	Yes
PP or HDPE or PET or PE buckets with lids and re-closable pots	25 g to 300 g	PP or HDPE or PET or PE	lid: PP or PE or HDPE or PET	General public	Yes
PP or PE or	25 g to	PP	lid: PP or	General public	Yes

PET or HDPE lined re-closable container such as a pot, tin or cardboard carton	300 g	or PE or PET or HDPE or tin or LDPE lined cardboard	PE or PET or HDPE or tin, or reclosable cardboard carton		

)* tamper resistant

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

New studies concerning the product Storm Ultra (BAS 322 20 I) have been submitted with respect to physical-chemical properties of the product, storage stability, analytical method validation for the a.s. in the product and efficacy of the product. The studies are listed in a reference list in ANNEX [3.1].

2.1.8.2 Access to documentation

The applicant BASF Nederland B.V. has full access to the active substance dossier for flocoumafen and the product dossiers of STORM Secure, STORM Pellets and STORM Paste (all containing 0.005% Flocoumafen) owned by BASF Agro B.V. The letter of access is attached to the dossier.

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Table 2. Intended use # 1 – in and around buildings

Product Type(s)	14
Where relevant, an exact description of the authorised use	Not applicable for rodenticides.
Target organism (including development stage)	*Rattus norvegicus* (Norway rat / brown rat), *Rattus rattus* (roof rat/black rat), *Mus musculus* (house mouse)
Field of use	In and around buildings
Application method(s)	Bait application: Application in bait boxes or in covered and protected bait points or in burrows.
Application rate(s) and frequency	Control of rats: Use 50 - 75 grams of bait per bait station. Place the bait

	stations at 5 to 10 metre intervals, depending on the size of the infestation. Control of mice: Use 15 - 25 grams of bait per bait station. Place the bait stations at 1 to 2 metre intervals, depending on the size of the infestation. Examine the bait points after 7 days and replace ~~those~~ eaten bait. Repeat at 7-day intervals, replacing blocks which have been eaten. If the infestation is heavy examine the bait points after 3 days and replace eaten bait. Replace any mouldy or contaminated bait. If all bait is eaten, increase number of bait points and / or visit frequency. Replace bait until consumption stops. Storm Ultra will control rats and mice resistant to other (first generation) anticoagulant rodenticides. For non-professional: If rodent control is not achieved after 35 days, consult a professional pest control operator. If control is not achieved, survey site again to establish reasons and consider re-siting or increasing bait points.
Category(ies) of user(s)	Professional users and general public (non-professional users)
Pack sizes and packaging material	Up to 10kg in PP or HDPE or PET or PE buckets with lids or PE and re-closable pots; Up to 10kg in PP or PE or PET/PE lined re-closable container such as a pot, tin or cardboard carton; Pre-filled PP bait boxes overpacked in 25 g to 10kg in PP, PET/PE re-closable container or re-closable cardboard carton. 25 g or HDPE or PET or PE 25 g

Instructions for use[2]

Rats: Place up to 75g at each bait point. Suitable baiting points will be in rat holes, at entry points, on indoor runs and near known nesting sites. Try to establish a barrier of bait blocks between living and feeding areas. Bait points should be up to 5 metres apart in heavy infestations and up to 10 metres apart in light infestations. Examine the bait points after 3 days and replace those eaten. Repeat four days later, then again at 7-day intervals, replacing blocks which have been eaten. Normally only 3-4 pulses (baiting rounds) are required. Secure the bait blocks with wire

into bait boxes and bait tubes, or with wire and or nails to the building structure. Any block fragments found away from a bait point should be picked up and disposed of.

Mice: Mice are more difficult to control and site exploration is particularly important. They have a limited range and do not need to drink. Place up to 25g at many points indoors up to 2 metres apart where activity has been found. Suitable points will be in holes, on runs, behind and under fittings and where droppings are present. Secure the bait blocks in bait boxes or bait tubes with wire or with wire and or nails to the building structure. Inspect and replace baits as for rats.

Risk mitigation measures

Keep locked up and out of the reach of children. Keep away from food, drink and animal feeding stuffs. When using do not eat, drink or smoke. If swallowed, seek medical advice immediately and show this container or label. Wash hands and exposed skin before meals and after use. For use only in areas that are inaccessible to infants, children, companion animals and non-target animals. Gloves are recommended to help to protect against rodent-borne diseases. When tamper-resistant bait stations are used, they should be clearly marked to show that they contain rodenticides and that they should not be disturbed.
The prevention of access by non-target animals is a priority. Baits must be securely deposited in a way so as to minimise the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away. The product must never be placed indiscriminately. Search for and remove moribund and dead rodents at frequent intervals during treatment, at least as often as when baits are checked and/or replenished. Daily inspection may be required in some circumstances. The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active substances is suspected, avoid their use. Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits. In most cases, anticoagulant bait should have achieved control within 35 days.

The product contains denatonium benzoate to help prevent accidental human consumption.

Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

This product contains an anticoagulant substance. If ingested, symptoms will be delayed up to 48 hours and may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.

If swallowed, seek medical advice immediately and show this container or label. Contact veterinary surgeon in case of pet ingestion.

Antidote: Vitamin K_1 administered by medical/veterinary personnel only.

[A sentence about who to contact is necessary but no harmonisation is possible due to national discrepancies.]

Instructions for safe disposal of the product and its packaging

Remove all baits after treatment and dispose of them in accordance with local requirements. Dispose of dead rodents in accordance with local requirements. Do not reuse the container for any other purpose.

Conditions of storage and shelf-life of the product under normal conditions of storage

Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight. Store in places prevented from the access of children, birds, pets and farm animals. Shelf life: 2 years.

Other information

None.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	GLP: Yes visual examination	BAS 322 20 I (0.0025% Flocoumafen w/w)	Solid free flowing blocks free from foreign matter. eCA comment: Acceptable.	Weatherhead, P. (2015) 2015/1178125
Colour at 20 °C and 101.3 kPa		BAS 322 20 I (0.0025% Flocoumafen w/w)	Blue eCA comment: Acceptable.	
Odour at 20 °C and 101.3 kPa	GLP: Yes organoleptic examination	BAS 322 20 I (0.0025% Flocoumafen w/w)	Cereal odour eCA comment: Acceptable.	
Acidity / alkalinity	GLP: Yes CIPAC MT 75.3	BAS 322 20 I (0.0025% Flocoumafen w/w)	pH 7.1 (1.0% dispersion in deionised water, T= 22.5°C) eCA comment: Acceptable. Acidity/alkalinity does not need to be determined.	
Relative density / bulk density	GLP: Yes CIPAC MT 186	BAS 322 20 I (0.0025% Flocoumafen w/w)	Bulk density: 0.49 g/mL Tap density: 0.52 g/mL eCA comment: Acceptable.	
Storage stability test – accelerated storage	GLP: Yes Reg (EU) No 1107/2009 and Reg (EU) No 284/2013 and Manual on Development and Use of FAO and WHO Specifications for Pesticides, Nov 2010	BAS 322 20 I (0.0025% Flocoumafen w/w)	Relevant physical and chemical properties of BAS 322 20 I were assessed initially and after storage for 2 weeks at 54°C in PP. For results please refer to Table 3 (p 38). eCA comment: Acceptable.	
Storage stability test – long term storage at	Manual on Development	BAS 322 20 I (0.0025%	Ongoing study. Three study	Weatherhead, P. (2015): Study

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
ambient temperature Reg (EU) 1107/2009 and Reg (EU) 284/2013.	and Use of FAO and WHO Specifications for Pesticides, Nov. 2010	Flocoumafen w/w)	protocols were provided for shelf-life studies in PP packaging with storage at 25°C for a duration of 104, 156 and 260 weeks respectively. eCA comment: Acceptable. Based on the data provided, a 2 year shelf-life is granted. However, generation of 3 and 5 year data is still ongoing. It is noted no palatability data was made available with aged bait. Considering the product contains a preservative, it is allowed to claim a 2 year shelf-life without the need for further testing. However, if the applicant wishes to extend the shelf-life to beyond years, palatability data will need to be provided with aged bait. See table 3 (p 38) for results after 2 years storage.	Plan Results should be available in August 2017. Weatherhead, P. (2015): Study Plan Results should be available in August 2018. Weatherhead, P. (2015): Study Plan Results should be available in August 2020.
Storage stability test – low temperature stability test for liquids	-	-	Not required, since the b.p. is a solid and no liquid formulation.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			eCA comment: Acceptable.	
Effects on content of the active substance and technical characteristics of the biocidal product - light	-	-	Not required since the product will be stored protected from light. eCA comment: Acceptable. The packages described as 'semi-opaque' in the storage stability studies, have an opaqueness of 19.6 (10kg packages), 16.6 (5 kg packages), 13.1 (3 kg packages) or 33.5 (300 g packages). The two smallest packages are further packed in cardboard during transport. Hence, exposure to light is limited and the sentence 'Protect from direct sunlight' is sufficient.	-
Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity	GLP: Yes AFL0199/04 MX/15/010/1	BAS 322 20 I (0.0025% Flocoumafen w/w)	The active substance content and relevant physical chemical properties of the product did not significantly change after storage at 54°C for 2 weeks. Effect of humidity: not required for storage as the product will be stored in a closed container.	Weatherhead, P. (2015) 2015/1178125

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			eCA comment: Acceptable.	
Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	GLP: Yes AGF 0065	BAS 322 20 I (0.0025% Flocoumafen w/w)	The pack appearance did not change on storage. It can be concluded that all proposed packs are suitable. Details see below this table)* eCA comment: Acceptable.	Weatherhead, P. (2015) 2015/1178125
Wettability	-	-	Not applicable since the product is a solid ready-for-use product. eCA comment: Acceptable.	-
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable since the product is a solid ready-for-use product. eCA comment: Acceptable.	-
Wet sieve analysis and dry sieve test	-	-	Not applicable since the product is a solid ready-for-use product. eCA comment: Acceptable.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable since the product is a solid ready-for-use product. eCA comment: Acceptable.	-
Disintegration time	-	-	Not applicable since the product is not designed to disintegrate. eCA comment: Acceptable.	-
Particle size distribution, content of dust/fines, attrition,	GLP: Yes CIPAC MT 178	BAS 322 20 I (0.0025% Flocoumafen w/w)	Attrition resistance: 100%	Weatherhead, P. (2015) 2015/1178125

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
friability			eCA comment: Acceptable.	
Persistent foaming	-	-	Not applicable since the product is a solid ready-to-use block bait. eCA comment: Acceptable.	-
Flowability/Pourability/ Dustability	-	-	Not applicable since the product is a solid ready-to-use block bait. eCA comment: Acceptable.	-
Burning rate — smoke generators	-	-	Not applicable since the product is a solid ready-to-use block bait. eCA comment: Acceptable.	-
Burning completeness — smoke generators	-	-	Not applicable since the product is a solid ready-to-use block bait. eCA comment: Acceptable.	-
Composition of smoke — smoke generators	-	-	Not applicable since the product is a solid ready-to-use block bait. eCA comment: Acceptable.	-
Spraying pattern — aerosols	-	-	Not applicable since the product is a solid ready-to-use block bait. eCA comment: Acceptable.	-
Physical compatibility	-	-	Not applicable since use with other products is not intended. eCA comment: Acceptable.	-
Chemical compatibility	-	-	Not applicable since use with	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			other products is not intended. eCA comment: Acceptable.	
Degree of dissolution and dilution stability	-	-	Not applicable since the product is a solid ready-for-use product not intended to be dissolved in water. eCA comment: Acceptable.	-
Surface tension	-	-	Not applicable since the product is a solid ready-for-use product not intended to be dissolved in water. eCA comment: Acceptable.	-
Viscosity	-	-	Not applicable since the product is a solid ready-for-use product not intended to be dissolved in water. eCA comment: Acceptable.	-

*Justification for appropriateness of packaging applied for: According to the data requirements (ECHA Guidance on BPR, Vol I, Part A) **for solid preparations all types of packaging are acceptable except for "*more flexible packs*"** which would require further testing on stacking. Firstly, all packaging listed are rigid containers and flexible packaging such as sacks, bags or sachets are not included. Therefore, a similar level of protection from physical stress is provided to Storm Ultra blocks for all packaging listed, and the data can thus be extrapolated from the packaging used in storage stability analysis.

Secondly, regarding stacking tests, it should further be noted that, when the necessary outer cartons are used e.g. during the transport of Storm Ultra, these comply with the appropriate international testing guidelines. i.e. ADR 6.1.5.6 (stacking test, European agreement concerning the international carriage of dangerous goods by road -ADR).

Thus, in conclusion the provided storage test for Storm Ultra in PP packaging is considered to cover the whole range of packages applied for herewith.

Table 3. Results accelerated storage and shelf-life study

-Weatherhead, 2015, 2015/1178125 (accelerated study, first interim report)
-Weatherhead, 2017, 2017/1136269 (second interim report including 2 year storage data)

Property	**Initial**	**2 wks 54°C PP bucket**	**104 wks 25°C PP bucket**	**156 wks 25°C**	**260 wks 25°C**
Flocoumafen content (%w/w)	0.0030	0.0028 (-6.7%)	0.0029 (-3.3%)	*Expected: August 2018*	*Expected: August 2020*
Appearance	Blue solid blocks, free from foreign matter, free flowing	Blue solid blocks free from foreign matter, slight caking)*	Blue solid blocks free from foreign matter, free flowing		
Odour	cereal	cereal	cereal		
pH of dispersion (1%)	7.1	6.7	6.1		
Weight loss	-	0.2%	0.7%		
Pack appearance	White semi-opaque 5 Kg PP bucket with red push fit lid. No deformation, corrosion/crazing/cracking or signs of external contamination or leakage.	pack as initial	pack as initial		

* A slight caking was observed after storage at 54°C which was ascribed to the high temperature of the accelerated test. This caking is not observed during storage over 2 years at 25°C .

Conclusion on the physical, chemical and technical properties of the product

Storm Ultra is a ready-to-use rodenticidal product in form of a solid bait block. Physico-chemical and technical properties have been evaluated and are deemed acceptable. The product was stable for 2 weeks at 54°C and 104 weeks at 25°C in PP container, indicating a shelf-life of at least 2 years. The data in PP is considered sufficient to represent all packaging types applied for.

No palatability data was made available with aged bait. Considering the product contains a preservative, it is allowed to claim a 2 year shelf-life without the need for further testing, according to the guidance on efficacy for PT14 products. However, if the applicant wishes

to extend the shelf-life to beyond 2 years, palatability data will need to be provided with aged bait.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	GLP: Yes UN class 1	BAS 322 20 I 0.0025% (w/w) Flocoumafen	Screening test: exothermic decomposition <500 J/g conclusion: Not explosive eCA remark: Acceptable	Dreisch, S. (2015) 2015/1179303
Flammable gases	-	-	Not applicable, the product is a solid. eCA remark: Acceptable	-
Flammable aerosols	-	-	Not applicable, the product is a solid. eCA remark: Acceptable	-
Oxidising gases	-	-	Not applicable, the product is a solid. eCA remark: Acceptable	-
Gases under pressure	-	-	Not applicable, the product is a solid. eCA remark: Acceptable	-
Flammable liquids	-	-	Not applicable, the product is a solid. eCA remark: Acceptable	-
Flammable solids	GLP: Yes UN N.1	BAS 322 20 I 0.0025% (w/w) Flocoumafen	Not flammable eCA remark: Acceptable	Dreisch, S. (2015) 2015/1179303
Self-reactive substances and mixtures	-	-	Not considered to be a self-reactive substance or mixture due to the physico-chemical	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			properties of the test item (not explosive, not oxidising, not organic peroxide) eCA remark: Acceptable	
Pyrophoric liquids	-	-	Not applicable, the product is a solid. eCA remark: Acceptable	-
Pyrophoric solids	-	-	Not applicable. The test item BAS 322 20 I is stable at room temperature under air for prolonged periods, therefore a test on pyrophoric properties is not required. eCA remark: Acceptable	-
Self-heating substances and mixtures	GLP: Yes UN N.4	BAS 322 20 I 0.0025% (w/w)	Not self-heating. eCA remark: Acceptable	Dreisch, S. (2015) 2015/1179303
Substances and mixtures which in contact with water emit flammable gases	-	-	Not required since The product BAS 322 20 I is stable in water. eCA remark: Acceptable	-
Oxidising liquids	-	-	Not applicable, the product is a solid. eCA remark: Acceptable	-
Oxidising solids	GLP: Yes UN O.1	BAS 322 20 I 0.0025% (w/w)	Not oxidising. eCA remark: Acceptable	Dreisch, S. (2015) 2015/1179303
Organic peroxides	-	-	Not applicable (none of the ingredients contain a bivalent –O-O- structure). eCA remark:	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Acceptable	
Corrosive to metals	-	-	Not applicable. BAS322 20 I represents a mixture of mainly neutral food- and feedstuffs with a low content of active substance and minor content of further formulants. None of the ingredients has the intrinsic property to materially damage metals. eCA remark: Acceptable	-
Auto-ignition temperatures of products (liquids and gases)	-	-	Not applicable, the product is a solid. eCA remark: Acceptable	-
Relative self-ignition temperature for solids	GLP: Yes UN N.4	BAS 322 20 I 0.0025% (w/w)	Not self-heating eCA remark: Acceptable	Dreisch, S. (2015) 2015/1179303
Dust explosion hazard	-	-	Not applicable, the product is a solid block, not a powder. eCA remark: Acceptable	-

Conclusion on the physical hazards and respective characteristics of the product
The ready-for-use bait BAS 322 20 I is not explosive, not oxidising, is not highly flammable and does not self-ignite. Based on the data provided, no classification or labelling is required based on physical and chemical properties of the product according to CLP criteria.

2.2.4 Methods for detection and identification

Product related data

For the biocidal product, an analytic method for detection and identification of the active substance is already available. The method has been additionally validated for the relevant concentration of Storm Ultra blocks and was proven to be appropriate for the determination of flocoumafen in the BAS 322 20 I.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD (precision)		
Flocoumafen	HPLC-UV 308 nm LC-MS/MS confirmation (RLA 12671.02 V)	50% level (n = 6) 100% level (n = 5) 150% level (n = 5)	Range: 50 – 150% of the working standard concentration, measured at 5 concentrations, in duplo y = 74.438 x – 2.0083 r > 0.999 (1.000))**	Yes (no interferences >3%))*	80-116	93	± 2.16 (n=6)	not required for a.s.	Weatherhead, P. (2011) 2011/1177797 Weatherhead, P. (2011) 2011/1177798 Weatherhead, P.(2015) 2015/1132576

) The available method for flocoumafen determination in baits was already evaluated and accepted by authorities. Flocoumafen concentrations in baits of 0.0025% to 0.0075% (w/w) are covered.*
*)** As the new formulation (BAS 322 20 I) has only half of the nominal content of Flocoumafen in comparison with BAS 322 07 I the weigh-in in the sample preparation was doubled. With this approach the validation requirements regarding linearity are fulfilled for BAS 322 20 I (Linearity 50 to 150 %, Accuracy 50 to 150 %) according to SANCO/3030/99.*

In the additional study, it was proven that specificity of the method is also fulfilled in the new bait matrix (<3% interference). The analysis of the a.s. content of BAS 322 20 I showed that the method is capable to determine the actual a.s. content of the sample (0.0028% w/w). Furthermore, this analytical method using acid digestion represents a very harsh method which is considered to work for a wide range of bait matrices.

Further substances in toxicologically or ecotoxicologically relevant amounts (substances of concern) are not contained in the product.

Active substance related data
Analytical methods for the active substance and impurities in the technical active substance as manufactured are available in the active substance dossier and were evaluated during the EU approval of Flocoumafen.

The analytical methods for the determination of residues of the active substance flocoumafen in soil, air, water and human and animal body fluids and tissues, in food and feeding stuff are also considered to be completely covered by the active substance dossier.

Conclusion on the methods for detection and identification of the product
The analytical method for flocoumafen in the bait product was successfully validated regarding linearity, precision, specificity and accuracy. The determination of the a.s. content and specificity of the test method was verified for the new bait in an additional validation study.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Storm Ultra is a rodenticide (PT14) containing 0.0025% (w/w) flocoumafen. The product is a ready-for-use bait block, which is intended for trained professional use, professional use and for the general public (non-professional use).

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

Storm Ultra is used to control:
- *Rattus norvegicus* (Norway rat / brown rat)
- *Rattus rattus* (roof rat / black rat)
- *Mus musculus* (house mouse).

Trained professional, professional and non-professional use: the control of rats and mice in and around buildings

The purpose of Storm Ultra includes:
- Prevention of infestations of rodents known to transmit disease
- Prevention of degradation or contamination of food and feeding stuffs
- Protection of buildings and structures including pipes, cables and overall integrity
- Prevention of social abhorrence

2.2.5.3 Effects on target organisms, including unacceptable suffering

Flocoumafen is a second generation anticoagulant. Ingestion of a lethal dose leads to death of the target rodents due to internal haemorrhaging usually within 3-8 days.

Efficacy studies with BAS 322 20 I at 2 bait sizes were conducted:
- a small compacted block with a nominal weight of 5 g
- a compacted block with a nominal weight of 25 g

The composition of both products is identical and only the physical form differs (shape and weight).

The results are described under point 2.2.5.5 below.

2.2.5.4 Mode of action, including time delay

Flocoumafen, as other coumarin derivatives, acts as a vitamin K antagonist. Vitamin K in its reduced form (KH2) is essential in the synthesis of intrinsic blood coagulation factors.

This synthesis takes place in the vertebrate liver. KH2 is recycled in a two-step process by reductases. Flocoumafen blocks these reductases, resulting in the depletion of Vitamin K stores. Consequently, the synthesis of intrinsic blood coagulation factors is disrupted, which leads to loss of blood clotting ability and subsequently to lethal haemorrhages. For flocoumafen containing products to be efficacious a single uptake is normally sufficient, i. e. single-feed potency. The death is delayed and occurs within 3-8 days.

2.2.5.5 Efficacy data

In total 28 efficacy trials were conducted with Storm Ultra (BAS 322 20 I, flocoumafen 0.0025% w/w: development code: BAS 322 HF I; also described as [redacted] block) and are summarised hereafter. Efficacy was shown against all target organisms and in the areas of use applied for.

Efficacy against *Rattus norvegicus* (Norway rat / brown rat)

19 efficacy studies are provided for Storm Ultra against *R. norvegicus* (7 no-choice, 8 choice tests and 4 field tests) which are summarised below. The test substance was BAS 322 20 I (development code: BAS 322 HF I, 0.0025% Flocoumafen). Laboratory studies were conducted with laboratory strains and wild strains. Of the lab trials, 11 trials were conducted with anticoagulant resistant (First Generation anticoagulants, difenacoum, or bromadiolone) or tolerant strains (Welsh L128Q), Berkshire (L120Q) and Hampshire (L120Q) strains).

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance / Test organisms	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
No-choice tests				
25g [redacted] block bait (BAS 322 HF I))* 25 ppm Flocoumafen *Rattus norvegicus*, Wistar strain	No-choice feeding of bait for 3 days individually caged 10 males 10 females	Cage (PP): 38.0 x 25.0 x 20.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation: 3 days, including 24h pre-test diet take assessment; test period: 3 days no-choice feeding observation period: up to 14 days.	100% mortality mean time to death, males: 5.2 (bait ingestion: mean total 64.9 g) mean time to death, females: 5.8 (bait ingestion: mean total 60.3 g)	[redacted] (2014) 2014/1273314
25g [redacted] block bait (BAS 322 HF I); 25 ppm	No-choice feeding of bait for 3 days individually	Cage (PP): 38.0 x 25.0 x 20.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%,	100% mortality mean time to death, males: 4.2 (bait ingestion:	[redacted] (2014) 2014/1273316

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance / Test organisms	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Flocoumafen *Rattus norvegicus,* Hampshire strain (difenacoum and bromadiolone tolerant)	caged 10 males 10 females	Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; test period. 3 days observation period: up to 14 days	mean total of 70.0g) mean time to death, females: 5.0 (bait ingestion: mean total of 53.9g)	
25g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Rattus norvegicus*, Welsh strain (first generation anticoagulant resistant)	No-choice feeding of bait for 3 days individually caged 10 males 10 females	Cage (PP): 38.0 x 25.0 x 20.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; test period. 3 days observation period: up to 14 days	100% mortality mean time to death, males: 3.2 (bait ingestion: mean total of 72.4g) mean time to death, females: 4.3 (bait ingestion: mean total of 54.1g)	[redacted] (2014) 2014/1273317
25g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Rattus norvegicus*, Berkshire strain (difenacoum and bromadiolone resistant)	No-choice feeding of bait for 3 days individually caged 10 males 10 females	Cage (PP): 38.0 x 25.0 x 20.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; test period. 3 days observation period: up to 14 days	100% mortality mean time to death, males: 4.4 (bait ingestion: mean total of 61.9g) mean time to death, females: 4.3 (bait ingestion: mean total of 47.5g)	[redacted] (2014) 2014/1273318
4g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Rattus norvegicus*, Wistar strain	No-choice feeding of bait for 3 days individually caged 10 males 10 females	Cage (PP): 38.0 x 25.0 x 20.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; Test period. 3 days observation period: up to 14 days	100% mortality mean time to death, males: 5.0 (bait ingestion: mean total of 71.0g) mean time to death, females: 4.8 (bait ingestion: mean total of 64.4g)	[redacted] (2014) 2014/1321393
4g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen	No-choice feeding of bait for 3 days individually caged	Cage (PP): 38.0 x 25.0 x 20.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light,	100% mortality mean time to death, males: 3.8 (bait ingestion: mean total of	[redacted] (2014) 2014/1321413

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance / Test organisms	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Rattus norvegicus, Hampshire strain (difenacoum and bromadiolone tolerant)	10 males 10 females	12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; Test period. 3 days observation period: up to 14 days	72.0g) mean time to death, females: 4.8 (bait ingestion: mean total of 57.6g)	
4g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Rattus norvegicus*, Berkshire strain (difenacoum and bromadiolone resistant)	No-choice feeding of bait for 3 days individually caged 10 males 10 females	Cage (PP): 38.0 x 25.0 x 20.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; Test period. 3 days observation period: up to 14 days	100% mortality mean time to death, males: 4.5 (bait ingestion: mean total of 71.3g) mean time to death, females: 4.2 (bait ingestion: mean total of 56.8g)	[redacted] (2014) 2014/1321414
Choice tests				
25g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Rattus norvegicus*; Wistar strain	Choice feeding of bait for 4 day Individually caged 10 males 10 females	Cage (PP): 38.0 x 25.0 x 20.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; Test period. 4 days observation period: 10 days	100% mortality mean time to death, males: 6.0 (palatability ratios of 3.11 and acceptance 75.6%) mean time to death, females: 6.1 (palatability ratios of 11.60 and acceptance 92.1%)	[redacted] (2014) 2014/1273288
25g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Rattus norvegicus*, Welsh strain (first generation anticoagulant resistant)	Choice feeding of bait for 4 day Individually caged 10 males 10 females	Cage (PP): 38.0 x 25.0 x 20.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; Test period. 4 days observation period: 10 days	100% mortality mean time to death, males: 3.9 (palatability ratios of 2.16 and acceptance 68.4%) mean time to death, females: 4.1 (palatability ratios of 3.77 and acceptance 79.0%)	[redacted] (2014) 2014/1273303
25g [redacted] block bait (BAS 322 HF I);	Choice feeding of bait for 4 day	Cage (PP): 38.0 x 25.0 x 20.0 cm (l x w x h); Temperature: 21 ± 2°C,	100% mortality mean time to death, males: 3.7	[redacted] (2014) 2014/1273304

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance / Test organisms	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
25 ppm Flocoumafen *Rattus norvegicus*, Hampshire strain (difenacoum and bromadiolone tolerant)	Individually caged 10 males 10 females	Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; Test period. 4 days observation period: 10 days	(palatability ratios of 2.41 and acceptance 70.6%) mean time to death, females: 5.0 (palatability ratios of 7.82 and acceptance 88.7%)	
25g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Rattus norvegicus*, Berkshire strain (difenacoum and bromadiolone resistant)	Choice feeding of bait for 4 day Individually caged 10 males 10 females	Cage (PP): 38.0 x 25.0 x 20.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; Test period. 4 days observation period: 10 days	100% mortality mean time to death, males: 4.8 (palatability ratios of 2.00 and acceptance 66.7%) mean time to death, females: 5.2 (palatability ratios of 3.38 and acceptance 77.2%)	[redacted] (2014) 2014/1273305
4g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Rattus norvegicus*, Wistar strain	Choice feeding of bait for 4 day Individually caged 10 males 10 females	Cage (PP): 38.0 x 25.0 x 20.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; Test period. 4 days observation period: 10 days	100% mortality mean time to death, males: 4.9 (palatability ratios of 3.35 and acceptance 77.0%) mean time to death, females: 5.8 (palatability ratios of 17.78 and acceptance 94.7%)	[redacted] (2014) 2014/1321332
4g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Rattus norvegicus*, Welsh strain (first generation anticoagulant resistant)	Choice feeding of bait for 4 day Individually caged 10 males 10 females	Cage (PP): 38.0 x 25.0 x 20.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; Test period. 4 days observation period: 10 days	100% mortality mean time to death, males: 3.9 (palatability ratios of 2.18 and acceptance 68.5%) mean time to death, females: 3.9 (palatability ratios of 8.33 and acceptance 89.3%)	[redacted] (2014) 2014/1321337

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance / Test organisms	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
4g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Rattus norvegicus*, Hampshire strain (difenacoum and bromadiolone tolerant)	Choice feeding of bait for 4 day Individually caged 10 males 10 females	Cage (PP): 38.0 x 25.0 x 20.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; Test period. 4 days observation period: 10 days	100% mortality mean time to death, males: 3.2 (palatability ratios of 4.03 and acceptance 80.1%) mean time to death, females: 4.5 (palatability ratios of 8.08 and acceptance 89.0%)	[redacted] (2014) 2014/1321372
4g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Rattus norvegicus*, Berkshire strain (difenacoum and bromadiolone resistant)	Choice feeding of bait for 4 day Individually caged 10 males 10 females	Cage (PP): 38.0 x 25.0 x 20.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; Test period. 4 days observation period: 10 days	100% mortality mean time to death, males: 4.6 (palatability ratios of 2.40 and acceptance 70.6%) mean time to death, females: 4.4 (palatability ratios of 4.24 and acceptance 80.9%)	[redacted] (2014) 2014/1321392
Field tests				
25g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Rattus norvegicus*	Field study, pulse baiting technique	Location: Carrigeen House Fram, County Waterford, Ireland 56 bait trays placed ca 5-10m apart 3 blocks (75g) per tray Bait was replenished on days 4, 8 and 15.	Pre and post-census diet and tracking data indicate 97-98% control.	Hughes, C. S. (2014) 2014/1321674
25g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Rattus norvegicus*	Field study, pulse baiting technique	Location: Ballyboy Farm, County Tipperary, Ireland 56 bait trays placed ca 5-10m apart 3 blocks (75g) per tray Bait was replenished on days 4, 8 and 15.	Pre and post-census diet and tracking data indicate 95-96% control.	Hughes, C. S. (2014) 2014/1321675
4g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen	Field study, pulse baiting technique	Location: Coppers Bar, County Tipperary, Ireland 30 bait trays placed ca 5-10m apart 18-19 blocks (75g) per	Pre and post-census diet and tracking data indicate 100% control.	Hughes, C. S. (2014) 2014/1321673

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance / Test organisms	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Rattus norvegicus		tray Bait was replenished on days 4 and 8.		
Storm® Ultra Secure Rodent Bait (BAS 322 20 I); 25 ppm Flocoumafen *Rattus norvegicus*	Field study, pulse baiting technique	Location: Old Crickett Farm, Shropshire, England 36 bait trays placed ca 5-10m apart 2 blocks (50g) per tray Bait was replenished on days 4, 8 and 15	Pre and post-census diet and tracking data indicate 97% control.	Hughes, C. S. (2018) LR003/18

)* BAS 322 HF I is the development code and is identical to BAS 322 20 I

Efficacy against *Rattus rattus* (roof rat/ black rat)

Two efficacy studies were provided for Storm Ultra against *R. rattus.* Semi-field trials (pen trials) were conducted which are considered as a surrogate for field trials.

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance / Test organisms	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Semi-field tests (Pen trial)				
25g [redacted] block bait (BAS 322 HF I))*; 25 ppm Flocoumafen *Rattus rattus*; wild derived	Semi-field test (pen trial); 4 bait points with 75 g of bait blocks. pulse baiting technique 34 rats (19 males and 15 females)	Pen: 2.5 x 1.1 x 2.1 m (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 1 month, pre-census period: 3 days, test period: 14 days, observation period: 10 days. The test period continued until, either 100% control or zero bait consumption.	100% mortality mean time to death: 6.3 days	[redacted] (2014) 2014/1273287
4g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Rattus rattus*: wild derived	Pen trial test; 4 bait points with 60 g of bait blocks. pulse baiting technique 43 rats (24 males and 19 females)	Pen: 2.5 x 1.1 x 2.1 m (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 1 month, pre-census period: 3 days, test period: 14 days, observation period: 10 days. The test period continued until, either 100% control or zero bait consumption.	100% mortality mean time to death: 7.9 days.	[redacted] (2014) 2014/1321672

)* BAS 322 HF I is the development code and is identical to BAS 322 20 I

Efficacy against *Mus musculus* (house mouse)

7 efficacy studies were provided with Storm Ultra against *M. musculus* (2 no-choice, 2 choice tests, 1 semi-field trial (pen trials) and 2 field trials) which are summarised below. The test substance was BAS 322 20 I (development code: BAS 322 HF I, 0.0025% Flocoumafen).

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance / Test organisms	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
No-choice tests				
25g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Mus musculus*	No-choice feeding of bait for 3 days individually caged 10 males 10 females	Cage (PP): 38.0 x 25.0 x 18.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; test period. 3 days observation period: up to 14 days	100% mortality mean time to death, males: 5.3 (bait ingestion: mean total of 17.8g) mean time to death, females: 4.6 (bait ingestion: mean total of 14.4g)	[redacted] (2014) 2014/1273315
4g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Mus musculus*	No-choice feeding of bait for 3 days individually caged 10 males 10 females	Cage (PP): 38.0 x 25.0 x 18.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; test period. 3 days observation period: up to 14 days	100% mortality mean time to death, males: 4.7 (bait ingestion: mean total of 21.8g) mean time to death, females: 5.1 (bait ingestion: mean total of 16.1g)	[redacted] (2014) 2014/1321412
Choice tests				
25g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Mus musculus*	Choice feeding of bait for 4 day Individually caged 10 males 10 females	Cage (PP): 38.0 x 20.0 x 18.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; test period. 3 days observation period: 10 days	100% mortality (male) mean time to death, males: 5.3 (palatability ratios of 1.71 and acceptance 77.9%) 90% mortality (female) mean time to death, females: 4.8 (palatability	[redacted] (2014) 2014/1273289

Experimental data on the efficacy of the biocidal product against target organism(s)				
			ratios of 1.52 and acceptance 73.9%)	
4g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Mus musculus*	Choice feeding of bait for 4 day Individually caged 10 males 10 females	Cage (PP): 38.0 x 20.0 x 18.0 cm (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 3 days, including 24-h pre-test diet take assessment; test period. 3 days observation period: 10 days	100% mortality (male) mean time to death, males: 5.3 (palatability ratios of 1.59 and acceptance 61.4%) 90% mortality (female) mean time to death, females: 7.0 (palatability ratios of 0.73 and acceptance 42.1%)	[redacted] (2014) 2014/1321335
Semi-field test (Pen trial)				
25g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Mus musculus* wild derived (Bromadiolone resistant strain)	Pen trial; 4 bait points with 25 g of bait blocks 43 mice (14 males and 29 females)	Pen: 3 x 2 x 0.75 m (l x w x h); Temperature: 21 ± 2°C, Rel. humidity: 55 ± 10%, Light cycles: 12h light, 12h dark acclimatisation period: 1 month, pre-census period: 3 days, test period: 14 days, observation period: 10 days. The test period continued until, either 100% control or zero bait consumption.	100% mortality mean time to death of 4.7 days.	[redacted] (2014) 2014/1273319
Field trials				
25g [redacted] block bait (BAS 322 HF I); 25 ppm Flocoumafen *Mus musculus*	Field study, pulse baiting technique	Location: New Crickett Farm, County Shropshire, England 37 bait boxes placed ca 1-2 m apart 1 block (25 g) per bait box Bait was replenished on days 4 and 8.	Pre and post-census diet and tracking data indicate 100% control.	Hughes, C. S. (2015) 2015/1195335
Storm Ultra® Block Bait (BB) (BAS 322 20 I); 25 ppm Flocoumafen	Field study, pulse baiting technique	Location: Angel, London, England 33 bait points 15g per bait point Bait was replenished on days 4, 8 and 15	Pre and post-census diet and tracking data indicate 100% control	Hughes, C. S. (2018) LR001/18

Experimental data on the efficacy of the biocidal product against target organism(s)				
Mus musculus				

)* BAS 322 HF I is the development code and is identical to BAS 322 20 I

Conclusion on the efficacy of the product

The studies demonstrate efficacy of Storm Ultra (BAS 322 20 I) against *Rattus norvegicus*:

- In 7 laboratory no-choice feeding tests, the pass criterion of ≥90% mortality within a relevant time frame (≤10days) was met with in all tests a mean time to death ≤ 6.1 days
- In 8 laboratory choice tests, the pass criterion of ≥0.25 for the palatability ratio (T/C) was met in all tests. Moreover in all 15 laboratory tests the mortality was 100%.
- In 4 field tests, 95-100% control was demonstrated based on pre- and post-census bait take, and tracking activity measurement. Depending on the trial, the bait points were applied with 50 or 75g baits and were stationed 5-10 meters apart.
- The effectiveness against certain resistant populations was proven by testing the *Rattus norvegicus* strains: Welsh (first generation anticoagulant resistant), Hampshire (difenacoum and bromadiolone tolerant) and Berkshire (difenacoum and bromadiolone resistant) in choice and no-choice feeding tests with an overall mortality of 100%.

The studies demonstrate efficacy of Storm Ultra (BAS 322 20 I) against *Rattus rattus*:

- Two efficacy studies are provided for Storm Ultra block. These are semi-field tests (pen trials) with colonies of wild derived *Rattus rattus*. According to TNsG semi-field trials can be used in addition or alternatively to field trials. Thus, the trials are acceptable to cover these data requirements. Especially for *R. rattus* locations for field trials may be difficult to find as in some regions infestation is low.
- In both efficacy studies a 100% mortality within 14 days was demonstrated with a mean time to death of 6.3 respectively 7.9 days.

The studies demonstrate efficacy of Storm Ultra (BAS 322 20 I) against *Mus musculus*:

- In 2 laboratory no-choice feeding tests, the pass criterion of ≥90% mortality within a relevant time frame (≤14 days) was met with in both tests a mean time to death ≤ 5.3 days.In both tests mortality was 100%.
- In 2 laboratory choice tests, the pass criterion of ≥0.25 for the palatability ratio (T/C) was met , resulting in a mortality of 90-100%.
- In a semi-field test (pen trial) with a wild-derived, bromadiolone resistant *Mus musculus* strain mortality was 100% within 11 days.
- In one field test, indoors, 100% control was achieved based on pre- and post-census bait take, and tracking activity measurement. The bait points were applied with 15g bait according to the label claim
- In one field test, in and around buildings, 100% control was achieved based on pre- and post-census bait take, and tracking activity measurement. The bait points were applied with 25 g bait (1 bait block) and were placed 1-2 m apart according to the label claim

Overall conclusion:

Storm Ultra (BAS 322 20 I) is very palatable to *Rattus norvegicus*, *Rattus rattus* and *Mus musculus* and causes mortality as required for satisfactory control of rodent infestations.

- Storm Ultra is effective in controlling *Rattus norvegicus* and *Rattus rattus* "In and around buildings" when used at a dosage of 50 to 75 grams of bait per bait station or covered and

protected bait points with bait points spaced 5-10 m, also using pulse baiting.

- Storm Ultra is effective in controlling *Mus musculus* "In and around buildings" when used at 15 - 25 grams of bait per bait station or covered and protected bait points with bait points spaced 1-2 m ,also using pulse baiting.

2.2.5.6 Occurrence of resistance and resistance management

To date, no case of resistance to flocoumafen is known. The long pharmacokinetic half-life of flocoumafen and its fluorinated side chain which prevents biotransformation may be seen as a reason why resistance to flocoumafen has not yet been reported. Rodenticide products containing flocoumafen like Storm Ultra are eligible for controlling rat and mouse infestations where resistance to first-generation anticoagulants as warfarin and also resistance to difenacoum and bromadiolone has evolved.

The risk of the development of resistance is not considered to be different for Storm Ultra with 0.0025% flocoumafen than the 0.005% product since the effectiveness of the product does not directly depend on the concentration in the bait but on the actually consumed amount of active substance.

As shown in the submitted efficacy trials (i) Storm Ultra (0.0025%) is highly palatable for target rodents and (ii) the active substance flocoumafen is very potent. In the Storm Ultra efficacy trials rats consumed a mean amount of 6.7 mg a.s./kg bw (males and females) which is significantly above the LD50(rat) of 0.13 – 0.5 mg/kg bw. The lethal dose is already reached with the consumed bait on the first day. In trials with mice, bait consumption of Storm Ultra was equivalent to 14.75 mg a.s./kg bw which is also significantly above the lethal dose for mice, LD50(mouse) of 0.79 – 2.9 mg/kg bw and also above the dose on the first day of approx. 4.9 mg/kg bw. Also in choice trials 100% mortality was reached with Storm Ultra.

Last but not least, Storm Ultra was completely effective against strains of rats resistant to difenacoum, bromadiolone, and warfarin. Complete control of resistant strains was achieved at the same ingested dose as in normal rat strains with 100% mortality in all tested strains. There were no cases of less susceptible animals surviving in any of the lab trials (no-choice and choice tests).

As explained above the high potency of flocoumafen is based on substance specific properties such as the long pharmacokinetic half-life and the inhibited biotransformation caused by the fluorinated side chain. Therefore, Storm Ultra is considered to present no risk of the development of resistance when used under practical conditions for the control of target rodents. There are no known cases of practical resistance to flocoumafen.

2.2.5.7 Known limitations

The bait should never be broadcast or placed indiscriminately and unprotected. Long-term-baiting should not be used.

2.2.5.8 Evaluation of the label claims

For the evaluation of the label claims see section 2.2.5.5.**Conclusion on the efficacy of the product**

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The product is not intended to be authorised for use with other biocidal products.

2.2.6 Risk assessment for human health

Introductory statement on human toxicity data:

Human toxicity data of a block bait formulation containing flocoumafen are available from the formulation BAS 322 05 I representing the products STORM BB (16 g block bait), STORM Secure (20 g block with hole in centre to allow fixing) and STORM 4G (4 g blocks) with regard to acute oral and dermal toxicity, skin and eye irritation and skin sensitisation. The studies have already been evaluated in the CAR of Flocoumafen (2009). Based on the results STORM Secure, STORM BB and STORM 4G do not need to be classified for acute oral and dermal toxicity, skin and eye irritation and sensitisation.

Study type	Reference	Result
Acute oral	[redacted] (2000): Oral LD50 study in albino rats with AC 183540 (Flocoumafen) 0.005% block bait (DF06826), DocID 2000/7000919	LD50 > 5,000 mg/kg
Acute dermal	[redacted] (2000): Dermal LD50 study in albino rats with AC 183540 (Flocoumafen) 0.005% block bait (DF 06826), DocID 2000/7000918	LD50 > 5,000 mg/kg
Acute inhalation	No test required since the following does NOT apply: -vapour pressure is $>1x10^{-2}$ Pa (20°C) -product is a powder with significant portion of particles <50 µm -applied in a manner that occur aerosols, particles of inhalable size (<50 µm)	no classification
Skin irritation	[redacted] (2000): Primary dermal irritation study in albino rabbits with AC 183540 (Flocoumafen) 0.005% block bait (DF 06826), DocID 2000/7000917	non-irritating
Eye irritation	[redacted] (2000): Primary eye irritation in albino rabbits with AC 183540 (Flocoumafen) 0.005% block bait (DF 06826), DocID 2000/7000916	non-irritating
Skin sensitisation	[redacted] (2000): Dermal sensitization study with AC 183540 (Flocoumafen) 0.005% block bait (DF06826) in Guinea pigs - Buehler method (nine inductions),	not sensitising

	DocID 2000/7000915	

The test product "**AC 183540 0.005% block bait (DF 06826)"** which was tested in the acute toxicity study package is identical to the formulation BAS 322 01 I.

BAS 322 01 I was the precursor formulation of the current block formulation BAS 322 05 I. The formulation BAS 322 01 I was considered similar to the current formulation BAS 322 05 I as only the very low amount of preservative was omitted. This was accepted and was considered by Ctgb as a minor change.

The existing toxicity data with BAS 322 05 I (0.005% flocoumafen) are considered appropriate for use in the hazard health assessment of the new block bait (BAS 322 20 I, 0.0025% flocoumafen) and the Bridging Principles for the classification of mixtures laid down in Regulation (EC) No 1271/2008 Part 1, 1.1.3 are fulfilled for the following reasons:

- The amount of flocoumafen as active substance and the solely relevant toxicological substance in the composition is reduced to 50% compared to the tested product, i.e. 0.0025% vs. 0.005% (w/w).
- The components in the reference formulation differ in an acceptable range compared to the new product according to their function.
- The bait base of both formulations are neutral food- and feedstuffs and thus are from a toxicological point of view insignificant.
- None of the co-formulants has a toxicological relevant potential or has any impact on the classification for human health hazard.

  For more details please refer to the confidential Annex.

Conclusion:

Comparison of the compositions of BAS 322 20 I and BAS 322 05 I shows that the products are substantially similar mixtures in view of their health hazard potential, thus BAS 322 20 I shall be considered as equivalent to BAS 322 05 I.

Using the bridging principles as an alternative approach for classification of oral and dermal toxicity, skin and eye irritation and skin sensitisation of BAS 322 20 I is considered to be acceptable and new studies are not considered to be justified for animal welfare according to the criteria laid down in the CLP Regulation (EC) 1272/2008.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Non-irritating
Justification for the value/conclusion	Based on read-across to the GLP-compliant study with the similar formulation BAS 322 05 I, which has already been evaluated in the CAR of flocoumafen, Storm Ultra (BAS 322 20 I) does not need to be classified for skin irritation.
Classification of the product according to CLP and DSD	No classification required.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Non-irritating
Justification for the value/conclusion	Based on read-across to the GLP-compliant study with the similar formulation BAS 322 05 I, which has already been evaluated in the CAR of flocoumafen, Storm Ultra (BAS 322 20 I) does not need to be classified for eye irritation.
Classification of the product according to CLP and DSD	No classification required.

Respiratory tract irritation

Submission of data is not considered to be required since there are currently no standard tests and no OECD guidelines available for respiratory irritation. In addition, respiratory irritation is unlikely for this product since it is not a skin sensitizer, there are no clinical signs to date and the vapour pressure of the active substance is low.

Data waiving	
Information requirement	Respiratory tract irritation
Justification	Data on respiratory irritation are not submitted, since there is no evidence of respiratory irritation potential of the biocidal product, the active substance or any other ingredient

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitising
Justification for the value/conclusion	Based on read-across to the GLP-compliant study with the similar formulation BAS 322 05 I, which has already been evaluated in the CAR of flocoumafen, Storm Ultra (BAS 322 20 I) does not need to be classified for skin sensitisation
Classification of the product according to CLP and DSD	No classification is required.

Respiratory sensitisation (ADS)

Data waiving	
Information requirement	Respiratory sensitisation
Justification	Data on information on respiratory sensitization is not considered to be required due to the fact that no sensitization or allergenicity is known or reported, no hypersensitivity or any evidence that the biocidal product can induce specific respiratory hypersensitivity is given.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD50 (male and female rats) >5000 mg/kg bw
Justification for the selected value	Based on read-across to the GLP-compliant study with the similar formulation BAS 322 05 I, which has already been evaluated in the CAR of flocoumafen, Storm Ultra (BAS 322 20 I) does not need to be classified for acute oral toxicity.
Classification of the product according to CLP and DSD	No classification required.

Acute toxicity by inhalation

Data waiving	
Information requirement	Acute inhalation toxicity
Justification	The biocidal product is a solid block, not volatile and not capable of producing inhalable dusts and/or vapours. Owing to the nature of the

	product, exposure of humans via air is not expected. Therefore, the generation of data on the inhalation toxicity is not considered to be required.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD50 (male and female rats) >5000 mg/kg bw
Justification for the selected value	Based on read-across to the GLP-compliant study with the similar formulation BAS 322 05 I, which has already been evaluated in the CAR of flocoumafen, Storm Ultra (BAS 322 20 I) does not need to be classified for acute dermal toxicity.
Classification of the product according to CLP and DSD	No classification is required.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Experimental data with the product itself is not available
Value(s)	4%
Justification for the selected value(s)	The default of 4% as set in the assessment reports of flocoumafen (2009 and 2016) will be used.

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

Apart from the active substance, the biocidal product does not contain further components that are defined as substances of concern according to classification Regulation (EC) No 1272/2008 (CLP). Synergistic effects between any of the components are not expected. Thus, no other study for the purpose of health hazard identification is considered to be required.

Endocrine disruption assessment

Active substance
The mode of action (MoA) of flocoumafen is explained in section 2.2.5.4 and the active substance acts as a vitamin K antagonist, resulting in the depletion of vitamin K storages which consequently leads to loss of blood clotting ability and subsequently to lethal haemorrhages.
In a 90-day oral toxicity study in rats, increased incidences of haemorrhage at histopathological examination were noted in several organs, including testes, prostate and

epididymides (flocoumafen CAR , 2009). In the available data on flocoumafen no information was available on sperm quality and/or oestrus cycle after exposure to flocoumafen. At the supportive data for reproduction toxicity, the applicant provided a reference from open literature (Sangha et al., 1992 *apud* CAR – Doc IIIA, Annex Point II A6.8.2). In this study, ovarian cyclicity was disturbed in all the treated rats and rate of ovary atresia was related to the dose with increased incidence of degenerated corpora lutea at higher doses; several of the biochemical parameters (total lipids, total cholesterol, phospholipids, free fatty acids, glycolipids and triglycerides) were out of control range. The treated rats used for mating showed a delayed onset of breeding and reduced litter size in their first reproductive event immediately after dosing. A the second reproductive event (45 days after first parturition), all these parameters returned to normal at the end of the study. However, this study did not fulfil requirements of guideline studies, and reporting of methods and results was very limited. Furthermore, the study indicated that effects on ovary and fertility occurred after single oral dosing with flocoumafen which were close to LD50 values and possibly causing internal bleeding. The second reproduction event may also indicate a recovery and/or no adverse effects on reproduction.
Additionally, the effects of flocoumafen on the pregnancy and embryonic or foetal development of the rabbit was investigated and there were no signs of treatment-related maternal or embryotoxic effects (CAR – Doc IIIA, Annex Point II A6.8.1). There is also a study on placental transfer ([redacted] 2009 – *apud* flocoumafen CAR 2009) comparing warfarin and flocoumafen. In this study, besides being able to pass through the placenta, flocoumafen showed a high first pass metabolism in the liver after oral exposure.
Based on the RAC opinion for flocoumafen (2014) and on the assumption that all anti-vitamin K rodenticides, including warfarin and other anticoagulant coumarin-based pharmaceuticals share the same MoA, the endocrine assessment of flocoumafen includes consideration of the total database for the anti-vitamin K rodenticides.
By analogy, long term experience with the hydroxycoumarin derivative warfarin as an anticoagulant widely used in anti-coagulation therapy in humans showed no association with adverse effects on fertility in humans (WHO/IPCS Environmental Health Criteria 175 Anticoagulant Rodenticides, WHO Geneva 1995 – *apud* CAR flocoumafen 2009). Currently, there were no data available on the outcome of maternal exposure to flocoumafen in humans.

When considering all the available data, the target organs for the anti-vitamin K rodenticides seem to be the liver and the blood system, and therefore, other organs and systems are secondarily affected, i.e. the effects are neither specific nor restricted to the reproductive system as are accompanied to severe generalised toxicity.
Furthermore, no significant ER (estrogen receptor α) or AR (androgen receptor) activity at ToxCast database for warfarin was observed [3].

There is also a publicly available report from the Institute of Environment and Health (IEH) in UK funded through specific grants, contracts and awards by UK Government Departments and Agencies where warfarin was investigated in a monitoring program to evaluate endocrine disrupting chemicals in drinking water. In this report, "no evidence

[3] U.S. Environmental Protection Agency. Chemistry Dashboard, DTXSID5023742 (accessed July 04, 2018, Warfarin.
https://comptox.epa.gov/dashboard/dsstoxdb/results?utf8=%E2%9C%93&search=warfarin

suggestive of endocrine disrupting activity per se has been identified in subsequent literature review"[4].

Considering non-target wildlife, no reproduction studies with flocoumafen are available. Only the standard studies with fish (acute), *Daphnia* (acute) and algae exposed to flocoumafen were performed. The only data relevant for indication of endocrine disruption are from an avian reproduction test for the lower potency second generation anticoagulant rodenticide difenacoum (CAR – Doc IIIA, Annex Point II A7.5.3.1.3). As discussed in the CAR for flocoumafen (2009), it was agreed to use data for difenacoum as representative for other secondary anticoagulants as read across. Difenacoum exposure resulted in dose related effects on survival, liver and spleen weight and symptoms of anticoagulant poisoning in adults, as well as some dose related effects on reproduction parameters (14-day survival of hatchlings). These results indicate that effects might be due to general toxicity and not specific to the reproductive system, as also discussed above for mammalian toxicology. However, it should be noted that this test was considered to be on the borderline of reliability by the RMS, but was accepted regarding animal welfare. Important reliability issues were that the test duration was much shorter (6 weeks) than recommended by the relevant guideline (OECD TG 206; ≥20 weeks) and that no statistical analysis was performed on several reproduction parameters. Moreover, as discussed in the Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 (EFSA/ECHA/JRC, 07 June 2018)[5], the avian reproduction test (OECD TG 206) includes parameters which are sensitive to but not diagnostic of EATS (estrogen, androgen, thyroid, steroidogenic) modalities. Hence, no data are available for flocoumafen and for species other than birds. The available (toxicological and ecotoxicological) data do not indicate flocoumafen as having endocrine disrupting properties.

Non active substance (co-formulants)
Storm Ultra co-formulants were also investigated and there are no indications of endocrine disruption for any of them based on the current scientific knowledge and information on the CLP available at the SDSs (Safety Data Sheet) submitted. However, one of the co-formulants was [redacted] and an assessment was conducted (see Confidential Annex for details). Using a weight of evidence approach, the available toxicological and ecotoxicological data do not indicate the co-formulant as having endocrine disrupting properties and therefore it was concluded that this substance does not represent a concern for the Storm Ultra formulation.

Conclusion
Storm Ultra formulation was not tested for potential endocrine disruption properties. However, the product does not have endocrine disruption indications based on the current scientific knowledge as well as toxicological and ecotoxicological information available on the active substance and co-formulants. Therefore, Storm Ultra is not considered as having endocrine disrupting properties.

[4] Institute of Environment and Health (IEH), A review of latest endocrine disrupting chemicals research implications for drinking water. Final Report DWI:70/2/266, March 2012. http://dwi.defra.gov.uk/research/completed-research/reports/DWI70_2_266.pdf
[5] https://www.efsa.europa.eu/en/efsajournal/pub/5311.

2.2.6.2 Exposure assessment

The biocidal product Storm Ultra contains the active substance flocoumafen (25 ppm, 0.0025%). Storm Ultra is a ready-to-use block bait used for the control of rats and mice in and around buildings, with the purpose of protecting human food and animal feedstuffs, and for general human hygiene. Storm Ultra is supplied in two different sizes: as a 25 g and a 5 g block bait for the use in and around buildings.

The product is intended for both professional users and non-professional users

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	No	No	n.a.	No	No	No
Dermal	n.a.	Yes	Yes	n.a.	No	No	No
Oral	n.a.	No	No	n.a.	No	Yes	No

n.a. = not applicable

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.1 in and around buildings	Application, (incl. clean-up)	Primary: Loading of the bait stations with the ready to use block bait including cleaning of bait stations.	Professional users
1.2 in and around buildings	Application, (incl. clean-up)	Primary: Loading of the bait stations with the ready to use block bait including cleaning of bait stations.	General public (non-professional users)
1.3 in and around buildings	Infants ingesting bait	Secondary: Indirect exposure of infants ingesting part of the block bait	General public (Non-users)

Exposure of industrial users

Not applicable. Industrial use is not envisaged.

Exposure of professional users

Scenario [1.1 Application in and around buildings]

For the exposure assessment of professional users the application in and around buildings of Storm Ultra against rats, the 5 g block is identified as worst case scenario since the assessment is based on potential dermal exposure per handled bait block and in the case of 5 g blocks Storm Ultra, 15 baits are to be placed per bait point instead of 3 in the case of 25 g blocks.

Description of Scenario [*1.1 Application in and around buildings*]

Type of product:	End-use product (EP)
Active substance:	Flocoumafen (BAS 322 I)
Code No.:	BAS 322 20 I
Biological activity:	Anticoagulant rodenticide
Type of formulation:	block bait, ready for use (RB)
Size:	5 g
A.S. content:	Flocoumafen (BAS 322 I): 25 mg/kg (0.0025% w/w)
Recommended application rate:	75 g of bait per bait station, (equivalent to a maximum of 15 of 5 g baits)
Number of loadings of bait boxes:	professionals: 60
Number of cleanings of bait boxes:	professional users: 15
Placing bait blocks:	
Indicative value (75th percentile, HEEG Opinion 12):	27.79 placing of 5 blocks into a bait station (=5.558 mg/bait block)
Cleaning bait boxes:	
Indicative value (75th percentile, HEEG Opinion 12):	5.7 mg/bait box

	Parameters	Value
Tier 1	Dermal absorption value:	4%*
	Bodyweight (HEAd hoc rec. 14)	60 kg
	No PPE	-
Tier 2	Dermal absorption value:	4%
	Bodyweight (HEAd hoc rec. 14)	60 kg
	Reduction by PPE (gloves)	95%**

* A default dermal absorption value of 4% was adopted from the AR of flocoumafen (2008 and 2016) as a worst case; as experimentally based dermal absorption values of wax-based and wax-free flocoumafen formulations are both <1%, the 4% value is considered a very conservative approach

** The use of the protection factors for gloves indicated in the HEEG opinion 9 (90% for challenges by a liquid and 95% for challenges by a solid) is agreed by HEAdhoc members. PT14 products are mainly solid formulations, the 95% protection factor is applicable for these solid formulations (agreed WGV 2017)

Calculations for Scenario [1.1 Application in and around buildings]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1.1]	1/no PPE	None	8.48×10^{-5} mg/kg bw/d	None	8.48×10^{-5} mg/kg bw/d
Scenario [1.1]	2/gloves	None	4.24×10^{-6} mg/kg bw/d	None	4.24×10^{-6} mg/kg bw/d

Further information and considerations on scenario [1.1 Application in and around buildings]
Post-application exposure (clean up and disposal) is already included in the scenario above. Apart from that no further information and considerations are relevant.

Combined scenarios

Combining scenarios for mixing/loading and application is not relevant for Storm Ultra as it is a ready-for-use bait product where mixing is not required.

Exposure of non-professional users

Scenario [1.2 Application in and around buildings]

For the exposure assessment of the general public (non-professional users) the application in and around buildings of Storm Ultra against rats, the 5 g block is identified as worst case scenario since the assessment is based on potential dermal exposure per handled bait block and in the case of Storm Ultra, 15 5 g baits are placed per bait point instead of 3 in the case of 25 g block.

Description of Scenario [1.2 Application in and around buildings]

Type of product: End-use product (EP)
Active substance: Flocoumafen (BAS 322 I)
Code No.: BAS 322 20 I
Biological activity: Anticoagulant rodenticide
Type of formulation: block bait, ready for use (RB)
Size: 5 g
A.S. content: Flocoumafen (BAS 322 I): 25 mg/kg (0.0025% w/w)
Recommended application rate: 75 g of bait per bait station, (equivalent to a maximum of 15 of 5 g baits)
Number of loadings of bait boxes: non-professionals: 5
Number of cleanings of bait boxes: non-professional users: 5
Placing bait blocks:
Indicative value (75th percentile, HEEG Opinion 12): 27.79 mg b.p for placing of 5 blocks into a bait station (=5.558 mg/bait block)
Cleaning bait boxes:
Indicative value (75th percentile, HEEG Opinion 12): 5.7 mg/bait box

	Parameters	Value
Tier 1	Dermal absorption value:	4%
	Bodyweight (HEAdhoc rec. 14)	60 kg
	No PPE	-

* A default dermal absorption value of 4% was adopted from the AR of flocoumafen (2008 and 2016) as a worst case; as experimentally based dermal absorption values of wax-based and wax-free flocoumafen formulations are both <1%, the 4% value is considered a very conservative approach

Calculations for Scenario [1.2 Application in and around buildings]

Summary table: systemic exposure from non-professional uses

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1.2]	1/no PPE	None	7.42×10^{-6} mg/kg bw/d	None	7.42×10^{-6} mg/kg bw/d

Further information and considerations on scenario [1.2 Application in and around buildings]

Post-application exposure (clean up and disposal) is already included in the scenario above. No further information and considerations.

Combined scenarios

Combining scenarios for mixing/loading and application is not relevant for Storm Ultra as it is a ready-for-use bait product where mixing is not required.

Exposure of the general public

Scenario [1.3 in and around buildings]

Non-users (adults, children and infants) will not be present during application. Nevertheless, it could be possible that despite of the risk mitigation measures infants may ingest part of the block bait.

Description of Scenario [1.3]		
Oral exposure assessment for infants based on default values: The exposure concentration via oral uptake is assumed to be equivalent to be 5 g is for products without a human aversive (bittering) agent (TNsG User Guidance, version 1, p. 70) and 10 mg of the bait (infants) for transient mouthing of poison bait treated with repellent (TNsG 2002, part 3, appendix 7.2.1, p58).		
	Parameters	Value
Tier 1	Amount of product ingested	5 g (User Guidance, bait without aversive (bittering) agent) 10 mg (TNsG)
	Concentration of flocoumafen	25 mg/kg
	Weight of toddler	10 kg
	Oral absorption (worst case)	100%

Calculations for Scenario [1.3 in and around buildings]

Summary table: systemic exposure from non-users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1.3] User Guidance Bait without aversive (bittering) agent	1/none	None.	Not applicable.	1.25×10^{-2} mg/kg bw/d	1.25×10^{-2} mg/kg bw/d
Scenario [1.3] TNsG	1/none	None.	Not applicable.	2.5×10^{-5} mg/kg bw/d	2.5×10^{-5} mg/kg bw/d

Further information and considerations on scenario [1.3 in and around buildings]
No further information and considerations.

Combined scenarios
Not applicable.

Monitoring data

Monitoring data are not available.

Dietary exposure

Any exposure of food, drinking water or livestock exposure is not foreseeable. Thus, dietary exposure is considered as not relevant. Furthermore, the label needs to display the following risk mitigation measures:

- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- When using the product do not eat, drink or smoke.
- Wash hands and directly exposed skin after using the product.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1.1	Professional users	1/no PPE	8.48×10^{-5} mg/kg bw/d
1.1	Professional users	2/gloves	4.24×10^{-6} mg/kg bw/d
1.2	General public (Non-professional users)	1/no PPE	7.42×10^{-6} mg/kg bw/d
1.3	Non-users: Infants (User Guidance)	1/no PPE	1.25×10^{-2} mg/kg bw/d
1.3	Non-users: Infants (TNsG)	1/no PPE	2.5×10^{-5} mg/kg bw/d

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	**Study**	**NOAEL (LOAEL)**	**AF[1]**	**Correction for oral absorption**	**Value**
AELshort-term	Teratogenicity study, rabbits	NOAEL 0.002 mg/kg bw/d	300	-	$6.7*10^{-6}$ mg/kg bw/d
AELmedium-term	28-days, rats	NOAEL 0.0025 mg/kg bw/d	300	-	$8.3*10^{-6}$ mg/kg bw/d
AELlong-term	90-days, rats	NOAEL 0.0025 mg/kg bw/d	300	-	$8.3*10^{-6}$ mg/kg bw/d

ARfD	Not applicable.
ADI	Not allocated, not necessary.

[1] The European Commission has decided that an assessment factor of 300 shall be applied to this NOAEL for establishing safe exposure levels (10 for intra-species variation × 10 for inter-species variation × 3 for severity of effects (teratogenicity by read-across from Warfarin). Although the existing developmental toxicity studies on Flocoumafen do not indicate a potential of this substance for teratogenicity or developmental toxicity, RAC has decided to classify flocoumafen with Repro. 1B, H360D based on the same mode of action as Warfarin and a weight of evidence approach (for more details please see RAC opinion: https://echa.europa.eu/documents/10162/da409d33-154e-45ed-92c6-20d444b2e3c5)

Maximum residue limits or equivalent

MRLs for Flocoumafen in food and feed stuff are not set and it was agreed on EU level that these are not required due to lack of exposure. However, flocoumafen was not approved under PPP regulation. Therefore, a according Reg. 396/2005 a default MRL of 0.01 mg/kg applies. The MRL for drinking water corresponds to the general drinking water limit of 0.1 µg/L.

Risk for industrial users

Not applicable. Industrial use is not envisaged.

Risk for professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application/1.1	1	0.0025 mg/kg bw/d	$8.3*10^{-6}$ mg/kg bw/d	$8.48*10^{-5}$ mg/kg bw/d	1021.6	no
Application/1.1	2	0.0025 mg/kg bw/d	$8.3*10^{-6}$ mg/kg bw/d	$4.24*10^{-6}$ mg/kg bw/d	51.1	yes

Combined scenarios

Combining scenarios for mixing/loading and application is not relevant for Storm Ultra as it is a ready-for-use bait product where mixing is not required.

Local effects

Storm Ultra does not show any local effects, therefore there is no need to consider local effects separately.

Conclusion

Based on the risk assessment of Storm Ultra, no adverse risk for professional users is expected when wearing gloves resulting from the intended uses.

Risk for non-professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application/1.2	1	0.0025 mg/kg bw/d	$8.3*10^{-6}$ mg/kg bw/d	$7.42*10^{-6}$ mg/kg bw/d	89.4	yes

Combined scenarios

Combining scenarios for mixing/loading and application is not relevant for Storm Ultra as it is a ready-to-use bait product where mixing is not required.

Local effects

Storm Ultra does not show any local effects, therefore there is no need to consider local effects separately.

Conclusion

Based on the risk assessment of Storm Ultra, no adverse risk for non-professional users resulting from the intended use is expected.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Indirect exposure/1.3 Bait without aversive (bittering) agent	1	0.0025 mg/kg bw/d	$6.7*10^{-6}$ mg/kg bw/d	$1.25*10^{-2}$ mg/kg bw/d	186567	no
Indirect exposure/1.3	1	0.0025 mg/kg bw/d	$6.7*10^{-6}$ mg/kg bw/d	$2.5*10^{-5}$ mg/kg bw/d	373	no

Combined scenarios

Combined exposure is not relevant in this assessment because any indirect exposure of non-professional user via the environment is considered to be negligible.

Local effects

Storm Ultra does not show any local effects, therefore there is no need to consider local effects separately.

Conclusion

Thus, based on this formal approach agreed among EU member states it has to be concluded that accidental secondary exposure of infants (mouthing or ingestion of bait) to Storm Ultra block-baits containing Flocoumafen at a concentration of 0.0025 % appears to pose a risk.

However, the following aspects should be noted:

- The above risk characterisation compares acute exposure (one single event) to reference value from a multidose study (maternal toxicity in a developmental study) and this may be conservative. The prescribed risk assessment procedure adopts the principle of occupational risk assessment; this means that exposure is implicitly assumed to be an unavoidable consequence of product use; the accidental nature of the type of exposure considered here is completely ignored; however, risk comprises hazard and the likelihood of exposure, which is indeed disregarded by the recommended approach
- In the very unlikely case that adverse effects actually become manifest in an exposed infant, an effective antidote is available with vitamin K1
- Storm Ultra contains denatonium benzoate as a very effective human taste deterrent, thus largely preventing ingestion of bait
- In order to prevent the likelihood of exposure the following risk mitigation are necessary:
    - Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
    - Bait should be secured so that it cannot be dragged away from the bait station
    - Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 5.3 of the SPC for the information to be shown on the label).Where possible, bait stations must be fixed to the ground or other structures.

In conclusion, despite the formally identified risk for infants from secondary exposure to Storm Ultra (mouthing or ingestion of bait) it is proposed that the likelihood of such exposure is low with all risk mitigation measures in place .The effects if these would occur can be effectively managed by vitamin K treatment (if at all necessary).

Risk for consumers via residues in food

The acute or chronic exposure to residues in food resulting from the intended uses is very unlikely since the product is not to be applied directly to food or feed but only at discrete sites in covered application and/or in bait boxes. Regarding consumer health protection, there are no objections against the intended uses. Furthermore, the label needs to display the following risk mitigation measures:

- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.

- When using the product do not eat, drink or smoke.
- Wash hands and directly exposed skin after using the product.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not required. The product does not contain several active substances or substances of concern.

2.2.7 Risk assessment for animal health

An additional risk assessment for animal health is not considered to be required for Storm Ultra since exposure to the product or residues thereof, directly or through drinking water, feed, air, or through other indirect effects can be excluded, due to the fact that the biocide is not applied directly on animals, in their surroundings or on food or feed either. Accidental exposure to companion or non-target animals (see for primary and secondary poisoning paragraph 2.2.8.1) may be possible, therefore the label needs to display the following risk mitigation measures:

- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Bait should be secured so that it cannot be dragged away from the bait station.

2.2.8 Risk assessment for the environment

The environmental exposure to Flocoumafen has already been assessed for the use of the active substance as a rodenticide (product type 14) in and around buildings.
Regional and continental environmental concentrations of Flocoumafen are generally regarded to be insignificant. Flocoumafen is produced in small batches in closed systems and appropriate control measurements are taken to largely exclude release of the active to the environment during production (including formulation of the product). In view of the small production volume and the adopted control measures, regional and continental PECs are therefore not considered in the exposure assessment for lack of relevance.

2.2.8.1 Effects assessment for the environment

The active substance Flocoumafen has been evaluated for the use as rodenticide (PT 14) according to Directive 98/8/EC and is currently[6] under review according to the Regulation (EU) n°528/2012 for the active substance renewal. There are 5 studies in this section which have not yet been evaluated in the first EU approval of Flocoumafen but are currently under evaluation in the renewal. However, four of these studies for the active substance Flocoumafen have already been evaluated by RMS during the product authorisation process for STORM Secure, STORM Pellets and STORM Paste. The new studies are as follows:

Already submitted and evaluated for product authorisations and submitted for EU renewal:

- [redacted] (2011): Fish, bioconcentration of Flocoumafen according to the OECD Guideline 305 and EU method C.13
- Simon, M. (2007): Soil microorganisms: Effects of Flocoumafen on nitrogen and carbon transformation.
- Simon, M. (2007): Earthworm acute toxicity test: acute toxicity of Flocoumafen on *Eisenia fetida.*
- Simon, M. (2007): Terrestrial plants, growth test: Effect of Flocoumafen on the seedling emergence and growth of *Avena sativa, Lactuca sativa, Phaseolus aureus, Raphanus sativus, Sinapis alba*, and *Triticum aestivum*.

Submitted for the EU renewal:

- Simon, M. (2012): Bioaccumulation in Terrestrial Oligochaetes - Uptake and elimination of Flocoumafen in *Eisenia fetida*

RMS considers all new studies acceptable, except the earthworm biocentration study as explained below.
The applicant has submitted a study in which bioaccumulation in the earthworm *Eisenia fetida* was investigated. The study was conducted according to the principles of GLP and according to the OECD 317 guideline without deviations. The following was concluded:

Endpoint)*	**steady state (ss)**	**kinetic (k)**
BAF	2.41	3.04
BSAF (= lipid normalised BAF)	0.54	0.68

)* **BAF** (expressed in kg soil·kg-1 worm), soil uptake rate constant ks (expressed in g soil kg-1 of worm day-1), and elimination rate constant ke (expressed in day-1);
BSAF (expressed in kg soil OC kg-1 worm lipid content) (Source: OECD 317)

6 In the moment of submission of the product authorisation dossier for BAS 322 20 I.

In the renewal AR of Flocoumafen it was concluded that equilibrium conditions and the uptake rate constant could not be derived accurately. Therefore, the RMS is of the opinion that the derived values are not applicable for the environmental risk assessment as the expected variation is too large. Nevertheless, the submitted study has demonstrated that actual bioaccumulation is clearly lower than QSAR-predicted values as Flocoumafen is rapidly eliminated from earthworms.

Below the four accepted studies are briefly summarised:

Soil microorganisms:	EC_{10} 12.1 mg/kg dry soil or 10.7 mg/kg wet soil (nitrogen mineralisation) EC_{50} > 1000 mg/kg dry soil or 882.4 mg/kg wet soil (nitrogen mineralisation) NOEC > 1000 mg/kg dry soil or 882.4 mg/kg wet soil (carbon mineralisation) EC_{50} > 1000 mg/kg dry soil or 882.4 mg/kg wet soil (carbon mineralisation)
Earthworms:	EC_{50} > 1000 mg/kg dry soil or 882.4 mg/kg wet soil
Plants:	EC_{50} ≥ 714 mg/kg dry soil or 630.0 mg/kg wet soil NOEC = 179 mg/kg dry soil or 157.9 mg/kg wet soil
Bioconcentration in fish:	BCF_{fish} (kinetic) = 24,300 L/kg wwt

The following endpoints relevant for environmental risk assessment are reported:

Compartment	Organism	Endpoint	AF	PNEC
Aquatic	Fish (*Oncorhynchus mykiss*)	LC50 = 0.07 mg/L	1000	0.07 µg/L
STP	Microorganisms from activated sludge	NOEC = 4 mg/L	10	0.4 mg/L
Soil	Equilibrium partitioning	-	-	0.0126 mg/kg wwt
Soil	Soil microorganisms	EC10 (10.7 mg/kg wwt)	50	0.21 mg/kg wwt)*
Terrestrial	Birds (*Coturnix japonica*)	NOEC > 0.063 mg/kg food NOEC > 0.0075 mg/kg bw/d (read across from study with difenacoum)	30	>0.0021 mg/kg food >0.00025 mg/kg bw/d
Terrestrial	Mammals (rat)	NOEC = 0.05 mg/kg food or 0.0025 mg/kg bw/d	90	0.00056 mg/kg food 0.000028 mg/kg bw/d

)* Revised PNEC based on new studies provided and evaluated for the renewal of flocoumafen, already agreed by authority for products' authorisation of STORM Secure, STORM Pellets and STORM Paste

Comments were provided by cMS in the mutual recognition phase regarding the new $PNEC_{soil}$ used, which was not officially approved by the WG. An e-consultation in the WG ENV was started up to establish the new $PNEC_{soil}$. In the meanwhile, PEC/PNEC calculations both using the old and the new $PNEC_{soil}$ were included in this PAR, the latter for consistency as it was used in earlier product authorisations with the active substance flocoumafen.

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

Classification and labelling of the formulation concerning environmental properties is not required.

Further Ecotoxicological studies

Data waiving	
Information requirement	9.2. Further ecotoxicological studies
Justification	The performance of further ecotoxicological studies with the biocidal product is not considered to be required since read-across from the environmental toxicity data of the active substance is justified.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

Data waiving	
Information requirement	9.3. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)
Justification	The performance of further testing with the biocidal product is not considered to be required since read-across from the environmental toxicity data of the active substance is justified.

Supervised trials to assess risks to non-target organisms under field conditions

Data waiving	
Information requirement	9.4.1 Supervised trials to assess risks to non-target organisms under field conditions
Justification	The performance of further testing with the biocidal product is not considered to be required since read-across from the environmental toxicity of the active substance is justified.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

Data waiving	
Information requirement	9.4.2 Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
Justification	Not required since the product is to be used in such a way that

	non-target animals have no access, i.e. in bait boxes or at covered and protected bait points.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Not relevant. According to the intended use a large proportion of a specific habitat type will not be treated. Therefore, no additional studies are required.

Foreseeable routes of entry into the environment on the basis of the use envisaged

The formulation is considered not to alter any of the physicochemical properties of the active substance since it is based on cereals as main component. Based on Level 1 Mackay modelling, Flocoumafen may be considered to partition predominantly to soil (> 97 %) and to a much lesser extent to sediment (2 %), with negligible amounts anticipated to be distributed to surface water and the atmosphere (<< 1 % in both cases). These figures represent fugacity estimates, outlining the general tendency of Flocoumafen to distribute into the respective compartments.

Since Flocoumafen is virtually non-volatile (≤ 1 × 10^{-3} Pa at 50 °C), partitioning of the active substance to the atmosphere to any relevant extent is not anticipated. However, any potentially volatilised material may be expected to be rapidly eliminated via photo-oxidative reactions.
Flocoumafen is poorly soluble in water under neutral conditions (0.114 mg/L at 20 °C, pH 7). Flocoumafen is hydrolytically stable, however it undergoes rapid photo-transformation in aqueous media (DT50 = 1.67 d at average conditions in Central Europe considered as the "normal" case in April).

Based on its octanol/water partition coefficient (log Pow = 6.12, pH 7, HPLC method) and the soil adsorption coefficient (Koc = 101 684 L/kg, mean value for cis- and trans-isomer), the active substance is expected to strongly adsorb to soil, sediment and sewage sludge. A bioaccumulation study ([redacted], 2011) in fish resulted in a kinetic bioconcentration factor BCFfish of 24 300 L/kg wwt. This BCF will be used for the calculation of the risk via the aquatic food chain. The terrestrial bioaccumulation factor in earthworms submitted for the renewal authorisation of the active substance alters from the theoretical derivation from the log Pow, since this bioaccumulation study was conducted in terrestrial oligochaeta and resulting in a low bioaccumulation factor (kinetic) BAF_k = 3.04 ($BSAF_k$ = 0.68). However as RMS did not accept this BAF_k, it will not be used for the calculation of the risk via the terrestrial food chain of earthworm eating predators. Instead, the BCF of 15 820 kg/kg wwt estimated based on the log Pow of 6.12 will be used for calculation of the risk via the terrestrial food chain.

Further studies on fate and behaviour in the environment (ADS)

Data waiving	
Information requirement	10.2. Further studies on fate and behaviour in the environment (ADS)
Justification	The formulation of the biocidal product is not expected to alter the physical and chemical properties, the environmental, and the toxicological profile of the active substance. Thus, read-across from the data on the active substance Flocoumafen is justified.

Leaching behaviour (ADS)

The relevant data indicate that Flocoumafen will adsorb to environmental compartments containing organic matter like soil and sewage sludge and that leaching will be negligible. (Koc= 101 684 L/kg; water solubility: 0.114 mg/L (pH 7, 20°C).

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	10.4.1. Testing for distribution and dissipation in soil (ADS)
Justification	The formulation of the biocidal product is not expected to alter the physical and chemical properties, the environmental, and the toxicological profile of the active substance. Thus, read-across from the data on the active substance Flocoumafen is justified.

Testing for distribution and dissipation in water and sediment (ADS)

Data waiving	
Information requirement	10.4.2 Testing for distribution and dissipation in water and sediment (ADS)
Justification	The formulation of the biocidal product is not expected to alter the physical and chemical properties, the environmental, and the toxicological profile of the active substance. Thus, read-across from the data on the active substance Flocoumafen is justified.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	10.4.3. Testing for distribution and dissipation in air (ADS)
Justification	The formulation of the biocidal product is not expected to alter the physical and chemical properties, the environmental, and the toxicological profile of the active substance. Thus, read-across from the data on the active substance Flocoumafen is justified.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not relevant. The product is neither intended to be sprayed nor has any potential for formation of dust.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not relevant. The product is neither intended to be sprayed nor has any potential for formation of dust.

2.2.8.2 Exposure assessment

For the use of the active substance as a rodenticide (product type 14) in and around buildings the environmental exposure to Flocoumafen was assessed according to the EUBEES emission scenario document (ESD). EUBEES emission scenarios have been implemented in Excel. The PEC in soil following burrow baiting was calculated according to the respective section of the "open area" emission scenario. It must be highlighted that, although an open area scenario was adopted, the corresponding PEC applies only to a particular case of the use pattern "in and around buildings", i.e. burrow baiting close to outer walls of rodent infested premises.

The environmental exposure assessment covers the application 75 g in and around buildings. Other use patterns are not foreseen for this product. Bait is replenished once per week on days 0, 7, 14 and 21 (additionally on day 4 if required) after the first application, i.e. pulse baiting. As a worst-case a total of five times refilling was assumed in the risk assessment.

Consequently, the following worst-case scenarios are considered:
- In around buildings, use of Storm Ultra against rats (up to 75 g per bait point)

General information

Assessed PT	PT 14
Assessed scenarios	In and around buildings
ESD(s) used	Emission Scenario Document for Product Type 14: Emission scenarios for biocides used as rodenticides (EUBEES, 2003)
Approach	Average consumption
Distribution in the environment	Calculated based on SimpleTreat prediction
Groundwater simulation	No simulation of leaching to groundwater was conducted since Flocoumafen is not considered to move to the groundwater due to its properties (low water solubility, high adsorption to soil) Tier 1 of groundwater assessment: Cporewater= 3.79×10^{-6} mg/L (realistic worst case) and is thus far below the drinking water threshold of 0.1 µg/L
Confidential Annexes	*None*
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	-

Emission estimation

In and around buildings

The use of Storm Ultra against rats and mice in and around buildings is not considered to result in any relevant emissions to the aquatic compartment. Therefore, no estimates of the concentration of Flocoumafen in surface water or sediment have been calculated. This is in accordance with the emission scenario document for biocides used as rodenticides (EUBEES 2). In view of the envisaged use pattern and the risk mitigation measures derived from CLP characteristics, the emission to surface water from leaching of rodenticides is considered negligible.

Furthermore, Flocoumafen is not considered to reach the ground water due to the restricted use pattern, which will result in a very low local soil concentration, and the strong adsorption to soil (log Koc > 6) and the very low water solubility (0.114 mg/L (pH 7, 20°C). Hence a calculation of PECgroundwater is not considered to be required.

In view of the limited volatility of Flocoumafen, emissions to air are regarded to be insignificant. Thus, the PEC of Flocoumafen in air is considered to be negligible.

(i) Standard scenario according to the EUBEES ESD:

According to the ESD, emission of the active substance to soil is the most relevant contribution to environmental exposure resulting from rodenticide application in and around buildings. For the estimation of emissions and local PEC_{soil}, the emissions scenario set out in the ESD is used. Therefore, two scenarios are considered: (a) a "realistic worst case" with 5 (re)fillings and 100% consumption, and (b) a "typical case" in which bait consumption progressively declines.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks)***
Scenario: *Application in and around buildings*			
Amount of product used at each refilling in the control operation for each bait box	75	g	S
Fraction of active substance in product	0.000025	–	S
Number of application sites	10	–	D
Number of refilling times, (a. realistic worst case)	5	–	S
Number of refilling times, (b. typical case)	1.5	–	S
Fraction of product released indirectly to soil)**	0.7	–	S
Fraction of product released directly to soil	0.01	–	D
Fraction of active ingredient metabolised	0.2	–	S

)* S: User-specified; D = Default; O = Output; P = Selected from a pick-list

)** $F_{release}$-ID, soil = 0.3+ (0.6 – F_{metab}) with F_{metab} = 0.2 (see Doc III-B 7.1/02 of final CAR of Flocoumafen)

(ii) Burrow baiting:

The scenario for "burrow baiting" is normally required for the use "open area" which is not supported by this application. However, in some cases it may also be required in the range

of the use "in and around buildings" to place bait in rat burrows in natural soil in close vicinity to buildings. For this instance, the assumptions and calculations from the EUBEES open area scenario are adopted, however stressing that this has to be considered within the "in and around buildings" scenario, since open area use is explicitly not supported.
The open area scenario is denoted as "pellets and impregnated grain" in the EUBEES ESD, but is considered to be also applicable to bait blocks. One modification was introduced: Since the use instructions for Storm Ultra block baits request the rat burrows to be closed following bait deployment, the number of refilling times is set to "2". The amount of bait applied is 3 blocks, i.e. 75 g in the worst case of Storm Ultra.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: *Application in and around buildings*			
Amount of product used at each refilling in the control operation	75	g	S
Fraction of active substance in product	0.000025	–	S
Number of application sites	1	–	D
Number of refilling times	2	–	S
Fraction of product released to soil during application	0.05	–	D
Fraction of product released to soil during use	0.2	–	D
Local emission to soil from the episode	0.00094	g	O
Soil volume exposed to rodenticide	0.0085	m^3	D
Density of exposed wet soil	1700	$kg \times m^{-3}$	D

Calculations

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [g]**	**Remarks**
Freshwater	-	*Not required.*
Freshwater sediment	-	*Not required.*
Seawater	-	*Not required.*
Seawater sediment	-	*Not required.*
STP	-	*Not required.*
Air	-	*Not required.*
$Soil_{standard}$	0.0009 ($Elocal_{soil\text{-}D\text{-}campaign}$) 0.0650 ($Elocal_{soil\text{-}ID\text{-}campaign}$)	(a. realistic worst case)

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [g]**	**Remarks**
	0.0003 ($Elocal_{soil\text{-}D\text{-}campaign}$) 0.0195 ($Elocal_{soil\text{-}ID\text{-}campaign}$)	(b. typical case)
$Soil_{burrow\ baiting}$	0.00094 ($Elocal_{soil\text{-}campaign}$)	

ID = indirect exposure; D = direct exposure

The environmental concentration in soil in direct vicinity of individual bait points (rat burrows in natural soil) is calculated as:
$C_{local,soil}$ = 0.065 mg/kg wwt (baiting of rat burrows in natural soil in and around buildings)
This figure must not be confounded with a PEC. PECs are related to a local environment. The minute soil volume regarded in the above scenario is only an insignificant fraction of a local terrestrial environment, to which the concept of a PEC is not applicable. Additionally, a Cporewater of 0.036 µg/L was calculated.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
In and around buildings	No	No	No	No	No	No	Yes	Yes	No
Burrow baiting	No	No	No	No	No	No	Yes	Yes	No

Data presented on the active substance are the same as included in the existing competent authority report, established during the evaluation of Flocoumafen (final CAR 2009).

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
Air	n.r.	
Water	n.r.	
Sludge	n.r.	
Degraded in STP	n.r.	

n.r. = not relevant

Calculated PEC values

Summary table on calculated PEC values							
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC seased**	**PEC_{soil} (Clocalsoil)**	**PEC_{GW}(Cporewat**	**PEC_{air}**

							er)	
		[mg/m^3]	[mg/l]	[mg/kg$_{wwt}$]	[mg/kg$_{wwt}$]	[mg/kg$_{wwt}$]	[µg/l]	[mg/m^3]
Application in and around buildings	Realistic worst case	n.r.	n.r.	n.r.	n.r.	0.0068	0.0038	n.r.
	Typical case	n.r.	n.r.	n.r.	n.r.	0.002	0.0011	

Primary and secondary poisoning

Primary poisoning

Flocoumafen is very toxic to birds and non-target mammals. Primary poisoning by rodenticides is the unwanted, hence accidental, consumption of rodenticides by non-target organisms, which gain access to bait blocks directly. The following quantification of the risk to birds and non-target mammals considers long-term situations and is in accordance with the EUBEES-ESD for rodenticides.
However it is explicitly noted that the label instructions of the product clearly specify that the bait is to be placed where the risk of primary poisoning of birds and other non-target animals is precluded. In particular, the bait should not be laid out open and unprotected.

In and around buildings

When Storm Ultra baits are applied according to the label instructions, 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. The estimated daily uptake rates are therefore considered to be **negligible** for all example species , as also acknowledged in the EUBEES-ESD.

Although it is proposed to take forward the normal case for risk characterisation, worst case estimates following the EUBEES-ESD are given in order to evaluate risks of accidental exposure.

Birds are usually unable to feed directly from the compact bait blocks. Nevertheless, crumbled bait blocks, resulting from gnawing and bait carriage by target rodents, may be considered to represent a potential source of exposure. The worst case scenario for such a situation as set out by the EUBEES-ESD was calculated using the parameters as given in the table below. The results, including a second tier refinement according to the EUBEES defaults, are also presented below. For livestock and pets the default maximum figure of 600 g bait consumption (equivalent to the maximum amount of bait available on a treated site) is adopted from the EUBEES-ESD.

Variable/parameter	Symbol	Unit	Default	S/D/O/P
Input				
Food intake rate of indicator species (fresh weight)	FIR	g/d	see Table below	S/P
Body weight	BW	g	see Table below	S/P
Concentration of active compound in fresh	C	mg/kg	25	S/P/D

diet (bait)				
Avoidance factor (1 = no avoidance, 0 = complete avoidance)	AV	–	1	S/D
Fraction of diet obtained in treated area (value between 0 and 1)	PT	–	1	S/D
Fraction of food type in diet (number between 0 and 1; one type or more types)	PD	–	1	S/D
Output				
Estimated daily uptake of active substance	ETE	$mg.kg.^{-1}d^{-1}$		

Species		**Body weight [g]**	**Daily mean food intake [g]**	**Bait consumption [g]**	**Concentration of a.i. after a single meal (one day) [mg/kg]**	
					Tier 1	**Tier 2**
Dog	*Canis familiaris*	10000	– $	600.0	1.5	1.08
Pig	*Sus scrofa*	80000	– $	600.0	0.19	0.14
Pig, young	*Sus scrofa*	25000	– $	600.0	0.6	0.43
Tree sparrow *)	*Passer montanus*	22	7.6	7.6	8.64	6.22
Chaffinch *)	*Fringilla coelebs*	21.4	6.42	6.42	7.5	5.4
Wood pigeon *)	*Columba palumbus*	490	53.1	53.1	2.71	1.95
Pheasant *)	*Phasianus colchicus*	953	102.7	102.7	2.69	1.94

*) Body weight and food intake values as given in the EUBEES-ESD by default

$) Not stated in the EUBEES-ESD; simplistically, a maximum bait consumption of 600 g is assumed

Step 1: AV= 1, PT = 1, PD = 1 and EL = 0.3 and 0.7 (mammals and birds);
Step 2: AV= 0.9, PT = 0.8, PD = 1 and EL = 0.3 and 0.7 (mammals and birds)

Species		**Estimated daily uptake of Flocoumafen [mg/kg] after one meal followed by a 24 hour elimination period**		
		Normal use	**Realistic worst case**	
			Tier 1	**Tier 2**
Dog	*Canis familiaris*	≅ 0	1.05	0.76
Pig	*Sus scrofa*	≅ 0	0.13	0.09
Pig, young	*Sus scrofa*	≅ 0	0.42	0.30
Tree sparrow	*Passer montanus*	≅ 0	2.6	1.9
Chaffinch	*Fringilla coelebs*	≅ 0	2.25	1.62

Woodpigeon	*Columba palumbus*	≅ 0	0.81	0.59
Pheasant	*Phasianus colchicus*	≅ 0	0.81	0.58

Step 1: AV= 1, PT = 1, PD = 1 and EL = 0.3 and 0.7 (mammals and birds);
Step 2: AV= 0.9, PT = 0.8, PD = 1 and EL = 0.3 and 0.7 (mammals and birds)

Long-term scenario

In the long-term scenario the acute exposure is refined by assessing the amount of food for 5 days of exposure (bait blocks ingested after 5 meals)

Tier 1 (step 1) resembles the worst case exposure with no avoidance, complete diet obtained in the treated area and elimination of 0.7 (birds) or 0.3 (mammals).

Tier 2 (step 2) was based on an avoidance factor of 0.9 instead of 1, a fraction of diet obtained in treated area of 0.8 instead of 1 and the same elimination.

Species		**Estimated uptake of Flocoumafen after 5 meals [mg/kg/d] (EC5)**	
		Tier 1 (Step 1)	**Tier 2 (Step 2)**
Dog	*Canis familiaris*	4.16	2.99
Pig	*Sus scrofa*	0.52	0.37
Pig, young	*Sus scrofa*	1.66	1.20
Tree sparrow	*Passer montanus*	12.3	8.86
Chaffinch	*Fringilla coelebs*	10.7	7.70
Woodpigeon	*Columba palumbus*	3.86	2.78
Pheasant	*Phasianus colchicus*	3.84	2.76

Step 1: AV= 1, PT = 1, PD = 1 and EL = 0.3 and 0.7 (mammals and birds);
Step 2: AV= 0.9, PT = 0.8, PD = 1 and EL = 0.3 and 0.7 (mammals and birds)

Secondary poisoning

Secondary poisoning of non-target organisms can take place either due to bioaccumulation in the food chain, involving bioconcentration from surface water to fish, and further bioaccumulation in predators. For rodenticides, this pathway would only be relevant for use in sewers since releases to the STP and subsequently to the aquatic environment are not relevant for the use pattern "in and around buildings".
However, rodenticide active substance may enter the food chain of terrestrial predators and scavengers directly via poisoned rodents which are taken by them or via earthworm-eating predators.

Estimation of exposure due to secondary poisoning via the aquatic food chain

In and around buildings

Not relevant, since emissions to aquatic environment from rodenticide use in and around buildings can be considered to be negligible.

Estimation of exposure due to secondary poisoning via the terrestrial food chain

The emission via the terrestrial food chain may occur via biomagnification in earthworms and worm-eating birds and mammals. The estimation is assessed according to the Guidance on BPR, Volume IV, Part B, and is based on the endpoint derived from a newly conducted bioaccumulation study in earthworm. The $PEC_{oral,\ predator}$ is equal to the $C_{earthworm}$ and was calculated as follows:

$$C_{earthworm} = \frac{BCF_{earthworm} \times C_{porewater} + C_{soil} \times F_{gut} \times CONV_{soil}}{1 + F_{gut} \times CONV_{soil}}$$

where:
$BCF_{earthworm}$ = 0. 84 + 0.012 * Kow = 15,820 L/kg wwt
(based on Kow = 10^6.12 = 1,318,256 L/kg wwt)
F_{gut} = 0.1
$CONV_{soil}$ = 1.13
$C_{porewater} = C_{soil} \times RHO_{soil} / (K_{soil\text{-}water} \times 1000)$, with $K_{soil\text{-}water}$ = 3050 m³/m³

In and around buildings

For the estimation of the PECoral, predator three concentrations for soil in and around buildings (surface of 550 m²) were used for the calculations as input: (1) worst case, (2) typical case and (3) in line with other assessments of rodenticides 50% of the maximum PECsoil (combined direct and indirect release).

Scenario	**C_{soil} (mg/kg wwt)**	**$C_{porewater}$ (mg/L)**	**$PEC_{oral,\ predator}$ (mg/kg wwt)**
Realistic worst case	0.0068	3.79×10^{-6}	0.054
Typical case	0.002	1.1×10^{-6}	0.016
50% of maximum PEC_{soil}	0.0034	1.9×10^{-6}	0.027

Estimation of exposure due to secondary poisoning via poisoned rodents

Owing to their nature and use pattern, the most relevant pathway by which rodenticides may enter the food chain is via poisoned rodents (target or non-target) captured by predatory birds and mammals. Accordingly, secondary poisoning hazards of Flocoumafen are assessed in detail following the scenarios set out in the EUBEES-ESD for rodenticides.

Tier 1: Short-term secondary poisoning

The predicted environmental concentrations for the predators (PEC_{oral}) in the Tier 1 assessment are equivalent to the expected concentrations of Flocoumafen in poisoned target rodents. According to EUBEES, these are estimated in the same way as the non-target body concentrations for primary poisoning.
As a worst case, the concentration in the target rodent after 5 days of successive feeding exclusively on rodenticide bait was assumed (immediately after the last meal on day 5). The 5 day default is consistent with the times until death reported in the CAR for Flocoumafen. Therefore, this default was accepted for the Tier 1 exposure estimation since it provides the maximum figure for body burdens of non-resistant rodents. Since resistance to Flocoumafen has to date not been reported, an assessment for addressing resistance is not required.
The following input parameters were selected:

Food intake rate of target species (fresh weight)/bw (FIR/BW)	0.1 EUBEES Default	
Concentration of active compound in fresh diet (bait) (C)	25	Product specific
Fraction of diet obtained in treated area (PT)	1	EUBEES Default
Fraction of rodenticide in diet (PD)	1	EUBEES Defaults
Fraction of daily uptake eliminated (EI)	0.3	Substance specific

Regarding the fraction of treated bait in the rodents' diet (PD), a refinement with the values 0.5 and 0.2 was used for the sake of completeness.
The maximum residue level in target rodents that arises on day 5 after the last meal is 6.93 mg/kg food (100% bait consumption).

Time	Residues of Flocoumafen in target rodent [mg/kg bw]		
	Worst case 100% bait consumption	**Intermediate case** 50% bait consumption	**Normal case** 20% bait consumption
Day 1, after first meal	2.50	1.25	0.50
Day 2, before new meal	1.75	0.88	0.35
Day 3, before new meal	2.98	1.49	0.60
Day 4, before new meal	3.83	1.92	0.77
Day 5, before new meal	4.43	2.22	0.89
Day 5, after the last meal	6.93	3.47	1.39

Tier 1: Long-term secondary poisoning

For chronic exposure, the fraction of poisoned rodents in predator's diet is assumed to be 50 %; thus, F_{rodent} = 0.5. As an additional refinement the daily bait consumption of the poisoned rodents is set to 0.5 (intermediate case) and 0.2 (Normal case).
The resulting oral predicted environmental concentrations for acute exposure of predators were estimated as follows:

Species	**PEC [mg/kg rodent]**		
	Worst case	**Intermediate case**	**Normal case**
Birds	3.40	1.70	0.68
Mammals	3.40	1.70	0.68

Tier 2: Long-term secondary poisoning

As with Tier 1 above, resistant rodents were not considered since resistance to Flocoumafen has not occurred so far.
In the following table the estimated uptake values for relevant predatory birds and mammals are presented after a single day of exposure. It is assumed that rodents fed 100% on rodenticides and that daily consumption of the predators with poisoned rodents is 50%. Therefore, the residue level at day 5 after the last meal is 6.93 mg/kg food respectively 4.43 mg/kg food before the last meal. The bodyweights and food intake of each predatory species are drawn from EUBEES. The concentrations in predators were calculated as follows:
Concentration in predator (mg/kg bw) when rodent was caught on day 5 *before* their last meal:

$$= \frac{\text{Conc. of a. i. in rodent on day 5 before feeding (mg/kg bw)} * \text{daily mean food intake (g fw/day)}/1000 * 0{,}5}{\text{bw predator (g)}}$$

Concentration in predator (mg/kg bw) when rodent was caught on day 5 *after* their last meal:

Species		Body weight [g]	Daily mean food intake [g]	Rodents caught on day 5	
				Before their last meal	After their last meal
				Concentration in predator [mg/kg bw predator]	
Barn Owl	*Tyto alba*	294	72.9	0.55	0.86
Kestrel	*Falco tinnunculus*	209	78.7	0.83	1.31
Little Owl	*Athene noctua*	164	46.4	0.63	0.98
Tawny Owl	*Strix aluco*	426	97.1	0.51	0.79
Fox	*Vulpes vulpes*	5700	520.2	0.20	0.32
Polecat	*Mustela putorius*	689	130.9	0.42	0.66
Stoat	*Mustela ermine*	205	55.7	0.60	0.94
Weasel	*Mustela nivalis*	63	24.7	0.87	1.36
Dog	*Canis domesticus*	10000	456	0.10	0.16

$$= \frac{\text{Conc.of a.i.in rodent on day 5 after last meal (mg/kg bw)} * \text{daily mean food intake (g fw/day)/1}}{\text{bw predator (g)}}$$

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: Due to the extremely low vapour pressure (≤ 10^{-5} Pa at 50 °C), Flocoumafen is not expected to partition into the atmosphere to any relevant extent. In addition, the rate constants of photochemical reactions of Flocoumafen with hydroxyl and ozone radicals were estimated based on a QSAR calculation to be 1.5 and 2.0 h. Thus, Flocoumafen may be expected to be quickly degraded by photo-oxidation provided that it has at all been volatilised.

In conclusion, the physicochemical properties (lack of exposure under any emission scenario) and the potential for atmospheric degradation do not indicate a risk to the atmosphere by the use of Flocoumafen bait.

Aquatic compartment (incl. sediment and STP)

There are no direct and indirect releases of Flocoumafen to surface water for the intended use (wax block, in and around buildings). In view of the envisaged use pattern, that includes cleaning operations at the end of a campaign to remove carcasses and residual bait, exposure to the STP is considered negligible (ESD, 'in and around buildings').

Terrestrial compartment

The $PNEC_{soil}$ for Flocoumafen was derived to be 0.242 mg/kg dry soil, based on the new developed experimental studies for soil organisms. The estimation of emissions results in predicted concentrations in natural wet soil, therefore the PNEC were converted accordingly. The conversion factor for wet/dry weight soil as specified by equation 82b in the Guidance on Biocidal Products Regulations Volume IV Environment Part B (Guidance on BPR IV/B, 2015) has a numerical value of 1.13.
$PNEC_{soil}$ = 0.21 mg/kg wet soil

Calculated PEC/PNEC values		
Application in and around buildings	**$PEC/PNEC_{soil}$** old PNEC = 0.0126 mg/kg wwt **(AR Flocoumafen 2009)**	**$PEC/PNEC_{soil}$** new PNEC = 0.21 mg/kg wwt
Typical case	0.54	0.010
Realistic worst case	0.16	0.032

Conclusion: The PEC/PNEC ratio is <1. Thus the risk to soil organisms is considered to be acceptable. However, the above presented PECs from the concentration in soil for the burrow baiting scenario are related to a local environment only. Thus, these values are not to be confounded with the normal PECsoil since the regarded soil volume in this scenario is only an insignificant fraction of a local terrestrial environment and therefore the concept of PEC derivation is not applicable. In conclusion, a risk characterisation considering the whole soil volume as in usual PEC soil calculations would result in no risk at all.

Groundwater

Due to very low soil concentrations, the restricted use pattern, the low water solubility (0.114 mg/L at at 20 °C, pH 7) and the strong adsorption of the active substance (Koc = 101 684 L/kg) to soil, Flocoumafen is not considered to leach to groundwater and hence no PECgroundwater was calculated.

A Tier 1 groundwater assessment was performed. The concentration in porewater of 0.0038 µg/L (realistic worst case); 0.0011 µg/L (typical case) and 0.036 µg/L (burrow baiting) show that the expected concentration of Flocoumafen is far below the drinking water threshold of 0.1 µg/L.

Primary and secondary poisoning

Flocoumafen is very toxic to birds and non-target mammals which may be exposed either directly by ingestion of baits or indirectly via the food chain by contaminated rodents.

The following risk quantification is in line with the Guidance on BPR, Volume IV Environment and therefore also with the TGD addendum for $PNEC_{oral}$ derivation of anti-coagulant rodenticides developed in 2006. This quantitative risk assessment for long-term exposure situations requires a tiered approach for assessing the risks:

	Primary poisoning	**Secondary poisoning**
Tier 1	Risk is quantified as the ratio between the concentration in the food for the non-target organism (PECoral) and the predicted no-effect-concentration for oral intake for the non-target organism (PNECoral)	Risk is quantified as the ratio between the concentration in the rodent immediately after a last meal on day 5 (EC5) and the predicted no-effect-concentration for oral intake for the non-target organism (PNECoral)
Tier 2	Risk is quantified as the ratio between the estimated daily intake of a compound (ETE) and the predicted no-effect-concentration for oral intake for the non-target organism (PNECoral). For the long-term exposure the estimated concentration of the active substance in the animal can be calculated and compared with the NOAEL.	Risk is quantified as the ratio between the estimated concentration in predatory mammals or birds and the no-observed-adverse-effect levels (NOAEL) for the organism.

Since no guideline is available how to derive a PNECoral for an acute exposure situation, the acute primary and secondary poisoning are only accomplished as qualitative risk assessment:

- Primary poisoning, Tier 1 (concentration in bait versus PNEC in food)
- Primary poisoning, Tier 2 for 1 day exposure
- Secondary poisoning; Tier 1 for acute exposure

For the following exposure scenarios a quantitative risk assessment is available:

- Primary poisoning, Tier 2 for 5 day exposure
- Secondary poisoning, Tier 1 (long-term exposure)
- Secondary poisoning, Tier 2 (long-term exposure)

Primary and secondary poisoning of birds and mammals in this risk characterisation are based on the scenario "in and around buildings".

Primary poisoning

Even if direct bait ingestion of non-target vertebrates is unwanted and only accidental poisoning, a worst case scenario for primary poisoning of birds as well as livestock and pets were calculated as requested by the EUBEES-ESD for rodenticides.

The amount of accidentally ingested Flocoumafen directly depends on the accessibility of the bait point content. Since the maximum amount of bait at one bait point is 75 g (0.0025% Flocoumafen), the worst case ingestion would be 1.875 mg Flocoumafen with a potential accessibility of 100 %. Hence, the quantity of Flocoumafen with an accessibility of 10% would be 0.19 mg.

As requested by the EUBEES-ESD, the risk characterisation for the worst-case scenario primary poisoning of birds as well as livestock and pets is performed on the basis of the estimated daily uptake (ETE), which may be considered as a surrogate for a PEC.

The first tier assessment for short term exposure assumes that there is no bait avoidance by the non-target animals and that ingested Flocoumafen amount depends directly on the accessibility of the bait point content.

The first tier of short term exposure assessment assumes that there is no bait avoidance by the non-target animals and that they obtain 100 % of their diet in the treated area. This assumption is considered as absolute worst case since non-target animals would have unlimited direct access to formulated products. In the second tier, the avoidance factor and the fraction of diet obtained in treated area are set to 0.9 and 0.8, respectively, according to EUBEES defaults and the elimination was based on 0.7 and 0.3 for birds, and mammals respectively, instead of 1. These values were compared in a qualitative assessment with the LD50 values for mammals/birds.

Qualitative assessment of acute exposure (1 meal) of non-target animals with single dose LD50 values.

Species	Estimated daily uptake of Flocoumafen [mg/kg]			LD50 [mg/kg bw]
	Normal use	Realistic worst case		
		Tier 1	Tier 2	
Dog	≅ 0	1.5	1.08	0.13 (rat)
Pig	≅ 0	0.19	0.14	0.13 (rat)
Pig, young	≅ 0	0.6	0.43	0.13 (rat)
Tree sparrow	≅ 0	8.64	6.22	24 (*Anas platyrhynchos*)
Chaffinch	≅ 0	7.5	5.4	24 (*Anas platyrhynchos*)
Woodpigeon	≅ 0	2.71	1.95	24 (*Anas platyrhynchos*)
Pheasant	≅ 0	2.69	1.94	24 (*Anas platyrhynchos*)

Step 1: AV= 1, PT = 1, PD = 1 and EL = 0; Step 2: AV= 0.9, PT = 0.8, PD = 1 and EL = 0

Qualitative assessment of acute exposure (1 meal and 24 h elimination) of non-target animals with single dose LD50 values.

Species	Estimated daily uptake of Flocoumafen [mg/kg]		LD50 [mg/kg bw]
	Normal use	Realistic worst case	

		Tier 1	Tier 2	
Dog	≅ 0	1.05	0.76	0.13 (rat)
Pig	≅ 0	0.13	0.09	0.13 (rat)
Pig, young	≅ 0	0.42	0.30	0.13 (rat)
Tree sparrow	≅ 0	2.59	1.87	24 (*Anas platyrhynchos*)
Chaffinch	≅ 0	2.25	1.62	24 (*Anas platyrhynchos*)
Woodpigeon	≅ 0	0.81	0.59	24 (*Anas platyrhynchos*)
Pheasant	≅ 0	0.81	0.58	24 (*Anas platyrhynchos*)

Step 1: AV= 1, PT = 1, PD = 1 and EL = 0.3 (mammals) and 0.7 (birds); Step 2: AV= 0.9, PT = 0.8, PD = 1 and EL = 0.3 (mammals) and 0.7 (birds)

The results of the of the qualitative assessment show in some cases that the ETE is below the single dose LD50 values. Nevertheless, a primary poisoning hazard for non-target animals could be identified due to the fact that it is a simple comparison of the acute exposure situation with the single dose LD50. The identified hazard is not unexpected since the assumption is made that their diet exclusively or predominantly consists of rodenticide bait.

Risk assessment for long-term primary poisoning

The long-term assessment is a refinement of the acute exposure and is estimated by assessing the amount of food after 5 meals. As given in the guidance, the Tier 1 worst case exposure estimates were based on neither avoidance nor elimination and 100% diet from the treated area. Whereas, in the Tier 2 long-term estimates the same reductions are considered as in short-term Tier 2 estimation with moderate corrections for avoidance (0.9), food ratio (0.8) and elimination (0.3 for mammals and birds).

Long-term PEC/PNECoral for non-target mammals and birds (Flocoumafen uptake by non-target animals via primary poisoning after 5 meals followed by elimination period, (Flocoumafen: 0.0025%).

Species	Estimated uptake of Flocoumafen after 5 meals [mg/kg/d] (EC5)		PNEC	PEC/PNEC	
	Tier 1	Tier 2		Tier 1	Tier 2
Dog	4.16	2.99	0.000028	~148,600	~106,800
Pig	0.52	0.37	0.000028	~18,600	~13,200
Pig, young	1.66	1.22	0.000028	~59,300	~43,600
Tree sparrow	12.31	8.86	0.00025	~49,200	~35,400
Chaffinch	10.69	7.70	0.00025	~42,800	~30,800
Woodpigeon	3.86	2.78	0.00025	~15,400	~11,100
Pheasant	3.84	2.76	0.00025	~15,400	~11,000

A high risk was identified when the PNECoral is compared to the estimated uptake of Flocoumafen over 5 consecutive days. In both Tiers for long-term exposure, dogs have the highest risk with PEC/PNEC ratio considering mammal species and sparrow of the bird species. In summary, small animals are at higher risk than larger animals.

Data from field trials and laboratory experiments

The notifier claims that, when Storm Ultra 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 field trials in the final CAR of Flocoumafen, 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 specimen contained Flocoumafen residues.

Conclusion
When comparing the concentration of Flocoumafen in food with the PNECoral a high risk can be identified. Regarding the short-term exposure at Tier 2, ETE values after 1 meal for non-target mammals exceed the lowest LD50 values for mammals both without and with excretion.

ETE values after 5 days intake of Flocoumafen (long-term exposure) are higher than those after a single day of exposure. Even though excretion from the non-target animal is anticipated accumulation of Flocoumafen in the non-target animals outweigh loss of Flocoumafen in non-target animals due to excretion. For the long-term assessment all PEC/PNECoral ratios are far above one. In general small animals have a higher risk than large ones.
The worst-case PEC/PNEC ratio for birds at step 1 is about **49,200** (sparrow) and about **148,600** for mammals (dog).

The worst-case PEC/PNEC ratio for birds at step 2 is about **35,400** (sparrow) and about **106,800** for mammals (dog).

Worst case assumptions have been made. It was assumed that the non-target animals have fed entirely, respectively mostly, on Flocoumafen containing products (PT was 1 and 0.8, respectively) and that no avoidance (AV = 1) respectively little avoidance (AV = 0.9) occurred due to bait blocks. Consumption of these quantities of Flocoumafen containing products is clearly a worst case and the risk in reality might probably not be as high as presented in these scenarios.

Based on the maximum recommended baiting regime that entails deployment of for example 75 g bait per secured bait point, the daily food intakes of 600 g for both dogs and pigs correspond to the contents of 10 bait points, respectively. However, as the PEC/PNEC ratio for dogs is above 100,000 the PEC/PNECoral value below 1 for dogs would only be achieved if the daily intake of bait blocks/pellets by dogs was less than 0.01 % of its daily food requirement (3 mg bait per day for dogs). This is much less than the weight of one bait block (5 or 25 g). As the EC5 is higher than the EC1 (ETE after 1 day) these values would be lower for the long-term assessment.

The values for birds are in the same range. Based on the recommended baiting regime that entails deployment of a maximum of 75 g bait blocks per secured bait point, the daily food intakes of 7.6, 6.42, 53.1 and 102.7 g for *P. montanus* (Tree sparrow), *F. coelebs* (Chaffinch), *C. palumbus* (Wood pigeon) and *P. colchicus* (Pheasant) correspond to the contents of at least 9, 11, 1 and 0.6 full bait boxes, respectively. It is unlikely that such amounts of bait would be available to the larger birds whereas smaller species may be able to reach bait inside the bait boxes by entering through the access hole, simply on the basis of their size. However, PEC/PNEC ratios for bigger birds are above 10,000 and for smaller birds above 30,000. Values below 1 for the different bird species would only be

achieved if the daily intake of bait blocks by birds were below 0.1 % of their daily food requirement.

Field monitoring data indicate that primary poisoning of birds and non-target mammals entering bait boxes cannot fully excluded and that risks will occur. The number of victims (non-rodent mammals and birds) found is, however, low. It should be noticed that in the field studies conducted in the past not all risk mitigation methods had been implemented which are in place now are obligatorily to be applied (see below)

Possible measures to reduce the risk of primary poisoning to non-target animals
As indicated by the PEC/PNEC ratios presented in the above tables, there is a clear primary poisoning hazard for non-target animals if the assumption is made that their diet exclusively or largely consists of rodenticide bait. This is the case regardless of whether moderate corrections for avoidance and food ratio are made. This necessitates the stringent use of careful baiting practice to avoid negative impact on non-target species. This is also acknowledged by the EUBEES-ESD, which states that normal use (adherence to good baiting practice) is expected to minimise primary poisoning hazards. In that case, exposure levels and PEC/PNEC ratios for normal use are estimated to be close to zero. The claim of negligible primary hazard is accepted provided that the submitted directions for use are made sufficiently strict to ensure negligible primary exposure of non-target animals. The adaptation must include that bait is placed in specially designed baiting boxes inaccessible to children and non-target animals. In case any other bait covers are used, it should be explicitly stated that these other covers should be tamper proof and heavy enough to avoid displacement by non-target organisms.
Conclusion: Calculated risks of primary poisoning are high. It is recognised, however, and confirmed in field trials with Flocoumafen, that the risk of Flocoumafen-poisoning of livestock and household animals as well as of wild seed-eating birds can be reduced when the rodenticide is handled with diligence and care (adherence to good baiting practice).

Secondary poisoning

Secondary exposure as a result of consumption of contaminated fish

Due to the lack of exposure of surface water to Flocoumafen from rodenticide baiting campaigns in and around buildings, a risk for the environment via the aquatic food chain can be safely excluded.

Secondary exposure as a result of consumption of contaminated earthworms

For the exposure assessment of non-target earthworm eating predators the concentration in earthworms was estimated for three scenarios: (1) worst case and (2) typical case, both derived from heterogeneous release related to the surface of 550 m² for application in and around buildings since it is considered that earthworms further away from the bait stations are the primary food source for predators. The third scenario is based on (3) 50% of the maximum PECsoil as input parameter for the calculation of the concentration in earthworms.

Summary table on secondary poisoning						
Scenario	**Exposure**	**PEC_{oral} predator**	**$PNEC_{bird}$**	**PEC/$PNEC_{birds}$**	**$PNEC_{mammals}$**	**PEC/PNEC mammals**
Application in and around	Realistic worst case	0.054	0.0021	**25.7**	0.00056	**96.4**
	Typical case	0.016	0.0021	**7.6**	0.00056	**28.6**

buildings	50% of maximum PEC_{soil}	0.027	0.0021	**12.9**	0.00056	**48.2**

Conclusion: The risk of poisoning via contaminated earthworms for all scenarios is considered to be high (PEC/PNEC > 1) for mammals and birds. However, the risk calculated here can be considered as very worst case since it was concluded by the RMS from the study on earthworm bioaccumulation that the actual bioaccumulation is clearly lower than the calculated BCF as Flocoumafen is actually rapidly eliminated from earthworms. Similarly, the uptake by earthworms is slow due to the strong adsorption of Flocoumafen to soil and its low water solubility.

Secondary exposure as a result of consumption of contaminated rodents

As described above the risk assessment for acute exposure is presented as qualitative assessment only in contrast to the risk assessments for long-term exposure which are estimated as quantitative risk assessment in agreement with the guidance laid down in the EUBEES ESD document and the Guidance on BPR, Volume IV Environment.

Tier 1 risk assessment for short-term secondary poisoning (qualitative assessment)

Since no PNECoral was estimated, the qualitative risk assessment is based on the comparison of predicted effect concentration with the short-term LC50 value for birds (4.1 mg/kg food). For mammals no such short-term value was determined.

For this comparison the worst case assumption is used as PECoral, predator which assumes that the target rodents consumed 100% of their daily food requirements with baits on 5 successive days. Furthermore, the non-target animals satisfy 100% of their daily requirements with poisoned rats. The maximum residue level is therefore 6.93 mg/kg food.

Time	Residues of Flocoumafen in target rodent [mg/kg bw]			LC50 (mallard duck) [mg/kg food]
	Worst case 100% bait consumption	**Intermediate case** 50% bait consumption	**Normal case** 20% bait consumption	
Day 5, after the last meal	6.93	3.47	1.39	4.1

Compared to the LC50 value for birds, the risk is acceptable after one single meal if the residue level is based on 50% bait consumption (3.47 mg/kg food).

Tier 1 risk assessment for long-term secondary poisoning (quantitative assessment)

For a long-term assessment it is assumed that the target rodents have fed entirely on rodenticide baits and that 50% of the non-target animal's prey are contaminated rats. Furthermore, the rodent bait consumption is assessed as graded refinement to be also 0.5 and 0.2 of the daily uptake.
The results for non-target birds and mammals are shown in the table below:

Species	**PEC [mg/kg rodent]**	**PEC/PNEC**

	Worst case	Intermediate case	Normal case	Worst case	Intermediate case	Normal case
Birds (PNEC = 0.0021 mg/kg diet)	3.40	1.70	0.68	~1,700	~850	~350
Mammals (PNEC = 0.00056 mg/kg diet)	3.40	1.70	0.68	~6,200	~3,100	~1,200

The risk of secondary poisoning for birds and mammals is considered to be high, based on the above PEC/PNEC values.

Tier 2 risk assessments for long-term secondary poisoning (quantitative assessment)

In the second tier approach the predicted effect concentrations are estimated in comparison to the specific food intake and body weights of the predators as described above.

Species	Rodents caught on day 5		PNEC [mg/kg bw]	PEC/PNEC	PEC/PNEC
	Before their last meal	After their last meal			
	Concentration in predator [mg/kg bw predator]				
Barn Owl	0.55	0.86	0.00025	~2,200	~3,450
Kestrel	0.83	1.31	0.00025	~3,300	~5,250
Little Owl	0.63	0.98	0.00025	~2,500	~3,900
Tawny Owl	0.51	0.79	0.00025	~2,050	~3,150
Fox	0.20	0.32	0.000028	~7,200	~11,400
Polecat	0.42	0.66	0.000028	~15,000	~23,600
Stoat	0.60	0.94	0.000028	~21,500	~33,600
Weasel	0.87	1.36	0.000028	~31,000	~48,600
Dog	0.10	0.16	0.000028	~ 3,600	~ 5,700

The risk of secondary poisoning for wild-life bird and mammal predators is very high under the assumption of one exposure day. Therefore, it is not required to estimate the risk for several days.

Tier 3: Field data on residues in target organisms

Residues were determined in rats, house mice and non-target rodents collected (carcasses) or live-trapped during the non-target hazard field trials (data already submitted during active substance authorisation). These data were considered acceptable and relevant for risk assessment and are used as the basis for evaluating the usefulness of the EUBEES estimates above.
In the table below an overview is presented of Flocoumafen residue levels in dead and alive rodents during rat control campaigns.

Sample type	Residue concentration [mg/kg]				
	Restricted baiting (B7.8.7.1/07)		Saturation baiting (B7.8.1/05)		
Species (B7.8.7.1/07)	n	Mean (range)	Species (B7.8.1/05)	n	Mean (range)
Rats found dead	21	0.45 (0.06-2.3)	Rat surface	12	1.1 (0.2-2.8)
			Rat sub-surface	12	1.3 (0.2-2.9)
Rats, trapped	17	0.8 (<0.01-2.3)			
Small rodents found dead	2	0.67 (0.65-0.69)	House mouse	6	3.5 (0.4-8.7)
			Wood mouse	7 (2)	1.6 (0.4-3.0)
			Voles	3	2.2 (0.9-4.3)
Small rodents, trapped	20	0.08 (<0.01-0.43)			

Residue data in carcasses were taken from references and pooled across the above studies, resulting in group-specific data sets for rat carcasses, trapped rats and small mammals (house mice, wood mice and bank voles mixed), respectively. Within each of these groups, data were approximately log-normally distributed, as confirmed by histogram plots. Trapped small rodents comprised of approx. 50 % animals without detectable Flocoumafen residues and were therefore not suitable for the percentile-based exposure estimation as set out below.

To obtain realistic worst case and normal case estimates of EC_{rodent}, the 90^{th} percentile (worst case) and the median (normal case) were calculated based on the log-transformed data for each of the above groups. Back-transformed quantiles, representing EC_{rodent}, are presented in Table below.

Residues from	EC_{rodent} [mg/kg b.w.]	
	Median (normal case)	90^{th} percentile (worst case)
Rat carcases	0.55	2.33
Trapped rats	0.87	2.54
Small rodent carcases	1.49	5.2

The EC_{rodent} values based on residue data were obtained under real-world conditions and are thus deemed to be reliable and relevant. Since the values for small rodents represent the upper limit within the residue data and mice and voles comprise the bulk of the prey of most predators, the small rodent data are considered most relevant.

The small rodent residues presented in the table above are well in line with the Tier 2 EUBEES estimates of EC_{rodent} given above (1.39–6.93 mg/kg bw). Accordingly, the Tier 2 estimates may be considered to be validated by field data and are therefore taken forward to the risk characterisation.

Conclusion for primary and secondary poisoning (consumption of contaminated rodents):

The aim of a rodenticide is to control rodent pests, which inevitably entails a risk of secondary poisoning of predators and scavengers. Primary exposure of non-target animals may also occur. An assessment based on theoretical assumptions indicates a risk of primary and secondary poisoning by Flocoumafen.
The risk to non-target mammals and birds may be overestimated because they do not take behavioural factors into account, such as specific feeding behaviour (only feeding on the less contaminated sections of a carcass, several species are generally gregarious and may consequently pick at the same carcass thus lowering the individual exposure).

Data from monitoring studies of wildlife mortalities show only a few isolated incidents of poisoning by Flocoumafen of non-target non-rodent mammals and birds. Identified cases in 3 studies were one barn owl, one cat, one stoat, one rabbit and one hedgehog. On the other hand the same studies show that non-target rodents such as house mouse, wood mouse and vole have a high risk for primary poisoning. Furthermore the PEC/PNEC ratios do not include the possibility of recurrent exposure. Many predatory birds are territorial and may therefore actively hunt in areas where they have experienced good success, even feeding young birds with contaminated prey. The latter exposure route to young birds was not part of the emission scenarios. In one study however it was stated that a total of 15 bird nests were recorded. Apart from one pheasant nest that was deserted early in the baiting period, all other birds reproduced successfully. Whether this is analysis is complete and representative for other campaigns is not known.

To conclude, Flocoumafen causes a high risk for secondary poisoning in field studies a clear primary poisoning risk was identified for non-target rodents. As non-target and target rodents have a similar feeding behaviour, it will be impossible to reduce the risks for non-target rodents. The true primary and secondary poisoning risks posed to non-target non-rodent mammals and birds by Flocoumafen containing products might be lower than those indicated in the quantitative assessment of risk as a result of mitigating factors. The most significant reductions in exposure and risk are achieved by restricting its use to treatment campaigns of limited duration, limiting access of non-target animals to the bait and removing unused bait and dead and moribund rodents during a baiting campaign to minimise the opportunity of primary secondary exposure of non-target animals.

Overall conclusion on the risk assessment for the environment of the product
Safe use for the environmental compartments air, water, sediment and soil could be demonstrated. Flocoumafen may cause high risk for primary and secondary poisoning. The risk posed to non-target mammals and birds might be reduced by mitigating factors. The most significant reductions in exposure and risk are achieved by restricted use during baiting campaigns, limiting the access of non-target animals to the bait by bait box use and removing unused bait and dead and moribund rodents during the baiting campaign.

2.2.9 Measures to protect man, animals and the environment

Recommended methods and precautions concerning handling, use, storage, transport or fire

Precautions of safe handling

No special measures necessary if stored and handled correctly. If dead and/or dying rats or mice are found during and after the control program, these must be cleared away immediately in order to avoid secondary poisoning. Do not apply in the open – cover bait points or use bait boxes. When using do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift. Ensure through ventilation of stores and work areas.

Avoid dust formation. Avoid deposition of dust. Dust can form an explosive mixture with air. Prevent electrostatic charge – sources of ignition should be kept well clear – fire extinguishers should be kept handy.

Conditions of safe storage, including any incompatibilities

Segregate from foods and animal feeds.
Further information on storage conditions: Keep away from heat. Protect against moisture. Protect from direct sunlight.

Protect from temperatures above: 30°C

Change in properties of the product may occur if substance/product is stored above indicated temperature for extended periods of time.

Recommended methods and precautions concerning handling and transport

No special measures necessary if transported. Not classified as dangerous good under transport regulations.

Recommended methods and precautions concerning fire; in case of fire nature of reaction products, combustion gases etc.

Extinguishing media:
Suitable extinguishing media: dry powder, foam, water spray
Unsuitable extinguishing media for safety reasons: carbon dioxide

Special hazards arising from the substance or mixture:

Flocoumafen consists exclusively of the elements carbon, oxygen and hydrogen and fluorine. Thus, hydrogen fluoride may be formed upon ignition. Other reaction products: carbon dioxide (CO_2), water (H_2O) and, under unfavourable conditions like oxygen deficit, carbon monoxide (CO) are to be expected.

Advice for fire-fighters

Special protective equipment: Wear self-contained breathing apparatus and chemical-protective clothing.
Further information: In case of fire and/or explosion do not breathe fumes. Keep containers cool by spraying with water if exposed to fire. Collect contaminated extinguishing water separately; do not allow reaching sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

Recommended accidental release measures

Personal precautions: Use personal protective clothing. Avoid contact with the skin, eyes and clothing. Avoid dust formation.

Environmental precautions

Do not discharge into the subsoil/soil. Do not discharge into drains/surface waters/groundwater.

Methods for cleaning up or taking up

For small amounts: Contain with dust binding material and dispose of.
For large amounts: Sweep/shovel up.
For residues: Pick up with suitable appliance and dispose of.

Avoid raising dust. Dispose of absorbed material in accordance with regulations. Collect waste in suitable containers, which can be labelled and sealed. Clean contaminated floors and objects thoroughly with water and detergents, observing environmental regulations.

Recommended first-aid measures

Remove contaminated clothing.

If inhaled:
Keep patient calm, remove to fresh air.

On skin contact:
Immediately wash thoroughly with soap and water.

On contact with eyes:
Rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
On ingestion:
If swallowed, seek medical advice immediately and show this container or label. Do not induce vomiting.

Rinse mouth and then drink plenty of water.

Note to physician
Treatment: Symptomatic treatment (decontamination, vital functions).
Antidote: Vitamin K1 preparation as antidote.

2.2.10 Assessment of a combination of biocidal products

Storm Ultra is not foreseen for the use with other biocidal products.

2.2.11 Comparative assessment

The RMS has processed an application for authorisation for the biocidal product Storm Ultra which contains the active substance Flocoumafen. The active substance Flocoumafen meets the criteria for exclusion according to Article 5(1) BPR as well as for substitution according to Article 10 BPR (for details see chapter 2.2.3).
Therefore, in line with Article 23 (1) BPR a comparative assessment for the product Storm Ultra has to be conducted.

At the 60th meeting of representatives of Members States Competent Authorities for the implementation of BPR held on 20 and 21 May 2015, all Member States submitted to the Commission a number of questions to be addressed at Union level in the context of the comparative assessment to be carried out at the renewal of anticoagulant rodenticide biocidal products ('anticoagulant rodenticides'). The questions submitted were the following:
(a) Is the chemical diversity of the active substances in authorised rodenticides in the Union adequate to minimise the occurrence of resistance in the target harmful organisms?;
(b) For the different uses specified in the applications for renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?;
(c) Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?;
d) Are these alternatives sufficiently effective?;
(e) Do these alternatives present no other significant economic or practical disadvantages?

The information addressing these questions is provided in the Annex of the Commission Implementing Decision (EU) 2017/1532 According to Article 1 of Commission Implementing Decision (EU) 2017/1532 the NL CA considered the information in the Annex during the comparative assessment of anticoagulant rodenticide biocidal products.

Conclusion
Based on the information provided in the Annex of the Commission Implementing Decision (EU) 2017/1532 the RMS came to the conclusion that in the absence of anticoagulant rodenticides, the use of rodenticides containing other active substances would lead to an inadequate chemical diversity to minimise the occurrence of resistance in the target harmful organisms. These products also showed some significant practical or economical disadvantages for the relevant uses.

The opinion also considered a number of non-chemical control or prevention methods ("non-chemical alternatives"), which may provide sufficient efficacy in certain circumstances on their own or in a combination of them. However, there is insufficient scientific evidence to prove that those non-chemical alternatives are sufficiently effective according to the criteria established in agreed Union guidance (1) with a view to prohibit or restrict the authorised uses of anticoagulant rodenticides.

In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled. Therefore, the authorisation of the product Storm Ultra will be granted.

3 ANNEXES

3.1 List of studies for the biocidal product

Section No acc. to Reg 528/2012. chapter III	**Author**	**Year**	**Title** **Test facility** **GLP status, published or not**	**Owner of data**	**Letter of Access (Yes/No)**	**Data protection claimed (Yes/No)**
3.1 3.2 3.3 3.4.1 3.4.2.2 3.5	Weatherhead, P.	2015	Physical and chemical properties of BAS 322 20 I: Accelerated storage stability for 2 weeks at 54°C stored in a polypropylene bucket. Battelle UK Ltd., Havant, Hampshire, UK Report no. MX/15/006/1; BASF DocID: 2015/1178125 GLP, Not published	BASF	Yes	Yes
3.4.1	Weatherhead, P.	2015	**Study plan:** Physical and Chemical Properties of BAS 322 20 I: Storage Stability for 104 weeks at 25°C stored in a polypropylene bucket. Report no. MX/15/007/1 Battelle UK Ltd., Havant, Hampshire, UK GLP, Not published Results should be available in August 2017.	BASF	Yes	Yes
3.4.1	Weatherhead, P.	2017	Physical and Chemical Properties of BAS 322 20 I: Storage Stability for 104 weeks at 25°C stored in a polypropylene bucket. Report no. MX/15/007/1, BAS DocID: 2017/1136269 Battelle UK Ltd., Havant, Hampshire, UK GLP, Not published	BASF	Yes	Yes
3.4.1	Weatherhead, P.	2015	**Study plan:** Physical and Chemical Properties of BAS 322 20 I: Storage Stability for 156 weeks at 25°C stored in a polypropylene bucket. Report no. MX/15/008/1	BASF	Yes	Yes

Section No acc. to Reg 528/2012. chapter III	**Author**	**Year**	**Title** **Test facility** **GLP status, published or not**	**Owner of data**	**Letter of Access (Yes/No)**	**Data protection claimed (Yes/No)**
			Battelle UK Ltd., Havant, Hampshire, UK GLP, Not published Results should be available in August 2018.			
3.4.1	Weatherhead, P.	2015	**Study plan:** Physical and Chemical Properties of BAS 322 20 I: Storage Stability for 260 weeks at 25°C stored in a polypropylene bucket. Report no. MX/15/009/1 Battelle UK Ltd., Havant, Hampshire, UK GLP, Not published Results should be available in August 2020.	BASF	Yes	Yes
4.1 4.2 4.4 4.17	Dreisch, S.	2015	Determination of physico-chemical properties according to UN Transport Regulations and Directive 94/37/EC (Regulation (EC) No. 440/2008 Report no. CSL-15-0961.01; BASF DocID: 2015/1179303 Consilab Gesellschaft für Anlagensicherheit mbH, Industriepark Höchst, Frankfurt a.M., Germany GLP, Not published	BASF	Yes	Yes
5	Weatherhead, P.	2015	Additional validation of analytical method AFL0199/04 for the determination of active ingredient in BAS 322 20 I. Report no. MX/15/010/1; BASF DocID: 2015/1132576 Battelle UK Ltd., Havant, Hampshire, UK GLP, Not published	BASF	Yes	Yes
5	Weatherhead, P.	2011	HPLC method for the determination of flocoumafen BAS 322 07 I rodenticide baits using acid digestion Report no. MX/10/022/2; BASF DocID: 2011/1177797 Battelle UK Ltd., Havant, Hampshire, UK	BASF	Yes	Yes

Section No acc. to Reg 528/2012. chapter III	**Author**	**Year**	**Title** **Test facility** **GLP status, published or not**	**Owner of data**	**Letter of Access (Yes/No)**	**Data protection claimed (Yes/No)**
			GLP, Not published			
5	Weatherhead, P.	2011	Validation of the analytical method AFL0199/04 HPLC method for the determination of BAS 322 07 I Report no. MX/10/022/2; BASF DocID: 2011/1177798 Battelle UK Ltd., Havant, Hampshire, UK GLP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Three day no-choice unrestricted feeding test on 25 ppm flocoumafen 25 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Rattus norvegicus, Wistar strain. Report no. LR029/14; BASF DocID: 2014/1273314 [redacted] GEP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Three day no-choice feeding test on 25 ppm flocoumafen 25 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Rattus norvegicus, Hampshire (difenacoum and bromadiolone tolerant) strain. Report no. LR031/14; BASF DocID: 2014/1273316 [redacted] GEP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Three day no-choice feeding test on 25 ppm flocoumafen 25 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Rattus norvegicus, Welsh (first generation anticoagulant resistant) strain Report no. LR032/14; BASF DocID: 2014/1273317 [redacted] GEP, Not published	BASF	Yes	Yes

Section No acc. to Reg 528/2012. chapter III	**Author**	**Year**	**Title** **Test facility** **GLP status, published or not**	**Owner of data**	**Letter of Access (Yes/No)**	**Data protection claimed (Yes/No)**
6.7	[redacted]	2014	Three day no-choice feeding test on 25 ppm flocoumafen 25 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Rattus norvegicus, Berkshire (difenacoum and bromadiolone resistant) strain. Report no. LR033/14; BASF DocID: 2014/1273318 [redacted] GEP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Three day no-choice unrestricted feeding tests on 25 ppm flocoumafen 4 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Rattus norvegicus, Wistar strain. Report no. LR042/14; BASF DocID: 2014/1321393 [redacted] GEP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Three day no-choice feeding tests on 25 ppm flocoumafen 4 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Rattus norvegicus, Hampshire (difenacoum and bromadiolone tolerant) strain. Report no. LR045/14; BASF DocID: 2014/1321413 [redacted] GEP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Three day no-choice feeding tests on 25 ppm flocoumafen 4 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Rattus norvegicus, Berkshire (difenacoum and bromadiolone resistant) strain. Report no. LR046/14; BASF DocID: 2014/1321414 [redacted] GEP, Not published	BASF	Yes	Yes

Section No acc. to Reg 528/2012. chapter III	**Author**	**Year**	**Title** **Test facility** **GLP status, published or not**	**Owner of data**	**Letter of Access (Yes/No)**	**Data protection claimed (Yes/No)**
6.7	[redacted]	2014	Choice feeding test on 25 ppm flocoumafen 25 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Rattus norvegicus, Wistar strains Report no. LR024/14; BASF DocID: 2014/1273288 [redacted] GEP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Choice feeding test on 25 ppm flocoumafen 25 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Rattus norvegicus, Welsh (first generation anticoagulant restistant) strain. Report no. LR026/14; BASF DocID: 2014/1273303 [redacted] GEP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Choice feeding test on 25 ppm flocoumafen 25 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Rattus norvegicus, Hampshire (difenacoum and bromadiolone tolerant) strain. Report no. LR027/14; BASF DocID: 2014/1273304 [redacted] GEP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Choice feeding test on 25 ppm flocoumafen 25 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Rattus norvegicus, Berkshire (difenacoum and bromadiolone resistant) strain. Report no. LR028/14; BASF DocID: 2014/1273305 [redacted] GEP, Not published	BASF	Yes	Yes

Section No acc. to Reg 528/2012. chapter III	**Author**	**Year**	**Title** **Test facility** **GLP status, published or not**	**Owner of data**	**Letter of Access (Yes/No)**	**Data protection claimed (Yes/No)**
6.7	[redacted]	2014	Choice feeding test on 25 ppm flocoumafen 4 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Rattus norvegicus, Wistar strain. Report no. LR037/14; BASF DocID: 2014/1321332 [redacted] GEP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Choice feeding test on 25 ppm flocoumafen 4 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Rattus norvegicus, Welsh (first generation antocoagulant resistant) strain. Report no. LR039/14; BASF DocID: 2014/1321337 [redacted] GEP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Choice feeding test on 25 ppm flocoumafen 4 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Rattus norvegicus, Hampshire (difenacoum and bromadiolone tolerant) strain Report no. LR040/14; BASF DocID: 2014/1321372 [redacted] GEP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Choice feeding test on 25 ppm flocoumafen 4 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Rattus norvegicus, Berkshire (difenacoum and bromadiolone resistant) strain. Report no. LR041/14; BASF DocID: 2014/1321392 [redacted] GEP, Not published	BASF	Yes	Yes

Section No acc. to Reg 528/2012. chapter III	**Author**	**Year**	**Title** **Test facility** **GLP status, published or not**	**Owner of data**	**Letter of Access (Yes/No)**	**Data protection claimed (Yes/No)**
6.7	Hughes, C.S.	2014	Field trial study on 25 ppm flocoumafen 25 g [redacted] Block Rodenticide Bait (BAS 322 HF I) for the control of the Norway rat, Rattus norvegicus, at Carrigeen House Fram, County Waterford, Ireland (experiment number 9211). Report no. LR053/14; BASF DocID: 2014/1321674 BASF, Liverpool Laboratory, UK GEP, Not published	BASF	Yes	Yes
6.7	Hughes, C.S.	2014	Field trial study on 25 ppm flocoumafen 25 g [redacted] Block Rodenticide Bait (BAS 322 HF I) for the control of the Norway rat, Rattus norvegicus, at Ballyboy Farm, County Tipperary, Ireland (experiment number 9212). Report no. LR054/14; BASF DocID: 2014/1321675 BASF, Liverpool Laboratory, UK GEP, Not published	BASF	Yes	Yes
6.7	Hughes, C.S.	2014	Field trial study on 25 ppm flocoumafen 4 g [redacted] Block Rodenticide Bait (BAS 322 HF I) for the control of the Norway rat, Rattus norvegicus, at Coppers Bar, County Tipperary, Ireland (experiment number 9213). Report no. LR052/14; BASF DocID: 2014/1321673 BASF, Liverpool Laboratory, UK GEP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Pen Trial Study On 25ppm Flocoumafen, 25g, [redacted] Block Bait (BAS 322 HF I), Using Pulse Baiting Method, Against A Colony Of Wild Derived Rattus rattus. Report no. LR018/14; BASF DocID: 2014/1273287 [redacted] GEP, Not published	BASF	Yes	Yes

Section No acc. to Reg 528/2012. chapter III	**Author**	**Year**	**Title** **Test facility** **GLP status, published or not**	**Owner of data**	**Letter of Access (Yes/No)**	**Data protection claimed (Yes/No)**
6.7	[redacted]	2014	Pen trial study on 25 ppm flocoumafen, 4 g, [redacted] Block Bait (BAS 322 HF I), using pulse baiting method, against a colony of wild derived Rattus rattus. Report no. LR047/14; BASF DocID: 2014/1321672 [redacted] GEP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Three day no-choice unrestricted feeding test on 25 ppm flocoumafen 25 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Mus domesticus, CD1 strain. Report no. LR030/14; BASF DocID: 2014/1273315 BASF, Liverpool Laboratory, UK. GEP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Three day no-choice unrestricted feeding tests on 25 ppm flocoumafen 4 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Mus domesticus, CD1 strain Report no. LR045/14; BASF DocID: 2014/1321412 [redacted] GEP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Choice feeding test on 25 ppm flocoumafen 25 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Mus domesticus, CD1 strain. Report no. LR025/14; BASF DocID: 2014/1273289 [redacted] GEP, Not published	BASF	Yes	Yes
6.7	[redacted]	2014	Choice feeding test on 25 ppm flocoumafen 4 g [redacted] Block Rodenticide Bait (BAS 322 HF I) against male and female Mus domesticus, CD1	BASF	Yes	Yes

Section No acc. to Reg 528/2012. chapter III	**Author**	**Year**	**Title** **Test facility** **GLP status, published or not**	**Owner of data**	**Letter of Access (Yes/No)**	**Data protection claimed (Yes/No)**
			strain Report no. LR038/14; BASF DocID: 2014/1321335 [redacted] GEP, Not published			
6.7	[redacted]	2014	Pen trial study on 25 ppm flocoumafen, 25 g, [redacted] Block Bait (BAS 322 HF I), using pulse baiting method, against a colony of wild derived Mus domesticus, bromadiolone resistant strain (experiment 9103) Report no. LR034/14; BASF DocID: 2014/1273319 [redacted] GEP, Not published	BASF	Yes	Yes
6.7	Hughes, C.S.	2015	Field trial study on 25ppm Flocoumafen 25g [redacted] Block Rodenticide Bait (BAS 322 HF I) for the control of the house mouse, Mus domesticus, at New Crickett Farm- Site A Farm, Shropshire, England (Experiment Number 15016) Report no. LR015/15; BASF DocID: 2015/1195335 BASF plc, Pest Control Solutions. GEP, Not published	BASF	Yes	Yes
6.7	Hughes, C.S.	2018	Field trial study on Storm Ultra® Block Bait (BB), BAS 322 20 I, for the control of house mouse, *Mus musculus*, in London. Report No. LR001/18 BASF plc, Pest Control Solutions GEP, Not published	BASF	Yes	Yes
6.7	Hughes, C.S.	2018	Field trial study on Storm® Ultra Secure rodent bait (BAS 322 20 I) for the control of the Norway rat, *Rattus norvegicus*, at Old Crickett Farm, Shropshire, England Report No. LR003/18	BASF	Yes	Yes

Section No acc. to Reg 528/2012. chapter III	**Author**	**Year**	**Title** **Test facility** **GLP status, published or not**	**Owner of data**	**Letter of Access (Yes/No)**	**Data protection claimed (Yes/No)**
			BASF plc, Pest Control Solutions GEP, Not published			
8.6	Roper, C	2008	The *in vitro* percutaneous absorption of [14C] Flocoumafen through human skin. Report no. 28079; BASF DocID: 2008/1010585 Charles River, Laboratories, Tranent, UK GLP, Not published	BASF	Yes	Yes
8.6	Anonymous	2015	**CONFIDENTIAL Position Paper:** Is a dermal absorption study required with the formulation BAS 322 20 I? Report no.: not applicable; BASF DocID: 2015/1168859 EBRC Consulting GmbH, Hannover, Germany Not GLP, Not published	BASF	Yes	Yes

3.2 Output tables from exposure assessment tools

Trained professional users – in and around buildings - Tier 1: Estimated exposure to flocoumafen from 5 g block baits without gloves using 4% dermal absorption

General exposure calculator		CALCULATION	UNITS
BAS 322 20 I, wax-free block bait, 5 g			
Active substance Flocoumafen		0.0025%	% (w/w)
Density		NR	g/ml (if w/v)
		Worst case	
POTENTIAL EXPOSURE		Value	
Mixing+Loading		not relevant	
Application			
Potential dermal exposure			
Indicative value (75th percentile, HEEG Opinion; 10/05/2011)	from study of Chambers, Snowdon	5.558	mg/wax block
Bait stations (HEEG opinion, 13/08/2010)		60	
Wax blocks per station		15	
Potential dermal deposit		5002.2	mg
Penetration through gloves		100%	%
Actual dermal deposit (*product*)		5002.2	mg
Active substance		0.12506	mg
Skin penetration		4.00%	%
Active substance via the skin		5.00E-03	mg
Total potential exposure of a.s. during application		5.00E-03	mg
Total potential dose of a.s. during application		8.34E-05	mg/kg bw/d
Post-Application			
Potential dermal exposure			
Indicative value (75th percentile, HEEG Opinion; 10/05/2011)	from study of Chambers, Snowdon	5.7	mg/bait box
Bait stations cleaned-up (HEEG opinion, 13/08/2010)		15	
Potential dermal deposit		85.5	mg
Penetration through gloves		100%	%
Actual dermal deposit (*product*)		85.5	mg
Active substance		2.14E-03	mg
Skin penetration		4.00%	%
Active substance via the skin		8.55E-05	mg
Total potential exposure of a.s. during post-application		8.55E-05	mg
Total potential dose of a.s. during post-application		1.43E-06	mg/kg bw/d
Dose			
Total		5.09E-03	mg
Body weight		60	kg
Systemic dose		**8.48E-05**	**mg/kg bw**
AOEL of Flocoumafen		8.30E-06	mg/kg bw/d
% of AOEL		1021.63	%

Trained professional users – in and around buildings - Tier 2: Estimated exposure to flocoumafen from 5 g block baits with gloves using 4% dermal absorption

General exposure calculator		CALCULATION	UNITS
BAS 322 20 I, wax-free block bait, 5 g			
Active substance Flocoumafen		0.0025%	% (w/w)
Density		NR	g/ml (if w/v)
		Worst case	
POTENTIAL EXPOSURE		Value	
Mixing+Loading		not relevant	
Application			
Potential dermal exposure			
Indicative value (75th percentile, HEEG Opinion; 10/05/2011)	from study of Chambers, Snowdon	5.558	mg/wax block
Bait stations (HEEG opinion, 13/08/2010)		60	
Wax blocks per station		15	
Potential dermal deposit		5002.2	mg
Penetration through gloves		5%	%
Actual dermal deposit (*product*)		250.11	mg
Active substance		0.00625	mg
Skin penetration		4.00%	%
Active substance via the skin		2.50E-04	mg
Total potential exposure of a.s. during application		2.50E-04	mg
Total potential dose of a.s. during application		4.17E-06	mg/kg bw/d
Post-Application			
Potential dermal exposure			
Indicative value (75th percentile, HEEG Opinion; 10/05/2011)	from study of Chambers, Snowdon	5.7	mg/bait box
Bait stations cleaned-up (HEEG opinion, 13/08/2010)		15	
Potential dermal deposit		85.5	mg
Penetration through gloves		5%	%
Actual dermal deposit (*product*)		4.275	mg
Active substance		1.07E-04	mg
Skin penetration		4.00%	%
Active substance via the skin		4.28E-06	mg
Total potential exposure of a.s. during post-application		4.28E-06	mg
Total potential dose of a.s. during post-application		7.13E-08	mg/kg bw/d
Dose			
Total		2.54E-04	mg
Body weight		60	kg
Systemic dose		**4.24E-06**	**mg/kg bw**
AOEL of Flocoumafen		8.30E-06	mg/kg bw/d
% of AOEL		51.08	%

Amateur users – in and around buildings - Estimated exposure to flocoumafen from 5 g block baits (without gloves) using 4% dermal absorption

General exposure calculator		CALCULATION	UNITS
BAS 322 20 I, wax-free block bait, 5 g			
Active substance Flocoumafen		0.0025%	% (w/w)
Density		NR	g/ml (if w/v)
		Worst case	
POTENTIAL EXPOSURE		Value	
Mixing+Loading		not relevant	
Application			
Potential dermal exposure			
Indicative value (75th percentile, HEEG Opinion; 10/05/2011)	from study of Chambers, Snowdon	5.558	mg/wax block
Bait stations (HEEG opinion, 13/08/2010)		5	
Wax blocks per station		15	
Potential dermal deposit		416.85	mg
Penetration through gloves		100%	%
Actual dermal deposit (*product*)		416.85	mg
Active substance		0.01042	mg
Skin penetration, *in-vitro* data		4.00%	%
Active substance via the skin		4.17E-04	mg
Total potential exposure of a.s. during application		4.17E-04	mg
Total potential dose of a.s. during application		6.95E-06	mg/kg bw/d
Post-Application			
Potential dermal exposure			
Indicative value (75th percentile, HEEG Opinion; 10/05/2011)	from study of Chambers, Snowdon	5.7	mg/bait box
Bait stations cleaned-up (HEEG opinion, 13/08/2010)		5	
Potential dermal deposit		28.5	mg
Penetration through gloves		100%	%
Actual dermal deposit (*product*)		28.5	mg
Active substance		7.13E-04	mg
Skin penetration, *in-vitro* data		4.00%	%
Active substance via the skin		2.85E-05	mg
Total potential exposure of a.s. during post-application		2.85E-05	mg
Total potential dose of a.s. during post-application		4.75E-07	mg/kg bw/d
Dose			
Total		4.45E-04	mg
Body weight		60	kg
Systemic dose		**7.42E-06**	**mg/kg bw**
AOEL of Flocoumafen		8.30E-06	mg/kg bw/d
% of AOEL		89.43	%

Non-users (adults, children and infants) – in and around buildings - Tier 1: Estimated oral exposure for infants to flocoumafen based on EU default values acc. to TNsG

General exposure calculator		CALCULATION	UNITS
BAS 322 20 I, STORM Ultra block bait			
Active substance Flocoumafen		0.0025%	% (w/w)
Density		NR	g/ml (if w/v)
		Worst case	
POTENTIAL EXPOSURE		Value	
Potential oral exposure			
Default value for amount of product ingested:		10	mg
Concentration of flocoumafen		25	mg/kg
Oral absorption (worst case)		100%	%
Active substance via oral uptake		0.00025	mg
Dose			
Total		2.50E-04	mg
Body weight		10	kg
Systemic dose		**2.50E-05**	**mg/kg bw/d**

Non-users (adults, children and infants) – in and around buildings - Tier 1: Estimated oral exposure for infants to flocoumafen based on EU default values acc. to User guidance

General exposure calculator		CALCULATION	UNITS
BAS 322 20 I, wax-free block bait, 25 g			
Active substance Flocoumafen		0,0025%	% (w/w)
Density		NR	g/ml (if w/v)
		Worst case	
POTENTIAL EXPOSURE		Value	
Potential oral exposure			
Default value for amount of product ingested:		5000	mg
Concentration of flocoumafen		25	mg/kg
Oral absorption (worst case)		100%	%
Active substance via oral uptake		0,125	mg
Dose			
Total		1,25E-01	mg
Body weight		10	kg
Systemic dose		**1,25E-02**	**mg/kg bw/d**

3.3 New information on the active substance

No data submitted.

3.4 Residue behaviour

No data submitted.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

Please refer to the IUCLID file for Storm Ultra.

3.7 Other

Not relevant.