Product Assessment Report

Biocidal product assessment report related to product authorisation under Directive 98/8/EC

SORICIDE DB

LARC

December 2011

Internal registration/file no:	PB-10-00011
Authorisation/Registration no:	FR-2012-0002 (professional) / FR-2012-0050 (non-professional)
Granting date/entry into force of authorisation/ registration:	23 February 2012
Expiry date of authorisation/ registration:	31/03/2015 except where a decision of the European Commission extends the registration of the active substance
Active ingredient:	DIFENACOUM (CAS 56073-07-5)
Product type:	14 - Rodenticide

Competent Authority in charge of delivering the product authorisation:
French Ministry of Ecology
Department for Nuisance Prevention and Quality of the Environment
Chemical Substances and Preparation Unit
Grande Arche, Paroi Nord
92 055 La Défense cedex – FRANCE
autorisation-biocide@developpement-durable.gouv.fr

Authority in charge of the efficacy and risk assessment:
Anses – French agency for food, environmental and occupational health and safety
Regulated Products Directorate
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1 General information about the product application

1.1 Applicant

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Postal Code:	F-29500
Country:	France
Telephone:	+33.298.595.757
Fax:	
E-mail address:	

1.1.1 Person authorised for communication on behalf of the applicant

Name:	Mr Rudi Vermeulen
Function:	Regulatory Affairs
Address:	Rijksweg 28
City:	Bornem
Postal Code:	B-2880
Country:	Belgium
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1.2 Current authorisation holder[1]

Company Name:	LARC
Address:	ZA de Quillihuec
City:	Ergue-Gaberic
Postal Code:	F-29500
Country:	France
Telephone:	+33.298.595.757
Fax:	
E-mail address:	
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	No

1.3 Proposed authorisation holder

Company Name:	LARC
Address:	ZA de Quillihuec
City:	Ergue-Gaberic
Postal Code:	F-29500
Country:	France
Telephone:	+33.298.595.757
Fax:	
E-mail address:	
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	No

[1] Applies only to existing authorisations

1.4 Information about the product application

Application received:	01/04/2010
Application reported complete:	30/08/2010
Authorisation granted:	23 February 2012
Type of application:	Product authorisation
Further information:	-

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	SORICIDE DB
Manufacturer's development code number(s), if appropriate:	EDI-550
Product type:	PT14 - rodenticide
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Active substance's identity and content: Difenacoum 0.005% w/w No substance of concern
Formulation type:	Solid block
Ready to use product (yes/no):	Yes
Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); **If yes: authorisation/registration no. and product name:** **or** **Has the product the same identity and composition like the product evaluated in connection with the**	No No

approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):	

1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	TP14 - Rodenticide VIII.3.3 Block bait Use in and around domestic, industrial and commercial buildings including in farm buildings. The wax block bait is also applicable in sewers and waste water treatment plants.
Target organisms:	I.1.1.1 Brown rat: *Rattus norvegicus* I.1.1.2 Roof rat, House rat: *Rattus rattus* I.1.1.3 House mouse: *Mus musculus*
Category of users:	V.1 non professional/ general public V.2 professional V.3 specialised professional
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	VI.2: covered application VI.2.1: covered application in bait stations. The product is a ready to use wax block bait and contains 0.005% w/w of difenacoum. Rat: 80 g up to 200 g of product / bait station at distances of 15 meters apart. Mouse: 25 g up to 30 g of product / bait station at distances of 3 meters apart. These distances, so as the number and timings of application, are in function of infestation rate and can be modified upon experience of bait uptake during the campaign. Bait must be securely deposited in a way to minimize the risk for non-target animals and for children. Where possible, baits are secured so that they cannot be dragged away by the rodents. Bait stations will be used where the bait can't be fixed or

	locked up. Some blocks have a metal hook. This hook can be attached to a fixing device of the station. The common strategy is to explore the site, locate runs, burrows, droppings or signs of damage and place the bait boxes at entry points into buildings and around areas where rats are known to feed. For the mice control, as mice are sporadic feeders, many bait points are placed throughout the areas where mice are known to feed. Bait points are inspected frequently and replenished when bait take is observed. Depending on infestation rate, an advised frequency of inspection is 3 to 5 days. Although a professional will eventually for practical reasons synchronise his inspection frequency with a work week so keeping inspections twice or once a week, so have 3.5 to 7 days inspection interval. During the bait inspections, also a search in the zone will be done for dead rodents. These rodents will be eliminated following local requirements in order to avoid secondary poisoning of predators. When no further bait take is observed, bait stations should not been left in place, All bait stations must be removed from the site, cleaned up and the bait and bait remainders must be disposed of in accordance with local requirements. As long as there is visual bait consumption, fresh bait will be placed. When during 5 consecutive inspections no uptake at all has been recorded and supplementary no other sign suggests the eventual presence of rodents, the campaign can be ended. Anyhow, during the first 6 months after the end, vigilance is required in order to be responsive on any re-infestation of the area. So with a minimal effort new uproar can be stopped. Rodent control can be initiated at any moment of the year upon the presence of the target animal through direct

	traces/signals/markers. Autumn and winter are more favourable times for indoor applications. In sewers, the application dose is 100 g per manhole (*i.e.* every 100 m as the distance between two manholes may vary between 50 m to 300 m, but is generally 100 m) or 200 g every 3 manholes. The product is applied preferably in large main sewers (diameter > 30 cm). In larger sewers which can be walked in, baits can be placed along their length on available anchors or on specially installed bait trays each 100 to 300 meters. In waste water treatment plants, the blocks are placed in temper resistant bait stations. The application dose is 100-200 g of product at distances of 15 meters apart. In sewerage, the wax blocks are fixed using a wire attached to an existing anchor (scale bar, ring ...) or created one for this purpose so the blocks cannot be carried away by the rodents. The block is positioned a few centimeters above the bottom of cesspools. Frequency of use in sewers: For preventive treatment, there is one passage for the treatment and one visit of verification per year. For curative treatment, a more curative campaign with a monthly inspection interval can be defined for a compartment. As long as there is visual bait consumption, fresh bait will be placed. Campaign stops when bait uptake has ended: it can last several months, with an interval of 3 to 5 years or earlier when re-infestation is noted, then the curative treatment for the specific compartment can be restarted. Intensive treatment is, in more general way, 2-4 applications per year, with a

	minimal interval of 3 to 6 months between 2 applications.
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/feedingstuff (yes/no)	No
Proposed Label:	Control of rats and mice in and around domestic, industrial and commercial buildings including in farm buildings. This type of block is applicable in sewers and waste water treatment plants. Rat: 80 g up to 200 g of product at intervals of 15 meters apart. Mouse: 25 g up to 30 g of product at intervals of 3 meters apart. For rat control in sewers: 100 g per manhole (about 100 m) up to 200 g every 3 manholes. For rat control in waste water treatment plants: 100 up to 200 g of product at distances of 15 meters apart.
Use Restrictions:	Use only in sewers, in waste water treatment plants, in and around buildings in secured bait stations out of reach of children and domestic animals. Good field practice of rodent control involves several measures as cleaning-up of bait and bait containers after treatment period, removing any potential harbourages, etc. Local authorities may give according to the existing sewage infrastructure specific instructions to contractors for treatment campaigns hereby defining specific parameters as other fixing places fixing instructions, treatment frequencies, inspection frequencies, and removal instructions. Sewage networks of channels are linked to sewage treatment plant (STP). It's advised to divide the sewage system as good as possible into smaller

	compartments: as an example a unit serving 10 000 persons equivalent (PE). So a control campaign can be limited to a specific area and scheduled per unit on a yearly to 5 yearly rotation program. So the normal rodenticide control in sewage is preventing an increase of rat populations at which the population could outgrow its sewer environment. Hereby is the structural integrity of sewers very important. Damage of sewer systems will result in rats on the surface.

1.5.3 Information on active substance(s)

Active substance chemical name:	Difenacoum
CAS No:	56073-07-05
EC No:	259-978-4
Purity (minimum, g/kg or g/l):	960 g/kg
Inclusion directive:	2008/81/EC
Date of inclusion:	01/04/2010
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes
Manufacturer of active substance(s) used in the biocidal product:	
Company Name:	Pelgar International Ltd
Address:	Unit 13, Newman Lane
City:	Alton, Hampshire
Postal Code:	GU34 2QR
Country:	Great Britain
Telephone:	++ 44(0) 1420 80744
Fax:	++ 44(0) 1420 80733
E-mail address:	info@pelgar.co.uk

1.5.4 Information on the substance(s) of concern

SORICIDE DB does not contain any substance of concern according to the Technical Notes for Guidance on data requirements[2].

1.6 Documentation

1.6.1 Data submitted in relation to product application

Identity, physicochemical and analytical method data

Physico-chemical studies on SORICIDE DB were provided by LARC: appearance, explosive properties, oxidising properties, autoflammability, flammability properties, density and storage stability.

An analytical method to determine the active substance in the formulation SORICIDE DB has been provided by LARC.

Data on the active substance required at the product authorization stage as stated in the AR about the active substance have been provided by Pelgar:

- Appearance of the active substance
- A validated method for the analysis of difenacoum in animal and human tissues
- Validation data for the determination of residues of difenacoum in meat and oil-seed rape
- Validation data for the determination of difenacoum in sediment

Efficacy data

The following efficacy studies were submitted:

- Bait choice - EDI 550 BB-ROD fresh bait with 0.005% difenacoum, Mice (*Mus musculus*)
- Bait choice - EDI 550 BB-ROD fresh bait with 0.005% difenacoum, Rats (*Rattus norvegicus*)
- Bait choice - EDI 550 BB-ROD aged bait with 0.005% difenacoum, Mice (*Mus musculus*)
- Bait choice - EDI 550 BB-ROD aged bait with 0.005% difenacoum, Rats (*Rattus norvegicus*)

Toxicology data

[2] Technical guidance document in support of the directive 98/8/ec concerning the placing of biocidal products on the market - Guidance on data requirements for active substances and biocidal products, October 2000.

The applicant did not submit new toxicological data on active substance. An acute dermal study, irritation and sensitisation studies on biocidal product were provided.

Ecotoxicology data

The applicant has not provided ecotoxicological study with the biocidal product. The environmental risk assessment for SORICIDE DB has been done by the Reference Member State, Competent Authority Report on the active substance difenacoum supported by the Task Force Activa/Pelgar.

1.6.2 Access to documentation

In the frame of the authorization of SORICIDE DB supported by LARC, the applicant LARC has submitted a letter of access to all data on difenacoum submitted by Pelgar International Ltd under directive 98/8/EC for the purpose of Annex I listing.

2 Summary of the product assessment

2.1 Identity related issues

A new 5-batch analysis has been submitted by Pelgar at the EU level in the frame of the work conducted by the PA&MRFG, after annex I inclusion and prior to the product authorization stage. The assessment of the technical equivalence of the new 5-batch analysis versus the reference source of Pelgar used for annex I inclusion has been performed. The conclusion is that the source of Pelgar with the new specifications used in SORICIDE DB is technically equivalent to the source of Pelgar assessed for annex I inclusion. The confidential document is attached to this PAR as the addendum to the CAR of difenacoum is not available yet. See the confidential appendix “Technical equivalence Difenacoum Pelgar (new specifications)” for detailed information.

The composition of the product is confidential and is presented in a confidential annex. There is no substance of concern.

2.2 Classification, labelling and packaging

2.2.1 Harmonised classification of the biocidal product

No classification is required for SORICIDE DB.

2.2.2 Labelling of the biocidal product

No labelling is required for SORICIDE DB.

2.2.3 Packaging of the biocidal product

Primary packaging:

SORICIDE DB is supplied:

- in small individual bait bags from 20 to 100 grams:
    - of polypropylene (PP) foil
    - of polyethylene (PE) foil
- - in extruded polystyrene (PS) trays (containing 1 to 30 blocks from 20 to 100 grams) with a size range from 80 g to 2.5 kg.

SORICIDE DB is also supplied in bulk without being packed in smaller individual bait bags:

- in bucket of polypropylene (PP) from 200 g to 10 kg
- in one big bag of polyethylene (PE) foil, this bag functions as a liner inside the cardboard box from 200 g to 10 kg.

SORICIDE DB is also supplied in prefilled bait station in polypropylene (PP) from 20 to 200g without being individually packed in PP or PE. Several blocks could be in one bait station.

Secondary packaging:

- Bucket of polypropylene (100 g – 10 kg)
- Cardboard box of corrugated cardboard (80 g – 10 kg)

Packaging size and category of users:

Category of users	Packaging size
Professional	>3 kg
Non professional	< 3 kg

Packaging size and target organisms:

Excluding the prefilled bait stations, the different kind of packaging are destined for both type of target organisms, rats and mice.
Prefilled mouse bait stations have a size range from 20 grams to 150 grams (i.e. 1 to 3 blocks of 20, 22.5, 25, 30, 35, 40 or 50 grams).

Prefilled rat bait stations have a size range from 50 grams to 200 grams (i.e. 1 to 5 blocks of 20, 22.5, 25, 30, 40, 50, 60, 80, or 100 grams).
These prefilled bait stations are grouped into 1 to 5 units per cardboard box.

2.3 Physico/chemical properties and analytical methods

Data on the active substance difenacoum were required at the product authorization stage as stated in the AR about the active substance and were provided by Pelgar:

- Appearance of the active substance

Results of the assessment: for appearance, the data provided are acceptable. The results are reported in 2.3.1.

2.3.1 Physico-chemical properties

Table 1: Physico-chemical properties of the active substance:

	Method/ Guideline	**Purity/Specification**	**Result**	Reference
Physical state	Visual assessment in accordance with Council Directive 98/8/EC, Annex IIA, III, 3.3	Purity: 99.5% w/w difenacoum, Batch number 04253	Slightly clumping powder at 20.0 ± 0.5℃	Walker JA and Mullee, DM (2007) Difenacoum: Determination of General Physico-chemical Properties SafePharm Laboratories Report No. 2109/0005
Colour			Off-white at 20.0 ± 0.5℃	
Odour			No determination was performed as the test material was considered to be harmful by inhalation	

Other physico-chemical properties are presented in the CAR of Difenacoum of the Activa / Pelgar Brodifacoum and Difenacoum Task Force. LARC has a letter of access for these data.

Table 2: Physico-chemical properties of the biocidal product:

	Method	**Purity/Specification**	**Results**	**Reference**

	Method	Purity/Specification	Results	Reference
Physical state and nature	Visual inspection	EDI-550 PS tray: 0.00523% Difenacoum PE bag: 0.00548% Difenacoum	PS tray/PE bag: Wax cuboids with integrated wire See comment and conclusion below the table	Broda, J.
Colour	Visual inspection		PS tray/PE bag: Reddish	
Odour	Comparison to other characteristic odors		PS tray/PE bag: No odor	
Explosive properties	OECD 113	EDI-550 0.00523% Difenacoum	The heat of decomposition was below 500J/g. Therefore test on explosive properties was not necessary Not explosive, stable until decomposition at 140℃	Nau, M.
Oxidizing properties	EC A.17	EDI-550 0.00523% Difenacoum	No oxidizing properties	Nau, M.
Flash point	Not applicable			
Autoflammability	EC A.16	EDI-550 0.00523% Difenacoum	No self-ignition up to 406℃	Nau, M.
Other indications of flammability	EC A.10	EDI-550 0.00523% Difenacoum	Not highly flammable	Nau, M.
Acidity / Alkalinity			See comment and conclusion below the table	
Relative density / bulk density	OCDE 109	EDI-550 PS tray: 0.00523% Difenacoum	PS tray: The mean density is 0.962 g/cm^3 PE bag:	Broda, J.

	Method	Purity/Specification	Results	Reference
		PE bag: 0.00548% Difenacoum	The mean density is 0.941 g/cm^3	
Storage stability – stability and shelf life	2-years storage stability		Study on-going until 13th week 2012 See conclusion below the table	
Effects of temperature	8 weeks at 40℃	EDI-550 PS tray: 0.00523% Difenacoum PE bag: 0.00548% Difenacoum	<u>PS tray:</u> The weight loss of the test item after storage for 8 weeks at 40℃ was between 0.38 and 1.10%. No other significant changes in the appearance were observed. Difference of content of the active substance: -7.6 % deviation from T=0 value after the accelerated storage procedure for 8 weeks at 40℃ <u>PE bag:</u> The weight loss of the test item after storage for 8 weeks at 40℃ was between 0.37 and 0.45%. No other significant changes in the appearance were observed. Difference of	Broda, J.

	Method	Purity/Specification	Results	Reference
			content of the active substance: +9.2 % deviation from T=0 value after the accelerated storage procedure for 8 weeks at 40℃ See comment and conclusion below the table	
Effects of light	Not submitted		See conclusion below the table	
Reactivity towards container material	Visual description (integrity, sealing, leakage, dimensional stability)	EDI-550 PS tray: 0.00523% Difenacoum PE bag, 80g: 0.00548% Difenacoum	PS tray/PE bag: The appearance of the packaging was unchanged throughout the study. The sample stayed in sound condition, sealed and without leakage after 8 weeks at 40℃. See conclusion below the table	Broda, J.
Other Melting point	EC A.01, OECD 102 OECD 113 (DSC)	EDI-550 0.00523% Difenacoum	The DSC shows that the product starts melting at 20℃ (first peak at 46℃ and second peak at 61.5℃) See comment below the table	Nau, M.
Technical characteristics in dependence of the formulation type	Not applicable			
Compatibility with other products			The product is a ready to use product and is not intended to be added to any	

	Method	Purity/Specification	Results	Reference
			other product.	
Surface tension	Not applicable			
Viscosity	Not applicable			
Particle size distribution	Not applicable			

Appearance:

There are blocks with different weights: from 20 to 100g but the different sizes (length, width and height) have not been provided. Moreover no precise information has been provided about the integrated wire.

Acidity/Alkalinity:

The fact that the product is solid and is not intended to be dispersed in water is not an acceptable justification for non submission of the pH and acidity/alkalinity.
pH value (1% in water) should have been provided and acidity/alkalinity too if relevant (depending of the pH).

Storage stability:

Storage stability was realized at 40℃ for 8 weeks.

The difenacoum content differs from more than 5% after storage 8 weeks at 40℃.
PS tray: Content of active substance decreased of 7.6%
PE bag: Content of active substance increased of 9.2%
The accepted difference is 5% according to the FAO Manual. A justification has been provided by the applicant:
The cast wax block formulation is composed of a matrix of different fractions (raw materials). Although upon manufacturing of the block all fractions are thoroughly mixed, due to the big difference of specific gravity of the different fractions, it cannot be avoided that – both during mixing of the bulk volume and during pouring into preformed trays – a certain gradient forms leading to a limited level of heterogeneous character of the block on a micro scale. It is therefore normal, for this kind of cast block formulation, that upon sampling of a part of the block for analysis, variations in the active ingredient concentration will occur.
The different physico-chemical fractions also exhibit a different affinity towards the solvents that are used for the extraction process. Due to this different affinity for the extraction solvent, subsamples that are characterised by heterogeneity at the micro scale level may therefore show slightly different active ingredient levels due to slightly different extraction efficiencies.

The appearance of tests items was observed after 8 weeks at 40℃ and no significant changes were observed.

Efficacity studies performed after 8 weeks at 40℃ show that product is palatable and effective.

Difenacoum is thermically stable (temperature of decomposition is upper 250°C).

Indeed the difference may be due to the heterogeneity of blocks within batches (blocks from a batch may have different contents of active substance). Therefore the sampling should be adapted to overcome this heterogeneity.

So the accelerated storage stability study is accepted despite of difference in difenacoum content upper than 5%.

Due to the melting range of the product, it is necessary to advise storage at ambient temperature (max 40°C).

Reactivity towards container material:

The compatibility of SORICIDE DB in individual polypropylene (PP) bag, in PP bucket, in big bag of PE foil and in PP pre-filled bait station has not been tested.
The compatibility of SORICIDE DB in big bag of PE foil is not necessary as the compatibility of block in polyethylene (PE) bag of 80g has been tested and accepted.
Only the compatibility of SORICIDE DB in individual polypropylene (PP) bag of 20g is required. The result could be used to accept the PP bucket and the PP pre-filled bait station.

Conclusion:
Precision about the appearance of the product have to be provided (different sizes of the block and information about the wire).
A 2-years storage stability study is on-going and have to be provided, the study should be performed with test items in quantity sufficient to overcome the heterogeneity. Intermediate results at one year have to be provided.
pH (acidity and alkalinity if relevant), effect of light and reactivity toward individual polypropylene (PP) bag of 20g, have to be provided also.

Due to the melting range of the product, it is necessary to advise storage at ambient temperature (max 40°C).

2.3.2 Analytical methods

Data on the active substance difenacoum were required at the product authorization stage as stated in the AR of the active substance and were provided by Pelgar:

- A validated method for the analysis of difenacoum in animal and human tissues,
- Validation data for the determination of residues of difenacoum in meat and oil-seed rape (food/feeding stuffs) ,
- Validation data for the determination of difenacoum in sediment.

Results of the assessment of the analytical methods provided by Pelgar on the active substance as required in the CAR:

- A validated method for the analysis of difenacoum in animal and human tissues

Results of the assessment: The method is validated and is acceptable.

- Validation data for the analytical method for determination of residues of difenacoum in meat and oil-seed rape (food/feeding stuffs)

Results of the assessment: The data provided were not validation data based on the analysis method already provided in the dossier, as requested. The submitted study report provided a new method with validation data. This new method is validated and is acceptable.

- Validation data for analytical method for determination of difenacoum in sediment (based on the analysis method for difenacoum in soil)

Results of the assessment: The data provided were not validation data based on the analysis method for difenacoum in soil, as requested. The submitted study report provided a new method with validation data. This new method is validated and is acceptable.

	Principle of method
Technical active substance as manufactured:	Difenacoum quantified in technical grade material by HPLC with UV detection at 254 nm using an internal standard.
Impurities in technical active substance:	Impurities in technical grade material quantified by HPLC with UV detection using either an internal or external standard.
active substance in the formulation:	HPLC-UV

Technical active substance as manufactured:

The determination of the active substance was performed by HPLC with method of the internal standard, using the UV detector. It is based on the comparison between the ratio of the difenacoum analytical standard peak area versus 1.3.5-triphenylbenzene internal standard peak area and the same ratio determined in the sample under examination where a known amount of internal standard (I.S) was added. The analytical method is considered to be acceptable.

Impurities in technical active substance:

The analytical method and the related validation data for the determination of impurities in the difenacoum technical substance described in the reference A4.1(2) is also considered to be acceptable but is confidential and can be found in Annex for Confidential Data and Information in the CAR of Difenacoum of Activa/Pelgar Brodifacoum and Difenacoum Task Force.

Active substance in the formulation:

After extraction in methanol, which is further boiled under reflux for 1 hour, the active substance content is determined by high performance liquid chromatography (HPLC) with

UV detection at 254 nm according to the internal standard method. The analytical method provided is validated.

2.4 Risk assessment for Physico-chemical properties

SORICIDE DB is a ready-to-use rodenticide. It is a reddish wax cuboid with integrated wire block. It is not highly flammable, not auto-flammable (up to 406℃), not explosive and does not have oxidizing properties.
Results of the accelerated storage study have been accepted but should be confirmed with the shelf-life study. Shelf life, effect of light and reactivity towards container material should be provided.
Due to the melting range of the product, it is necessary to advise storage at ambient temperature (max 40℃).

2.5 Effectiveness against target organisms

2.5.1 Function

MG 03: Pest Control
Product Type 14: Rodenticide

2.5.2 Organism(s) to be controlled and products, organisms or objects to be protected.

SORICIDE DB is used to control rodents. The target organisms to be controlled are brown rat (*Rattus norvegicus*), roof rat or house rat (*Rattus rattus*) and house mouse (*Mus musculus*).
The products, organisms or objects to be protected are stored products or food, public health, historical buildings or technical objects, sewers and waste water treatment plants.

2.5.3 Effects on Target organisms

Anticoagulants Rodenticides disrupt the blood-cutting mechanisms. Signs of poisoning in rodents are those associated with an increased tendency to bleed, leading ultimately to profuse haemorrhage. After feeding on bait containing the active substance for 2-3 days the animal becomes lethargic and slow moving. Signs of bleeding are often noticeable and blood may be seen around the nose and anus. As symptoms develop, the animal will lose its appetite and will remain in its burrow or nest for increasingly long periods of time. Death will usually occur within 3-7 days of ingesting a lethal dose and animals often die out of sight in their nest or burrow.

<u>The application rates recommended by the applicant are the following:</u>

Rats: (*Rattus norvegicus and Rattus rattus)*
80 g up to 200 g product/secured bait point at intervals of 15 m apart.

Mice: (*Mus musculus*)
25 g up to 30 g product/secured bait point at intervals of 3 m apart.

For rat control in sewers:
100 g per manhole (about 100 m) up to 200 g every 3 manholes.

For rat control in waste water treatment plants:
100 g up to 200 g product/secured bait point at intervals of 15 m apart.

The product is applied in bait stations by professional and non-professional users in discrete locations within the infested area. In sewerage, the wax blocks are fixed using a wire attached to an existing anchor. Distances between each bait station, so as the number and timings of application and the amount of product depends of several factors: the treatment site, the size and severity of the infestation.

It must be noted that total eradication in sewers is generally not achievable. The aim of rodent campaigns is to maintain acceptable population levels.

Therefore the frequency of use in sewers is different:

- For preventive treatment, there is one passage for the treatment and one visit of verification per year.

- For curative treatment, a more curative campaign with a monthly inspection interval can be defined for a compartment. As long as there is visual bait consumption, fresh bait will be placed. Campaign stops when bait uptake has ended: it can last several months, with an interval of 3 to 5 years or earlier when re-infestation is noted, then the curative treatment for the specific compartment can be restarted.

- For intensive treatment, 2-4 applications per year, with a minimal interval of 3 to 6 months between 2 applications.

The treatment is curative for the other locations (i.e. in and around domestic, industrial and commercial buildings and waste water treatment plants). So all bait stations, baits and bait reminders must be removed at the end of the treatment.

Choice feeding tests on SORICIDE DB on rats and mice on fresh and aged baits were conducted and the results are presented in annex 2. The studies show that the product is palatable (treated bait intake at least 20% of the total food consumption in choice feeding tests) and effective (90% to 100% mortality in less than 14 days in the choice feeding tests).

No study on the efficacy of SORICIDE DB in damp conditions has been submitted by the applicant. So the uses of SORICIDE DB in sewers and waste water treatment plants are not validated.

2.5.4 Occurrence of resistance

The use of massive anticoagulants in the management of rodents since the 1970's has been at the origin of the first batches of resistance (genetic and not behavioral) to the first generation of anticoagulants (coumafene in particular).

Recent studies carried out in different European countries, in the UK more particularly (Kerins *et al*, 2001, see annex 1) revealed the occasional occurrence of cross-resistances to second-generation anticoagulants, such as difenacoum and bromadiolone on resistant brown rats populations to coumafene.

Only an exhaustive study carried out at the French and European levels could enable pointed-out resistant areas with first-generation anticoagulants and potential cross-resistances to second-generation anticoagulants. It is one of the actions undertaken since 2010 in France by a group of scientists (Rodent program “impacts of anticoagulants rodenticides on ecosystems-adaptations of target rodents and effects on their predators”).

Indeed, we cannot sustain that resistance to difenacoum in all geographical areas where it could be used cannot occur and the occurrence of resistance has an impact on the dosages and efficacy of rodenticides used in a more consequent way. Thus, it compels users to take into account the following precautions to reduce the possibility of rodents developing a resistance to difenacoum:

- Products have always to be used in accordance with the label.
- Efficacy level has to be monitored (periodic check), and the case of reduced efficacy has to be investigated for possible evidence of resistance.
- Treatment has to be alternated with active substances having different mode of action.
- Integrated pest management (combination of chemical control, physical and hygienic measures) has to be taken into account.
- Difenacoum must not be used in an area where resistance to this active substance is suspected or established.
- If signs of resistance begin to appear, then, every effort has to be made to eradicate the population. The measures necessary for eradication will vary in different situations; they may involve a number of procedures using both chemical and non-chemical ways.

The authorization holder should report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management every two years.

2.5.5 Evaluation of the Label Claims

French Authority in charge of the risk assessment assessed that SORICIDE DB has shown a sufficient efficacy for the control of mice and rats in and around domestic, industrial and commercial buildings including in farm buildings.

<u>The application rates validated are the following:</u>

<u>Rats</u>: (*Rattus norvegicus and Rattus rattus)*
80 g up to 200 g product/secured bait point at intervals of 15 m apart.

Mice: (*Mus musculus*)
25 g up to 30 g product/secured bait point at intervals of 3 m apart.

In addition to the bulk packaging, SORICIDE DB is also supplied in sachets and pre-filled bait stations of different amounts. The applicant has to adapt the amount per sachet and bait boxes to the efficient doses. The amount of bait per bait station must not exceed the recommended application rates.

The label claim reflects the efficacy data of the product. Furthermore it mentions that applicators and customers are required to report straightforward to the registration holder any alarming signals which could be assumed to be resistance development. Because of cross-resistances occurrence to second-generation anticoagulants, the product label has to contain information on resistance management for rodenticides:

- Products have always to be used in accordance with the label.
- The level of efficacy have to be monitored (periodic check), and the case of reduced efficacy has to be investigated for possible evidence of resistance.
- The treatment has to be alternated with other kinds of active substances.
- Difenacoum must not be used in an area where resistance to this substance is suspected or established.
- The users should report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

Difenacoum is used as rodenticide (product type PT14 according to EU Biocidal Product Directive).

Table 2.6.1 Summary of intended uses

MG/PT	Field of uses envisaged	Likely concentrations at which a.s. will be used
Main group 03; PT 14	Professional uses	
	Rodenticide used indoors and outdoors in industrial and commercial buildings including in farm buildings Use in sewerage and waste water treatment plants (only against rats)	0.005% w/w
	Non-professional uses	
	Rodenticide used indoors in domestic areas	0.005% w/w

SORICIDE DB is intended to be used for control of mice *(Mus musculus)*, brown rats *(Rattus norvegicus)* and black rats *(Rattus rattus),* in sewers, in waste water treatment plants, in and around domestic, industrial and commercial buildings including in farm buildings. The control of mice and rats is based on the principle of applying baits on infested areas with obvious tracking of faeces, and smears next to holes and harbourages.
The product is ready-to-use block bait with no dilution and or other substances added for application. It is manually applied by trained professional users and by non-professional users in secured bait boxes or bait stations or fixed using a wire attached to an existing anchor when used in sewerage.

For rat control, the recommended dose is 80 g up to 200 g of product at intervals of 15 meters apart.

For mouse control, the recommended dose is 25 g up to 30 g of product at intervals of 3 meters apart.

For rat control in sewers, the recommended dose is 100 g per manhole (about 100 m) up to 200 g every 3 manholes .

For rat control in waste water treatment plants, the recommended dose is 100 g to 200 g at intervals of 15 meters apart.

2.6.2 Assessment of exposure to humans and the environment

Assessment of human exposure

No new human exposure studies have been submitted. In the dossier, Larc assessed the human exposure based on the default values of the TNsG on human exposure, 2007[3]. Therefore, since Larc provided a letter of access for the CEFIC unpublished study "*Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits*" of Chambers J.G. and Snowdon P.J. (2004)[4]; the FR CA decided to base the human exposure assessment for professionals on this study as done by the RMS (Finland) of the active substance in the assessment report of difenacoum. This study examined exposure to 20 g wax block baits containing flocoumafen (five blocks/bait box) using 10 replicates for each measurement. This study is considered as representative of the human exposure of wax block rodenticide baits. Considering that a similar application/manipulation is expected for wax and cereal blocks, the FR CA decided to use the exposure estimations from the CEFIC study for the assessment of SORICIDE DB.

For non professional users, the same CEFIC study and assumptions were used for the estimation of human exposure since the values available in the TNsG and User Guidance (Human exposure to biocidal products – TNsG June 2002 – version 1) are considered as unrealistic (see argumentation in the Assessment report on difenacoum).

Additionally, the Human Exposure Expert Group (HEEG) opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant)[5], agreed at the European Technical meeting TMII2010 was taken into account for the estimation of exposure for professionals and non professionals.

2.7 Risk assessment for human health

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

The toxicology of the active substance was examined extensively according to standard requirements of Directive 98/8/EC. The results of this toxicological assessment can be found in the CAR. The threshold limits and labelling regarding human health risks listed in Annex 3 "Toxicology and metabolism" of this report must be taken into consideration.

[3] Human exposure to biocidal products – TNsG June 2007

[4] Chambers JG and Snowdon PJ - Study to Determine Potential Exposure to Operators During Simulated Use of Anticoagulant Rodenticide Baits - Synergy Laboratories Ltd., Report No. SYN/1302. Unpublished.

[5] HEEG (Human Exposure Expert Group) opinion on Harmonising the number of manipulations in the assessment of rodenticides (anticoagulants); June 2010

The following corresponds to the summary of the derivation of the AELs from the Doc I of the final CAR of difenacoum:
"The lowest LOAEL in a repeated dose study, i.e. the teratogenicity study in rabbits, is chosen as the basis to establish the AOEL (there was no NOAEL). In this study, the maternal LOAEL was 0.001 mg/kg bw/day. Default assessment factors of 10 for inter-species variability and 10 for inter-individual variability are applied. Furthermore, due to the toxicological significance and uncertainty in the database, an additional safety factor of 3 for teratogenicity is used for all anticoagulant rodenticides according to the agreement during peer-review discussion. A further supportive argument for an additional assessment factor comes from the higher potency of the second generation anticoagulants compared to warfarin, and from the much higher vulnerability of human foetuses to vitamin K deficiency compared to rodents. To extrapolate from LOAEL to NOAEL an assessment factor of 2 is considered justified due to the deep slope of the dose response curve. After correction for bioavailability of 68%, a NOAEL for MOE (0.00034 mg/kg bw/day) and an AOEL of 0.0000011 mg/kg bw/day are used for risk characterisation. These values are applied both to acute and repeated exposure scenarios."

2.7.1.2 Toxicology of the substance(s) of concern

Considering the following definition of a substance of concern set in the TNsG on data requirement chapter 4[6], "*the substance is regarded as a substance of concern if [...] it is classified as dangerous* ***and*** *its concentration in the product exceeds the classification limit set in the Council Directive 88/379/EEC, as amended by Directive 1999/45/EC, for a particular dangerous property* ***or*** *the other classification limit indicated for the substance in a preparation set in Annex I of Council Directive 67/548/EEC* ***or*** *causes that the overall sum of the concentrations of dangerous substances in the product exceeds the limit for classification of the preparation set in Council Directive 88/379/EEC, as amended by Directive 1999/45/EC, for a particular dangerous property*", SORICIDE DB does not contain any substance of concern.

2.7.1.3 Toxicology of the biocidal product

The toxicology of the biocidal product was examined according to standard requirements of Directive 98/8/EC. The product was not a dummy product in the EU- review program for inclusion of the active substance in Annex I of Directive 98/8/EC.
The basis for the health assessment of the biocidal product is laid out in Annex 4 of this report "Toxicology – biocidal product".

Acute dermal toxicity, skin and eye irritation and skin sensitisation studies have been provided on the product containing 0.005% of difenacoum, according to the OECD guidelines.
Justifications for non-submission of data have been submitted for acute oral and inhalation toxicity studies and dermal absorption study.

[6] TNsG chapter 4 Data requirements for substances of concern version 4.3.1; April 2000

- Acute dermal toxicity

No effects were observed during the duration of the study or noted at necropsy in the acute dermal toxicity study. Therefore, the LD_{50} of SORICIDE DB is higher than 2000 mg/kg body weight by dermal route in the rat.

Based on the results, no classification is required for SORICIDE DB.

- Irritation and corrosivity

A slight erythema was observed on the treated area of two animals one hour after the patch removal. This erythematous reaction was totally reversible between day 1 and day 2. The average scores (24, 48, 72 h) were 0.11 and 0.0 for erythema and for oedema, respectively. The ocular conjunctivae reactions observed during the eye irritation study have been slight to moderate and totally reversible in the three animals.

Based on the results of the irritation guideline assays on rabbit's skin and eye, no classification is required for SORICIDE DB.

- Sensitisation

A non-radioactive LLNA using cell counting was submitted. This method is not currently validated. Furthermore, according to the publication of Basketter *et al*.[7], the "*proposed non-RI LLNA*[8] *uses cell number as a correlate of cell proliferation, but, as other modifications to the standard LLNA were also made, the method constitutes a major change*." Therefore this test was considered non acceptable by the RMS.
Based on the composition of SORICIDE DB, no ingredients were listed as a skin sensitizer. Therefore, it is expected that this product is not a skin sensitizer.

<u>Justification for non submission</u>:

- Dermal absorption

A dermal absorption percentage of 0.047% for wax block bait, according to an *in vitro* study on human skin from the assessment report on difenacoum of Activa/Pelgar.
Consequently, the justification for non-submission of data is acceptable.

- Acute oral and inhalation toxicity:

According to the CLP exemptions rules based on calculations, the product would not be classified for its acute oral toxicity.
Concerning the inhalation route, as the preparation is neither a gas nor a volatile liquid, nor a powder and the application method does not generate aerosol, particles or droplets in an

[7] "An evaluation of performance standards and non-radioactive endpoints for the LLNA – The report and recommendations of ECVAM Workshop 65" (2008)
[8] Non-radioactive LLNA

inhalable size range (MMAD < 50 µm), it can be considered that inhalatory exposure is not a relevant route of human exposure.
In conclusion, the justifications for non-submission of data are considered as acceptable.

The harmonised classification of the active substance is the following:

Classification under directive 67/548/EEC	Classification under regulation (EC) 1272/2008
T+ R28 T R48/25 N, R50/53 No specific concentration limit	Acute Tox. 2 H300 STOT Rep. 1 H372 Aquatic. Acute 1 H400 Aquatic Chronic 1 H410 No specific concentration limit

Based on the results of the studies, the concentration of the active substance and of the compounds contained in the product and according to the above classification, SORICIDE DB is not classified.

- Other studies

The product is not intended to be used with other biocidal products. Therefore, no additional study was conducted.
In addition, the product is not intended to be used in feedingstuff and no industrial processing or domestic preparation are intended. Therefore, no data on residue was submitted.

2.7.2 Exposure

SORICIDE DB is a ready-to-use block bait with no dilution and or other substances added for application. It contains 0.005% (w/w) of difenacoum (purity: 960 g/kg). It is manually applied by trained professional users and by non-professional users in secured bait boxes or bait stations.

SORICIDE DB is provided into three different kinds of packaging: blocks in bulk, blocks packed individually and pre-filled bait station. Concerning the last one, the exposure is considered as negligible during the first application. However, if they are refilled with recharge baits (bulk or individually packed), the exposure will be similar to the exposure scenario presented in the followings paragraphs for professional or non-professional users.

2.7.2.1 Exposure of professional users

Primary exposure

The product is used indoors and outdoors in industrial and commercial buildings including in farm buildings. There is a usage in sewerage and waste water treatment plants (only against rats). In the case of application in the sewers, the exposure of sewermen is considered as covered by that of professional users during the loading and cleaning of bait boxes. Consequently, the assessment below covers both modes of application (indoors/outdoors and sewerage).

During professional use, the major route of primary exposure is dermal. The inhalation exposure could be considered as a non relevant route of human exposure considering the low vapour pressure of difenacoum (< $5x10^{-5}$ Pa at 45°C based on an Activa/Pelgar estimation) and of the other compounds. Moreover, the preparation is neither a gas nor a volatile liquid, nor a powder. The application method does not generate aerosol, particles or droplets in an inhalable size range (MMAD < 50 µm).

Based on all the measured exposure data (75th percentile) in the CEFIC study, the amount of exposure to product **during loading** of 5 wax blocks per one manipulation was 27.79 mg (value retained by the HEEG). The following parameters were taken into account for the treatment against rats:

- Active substance in product: 0.005%,
- Number of blocks per bait site: 10
- Dermal absorption: 0.047% (value retained by FI RMS in the CAR of difenacoum and adopted for all wax blocks),
- Body weight: 60 kg.

The number of blocks per bait site (10 blocks) is determined to reach a dose of 200 g (10 blocks of 20 g) which is the efficient dose for rat. The smallest size of block (20 g) is actually used as a worst case since the number of manipulations and thus, the exposure will be higher than for block which has a bigger size.

Consequently, the systemic dose of difenacoum per placing of one bait site is $2.18x10^{-8}$ mg/kg bw/event.

Based on all the measured exposure data (75th percentile) in the CEFIC study, the amount of exposure to product is 5.7 mg **during the cleaning** of one bait site (value adopted by the HEEG). Considering a content of 0.005% of difenacoum in the product, a dermal absorption of 0.047% and a body weight of 60 kg, the systemic dose of difenacoum per cleaning of one bait site is $2.23x10^{-9}$ mg/kg bw/event[9].

In application of the HEEG opinion agreed at the European Technical meeting TM III 2010 about the harmonized number of manipulations for rodenticides anticoagulant, 60 loadings and 15 cleanings per day were taken into account for the exposure assessment. Based on these values, the systemic dose via skin is $1.34x10^{-6}$ mg a.s/kg bw/day. The exposure is reduced by a factor of 10 down to $1.34x10^{-7}$ when gloves are worn (10% gloves penetration factor). According to the HEEG opinion agreed at the European Technical meeting TMI10 (default protection factors for protective clothing and gloves), a further refinement is possible

[9] Unlike the value for the loading phase, the number of blocks is not taken into account.

considering a glove penetration factor of 5% for solids. In this case, the total systemic dermal exposure is 6.70 $x10^{-8}$ mg/kg bw/day.

The estimations above are representative for exposure to SORICIDE DB in bulk but for the packaging in sachet, they represent a very worst case. In this case, it can be assumed that no exposure is expected during loading in bait points as the sachet prevents dermal contacts. Therefore, only exposure during cleaning can be considered: $3.35x10^{-8}$ mg a.s/kg bw/day without gloves and $3.35x10^{-9}$ mg a.s/kg bw/day with gloves (10% penetration factor).

Secondary exposure

Secondary exposure of users could result in the handling of dead rodents. However, this scenario is excluded due to unrealistic assumptions (very low amount of difenacoum is expected on the fur because SORICIDE DB is an oral bait and toxicokinetics data showed that urine is a minor route of excretion for difenacoum).

In Annex 5 “Safety for professional operators” of this report, the results of the exposure calculations for the active substance for the professional user are laid out.

2.7.2.2 Exposure of non-professional users and the general public

Primary exposure

During non-professional use, the major route of exposure is dermal. The inhalation exposure could be considered as a non relevant route of human exposure, like for professional users.

As a worst case, the same assumptions as for professional exposure was considered except for the number of manipulations set at 5 loadings and 5 cleaning per day for non-professional according to the HEEG opinion document and in the absence of PPE. The systemic exposure via skin is therefore at 1.20 $x10^{-7}$ mg a.s/kg bw/day.

The estimations above are representative for exposure to SORICIDE DB in bulk but they represent a very worst case, since SORICIDE DB is only supplied and applied in sachet for non professional uses. It can be assumed that no exposure is expected during loading in bait points as the sachet prevents dermal contacts. Therefore, only exposure during cleaning can be considered: $1.12x10^{-8}$ mg a.s/kg bw/day.

Secondary exposure

Exposure of non users, especially infants, could result from the handling of dead rodents or ingesting poison baits. The “*handling of dead rodents*” scenario is excluded due to unrealistic assumptions (very low amount of difenacoum is expected on the fur because SORICIDE DB is an oral bait and toxicokinetics data showed that urine is a minor route of excretion for difenacoum).

For the scenario "*oral exposure by ingesting bait*", a reverse scenario was calculated. Based on the AEL of $1.1x10^{-6}$ mg a.s/kg bw/day, a body weight of 10 kg and an oral absorption of 68% (as stated in the Assesment report of difenacoum [Activa/Pelgar Study]), ingestion of more than 0.3 mg of product per day is needed to exceed the AEL.

In Annex 6 "Safety for non-professional operators and the general public" of this report, the results of the exposure calculations for the active substance for the non-professional user and the general public are laid out.

2.7.2.3 Exposure to residues in food

Since no contamination is expected for feeding stuffs, no residue assessment was performed (Annex 7 "Residue behaviour").

2.7.3 Risk characterisation

With proper use in accordance with regulations harmful effects on the health of users and third parties are not expected. The estimated exposures for the intended use are compared to the respective systemic AEL.

2.7.3.1 Risk for professional users

The estimated exposures for the professional users are compared to the systemic AEL of difenacoum set in the Assessment report ($1.1x10^{-6}$ mg/kg bw/day for short, medium and long-term exposures).

Primary exposure

Based on the risk assessment of the active substance, the risk for professional users when SORKIL BLOC is supplied in bulk could be considered as acceptable only with the wear of gloves, based on the %AEL of 12% with a glove penetration factor of 10 % (122% without gloves). Moreover, gloves are recommended to help preventing rodent-borne disease.

For SORICIDE DB supplied and applied in sachet, exposure can be expected only during cleaning. In this context, the risk resulting from the intended use is acceptable even if professionals are not wearing gloves (%AEL at 3%). Additionally, gloves are anyway recommended to help prevention against rodent-borne disease.

The conclusion is the same for the pre-filled boxes. Consequently, the rechargement of the boxes must be done with the wear of gloves in the case of bulk and without gloves for sachet.

The results of the risk characterisation for mice control are, consequently, considered as acceptable for SORICIDE DB supplied in bulk or in sachet applied by a professional user, as

only one block of 25 g is sufficient to be efficient. The total dermal exposure corresponds to 14.9% of the AEL without gloves. Even if a block of 20 g exists, the potential risks is covered by those calculated for rats as only 2 blocks of 20 g would be efficient to control mice.
Furthermore gloves are recommended to help prevention against rodent-borne disease.

Secondary exposure

As no secondary exposure is expected for professional users, no risk has been identified.

2.7.3.2 Risk for non-professional users and the general public

The estimated exposure for the non-professional users is compared to the systemic AEL of difenacoum set in the Assessment report ($1.1x10^{-6}$ mg/kg bw/day for short, medium and long-term exposures).

Primary exposure

Based on the risk assessment of the active substance, the risk for non-professional users resulting from the intended use is acceptable, even considering an exposure to a bulk (%AEL at 11%). In case of application of sachets, the %AEL is 1%.
For the pre-filled boxes, the risks are thus, considered as acceptable for non-professional users.

The results of the risk characterisation for mice control are, consequently, considered as acceptable for SORICIDE DB supplied in bulk or in sachet applied by a non-professional user, as only one block of 25 g is sufficient to be efficient. Even if a block of 20 g exists, the potential risks is covered by those calculated for rats as only 2 blocks of 20 g would be efficient to control mice.

Secondary exposure

Based on a reverse scenario, more than 0.3 mg of product per day should be ingested by an infant to exceed the AEL. This indicates that infants are at significant risk of poisoning (corresponding to about 0.0015 % of a 20 g piece of SORICIDE DB). Therefore, even if SORICIDE DB contains a bittering agent which reduces the likelihood of ingestion, the baits should be placed in bait boxes which do not allow access to children in secured areas. Product label (“do not open the sachet”) and good practice must advise users preventing access to bait by children and infants.

2.7.3.3 Risk for consumers via residues

Since no contamination is expected for feeding stuffs, the risk for consumers via residues was not assessed.

2.7.3.4 Summary of risks characterisation for SORICIDE DB

Treatment against rats:

Scenario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	% AEL	Conclusion
bulk formulation (exposure during decanting, loading and cleaning phases)				
Professional (without gloves)	1.1 x 10^{-6}	1.34x10^{-6}	122	Unacceptable
Professional (with gloves ; penetration factor of 10 %)	1.1 x 10^{-6}	1.34x10^{-7}	12	**Acceptable**
Non professional	1.1 x 10^{-6}	1.20x10^{-7}	11	**Acceptable**
sachet formulation (exposure during cleaning phase)				
Professional (without gloves)	1.1 x 10^{-6}	3.35x10^{-8}	3	**Acceptable**
Non professional	1.1 x 10^{-6}	1.12x10^{-8}	1	**Acceptable**

2.8 Risk assessment for the environment

2.8.1 Fate and distribution of the active substance, difenacoum, in the environment

The summary of information about the active substance is carried out with the data from the CAR of Difenacoum owned by the Activa/Pelgar Difenacoum & Brodifacoum Task Force. No new ecotoxicological information on the active substance difenacoum has been submitted in the product dossier.

2.8.1.1 Biodegradation of difenacoum

According to the OECD tests 301B and 302D, difenacoum is not readily or inherently biodegradable. No studies on degradation in soil is available, but using the calculated value of Kp of 1.34 and considering the absence of biodegradation of difenacoum, it can be assumed that half life in soil is over 300 days. It was assumed during technical meeting (TMII-04) that no further degradation studies are needed for intended uses in sewers and in and around building.

So the risk assessment is based on the assumption that difenacoum is not readily biodegradable and that the half life in soil is over 300 days.

2.8.1.2 Hydrolysis as a function of pH

According to the test OECD 111, the half-life (DT_{50}) of difenacoum is over 1 year at pH 4, 7 and 9 at 25℃. The active substance is hydrolytical ly stable.

2.8.1.3 Photolysis in water

The active substance undergoes rapid photodegradation. Half-life varied from 0.6 hours to 3.8 hours. Greater than 80% photolysis was noted to have occurred by around five hours. Two breakdown products above 10% of the initial difenacoum concentration were detected and the proposal for the identification of structures was made. The photodegradation is regarded as a minor removal process for difenacoum and the exposure to water is low, therefore it was stated that no further characterisation of metabolites was requested.

2.8.1.4 Photodegradation in air

Photodegradation characteristics of the active substance have been estimated using the EPIWIN v. 3.12 models in the CAR of the Task Force Difenacoum dossier. Difenacoum has an estimated half-life of approximately 2 hours, therefore it is predicted to have a negligible effect on stratospheric ozone. It is predicted not to be a potential greenhouse gas. Finally, difenacoum has a low volatility (Henry's law constant< 0.046 $Pa.m^3.mol^{-1}$) and emissions to the air compartment are expected to be low.

2.8.1.5 Distribution

2.8.1.5.1 Adsorption/desorption

The experimentally derived Koc value is not supported by the physical and chemical properties of difenacoum. Difenacoum is a large aromatic molecule with two polar groups which can potentially ionise at environmental relevant pH. Difenacoum has also a low water solubility and a high log Kow.
According to the Technical Guidance Document (TGD)[10] (Part 3, Table 4) the QSAR equation used to calculate log Koc from log Kow (7.62, QSAR estimation) is:

log Koc = 0.81 log Kow + 0.1 (chemical class: Predominantly hydrophobics)

The properties of difenacoum may hamper the estimation of log Kow that is why it should be considered with some caution. The calculated log Koc is 6.27 and Koc = 1 871 544.

In the difenacoum dossier it has been stated that, according to its behaviour, the active substance would not be mobile and would be expected to absorb irreversibly to soil particles. Significant leaching could be expected to occur only in recently contaminated soil under alkaline conditions. Under other conditions, binding to the inorganic component of soil would be largely irreversible. The rate of binding is likely to be limited by steric hindrance of reaction in forming the cation bridge from the organic material.

[10] Technical Guidance Document on Risk Assessment, Part II, 2003

2.8.1.5.2 Accumulation

The aquatic BCF has been estimated with calculation method because the fish bioconcentration test was invalid. In the absence of valid measured log Kow, the estimated value of log Kow used is 7.6. This value allows to calculate an estimated BCF for fish: 9010 (according to EPIWIN v 3.12) and 35 645 (Equation 75, TGD).
In order to remain coherent with the Annex I inclusion dossier, BCF for fish value of 9010 is used to perform secondary poisoning evaluation via aquatic trophic chain.

This log Kow is also entered the equation 82d of the TGD to get a $BCF_{earthworm}$ equal to 477 729.

The calculations show that difenacoum has a considerable bioaccumulation potential in aquatic and terrestrial organisms.

2.8.2 Effects of the active substance on environmental organisms

2.8.2.1 Aquatic compartment (including water, sediment and STP)

Difenacoum is very toxic to aquatic organisms. Difenacoum was equally toxic to fish (LC_{50}= 0.33 mg a.s/L, OECD 203), daphnia (EC_{50}= 0.91 mg a.s/L, OECD 202) and algae (E_bC_{50} =0.14 mg a.s/L, OECD 201). Nevertheless, a lower fish test result (LC_{50}=0.064 mg/L) is available in the difenacoum dossier of Sorex Limited. Therefore, it is used for the derivation of PNECwater in the Difenacoum Task force Annex I inclusion dossier as recommended in the CAR.

In the absence of any ecotoxicological data for sediment-dwelling organisms, the $PNEC_{sediment}$ was calculated using the equilibrium partitioning method.

Difenacoum has shown to degrade photolytically in water in laboratory conditions and it may form degradation products exceeding 10% of the parent compound. The metabolites are not considered to have ecotoxicological significance, because photolysis is considered to be a minor transformation path for difenacoum and the exposure to water via the STP is expected to be low.

Difenacoum did not cause any effects on the activated sludge respiration inhibition up to the nominal concentration of 999.7 mg/L (OECD 209). Because all test concentrations exceeded the water solubility of Difenacoum, the water solubility of 0.48 mg/L will be used as $PNEC_{STP}$.

2.8.2.2 Atmosphere

No data are available on the biotic effects in the atmosphere. Difenacoum is not expected to con-tribute to global warming, ozone depletion in the stratosphere, or acidification on the basis of its physical or chemical properties.

2.8.2.3 Terrestrial compartment

Difenacoum caused no toxic effects on earthworms up to the nominal concentration of 994 mg/kg dry weight (OECD 207). Difenacoum may not be bioavailable to earthworms in soil which would explain the low toxicity. No studies on soil microorganisms or plants were submitted.

The photolysis degradation products are not considered ecotoxicologically relevant because the direct exposure of difenacoum to soil is expected to be low.
Toxicity of difenacoum in birds increased with exposure time. Difenacoum was considered as moderately toxic in acute oral exposure (LD50= 153 mg/Kg bw), toxic in 5-day dietary test (LC_{50}=1.4 mg/Kg feed) and very toxic in the reproduction test (NOEC= 0.31 mg/Kg water, exposure via drinking water). Several dose related effects were detected in the reproduction test: increased adult mortality, increased mortality of 14-day old hatchlings, increased liver and spleen weights in adult females, a declining trend in number of eggs laid/hen/day, declining trend in viability of eggs. Due to methodological deficiencies the reproduction test is not considered to represent the worst case, and therefore the PNECoral of birds was derived from the dietary test. Difenacoum is very toxic to mammals, and rats seem to be particularly susceptible. The PNECoral for birds and mammals has been used for the risk characterization of primary and secondary poisoning.

2.8.2.4 PBT Assessment

Due to the properties of persistence, accumulation and toxicity of difenacoum, this substance fulfills the PBT criteria.

2.8.2.5 Non compartment specific effects relevant to the food chain

As already stated in the previous sections, difenacoum is concern for bioaccumulation with a calculated log Kow of 7.62, a high predicted aquatic BCF of 9 010 (US EPA EPIWIN) or 35 645 (TGD) and a high predicted terrestrial BCF of 477 729 (TGD). The active substance is not readily biodegradable and is of low solubilty (0.5 mg/L pH7). Therefore, difenacoum has a considerable bioaccumulation potential in aquatic and terrestrial organisms.

The primary concern is from predators eating the rodent carcasses and earthworms which have ingested the active substance absorbed to soil. In guidance document for TP14, the active substance is considered to be placed in protected bait point. Therefore, a risk should be taken into account for primary poisoning mainly for birds and mammals of equal or smaller size than the target rodents. Also when target animals carry bait away from e.g. bait stations, non-target animals may be exposed. For the risk characterization of primary poisoning, the $PNEC_{oral}$ described in section 2.8.2.6 will be used.

Also requiring consideration are predators eating fish or earthworms which have accumulated difenacoum from water and soil. The secondary exposure should be taken in consideration. The applicant has submitted, in the Annex I inclusion dossier, one acceptable study report where effects of difenacoum are studied in Barn Owls which have been exposed

to poisoned mice. However, the $PNEC_{oral}$ for birds and mammals are derived from a bird 5-day dietary test and a 90-day subchronic test in rat provided in the Activa/Pelgar Difenacoum Task Force Annex I inclusion dossier as described below (part 2.8.2.6).

2.8.2.6 Effects assessment of metabolites formed in target organisms

A metabolism study presented in the Activa/Pelgar Difenacoum Task Force Annex I inclusion dossier (doc IIIA-6.4 of the CAR) shows that total excreted radioactivity in rat faeces and urine (7 days after single dosing, low and high dose) was 41-71% of the dose administered. Two major faecal metabolites F7 and F8 (max 11.3% and 7.3%, respectively) were identified as isomers of hydroxylated difenacoum. Two other major metabolites, F5 and F6 (max 12.2% and 8.0 %, respectively) were characterised as isomers of difenacoum-based structure which formed glucuronide conjugates. Unchanged difenacoum was present at maximum at 2.9 %. The excretion and retention of radioactivity was also investigated after the final dose following administration of seven consecutive daily oral doses, no substantial differences in excretion patterns between single and repeated level oral doses was observed.

No information on toxicity of these four major metabolites is available. Considering that the metabolites could be potent as anticoagulants, the sum of these four metabolites and unchanged difenacoum in faeces will be taken into account in PEC calculation with assumption that the toxicity of metabolites is comparable to parent (data from the validated CAR of the Activa/Pelgar Difenacoum Task Force Annex I inclusion dossier). Therefore in the environmental exposure calculations, it is assumed that 40% of excreted amount in urine and faeces is metabolised and that 40 % of administered total amount is unchanged difenacoum in faeces (data from the validated CAR of the Activa/Pelgar Difenacoum Task Force Annex I inclusion dossier). These assumptions represent a worse case for release.

2.8.2.7 Summary of PNEC

2.8.2.7.1 PNEC for aquatic organisms:

The $PNEC_{water}$ is derived from the lowest available LC_{50} value 0.064 mg/L (fish test) with an assessment factor of 1000 as only data on acute toxicity is available. Therefore,

PNECwater = 0.06 µg/L

2.8.2.7.2 PNEC for sediment-dwelling organisms:

In the absence of data on sediment-dwelling organisms, the PNECsediment is derived from the equilibrium partitioning method.

$PNEC_{sediment}$ = 2.51 mg/kg wet weight.

2.8.2.7.3 PNEC for STP micro-organisms:

As described in section 2.8.2.1, the water solubility of 0.48 mg/L will be used as the $PNEC_{STP}$.

$PNEC_{STP}$ = 0.48 mg/L

2.8.2.7.4 PNEC for terrestrial organisms:

The $PNEC_{soil}$ is derived from the experimental data. An assessment factor of 1000 was applied to the LC_{50} > 994 mg/kg issued from an earthworms study to derive the $PNEC_{soil}$.

$PNEC_{soil}$ = 0.994 mg/kg dry weight (0.877 mg/kg wet weight)

Nevertheless, as only one experimental test result is available, the $PNEC_{soil}$ derived with the equilibrium partitioning method (EPM) from the aquatic PNEC has also been taken into account:

$PNEC_{soil}$ = 2.04 mg/kg wet weight

Because the $PNEC_{soil}$ derived from the earthworms test is lower, it will be used for the risk characterization. So,

PNECsoil = 0.994 mg/kg dry weight (0.877 mg/kg wet weight)

2.8.2.7.5 PNEC for birds and mammals

PNECoral for birds is derived from the LC_{50} of 1.4 mg/kg food origin from the 5-day dietary test. The appropriate assessment factor according to the TGD is 3000. In order to transform the LC_{50} to LD_{50}, LC_{50} is multiplied with average food consumption (13.5 g) and divided by average body weight 71.3 g. The food consumption and body weight are averaged for all treatment groups and over the 5-day exposure period. The resulting LD_{50} is 0.3 mg/kg bw/d. The $PNEC_{oral}$ value kept for the risk assessment is:

$PNEC_{oral}$ for birds = 0.5 µg/kg food equivalent to
$PNEC_{oral}$ for birds = 0.1 µg/kg bw/d

PNECoral for mammals is derived from the NOAEL of 0.03 mg/kg bw/d origin from the 90-day subchronic test in rat (A6.4.1). The NOAEL is transformed to NOEC (concentration in food) by multiplying with the conversion factor of 20 (TGD, Table 22). The appropriate assessment factor according to the TGD is 90. The $PNEC_{oral}$ value kept for the risk assessment is:

$PNEC_{oral}$ for mammals = 7 µg/kg food equivalent to
$PNEC_{oral}$ for mammals = 0.3 µg/kg bw/d

The PNECoral for birds and mammals have been used for the risk characterization of primary and secondary poisoning.

Table 2.8.2.7: summary of the difenacoum PNECs

Compartment		Test Value	AF	PNEC Unit
Aquatic	$PNEC_{water}$	LC50 =0.064 mg/l	1000	0.064 µg/L
	$PNEC_{sediment}$	PNECwater in eq. 70 (TGD)		2.51 mg/kg wet weight
	$PNEC_{STP}$	Water solubility= 0.48 mg/l		0.48 mg/L
Terrestre	$PNEC_{soil}$	LC50 >994 mg/kg	1000	0.994 mg/kg dry weight 0.877 mg/kg wet weight
	$PNEC_{oral\ for\ birds}$	LC_{50} =1.4 mg/kg food LD_{50}= 0.3 mg/kg bw/d	3000	0.5 µg/kg food eq. to 0.1 µg/kg bw/d
	$PNEC_{oral\ for\ mammals}$	NOEC= 0.6 mg/kg food NOAEL=0.03 mg/kg bw/d	90	7 µg/kg food eq. to 0.3 µg/kg bw/d

2.8.3 EFFECTS on environmental organisms for biocidal product

It is important to notice that the applicant did not provide ecotoxicological data about the biocidal product SORICIDE DB. Therefore the whole environmental risk assessment is based on data obtained from the active substance, difenacoum. There is no substance of concern in the formulated product.

2.8.3.1 Aquatic compartment (including water, sediment and STP)

The product SORICIDE DB is a ready to use wax block bait that contains difenacoum as active substance and denatonium benzoate as an aversive compound. Since difenacoum is the only substance of concern, the ecotoxicological effects can be derived from the effect studies conducted with the active substance.

2.8.3.2 Terrestrial compartment

According to the TNsG on data requirements (Ch. 2.5, Part B) additional data are required from rodenticidal products if they are used outside buildings in the form of baits, granulates and powder. In order to assess the risk for secondary poisoning, acute oral toxicity study and study by acceptance by ingestion of the biocidal product by any non-target organisms should be investigated. Nevertheless, it can be noted that in the active substance dossier for annex I inscription, the applicant has submitted two reports, with the representative products (wax block bait product) which deal with the UK national monitoring scheme of pesticide poisoning cases.

2.8.3.3 Non compartment specific effects relevant to the food chain (secondary poisoning)

In the SORICIDE DB Wax Blocks bait no substance of concern has been identified, and hence the secondary poisoning is caused entirely by the active substance difenacoum.

2.8.3.4 Summary of PNECs

In the product SORICIDE DB Wax Blocks bait no substance of concern has been identified. Therefore the whole environment risk assessment is based on data obtained from the active substance, difenacoum, with PNECs values presented in section 2.8.2.7.

2.8.4 ENVIRONMENTAL EXPOSURE ASSESSMENT

The product SORICIDE DB is made up of wax blocks with 0.005% of difenacoum, provided either in individual package (PP or PE bags) or in bulk. The wax blocks are placed in secured bait stations (except when used in sewer systems). According to the applicant, the product is intended to be used in sewer systems and in and around industrial, commercial and residential buildings (in bait boxes).

The applicant considers the following application rates:

- For rat control in sewers, the recommended dose is 100 g per manhole (about 100 m) up to 200 g every 3 manholes.

- For rat control in waste water treatment plants, the recommended dose is 100 g up to 200 g product/secured bait point at intervals of 15 m apart.
-
- In and around buildings :
  - Rat: from 80 g up to 200 g of product / bait station at distances of 15 meters apart.
  - Mouse: from 25 g to 30 g of product / bait station at distances of 3 meters apart.

Bait points are inspected frequently and replenished when bait take is observed. Depending on infestation rate, an advised frequency of inspection is 3 to 5 days. Although a professional will eventually for practical reasons synchronise the inspection frequency with a work week so keeping inspections twice or once a week, so have 3.5 to 7 days inspection interval.

The physico-chemical input parameters which were used are as follows:

PHYSICO-CHEMICAL PROPERTIES	Value	Unit
Molecular weight	444.5	[g.mol-1]
Melting point	216.3	[℃]
Vapour pressure at test temperature	5.00E-05	[Pa]

Temperature at which vapour pressure was measured	45	[℃]
Octanol-water partition coefficient	7.62	[log10]
Water solubility at test temperature	0.43	[mg.L-1]
Temperature at which solubility was measured	20	[℃]
Organic carbon-water partition coefficient	1 871 544	[L.kg-1]
Half-life in soil	Not biodegradable*	[d]
BCF	9010	L.kg-1

*according to EUSES, the default DT_{50} value for soil to be used for risk assessment is 1.0E+06 d when the substance is not biodegradable

2.8.4.1 Sewer system – Wax block

The product SORICIDE DB is made up of wax blocks with 0.005% of difenacoum, provided either in individual package (PP or PE bags) or in bulk. In the case of application in sewers, wax blocks are not placed in secured bait stations.

In sewers, the application dose is 100 g per manhole (*i.e.* every 100 m as the distance between two manholes may vary between 50 m to 300 m, but is generally 100 m) or 200 g every 3 manholes. The product is applied preferably in large main sewers (diameter > 30 cm). In larger sewers which can be walked in, baits can be placed along their length on available anchors or on specially installed bait trays each 100 meters or other distance interval.
It was considered that the use in waste water treatment plant was covered by the sewer scenario from the EUBEES ESD PT14 (2003)[11].

From sewer use, the exposed compartments are:

- the sewage treatment plant (primary compartment)
- the aquatic compartment (surface water and sediment)
- the terrestrial compartment (agricultural soil after STP sludge spreading, groundwater)

The release to sewage water for the realistic worst case scenario is:

$$Elocal\ water = \frac{Q\ prod \times Fc\ product}{Temtsstion} \times F\ released$$

Q_{prod} = amount of product used in control operation after one week (kg),
Fc_{prod} = fraction of active substance in product (-),
$T_{emission}$ = number of emission days (d),
$F_{released}$ = fraction of active ingredient released (-).

Emission calculations are carried out considering the default parameters of the ESD PT14 (Default values) as well as specific information on the product provided by the applicant (Normal case) concerning the fraction of the active ingredient released (Table 2.8.4.1-1).

[11] ESD PT14: Emission scenario document (ESD) for biocides used as rodenticides (PT14) (EUBEES ESD, 2003)

In the worst case approach (Default values), no metabolisation of the active substance is considered ($F_{released}$ = 0.9). For the normal case approach, according to the metabolism and toxicokinetics study (cf. section 2.8.2.6), it is assumed that 40% of excreted amount in faeces and urine is metabolised. Therefore, the metabolised fraction of the total amount applied (F_{metab}) is 0.6 x 0.4 = 0.24 considering an ingested fraction of 0.6.
According to the ESD PT14, the refined $F_{released}$ is 0.3 + (0.6-0.24) = 0.66.

Elimination processes in STP are calculated using a Koc calculated from the Kow, the Henry's law constant and the results of biodegradation tests according to TGD by EUSES 2.1. Due to the low vapour pressure and Henry's law constant and because difenacoum is not readily biodegradable, only relevant elimination process is partitioning to suspended matters. EUSES calculations predict that 8.37 % is directed to water, 91.6 % to sludge and 0 % to air.

From the sewer use also an exposure to soil via the sludge application is possible. PECsoil and subsequent concentration in groundwater (porewater) calculated by EUSES are presented in the table below.

According to the ESD, the default amount of product used in the control operation in sewer is 30 kg during the first 7 days of the control operation which corresponds to the realistic worst case situation.

Table 2.8.4.1-1: Input values, emission and concentration in sewage water calculated according to the ESD PT14 for sewer system and the TGD - Worst case scenario with the default values from the ESD PT14 and normal case scenario.

Local emission of active substance to waste water during episode:			Default values	Normal case	unit
INPUTS	$Q_{prod:}$	Amount of product used in control operation after one week	30	30	kg
	$Fc_{product}$:	Fraction of active substance in product	0.005	0.005	%
	$T_{emission:}$	Number of emission days (realistic worst case during the control operation)	7	7	d
	$F_{metabolised:}$	Fraction of active ingredient metabolised	0	0.24	-
	$F_{released:}$	Fraction of product released	0.9	0.66	-
OUTPUTS	$Elocal_{water}$	Mean local emission of active substance to waste water during episode	1.93E-04	1.41E-04	kg/d
	Cinfl *(default STP)*	Concentration in sewage water to default STP	9.64E-05	7.07E-05	mg/L
PEC calculated according to the TGD, part II (2003)					
PEC STP (eq. 33)		PEC for microorganisms in the STP	8.07E-06	5.92E-06	mg/L
PEC local water (eq. 45)		PEC in surface water during emission episode	2.18E-07	1.60E-07	mg/L
PEC local sed (eq. 50)		PEC in sediment during emission episode	8.55E-03	6.27E-03	mg/kg wwt
PIEC local soil (eq. 66)		PEC initial in soil	3.29E-04	2.41E-04	mg/kg wwt
PEC local soil 10 years (eq. 62)		PEC in soil after 10 years of application	3.29E-03	2.41E-03	mg/kg wwt
PEC local soil porewater (eq. 67)		PEC in porewater (based on PEC local soil after 10 years)	1.03E-04	7.57E-05	µg/L
PEC fish (eq. 76)		PEC in food via aquatic food chain	9.83E-03	7.21E-03	mg/kg wet fish
PEC earthworm (eq. 82c)		PEC in food via terrestrial food chain	2.24E-02	1.64E-02	mg/kg wet earthworm

2.8.4.1.1 PEC in surface water and sediment

PEC values in the aquatic compartment and the STP from EUSES calculation are reported in the table 2.8.4.1-2 below.

Table 2.8.4.1-2: PEC values for the aquatic compartment and the STP

	Default values	Normal case	Unit
PEC in surface water during emission episode	2.18E-07	1.60E-07	mg/L
PEC in sediment during emission episode	8.55E-03	6.27E-03	mg/kg wwt
PEC for microorganisms in the STP	8.07E-06	5.92E-06	mg/L

2.8.4.1.2 PEC in air

Difenacoum is not expected to partition to the atmosphere to any significant extent due to low vapour pressure and Henry's Law constant. Difenacoum has a potential for rapid photo-oxidative degradation in the air (half-life about two hours). The exposure of air is therefore considered negligible for the application of SORICIDE DB biocidal product.

2.8.4.1.3 PEC in soil and groundwater

PEC values in terrestrial compartment and groundwater from EUSES calculation are reported in the table 2.8.4.1-3 below.

Table 2.8.4.1-3: PEC values in terrestrial compartment and groundwater

	Default values	Normal case	Unit
PEC initial in soil	3.29E-04	2.41E-04	mg/kg wwt
PEC in soil after 10 years of application	3.29E-03	2.41E-03	mg/kg wwt
PEC in porewater (based on PEC local soil after 10 years)	1.03E-04	7.57E-05	µg/L

2.8.4.1.4 Non-compartment specific effects relevant to the food chain (primary and secondary poisoning)

2.8.4.1.4.1 Primary poisoning

According to the ESD PT14, no primary poisoning hazard to mammals or birds is relevant for the sewer scenario because no other mammals (or birds) are living or occurring in sewers.

2.8.4.1.4.2 Secondary poisoning

According to the ESD PT14, the secondary poisoning hazard is relevant only if poisoned rats or cockroaches move to the surface. In the case of rats the risk is covered by the 'in and around buildings' scenario performed in section 2.8.4.2. According to CEFIC (2002) cockroaches are predominantly nocturnal and the species found in sewers e.g. *Blatta orientalis* will remain underground and are not significant prey items for birds.

Nevertheless, for the sewer scenario, the contamination of the food chain (via the contaminated terrestrial and aquatic compartment) is possible after the STP according to EUSES 2.1.0. These PEC values are therefore reported in table 2.8.4.1-4 below.

Table 2.8.4.1-4: PEC in food via aquatic chain and terrestrial chain

	Default values	Normal case	Unit
PEC in food via aquatic food chain	9.83E-03	7.21E-03	mg/kg wet fish
PEC in food via terrestrial food chain	2.24E-02	1.64E-02	mg/kg wet earthworm

2.8.4.2 In & around building – Wax block

The product SORICIDE DB is made up of wax blocks with 0.005% of difenacoum provided either in individual package (PP or PE bags) or in bulk. The wax blocks are always placed in secured bait stations when used in and around buildings.

According to the product instructions:

- The product SORICIDE DB is made up of wax blocks with 0.005% of difenacoum provided either in individual package (PP or PE bags) or in bulk but always placed in secured bait stations.
- The application types "wax block" or "bait-box" of the ESD PT14 are applied for the following calculations in the exposure scenarios.
- According to the product instructions, the SORICIDE DB baits are placed in bait stations only.
- Number of bait stations: 30 (20 inside and 10 outside, 15 meters apart for rats, 3 meters apart for mouse)
- Day 1: Treatment with 200 g product per box for rat, 30 g product per box for mouse
- Day 7, 14 and 21: bait refilling.

The only primary compartment to be exposed during 'in and around use' is the soil.

Emission calculations are carried out considering the default parameters of the ESD PT14 (Default values) as well as specific information on the product provided by the applicant (Normal case ;

Table 2.8.4.2-1).

For the normal case approach, as a worst case assumption, 40% of ingested active substance is released via urine and faeces as unchanged difenacoum and difenacoum-based metabolites according to metabolism and toxicokinetics study (section 2.8.2.6).

The scenario in the ESD PT14 is primarily based on grains and wax blocks. The formulation for difenacoum supported is a formulation/delivery type which does not strictly fit any of the product types for which emissions scenarios have been detailed in the ESD PT14. In fact, SORICIDE DB is not handled in a loose form during application; it is enclosed in a PP or PE bags which is not removed. Due to the special formulation of this product, an estimated direct release during application and use is estimated to be at least 10 times lower compared to the 1% stated in the ESD PT14. Therefore the estimated direct release ($F_{release\text{-}D\text{-}soil}$) during application and use is set to 0.1% (this refinement was agreed during TMI06). Moreover, according to the product instructions, bait stations are placed 15 m apart, which gives an exposed soil area of 1650 m² (instead of 550 m² calculated with the distance of 5 m from the ESD PT14).

According to the ESD PT14 and the applicant's usage, the normal campaign baiting is:

- Day 1: Treatment with one normal bait per box ,
- Day 3: 100 % replenishment,
- Day 7: 25-50 % replenishment,
- Day 14: 10 % replenishment,
- Day 21: 0% replenishment

The normal campaign baiting is roughly equivalent to 1.5 replenishments corresponding to a total direct release over 28 days.

Table 2.8.4.2-1: In and around buildings - Rat and mouse control campaign – Scenarios considering the default values from the ESD PT14 and the Normal cases according to the product instructions.

IN AND AROUND BUILDING (Bait boxes)			Default values Rat	Normal case Rat	Normal case Mouse	Unit
INPUTS	$Q_{prod:}$	Amount of product used in control operation for each bait box	250	200	30	g
	$Fc_{product}$:	Fraction of active substance in product	0.005	0.005	0.005	%
	Nsites:	Number of outsite application sites	10	10	10	-
	N_{refil}:	Number of refilling times	5	1.5	1.5	-
	$F_{release\text{-}D,\ soil}$:	Fraction of product released directly to soil	0.01	0.001	0.001	-
	$F_{release\text{-}ID,\ soil}$:	Fraction released indirectly to soil	0.9	0.4	0.4	-
	$F_{metabolised:}$	Fraction of active ingredient metabolised	0	0.6	0.6	-
	$AREA_{exposed}$:	Area directly exposed to rodenticide originating from bait box	0.09	0.09	0.09	m2
	$DEPTH_{soil}$:	Depth of exposed soil	0.1	0.1	0.1	m
	RHO_{soil}:	Density of exposed soil	1700	1700	1700	kg/m3
OUTPUTS	$Elocal_{soil\text{-}campaign,\ direct}$:	Direct emission to soil from a campaign	6.25E-03	1.50E-04	2.25E-05	g/camp
	$Elocal_{soil\text{-}campaign,\ indirect}$:	Indirect emission to soil from a campaign	5.57E-01	5.99E-02	8.99E-03	g/camp
	$Elocal_{soil\text{-}campaign}$:	Total emission to soil from a campaign	5.63E-01	6.01E-02	9.01E-03	g/camp
	$AREA_{exposed\text{-}ID}$	Area indirectly exposed to rodenticide	550	1650	330	m2
	$Clocal_{soil\text{-}D}$	Local concentration in soil due to direct release after a campaign:	4.08E-02	9.80E-04	1.47E-04	mg/kg_{wwt}
	$Clocal_{soil\text{-}ID}$	Concentration in soil due to indirect (disperse) release after a campaign:	5.96E-03	2.14E-04	1.60E-04	mg/kg_{wwt}
	$Clocal_{soil}$	Total concentration in soil	4.68E-02	1.19E-03	3.07E-04	mg/kg_{wwt}
PEC are calculated according to the TGD, part II (2003)						
PEC local soil		PEC in soil	4.68E-02	1.19E-03	3.07E-04	mg/kg_{wwt}
PEC local soil porewater = $C_{porewater}$		PEC in porewater	1.42E-06	3.62E-08	9.31E-09	mg/L

2.8.4.2.1 PEC in surface water and sediment

Exposure of surface water and sediment after the treatment with rodenticides in and around buildings is only relevant for indoor application of liquid poisons, residues from mixing and

cleaning (ESD PT14) when a release is foreseen via the STP. Therefore the exposure of surface water and sediment is considered negligible for the application of SORICIDE DB.

2.8.4.2.2 PEC in air

Difenacoum is not expected to partition to the atmosphere to any significant extent due to low vapour pressure and Henry's Law constant. Difenacoum has a potential for rapid photo-oxidative degradation in the air (half-life about two hours). The exposure of air is therefore considered negligible for the application of SORICIDE DB product.

2.8.4.2.3 PEC in soil and groundwater

The PEC values for the terrestrial compartment and groundwater are reported in the table 2.8.4.2-2 below.

Table 2.8.4.2-2: PEC values in terrestrial compartment and groundwater

	Default values	Normal case for Rat	Normal case for Mouse	Unit
PEC in soil	4.68E-02	1.19E-03	3.07E-04	mg/kg wwt
PEC in porewater	1.42E-06	3.62E-08	9.31E-09	mg/L

2.8.4.2.4 Non-compartment specific effects relevant to the food chain (primary and secondary poisoning)

2.8.4.2.4.1 Primary poisoning

The risk assessment for the primary poisoning presented below was extracted from the Annex I inclusion dossier for the active substance considering that difenacoum concentration is identical in the product SORICIDE DB and in the representative product presented in the Annex I inclusion dossier for the active substance..

According to the ESD PT14, primary poisoning hazard to mammals and birds (both wild and domestic) can be considered small in the scenario “In and around buildings”. In used scenarios where difenacoum is placed in protected bait point, there is the risk for primary poisoning mainly for birds and mammals of equal size or smaller as the target rodents, which may be able to enter the bait stations. Also when target animals carry bait away from e.g. bait stations, non-target animals may be exposed.

Worst case exposure estimations are based on the equations and default values proposed by the ESD PT14. Some defaults may be replaced by product-specific properties. The Tier 1 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. **The worst case Tier 1 PECoral is 50 mg/kg** (difenacoum present at 0.005% w/w in SORICIDE DB) and is used in quantitative risk assessment for the long-term situation.

According to the ESD PT14, a Tier 2 evaluation assessment can be done estimating the daily uptake of a compound (ETE) by non-target animals according to the equation 19 of the ESD PT14.

(ETE = (FIR/BW) * C * AV * PT * PD (mg/kg bw/day) ;

FIR: food intake rate of the indicator species,
BW: indicator species body weight,
C: concentration of the active substance in fresh diet,
AV: avoidance factor,
PT: fraction of diet obtained in treated area and
PD: the fraction of the food type in the diet.

In Tier 2 Step 1 (worst case) AV, PT and PD are all set at 1; in Step 2 (realistic worst case) these AV and PT are refined to 0.9 and 0.8, respectively.

When the elimination of the active substance is taken into account the expected concentration of active substance (EC) in animal is calculated with the following equation:

EC = ETE x (1-El)

where El is the fraction of daily uptake eliminated (number between 0 and 1, default 0.3).

According to the toxico-kinetic study (section 2.8.2.6), the total daily elimination in rats taking into account excretion through faeces and metabolism of difenacoum in rat liver, is approximately 40% (elimination factor 0.4), which is also used in calculations for non-target animals as there is no other data available. Calculations of ETE and EC values for worst case and realistic worst case situations are presented in the Table below. According to the guidance agreed at 23rd Competent Authority meeting these values are used for qualitative risk assessment of primary poisoning in acute situation.

Table 2.8.4.2-3: Expected concentrations of difenacoum in non-target animals in the worst case (Step 1) and realistic worst case (Step 2) for acute situations with and without elimination

Species		Body weight (g)	Daily mean food intake (dw) (g)	Rodenticide consumption (g)	Estimated daily uptake of difenacoum (ETE) after single meal (mg/kg bw)		Expected concentration (EC) of a.i. in the animal after one day elimination (mg/kg bw)	
					Step 1 [1]	Step [2]	Step 1[1]	Step 2[2]
Dog	*Canis familiaris*	10000	4563	600	2.28	1.37	1.64	0.98
Pig	*Sus scrofa*	80000	25203 (600)4	600	0.4	0.27	0.23	0.16
Pig, young	*Sus scrofa*	25000	969[3] (600)[4]	600	1.2	0.86	0.72	0.52
Fox Representing General non-target mammal	*Vulpes vulpes* 5700	5700	520 [5] 287[3]	520 287	4.56 2.5	3.28 1.5	2.73 1.8	1.97 1.08
Tree sparrow	*Passer montanus*	22	7.6	7.6	17.3	12.44	10.36	7.46
Chaffinch	*Fringilla coelebs*	21.4	6.42	6.42	15.0	10.8	9.0	6.48
Wood pigeon	*Columba palumbus*	490	53.1	53.1	5.4	3.9	3.25	2.34
Pheasant	*Phasianus colchicus*	953	102.7	102.7	5.4	3.9	3.23	2.33

[1] avoidance (AV), Fraction of diet from treated area (PT) and Fraction of food type in diet (PD) are set at 1.
[2] according to ESD AV to 0.9 and PT 0.8.
[3] according to ESD3.2.1. logFIR = 0.822 logBW – 0.629.
[4] according to ESD 600g is maximum for rodenticide consumption in one daily meal.
[5] ESD table 3.5.

Calculations of the expected concentrations (EC) for 5 days exposure considering elimination are calculated according to the ESD PT14 equation 21 as a worst case i.e. AV, PT and PD are set to 1.

According to the guidance agreed at 23rd CA meeting EC5 values are used for quantitative risk assessment of primary poisoning in the long-term situation.

Table 2.8.4.2-4: Expected concentrations of difenacoum (EC5) in non-target animals for the long-term situations (worst case).

Species		Body weight(g)	Daily mean food intake (dw) (g)	Rodenti-cide con-sumption (g)	Expected concentration (EC_5) of a.i. in the animal after 5 days exposure, elimination taken into ac-count (mg/kg bw)
Dog	*Canis familiaris*	10000	456[3]	456	8.43
Pig	*Sus scrofa*	80000	2520[3] (600)[4]	600	0.52
Pig, young	*Sus scrofa*	25000	969[3] (600)[4]	600	1.57
Fox Representing General non-target mammal	*Vulpes vulpes*	5700 5700	520[5] 287[3]	520 287	5.95 3.33
Tree sparrow	*Passer montanus*	22	7.6	7.6	22.56
Chaffinch	*Fringilla coelebs*	21.4	6.42	6.42	19.58
Wood pigeon	*Columba palumbus*	490	53.1	53.1	7.05
Pheasant	*Phasianus colchicus*	953	102.7	102.7	7.04

1avoidance (AV), Fraction of diet from treated area (PT) and Fraction of food type in diet (PD) are set at 1.
[2] according to ESD AV to 0.9 and PT 0.8.
[3] according to ESD3.2.1. logFIR = 0.822 logBW – 0.629.
[4] according to ESD 600g is maximum for rodenticide consumption in one daily meal.
[5] ESD table 3.5.

Among the anticoagulant poisoning incidents, dogs are common victims. The intoxication of dogs is easily detected as they live together with man. Intoxication incidents of wild animals may often remain unobserved. Small non-target rodents, such as voles, and small, granivorous birds can feed on rodenticidal baits because they can pass through the entrance hole of a bait station. Exposure may also arise if target animals carry bait away from the bait station. The domestic animals at risk are dog, pig and hen. Birds eating cereal and weed seeds like sparrows, pigeons and pheasants are possible wild species that may be at risk of primary poisoning.

2.8.4.2.4.2 Secondary poisoning

- ***Secondary poisoning via the aquatic food chain***

As no exposure of the aquatic compartment is foreseen with the use of SORICIDE DB in and around buildings, no risk assessment for secondary poisoning through the aquatic food chain is required.

- ***Secondary poisoning via the terrestrial food chain***

<u>The earthworm-eating mammal or bird</u>

According to the TGD secondary poisoning through the terrestrial route is soil → terrestrial organisms (earthworm) → earthworm-eating mammal or bird. Since birds and mammals

consume worms with their gut contents and the gut of earthworms can contain substantial amounts of soil, the exposure of the predators may be affected by the amount of substance that is in the soil.
$PECoral_{predator}$ is calculated for rat application for the refined scenario as:

$PEC\ oral_{,predator} = C_{earthworm}$ (eq 80, TGD, 2003)

$C_{earthworm} = (BCF_{earthworm} * C_{porewater} + Clocal_{soil} * F_{gut} * CONV_{soil})/ (1+Fg_{ut\ kgdwt/kgwwt} * CONV_{soil\ kgwwt/kgdwt})$ (eq 82c, TGD 2003).

No measured BCF for earthworm is available and the calculated **BCF of 477 729 $L/kg_{wet\ earthworm}$** (section 2.8.1.5.2) is used in the calculations.

$C_{earthworm}$ = (477 729 $L/kg_{wet\ earthworm}$ x 3.62E-08 mg/L + 1.19E-03 mg/kg_{wwt} x 0.1 kg_{dwt}/kg_{wwt} x 1.13 kg_{wwt}/kg_{dwt})/(1+0.1 *1.13) = **1.57E-02 $mg/kg_{wet\ earthworm}$.**

According to the TGD, the most appropriate scenario is that 50% of the diet comes from a local area and 50% comes from the regional area, thus when the $PEClocal_{,soil}$ is used in calculation, the **$PECoral_{,predator}$** to be used in risk assessment is 0.0162 $mg/kg_{wet\ earthwom}$ x 0.5 = **7.85E-03 $mg/kg_{wet\ earthworm}$.**

<u>The rodent-eating mammal or the rodent-eating bird</u>

As secondary poisoning assessment according to the TGD considers the oral intake of a chemical only via fish or worms, another food chain rodenticide (bait) →rodent → rodent-eating mammal or rodent-eating bird is assessed in the ESD PT14.

The risk assessment for the secondary poisoning presented below was extracted from the Annex I dossier for the active substance inclusion considering that difenacoum concentration is identical in the product SORICIDE DB and in the representative product presented in the Annex I inclusion dossier for the active substance..

According to the ESD PT14, for secondary poisoning hazard, in uses in and around buildings, it is assumed that predators among mammals and birds may occur inside buildings or they may hunt rats in the immediate vicinity of buildings (parks and gardens or further away); also scavengers may search for food close to buildings and thus secondary poisoning through poisoned rats exists.

For estimation of secondary poisoning risk through poisoned rats, tiered approach is presented in the ESD PT14:

- The Tier 1 assessment of secondary poisoning is based on the concentration in the predator's or scavenger's food i.e. poisoned rodents (concentration in food); the predator is assumed to catch the rodent after last meal on day 5 or day 14.
- The Tier 2 assessment of long-term secondary poisoning is based on the expected concentration in predators compared to $PNEC_{oral}$ expressed as a daily dose; the predators accumulate difenacoum by feeding on poisoned target rodents during one day (rodents ate baits every day during 5 and 14 days).

Therefore, the amount of difenacoum in rats is estimated according to equations 19 and 21 in the ESD PT14:

ETE = (FIR/BW) * C * AV * PT * PD (mg/kg bw/day),

$$EC_n = \sum_{n=1}^{n-1} ETE \times (1 - El)^n$$

In calculations AV and PT for rodent are set to 1 and PD values to 1, 0.5 and 0.2.
The daily elimination is assumed to be 40%, see details in section 2.8.2.6**.** Results are presented in the following Table.

Table 2.8.4.2-5: Estimated concentration (EC) of difenacoum in target rodents (rats) in mg a.s./kg bw at different times during a control operation

	Residues of rodenticide in target rodent, mg/kg		
	Worst case 100% bait consumption by rodent (PD 1)	**Normal case** 50% bait consumption by rodent (PD 0.5)	**ESD minimum** 20% bait consumption by rodent (PD 0.2)
normal non-resistant target rodent which stops eating on day 5			
Day 1 after 1st meal	5.0	2.5	1.0
Day 2 before new meal	3.0	1.5	0.6
Day 5 before meal	6.53	3.26	1.31
Day 5 after last meal	11.53	5.76	2.31
Day 6*	6.92	3.46	1.38
Day 7 (mean time to death)*	4.15	2.08	0.83
Extreme case – rodent continues eating due to resistance			
Day 14 after the meal	12.49	6.25	2.5

* - The feeding period has been set to a default value of 5 days until the onset of symptoms after which it eats nothing until its death.

- Tier 1 PEC_{oral} for short term situation is calculated according to the equation 22 in the ESD PT14;

  PEC oral, predator = (ECn +ETE) x F rodent)
  using value 1 for F_{rodent} (non-target animal consume 100% of their daily intake on poisoned rodents).

where

F_{rodent} : fraction of poisoned rodents in predator's diet
EC_n: expected concentration of a.s. in the rodent on day 'n' before the last meal
N: the number of days the rodent is eating rodenticide until caught, default 5.

These values, presented in the table 2.8.4.2-6 below, are used for qualitative risk assessment of secondary poisoning in acute situation.

- Tier 1 PEC_{oral} for long term situation is calculated in a similar way, but the F_{rodent} is set to 0.5, which means that it is assumed that non-target animal consume 50 % of their daily intake on poisoned rodents. These values, presented in the table 2.8.4.2-6 below, are used for Tier 1 quantitative risk assessment of secondary poisoning in the long-term situation.

Table 2.8.4.2-6: Predicted environmental concentrations of difenacoum in food of predator (PEC oral) for acute and long-term situations.

$PEC_{oral,predato}$,mg/kg			
	Worst case 100% bait consumption by rodent (PD 1)	**Normal case** 50% bait consumption by rodent (PD 0.5)	**ESD minimum** 20% bait consumption by rodent (PD 0.2)
Normal non-resistant target rodent which stops eating on day 5			
PEC_{oral} on day 5 for 'acute situation'	11.53	5.76	2.31
PEC_{oral} on day 5 for 'long term situation'	5.76	2.88	1.15
Extreme case – rodent continues eating due to resistance			
$PEC_{oral,predator}$ on day 14 'acute'	17.49	8.75	3.5
$PEC_{oral,predator}$ on day 14 'chronic'	8.74	4.37	1.75

- Tier 2 for long-term exposure: According to guidance agreed by the CA the PEC_{oral} is the concentration of active substance in non-target animals after a single day of exposure (mg/kg bw) using values PD of 1 (100% bait consumption by rodent) and F_{rodent} of 0.5. PEC_{oral} values presented in the table below are used for Tier 2 quantitative risk assessment of secondary poisoning in the long-term situation.

  Table 2.8.4.2-7: Expected concentrations of difenacoum in non-target animals due to secondary poisoning after a single day exposure (concentration of difenacoum in rodenticide bait 0.005 %); rodents caught by predators on day 5 and 14 (after feeding), PD 1, Frodent 0.5.

Species		Body wt [g]	Daily FIR [g]	Rodent caught on day 5 after feeding mg ai/kg predator	Rodent caught on day 14 after feeding mg ai/kg predator
Barn owl	*Tyto alba*	294	72.9	1.43	1.55
Kestrel	*Falco tinnunculus*	209	78.7	2.17	2.35
Little owl	*Athene noctua*	164	46.4	1.63	1.77
Tawny owl	*Strix aluco*	426	97.1	1.31	1.42
Fox	*Vulpes vulpes*	5700	520.2	0.53	0.57
Polecat	*Mustela putorius*	689	130.9	1.10	1.19
Stoat	*Mustela erminea*	205	55.7	1.57	1.70
Weasel	*Mustela nivalis*	63	24.7	2.26	2.45

2.8.5 RISK CHARACTERISATION FOR THE ENVIRONMENT

2.8.5.1 Sewer system – Wax block

2.8.5.1.1 Aquatic compartment (including water, sediment and STP)

PNEC values for the water compartment were calculated in the section 2.8.2.7. While PEC values for the sewer system were presented in section 2.8.4.1.
Table 2.8.5.1-1 below presents PEC/ PNEC ratios for surface water, sediment and STP:

Table 2.8.5.1-1: PEC/PNEC ratios for the aquatic compartment

	PEC		PNEC	PEC/PNEC	
	Default values	Normal case		Default values	Normal case
Surface water (mg/L)	2.18E-07	1.60E-07	6.40E-05	3.41E-03	2.50E-03
Sediment (mg/kg wwt)	8.55E-03	6.27E-03	2.51	3.41E-03	2.50E-03
STP (mg/L)	8.07E-06	5.92E-06	0.48	1.68E-05	1.23E-05

No unacceptable risk is identified for the aquatic compartment including surface water, sediment and STP when the product SORICIDE DB is used in sewer system against rats.

2.8.5.1.2 Terrestrial compartment

PNEC values for the terrestrial compartment were calculated in the section 2.8.2.7. While PEC values for the sewer system were presented in section 2.8.4.1.
Table 2.8.5.1-2 below presents PEC/ PNEC ratios for terrestrial compartment including groundwater.

Table 2.8.5.1-2: PEC/PNEC ratios for the terrestrial compartment (incl. Groundwater)

	PEC	PNEC	PEC/PNEC

	Default values	Normal case		Default values	Normal case
Agricultural soil (mg/kg wwt)	3.29E-03	2.41E-03	0.877	3.76E-03	2.75E-03
Groundwater (µg/L)	1.03E-04	7.57E-05	0.1*	1.03E-03	7.57E-04

*threshold value for the groundwater assessment

No unacceptable risk is identified in terrestrial compartment (including the groundwater) when the product SORICIDE DB is used in sewer system against rats.

2.8.5.1.3 Primary poisoning

According to the ESD PT14, no primary poisoning hazard to mammals or birds is relevant for the sewer scenario because no other mammals (or birds) are living or occurring in sewers. Moreover, the risk assessment is covered by the assessment of the "in and around building" uses presented in section 2.8.5.2.2.

2.8.5.1.4 Secondary poisoning

According to the ESD PT14, the secondary poisoning hazard is relevant only if poisoned rats or cockroaches move to the surface. In the case of rat control in sewer the risk is covered by the 'in and around buildings' scenario. According to CEFIC (2002) cockroaches are predominantly nocturnal and the species found in sewers e.g. *Blatta orientalis* will remain underground and are not significant prey items for birds.

Nevertheless, for the sewer scenario, the contamination of the food chain (via the terrestrial and the aquatic compartment) is possible after the STP according to EUSES 2.1.0.
The PEC/PNEC ratios are reported below.

Table 2.8.5.1-3: Secondary poisoning via aquatic and terrestrial food chain in sewer system.

	Aquatic $PEC_{oral,predator}$ mg/kg wet		Terrestrial $PEC_{oral,\ predator}$ mg/kg wet		$PNEC_{\ oral}$ µg/kg food	Aquatic PEC/PNEC		Terrestrial PEC/PNEC	
	Default values	Normal case	Default values	Normal case		Default values	Normal case	Default values	Normal case
Birds	9.83E-03	7.21E-03	2.24E-02	1.64E-02	0.5	19.7	14.4	44.80	32.80
Mammals					7	1.4	1.0	3.20	2.34

In any case, the risk assessments for secondary poisoning are unacceptable via the terrestrial or aquatic food chain in sewer system.
However, as conclude in the CAR, the risk of secondary poisoning via the aquatic food chain is considered insignificant due to low water solubility and high adsorption tendency of

difenacoum. It is also assumed that mechanical screening of sewage water reduces the concentration in the recipient water, although this reduction cannot be quantified.
The risk for secondary poisoning via the terrestrial food chain is higher compared to the aquatic environment. Despite of the calculated risk, the RMS considers the secondary poisoning via earthworms less important than secondary poisoning via the food chain bait → rodent → rodent-eating birds or mammals. The secondary poisoning risk assessment via the food chain bait→ rodent → rodent-eating birds or mammals is performed under the scenario "In and around buildings – wax block (section 2.8.5.2).

The application in sewer systems should be authorised only if the specific use restrictions can be applied to reduce the risk for primary and secondary poisoning, including the application of bait blocks in zone not liable to flooding.

2.8.5.2 In and around buildings – Wax block

2.8.5.2.1 Terrestrial compartment

PNEC values for the terrestrial compartment were calculated in the section 2.8.2.7. While PEC values for the in and around buildings were presented in section 2.8.4.2.3.
The Table 2.8.5.2-1 below presents PEC/ PNEC ratios for terrestrial compartment including groundwater.

Table 2.8.5.2-1: PEC/PNEC ratios for the terrestrial compartment (incl. groundwater)

	PEC			PNEC	PEC/PNEC		
	Default values	Normal case			Default values	Normal case	
		rat	mouse			rat	mouse
Terrestrial (mg/kg wwt)	4.68E-02	1.19E-03	3.07E-04	0.877	5.34E-02	1.36E-03	3.50E-04
Groundwater (µg/L)	1.42E-03	3.62E-05	9.31E-06	0.1*	1.42E-02	3.62E-04	9.31E-05

*threshold value for the groundwater assessment

No unacceptable risk is identified in the terrestrial compartment (including groundwater) when the product SORICIDE DB is used in and around building against rats and mice.

2.8.5.2.2 Primary poisoning

Concentration of the bait is compared to the PNECoral expressed as the concentration in food.

Table 2.8.5.2-2: Tier 1 risk characterisation of primary poisoning.

	PEC mg/kg food	PNEC µg/kg food	PEC/PNEC
Birds	50	0.5	100000
Mammals	50	7	7143

With a Tier 1 Approach, the risk for primary poisoning in birds and mammals is not acceptable.
The expected concentrations (EC) in the non-target animals after five days exposure have been calculated with the tier 2 assumptions, i.e, PT=0.8 and AV=0.9. The $PNEC_{oral}$ is expressed as the daily dose.

Table 2.8.5.2-3: Tier 2 risk characterisation of primary poisoning.

Species		PEC EC_5 µg/kg bw	$PNEC_{oral}$ µg/kg bw/d	PEC/PNEC
Dog	*Canis familiaris*	8 430	0.3	28 100
Pig	*Sus scrofa*	520	0.3	1 733
Pig, young	*Sus scrofa*	1 570	0.3	5 233
Fox	*Vulpes vulpes*	5 950	0.3	19 833
Fox, representing general non-target mammal		3 330	0.3	11 100
Tree sparrow	*Passer montanus*	22 560	0.1	225 600
Chaffinch	*Fringilla coelebs*	19 580	0.1	195 800
Wood pigeon	*Columba palumbus*	7 050	0.1	70 400
Pheasant	*Phasianus colchicus*	7 040	0.1	70 400

With a Tier 2 Approach, the risk for primary poisoning is not acceptable in the non-target animals.
The risk characterisation indicates a very high risk to non-target mammals and birds from direct eating of bait. Primary poisoning incidents can be minimised by preventing the access of non-target animals to the baits. It is assumed in the ESD that if the rodenticide baits are used according to the label instructions, the risk for primary poisoning is negligible. However, it is stated at the EU level that it may not be possible to exclude exposure of all non-target animals, as the baits have to be accessible to target rodents, they may as well be accessible to non-target mammals and birds of equal or smaller size than the target rodents.

2.8.5.2.3 Secondary poisoning

2.8.5.2.3.1 Secondary poisoning via aquatic food chains

As no exposure of the aquatic environment is foreseen with the use of SORICIDE DB in and around buildings, no risk assessment for secondary poisoning through the aquatic food chain is needed.

2.8.5.2.3.2 Secondary poisoning via the terrestrial food chain

The earthworm-eating mammal or bird

In the terrestrial environment birds and mammals may be at risk for secondary poisoning if they feed on contaminated soil organisms. The risk characterization is done separately for birds and mammals to be consequent with the calculations done according to the ESD PT14.

Table 2.8.5.2-4: Secondary poisoning via aquatic and terrestrial food chain in "in and around buildings".

	Terrestrial $PEC_{oral,predator}$ mg/kg wet earthworm	$PNEC_{oral}$ µg/kg food	Terrestrial PEC/PNEC
Birds	7.85E-03	0.5	15.70
Mammals		7	1.12

The PEC/PNEC ratio exceeds 1 for both earthworm eating birds and mammals (

Table 2.8.5.2-4).
The risk is due to feeding on contaminated soil invertebrates in a soil volume of 0.009 m^3. Despite of the calculated risk, the RMS considers the secondary poisoning via earthworms less important than secondary poisoning via the food chain bait → rodent → rodent-eating birds or mammals.

The rodent-eating mammal or bird

A qualitative assessment of the acute secondary poisoning is made by comparing the concentration in the rodents to LD_{50} values from acute oral studies. Rodents are assumed to eat entirely on bait containing difenacoum and the non-target animals are assumed to consume entirely poisoned rodents. The qualitative assessment indicates that birds are likely to survive and mammals are likely to die if they eat poisoned rats (**Erreur ! Source du renvoi introuvable.**). The species specific sensitivity differences or other aspects normally covered by the assessment factors are not taken into account in the qualitative assessment.

Table 2.8.5.2-5: Qualitative assessment of acute secondary poisoning.

	EC in rat on day 5 after last meal mg/kg	Birds LD50 mg/kg bw	Mammals LD50 mg/kg bw
PD=1	11.53	56	1.8
PD=0.5	5.76	56	1.8
PD=0.2	2.31	56	1.8

- **Tier 1 assessment of long term secondary poisoning**

The Tier 1 assessment of secondary poisoning is based on the concentration in the predator's or scavenger's food, i.e. poisoned rodents. The rodents are assumed to consume entirely the bait (PD = 1), while half of the predator's or scavenger's daily food intake is poisoned rodents (F_{rodent} = 0.5). The rodents are assumed to eat the baits in five or fourteen successive days, whereas the predator or the scavenger is assumed to eat the poisoned

rodents during one day. The predator is assumed to catch the rodent after last meal on day 5 or day 14. Only resistant rodents are assumed to eat bait 14 day. The calculation of concentrations in rodents is explained in detail in Section 2.8.4.2.4.2. The $PNEC_{oral}$ is based on the highest concentration causing no effects in the test with long-term exposure. The derivations of PNECs are explained in Section 2.8.3.3.

Table 2.8.5.2-6: Tier 1 risk characterisation of secondary poisoning. Expected concentration in target rodents is compared to the $PNEC_{oral}$ expressed as concentration in food. Rodents are assumed to consume entirely bait (PD=1). Half of the predator's diet is poisoned rodents (F_{rodent}=0.5).

	PEC EC in rodent µg/kg	$PNEC_{oral}$ µg/kg food	PEC/PNEC
Rodents caught on day 5 after meal			
Birds	5760	0.5	11 520
Mammals	5760	7	823
Rodents caught on day 14 after meal			
Birds	8740	0.5	17 480
Mammals	8740	7	1 249

The Tier 1 risk characterisation shows that there is an unacceptable risk for secondary poisoning of mammals and birds (Table 2.8.5.2-6).
Resistant rodents can feed on the poisoned baits longer and accumulate higher difenacoum residues than non-resistant rodents. Resistant rodents can continue to feed difenacoum up to two weeks, while the non-resistant rodents stop feeding after 5 days. Based on the calculations, the resistant rodents cause about 1.5 times higher risk for secondary poisoning of birds and mammals than non-resistant rodents.

- **Tier 2 assessment of long term secondary poisoning**

In the Tier 2 assessment of long-term secondary poisoning the expected concentration in predators is compared to PNECoral expressed as a daily dose. The predators accumulate difenacoum by feeding on poisoned target rodents during one day. The rodents are assumed to eat entirely the bait (PD = 1), whereas half of the predator's or scavenger's daily food intake is poisoned rodents (Frodent = 0.5). The rodents are assumed to eat the baits in five or fourteen successive days. The susceptible rodents are assumed to stop feeding after 5 days, but resistant rodents are assumed to continue feeding until day 14. The calculation of expected concentrations is explained in detail in Section □.

Table 2.8.5.2-7:: Tier 2 risk characterisation of long term secondary poisoning. The expected concentrations in predatory birds and mammals are compared to the $PNEC_{oral}$ expressed as daily dose.

Species		PEC EC in predator µg/kg bw Rodent caught on day 5	PEC EC in predator µg/kg bw Rodent caught on day 14	$PNEC_{oral}$ µg/kg bw/d	PEC/PNEC Rodent caught on day 5	PEC/PNEC Rodent caught on day 14
Barn owl	*Tyto alba*	1430	1550	0.1	14 300	15 500
Kestrel	*Falco tinnunculus*	2170	2350	0.1	21 700	23 500
Little owl	*Athene noctua*	1603	1770	0.1	16 030	17 700
Tawny owl	*Strix aluco*	1310	1420	0.1	13 100	14 200
Fox	*Vulpes vulpes*	530	570	0.3	1 767	1 900
Polecat	*Mustela putorius*	1100	1190	0.3	3 667	3 967
Stoat	*Mustela erminea*	1570	1700	0.3	5 233	5 667
Weasel	*Mustela nivalis*	2260	2450	0.3	7 533	8 167

Also the Tier 2 risk characterisation shows a high risk for secondary poisoning (Table 2.8.5.2-7). The $PNEC_{oral}$ expressed as a dose is approximately equal for birds and mammals, and the sensitivity of the species used in calculations is determined predominantly by the ratio of daily food consumption to body weight so that the higher ratio results in the higher risk. No data are available on the sensitivity of the example species (the species listed in Table 12 of the ESD) to difenacoum. Only one day exposure of predators is assumed in the ESD, but it is mentioned that predators could be exposed over several days. This would mean higher accumulation in predators, because daily elimination of difenacoum from the predators is assumed to be less than the ingested amount. On the other hand, it is unlikely that all worst case assumptions would materialize simultaneously in nature. It is likely that in the long-term exposure, the prey rodents do not eat only the bait and also the fraction of poisoned rodents in the predator's diet can be lower than 50%. The resistant rodents cause somewhat higher risk for predators than non-resistant rodents, but the difference is smaller than in the Tier 1 assessment.

The applicant has submitted two experimental studies on the secondary poisoning in Barn Owls. Tier 1 and Tier 2 risk characterisation are recalculated for the Barn Owl on the basis of the measured concentrations in rats and mice with the experimental data provided in the difenacoum Task Force Annex I inclusion dossier. The risks are significantly lower than with the ESD calculations however they are still considerably higher than 1 indicating risk for secondary poisoning of the Barn Owls.

A review of the available monitoring data was provided in the difenacoum Task Force Annex I inclusion dossier to characterize the risk of secondary poisoning. Most of the incidents were due to misuse, abuse or unspecified use. Only few incidents resulted from approved use of difenacoum. However, like theoretical calculations and experimental results, the monitoring data clearly show that difenacoum poses an inacceptable risk for secondary poisoning. While all available information indicates risk, it does not tell the frequency of secondary poisoning incidents among wildlife.

In order to reduce the risk of primary and secondary poisoning, it is mandatory to follow the use instructions of rodenticidal baits. It is considered that these instructions will be respected by trained professional users.

Regarding the non-professional users, the risk of primary and secondary poisoning is considered as limited for indoor application. The outdoor application for non-professional users should be authorised only if the specific use restrictions can be applied to reduce the risk for primary and secondary poisoning.

The risk reduction measures are considered in the Section 2.9.

2.9 Measures to protect man, animals and the environment

The measures to protect man, animals and the environment are extracted from the Doc IIIB8 of the SORICIDE DB dossier.

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

The product is supplied in a secure packaging. The size of the packaging is appropriate to the end user, small packaging up to 3 kg for amateur users and bigger packaging up to 10 kg for professional users. Loose baits are reserved for professional use only.

Handling and use

The product must be used in accordance with the label.
Avoid contact with eyes, skin and mouth. The use of rubber gloves is recommended for the handling and disposal of the product, dead rodents and used packaging. Wash hands after treatment.
Avoid uncontrolled disposal into the environment.
Use secured bait boxes to prevent access to non-target species.

Storage

Store in the original container in dry, well-ventilated area, inaccessible to children and away from food and animal feedstuffs. Keep away from strong smelling stuff.
Store at ambient temperature (max 40℃) and away fr om light
Keep away from sun radiation and keep away from all other heat sources.
Protect against frost.

Methods and precaution concerning transport

Non hazardous for transport, not regulated.

Methods and precautions concerning fire (proposed by the applicant)

The product is not highly flammable but is combustible. Use water spray, foam, carbon dioxide or powder as suitable extinguishing media. Do not use a heavy water stream.
Do not smoke.
Combustion produces dangerous gases.
Special protective equipment for fire-fighters: wear protective clothing and self-contained breathing apparatus.

2.9.2 Emergency measures in case of an accident

Personal precautions (proposed by the applicant)

Inhalation:
Not likely. Assure fresh air breathing. Rest. If you feel unwell, seek medical advice (show the label where possible).

Skin contact:
Wash with water and soap. Seek medical attention if ill effect develops. If possible show packaging or label.

Eye contact:
In case of eye contact, immediately rinse with plenty of clean water. Rinse away from the eye that has not been contaminated. If contact lenses are easy to remove, remove them first then clean. Seek medical advice. If possible show the label or packaging.

Ingestion:
Rinse mouth with plenty of water. Do not induce vomiting. Seek medical advice immediately (show the label where possible).Call the emergency help centre. A treatment with vitamin K1 should be necessary during a long period.

Environmental precautions

Avoid uncontrolled disposal into the environment because of danger for non-target animals.

Do not throw the product on the ground, into a water course, into the sink or down the drain.

Any spillage should be cleared up immediately.

2.9.3 Disposal considerations

Make sure that adequate measures are taken to avoid exposure to wildlife and non-target organisms. Do not dispose along with household waste. Any contaminated material must be disposed as controlled waste. Any disposal must comply with Local and National requirements.

Search for and remove dead rodents at frequent intervals during treatment, at least as often as when baits are checked and/or replenished. Dispose of dead rodents in accordance with local requirements. Remove all baits after treatment and dispose of them in accordance with National requirements.

Do not clean the bait stations with water between two applications and dispose of them in accordance with local requirements after treatment.

The packaging must not be re-used or recycled.

3 Proposal from authority in charge of the risk assessment (ANSES) for the decision to be adopted by the competent authority in charge of the decision (French Ministry of Ecology)

This section is a proposal from the authority in charge of the risk assessment (ANSES) for the decision to be adopted by the competent authority in charge of the decision (French Ministry of Ecology).
In case of inconsistency between the risk assessment and the decision, only the original and signed decision has a legal value. The decision specifies the terms and conditions to the making available on the market and use of the biocidal product.

The product SORICIDE DB has shown a sufficient efficacy and can be used for the control of mice *(Mus musculus)* and rats (*Rattus novegicus* and *Rattus rattus*), in and around domestic, industrial and commercial buildings including in farm buildings.

Resistant strategies management must be taken into account and difenacoum must not be used in an area where resistance to this substance is suspected.

Concerning the human health part, for the bulk formulation, the risks are considered as acceptable for professional users wearing gloves and acceptable without gloves for non professionals. For the use in sewerage, the risk has not been characterised as none efficacy data have been submitted. However, the exposure of these users is covered by that of professionals. When the product is applied in sachet formulation, the risks are considered as acceptable for professionals and non professionals. Concerning the pre-filled boxes, the risks are similar than those calculated for bulk and sachet formulations.

The risks associated to the scenario "*oral exposure by ingesting bait*" by an infant or a child are considered as unacceptable. Therefore, even if SORICIDE DB contains a bittering agent which reduces the likelihood of ingestion, the baits should be placed in bait boxes which do not allow access to children in secured areas.

Since no contamination is expected for feeding stuffs, the risk for consumers via residues was not assessed. The product must be kept away from food, animal feedstuffs or drinking water.

No studies were conducted with SORICIDE DB for the environment part. The environmental risk assessment has been realized by the French authority in charge of the risk assessment with data from the CAR of difenacoum. The environmental risk is considered as limited for the intended uses, in strict compliance with the specific use restrictions to reduce the risk for primary and secondary poisoning and the use instructions of rodenticidal baits.

The outdoor application for non-professional users should be authorised only if the specific use restrictions can be applied to reduce the risk for primary and secondary poisoning.

Specific use restriction and issues accounted for product labelling:

- Adequate protective gloves must be worn during handling of the product and dead rodents.
- Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
- Use only in tamper-resistant bait stations. Tamper-resistant bait stations should be clearly marked to show that they contain rodenticides and that they should not be disturbed.
- The size of the package placed on the market should be proportionate to the duration of the treatment.
- For product sale in sachets, the product and the sachet labels have to mention “Do not open the sachet”.
- In order to prevent primary and secondary poisoning for children, for domestic and wild animals, bait point must be securely deposited, and placed in non accessible aeras
- Unconsumed baits and dead rodents must be collected every week during the treatment, at least as often as when baits are checked and/or replenished. Dispose of dead rodents in accordance with local requirements.
- Authorisation holder should assure the availability of the bait box to professional users.
- Do not clean the bait stations with water between two applications.
- Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment
- Remove all baits after treatment and dispose of them in accordance with local requirements.
- The packaging must not be re-used or recycled.
- Keep away from food, animal feedstuffs or drinking water.
- Secured bait point must be securely deposited in a way so as to minimise the risk of consumption by children or domestic animals.
- Store at ambient temperature (max 40℃)
- To avoid resistance and because of cross-resistances occurrence to second-generation anticoagulants,
    - The product label has to contain information on resistance management for rodenticides

- The amount of bait per bait station and distances between bait stations must be respected. Products have always to be used in accordance with the label.
- The treatment has to be alternated with active substances having different mode of action.
- Integrated pest management (combination of chemical control, physical and hygienic measures) has to be taken into account.
- The level of efficacy have to be monitored (periodic check), and the case of reduced efficacy has to be investigated for possible evidence of resistance.
- Resistant management strategies have to be developed, and difenacoum must not be used in an area where resistance to this substance is suspected or established.
- The users should report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.

Further information is required:

Precision about the appearance of the product (different sizes of the block and information about the wire) have to be provided.

A 2-year storage stability study is on-going. Results should be given with test items in quantity sufficient to overcome the heterogeneity. Intermediate results at 1 year have to be provided. pH and acidity/alkalinity if relevant and effect of light should be provided also.

The compatibility of SORICIDE DB in individual polypropylene (PP) bag of 20g,have to be provided also.

The authorization holder has to report any observed resistance incidents to the French authority in charge of the risk assessment or other appointed bodies involved in resistance management every two years.

Annex 0: Practical use of Biocides - PT14

This chart reflects the claim uses and the results of the risk assessment for each of them. Please refer to the decision/SPC for final authorised uses.

SORICIDE DB **Type of formulation (grains, powder, paste, block…)** **Grains**	**Target organism (rat, mice…)***	**User category (professional/non professional)***	**Area of use (sewers, in and around buildings, indoor only, open areas, waste dumps,…)***	**Dosage claimed expressed in g/bait point, for high and low infestation (if appropriate)**	**Time delay of the action of the product**	**Frequency and method of controls**	**Size(s) of the bait (g/bloc, g/grain, g/sachet, g/paste …)**	**Distance between 2 bait points, for high and low infestation (if appropriate)**	**Methods of application of the bait (ex: pre-filled secured bait box)**	**Package details : Individual packaging (yes/no)* **for more details please fulfill the column related to primary packaging and secondary packaging***	**Primary packaging : type : bulk, individual wrapping…/ nature: bucket, bottle, sachet…/ material: paper, polyethylene…/ sizes**	**Secondary packaging**	**Conclusion of the efficacy and risk assessment**
SORICIDE DB Formulation : grains	Rats (Rattus norvegicus and Rattus rattus)	Professional	Indoor and around buildings	80-200 g product / secured bait	3-7 days	3 to 7 days inspection interval	- 1 – 30 blocks	intervals of 15 m apart	Bulk in secured bait box	No	Bucket in PP 3 – 10kg Bag of PE 3 – 10kg Polystyrene tray 80g – 2.5kg	- Cardboard box 3 - 10kg	Acceptable
	Rats (Rattus norvegicus and Rattus rattus)	Professional	Indoor and around buildings	80-200 g product / secured bait	3-7 days	3 to 7 days inspection interval	One block per bag	intervals of 15 m apart	Sachets in secured bait box	Yes	Bag of PE foil 20g – 100g	Bucket in PP 3 – 10kg Cardboard box 3 – 10kg	Acceptable

											Bag of PP foil 20g 100g	Bucket in PP 3 – 10kg Cardboard box 3 – 10kg	
	Rats (*Rattus norvegicus and Rattus rattus)*	Professional	Indoor and around buildings	80-200 g product / secured bait	3-7 days	3 to 7 days inspection interval	1-5 blocks	intervals of 15 m apart	Prefilled secured bait box	No	Bait station in PP 50g -200g	Cardboard box 1 – 5 prefilled bait stations	Acceptable
	Mice *(Mus musculus)*	Professional	Indoor and around buildings	25 to 30 g / secured bait	3-7 days	3 to 7 days inspection interval	-	intervals of 3 m apart	Bulk in secured bait box	No	Bucket in PP 3 – 10kg Bag of PE 3 – 10kg Polystyrene tray 80g – 2.5kg	- Cardboard box 3 - 10kg	Acceptable
	Mice (*Mus musculus)*	Professional	Indoor and around buildings	25 to 30 g / secured bait	3-7 days	3 to 7 days inspection interval	One block per bag	intervals of 3 m apart	Sachets in secured bait box		Bag of PE foil 20g – 100g Bag of PP foil 20g 100g	Bucket in PP 3 – 10kg Cardboard box 3 – 10kg Bucket in PP 3 – 10kg Cardboard box 3 – 10kg	Acceptable

	Mice (*Mus musculus)*	Professional	Indoor and around buildings	25 to 30 g / secured bait	3-7 days	3 to 7 days inspection interval	1-3 blocks	intervals of 3 m apart	Prefilled secured bait box	No	Bait station in PP 20g -150g	Cardboard box 1 – 5 prefilled bait stations	Acceptable
	Rats *(Rattus norvegicus)*	Professional	sewers	100 g per manhole up 200g every 3 manhole 1 treatment / year	3-7 days	1 per year	-	NA	Fixed bulk	No	Bucket in PP 3 – 10kg	-	Unacceptable
											Bag of PE 3 – 10kg	Cardboard box 3 - 10kg	
							1 – 30 blocks				Polystyrene tray 80g – 2.5kg		
	Rats (*Rattus norvegicus)*	Professional	Sewers (high infestation level)	100 g per manhole up 200g every 3 manhole 2-4 treatments /year (minimal interval of 3-6 months between 2 applications	3-7 days	NA	-	NA	Fixed bulk	No	Bucket in PP 3 – 10kg	-	Unacceptable
											Bag of PE 3 – 10kg	Cardboard box 3 - 10kg	
							1 – 30 blocks				Polystyrene tray 80g – 2.5kg		
	Rats (*Rattus norvegicus)*	Professional	Waste water treatment plants	100-200g secured bait	3-7 Days	3 to 7 days inspection interval	1 – 30 blocks	intervals of 15 m apart	Bulk	No	Bucket in PP 3 – 10kg	-	Unacceptable
											Bag of PE 3 – 10kg	Cardboard box	

							1 – 30 blocks				Polystyrene tray 80g – 2.5kg	3 - 10kg	
	Rats (*Rattus norvegicus)*	Professional	Waste water treatment plants	100-200 g secured bait	3-7 Days	3 to 7 days inspection interval	One block per bag	intervals of 15 m apart	Sachets in secured bait box	Yes	Bag of PE foil 20g – 100g	Bucket in PP 3 – 10kg Cardboard box 3 – 10kg	Unacceptable
											Bag of PP foil 20g 100g	Bucket in PP 3 – 10kg Cardboard box 3 – 10kg	
	Rats (*Rattus norvegicus)*	Professional	Waste water treatment plants	100-200 g secured bait	3-7 Days	3 to 7 days inspection interval	1-5 blocks	intervals of 15 m apart	Prefilled secured bait box	No	Bait station in PP 50g -200g	Cardboard box 1 – 5 prefilled bait stations	Unacceptable
SORICIDE DB Formulation : grains	Rats (*Rattus norvegicus and Rattus rattus)*	Non Professional	Indoor and around buildings	80-200 g product / secured bait	3-7 days	3 to 7 days inspection interval	One block per bag	intervals of 15 m apart	Sachets in secured bait box	Yes	Bag of PE foil 20g – 100g	Bucket in PP 100g – 3kg Cardboard box 100g – 3kg	**Indoor :** acceptable **Around buildings :** depending on the applicability of risk mitigation measures
											Bag of PP foil 20g 100g	Bucket in PP 100g – 3kg Cardboard box 100g – 3kg	

	Rats (*Rattus norvegicus and Rattus rattus)*	Non Professional	Indoor and around buildings	80-200 g product / secured bait	3-7 days	3 to 7 days inspection interval	1-5 blocks	intervals of 15 m apart	Prefilled secured bait box	No	Bait station in PP 50g -200g	Cardboard box 1 – 5 prefilled bait stations	**Indoor :** acceptable **Around buildings :** depending on the applicability of risk mitigation measures
	Mice (*Mus musculus)*	Non Professional	Indoor and around buildings	25 to 30 g product / secured bait	3-7 days	3 to 7 days inspection interval	One block per bag	intervals of 3 m apart	Sachets in secured bait box	Yes	Bag of PE foil 20g – 100g	Bucket in PP 100g – 3kg Cardboard box 100g – 3kg	**Indoor :** acceptable **Around buildings :** depending on the applicability of risk mitigation measures
											Bag of PP foil 20g 100g	Bucket in PP 100g – 3kg Cardboard box 100g – 3kg	
	Mice (*Mus musculus)*	Non Professional	Indoor and around buildings	25 to 30 g product / secured bait	3-7 days	3 to 7 days inspection interval	1-3 blocks	intervals of 3 m apart	Prefilled secured bait box	No	Bait station in PP 50g -200g	Cardboard box 1 – 5 prefilled bait stations	**Indoor :** acceptable **Around buildings :** depending on the applicability of risk mitigation measures

Annex 1: List of studies reviewed

List of <u>new data</u>[12] submitted in support of the evaluation of the active substance

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
A3.3	Report No. 2109/0005	Walker JA and Mullee, DM	2007	Difenacoum: Determination of General Physico-chemical Properties SafePharm Laboratories	Pelgar	☐	☐	☒	☐
A4.2 (c)	CEMR-4470	Marshall L.	2009	Validation of a method for the determination of Difenacoum residues in sediment	Activa / PelGar Brodifacoum and Difenacoum Task Force	☐	☐	☒	☐
A4.2 (c)	CEMR-4469	Marshall L.	2009	Validation of a method for the determination of Difenacoum residues in animal Matrices (Liver and Muscle) and Crop matrix	Activa / PelGar Brodifacoum and Difenacoum Task Force	☐	☐	☒	☐
A4.2 (e)	CEMR-4469	Marshall L.	2009	Validation of a method for the determination of Difenacoum residues in animal Matrices (Liver and Muscle) and Crop matrix	Activa / PelGar Brodifacoum and Difenacoum Task Force	☐	☐	☒	☐

12 Data which have not been already submitted for the purpose of the Annex I inclusion.

List of <u>new data</u> submitted in support of the evaluation of the biocidal product

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
Doc IIIB 3.2	Report No 20100218.03	Nau, M.	2010	EDI-550 [Wax Block (block bait, BB)] Explosive properties A.14 Study Mo3936	Edialux Formulex NV	☐	☒	☒	☐
Doc IIIB 3.3	Report No 20100218.05	Nau, M.	2010	EDI-550 [Wax Block (block bait, BB)] Oxidising Properties A.17 Study Mo3936	Edialux Formulex NV	☐	☒	☒	☐
Doc IIIB 3.4	Report No 20100218.04	Nau, M.	2010	EDI-550 [Wax Block (block bait, BB)] Flammability (solids) A.10 Study Mo3936	Edialux Formulex NV	☐	☒	☒	☐
Doc IIIB 3.4	Report No 20100218.02	Nau, M.	2010	EDI-550 [Wax Block (block bait, BB)] Auto-flammability (solids – determination of relative self-ignition temperature) A.16 Study Mo3936	Edialux Formulex NV	☐	☒	☒	☐
Doc IIIB 3.1, 3.6, 3.7	Report No Mo3917	Broda, J.	2010	Determination of physic-chemical properties and storage stability test for EDI-550 [Wax Block (block bait, BB)] packed in PS Trays	Edialux Formulex NV	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
Doc IIIB 3.1, 3.6, 3.7	Report No Mo3918	Broda, J.	2010	Determination of physic-chemical properties and storage stability test for EDI-550 [Wax Block (block bait, BB)] packed in PE bag	Edialux Formulex NV	☐	☒	☒	☐
Doc IIIB 3	Report No 20100218.01	Nau, M.	2010	EDI-550 [Wax Block (block bait, BB)] Melting point A.1 (OCDE 102) Study Mo3936	Edialux Formulex NV	☐	☒	☒	☐
Doc IIIB 4	Report No MV031	M.T. Garcia	2010	Determination of Difenacoum in Grain Baits	Edialux Formulex NV	☐	☒	☒	☐
Doc IIIB 4	Report No Mo3916	M.T. Garcia	2010	Supplement to method MV031-E01: EDX Determination of Difenacoum in Grain Baits and Block Baits, Biogenius	Edialux Formulex NV	☐	☒	☒	☐
Doc IIIB 5.10.1	EDI 550 BB-ROD fresh (m1)	Karg G. and Pfeiffer H.J.	2010	Bait choice- EDI 550 BB-ROD fresh bait with difenacoum, Mice (*Mus musculus*) Eureka Lab.	Edialux Formulex NV	☐	☒	☒	☐
Doc IIIB 5.10.2	EDI 550 BB-ROD fresh (r1)	Karg G. and Pfeiffer H.J.	2010	Bait choice- EDI 550 BB-ROD fresh bait with difenacoum, Rats (*Rattus norvegicus*) Eureka Lab.	Edialux Formulex NV	☐	☒	☒	☐
Doc IIIB 5.10.3	EDI 550 BB-ROD aged (m2)	Karg G. and Pfeiffer H.J.	2010	Bait choice- EDI 550 BB-ROD aged bait with difenacoum, Mice (*Mus musculus*) Eureka Lab.	Edialux Formulex NV	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
Doc IIIB 5.10.4	EDI 550 BB-ROD aged (r2)	Karg G. and Pfeiffer H.J.	2010	Bait choice- EDI 550 BB-ROD aged bait with difenacoum, Rats (*Rattus norvegicus*) Eureka Lab.	Edialux Formulex NV	☐	☒	☒	☐
Doc IIIB 6.1.2	TAD-PH-10/0041	Colas S.	2010	Sorkil rodenticide wax block – block bait (BB) EDI-550, Evaluation of acute dermal toxicity in rats Phycher Bio Développement, Cestas, France	Edialux Formulex NV	☐	☒	☒	☐
Doc IIIB 6.2	IC-OCDE-PH-10/0041	Colas S.	2010	Sorkil rodenticide wax block – block bait (BB) EDI-550, Assessment of acute dermal irritation Phycher Bio Développement, Cestas, France	Edialux Formulex NV	☐	☒	☒	☐
Doc IIIB 6.2	IO-OCDE-PH-10/0041	Colas S.	2010	Sorkil rodenticide wax block – block bait (BB) EDI550, Assessment of acute eye irritation Phycher Bio Développement, Cestas, France	Edialux Formulex NV	☐	☒	☒	☐
Doc IIIB 6.3	LLNA-PH-10/0041	Colas S.	2010	Sorkil rodenticide wax block – block bait (BB) EDI-550, Assessment of the skin sensitisation potential in the mouse using the local lymph node assay (LLNA) Phycher Bio Développement, Cestas, France	Edialux Formulex NV	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
Doc IIC B6.6 (1)	-	Chambers JG and Snowdon PJ	2004	Study to Determine Potential Exposure to Operators During Simulated Use of Anticoagulant Rodenticide Baits Synergy Laboratories Ltd., Report No. SYN/1302. Unpublished.	CEFIC	☒	☐	☒	☐
Doc IIC B6.6 (2)	-	Vetter D and Sendor T	2006	Estimation of the frequency of dermal exposure during the occupational use of rodenticides. Report of EBRC Consulting under contact to CEFIC Rodenticide Working Group. Unpublished.	CEFIC	☒	☐	☒	☐

Annex 2: Analytical methods residues – active substance

Difenacoum

Date: 12/2011

Matrix, action levels, relevant residue and reference

matrix	limit	relevant residue	reference or comment
plant products	LOQ= 0.01mg/kg	Difenacoum	
food of animal origin	LOQ= 0.01mg/kg	Difenacoum	
soil	LOQ= 0.0214 µg/g	Difenacoum	
drinking water	LOQ = 0.05 µg/L	Difenacoum	
surface water	LOQ = 0.05 µg/L	Difenacoum	
air	Unnecessary due to the low vapour pressure of difenacoum		
body fluids / tissues	LOQ= 0.01mg/kg	Difenacoum	

Methods suitable for the determination of residues (monitoring methods)

Methods for products of plant origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner
Marshall, L., 2009, Method Validation for the Determination of Difenacoum in Animal Matrices (Liver and Muscle) and Crop Matrix (Oilseed Rape), CEM Analytical Services Limited, Study CEMR-4469	Oil-seed rape	LOQ= 0.01mg/kg	*LC-MS/MS*		Activa / PelGar Brodifacoum and Difenacoum Task Force

Methods for foodstuffs of animal origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner
Marshall, L., 2009, Method Validation for the Determination of Difenacoum in Animal Matrices (Liver and Muscle) and Crop Matrix (Oilseed Rape), CEM Analytical Services Limited, Study CEMR-4469	Meat	LOQ= 0.01mg/kg	*LC-MS/MS*		Activa / PelGar Brodifacoum and Difenacoum Task Force

Methods for soil

reference	LOQ (mg/kg)	principle	comment	owner
Morlacchini, M., 2006, Residues determination of Brodifacoum, Difenacoum and Bromadiolone in soil, CERZOO (Italy), Study CZ/05/002/Activa/Soil	LOQ= 0.0214 µg/g	*HPLC – UV-VIS*		Activa / PelGar Brodifacoum and Difenacoum Task Force

Methods for sediment

reference	LOQ (mg/kg)	principle	comment	owner
Marshall, L., 2009, Validation of a Method for the Determination of Difenacoum Residues in Sediment, CEM Analytical Services Limited, Study CEMR-4470	LOQ= 0.01mg/kg	LC-MS/MS		Activa / PelGar Brodifacoum and Difenacoum Task Force

Methods for drinking water and surface water

reference	matrix	LOQ (µg/l)	principle	comment	owner
Martinez M.P. 2005. Difenacoum Technical: Validation of the Analytical Method for the Determination of the Residues in Drinking, Ground and Surface waters, Test Laboratory of ChemService S.r.l. ChemService Study No. CH-288/2005	Water	LOQ = 0.05 µg/l	*HPLC – MS/MS*		Activa / PelGar Brodifacoum and Difenacoum Task Force

Methods for air

reference	LOQ (µg/m3)	principle	comment	owner
Unnecessary due to the low vapour pressure of difenacoum				

Methods for body fluids/tissue

reference	matrix	LOQ (mg/kg)	principle	comment	owner
Marshall, L., 2009, Method Validation for the Determination of Difenacoum in Animal Matrices (Liver and Muscle) and Crop Matrix (Oilseed Rape), CEM Analytical Services Limited, Study CEMR-4469	Liver	LOQ= 0.01mg/kg	*LC-MS/MS*		Activa / PelGar Brodifacoum and Difenacoum Task Force

Annexe 3: Efficacy of the Active Substance from its Use in the EDI-550

Test product	Test organisms	Test system / Concentrations applied / exposure time	Test results: effects, mode of action, resistance	Reference
SORICIDE DB	CD1 mice (*Mus musculus*) 10 mice (5 males, 5 females)	Laboratory test. Choice feeding test: fresh baits. The quantity of food placed in each pot was sufficient to meet each animal's daily needs 4-day acclimatization period, 8-day pre-test control diet intake assessment, 4-day bait feeding period and 14-day control bait period.	Amount of intake of the treated baits: - 89.62% for male - 91.34% for female 100% mortality was observed in 14 days in both male and female. The times to death were 4 to 7 days after the first intake of treated baits.	B5.10.1-mice-fresh
SORICIDE DB	CD rat (*Rattus norvegicus*) 10 rats (5 males, 5 females)	Laboratory test. Choice feeding test: fresh bait. The quantity of food placed in each pot was sufficient to meet each animal's daily needs 4-day preconditioning, 8-day pre-test control diet intake, 4-day choice feeding period and at least 14-day post-treatment observations.	Amount of intake of the treated baits: - 52.13% for male - 65.62% for female 100% mortality was observed in both male and female. The times to death were 3 to 7 days after the first intake of treated baits for male and 4 to 6 days for female.	B5.10.2-rat-fresh

Test product	Test organisms	Test system / Concentrations applied / exposure time	Test results: effects, mode of action, resistance	Reference
SORICIDE DB	CD1 mice (*Mus musculus*) 10 mice (5 males, 5 females)	Laboratory test. The quantity of food placed in each pot was sufficient to meet each animal's daily needs Choice feeding test: aged baits. 4-day acclimatization period, 8-day pre-test control diet intake assessment, 4-day bait feeding period and 14-day control bait period.	Amount of intake of the treated baits: - 84.96% for male - 77.85% for female 100% mortality was observed in both male and female. The times to death were 6 to 7 days after the first intake of treated baits for male and 7 to 11 days for female.	B5.10-3-mice-aged
SORICIDE DB	CD rat (*Rattus norvegicus*) 10 rats (5 males, 5 females)	Choice feeding test: aged bait. The quantity of food placed in each pot was sufficient to meet each animal's daily needs 4-day preconditioning, 8-day pre-test control diet intake, 4-day choice feeding period and at least 14-day post-treatment observations.	Amount of intake of the treated baits: - 28.89% for male - 33.29% for female 100% mortality was observed in female rats. The times to death were 5 to 8 days after the first intake of treated baits for female rats. 4 of the 5 male rats (80%) died within the timeframe required (14 days). Thus the required mortality of 90% of all treated animals has been achieved.	B5.10.4-rat-aged

Annex 4: Toxicology and metabolism –active substance

Difenacoum

Threshold Limits and other Values for Human Health Risk Assessment

Date: 12/2011

Summary			
	Value	Study	SF
AEL long-term	0.0000011 mg/kg bw/day	Teratogenicity in rabbit	600
AEL medium-term	0.0000011 mg/kg bw/day	Teratogenicity in rabbit	600
AEL acute	0.0000011 mg/kg bw/day	Teratogenicity in rabbit	600

Inhalative absorption: not reported

Oral absorption: 68 %

Dermal absorption: 0.047 % for wax block bait and paste (Activa Pelgar study) – 3 % for pellet and grain baits (Sorex study)

Classification	
with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	Current classification: T+ ; R28, R48/25 - N; R50/53 Proposed classification by the RMS: T+; R26/27/28, Repr. Cat. 1, R61 - T; R48/23/24/25 - N ; R50/53
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Current classification: Acute Tox 2, H300; STOT RE 1, H372 ; Aquatic Acute 1, H400; Acute chronic 1, H410 Proposed classification by the RMS: Acute Tox 2, H330, H310, H300; Repr. 1A, H360D; STOT RE 1, H372; Aquatic Acute 1, H400; Acute chronic 1, H410

SORICIDE DB

Date: 12/2011

General information
Formulation Type: was block
Active substance(s) (incl. content): 0.005% difenacoum
Category

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)

LD50 oral : not classified for acute oral toxicity based on CLP exemptions based on calculations
Rat LD50 dermal (OECD 402) > 2000 mg/kg bw
Rat LC50 inhalation: justification for non-submission of data
Skin irritation (OECD 404) : non irritant
Eye irritation (OECD 405): non irritant
Skin sensitisation (OECD 429; modified LLNA): Study not acceptable – not sensitising based on CLP exemptions based on calculations

Acute toxicity tests:

Route	**Method Guideline**	**Species Strain Sex no/group**	**dose levels duration of exposure**	**Value LD_{50}/LC_{50}**	**Remarks**	**Reference**
Dermal	OECD 402	Sprague Dawley rats 5/sex	2000mg/kg bw	> 2000mg/kg bw	No effect	Colas S. 2010

Dermal irritation test:

Species	**Method**	**Average score 24, 48 and 72 h**		**Reversibility yes/no**	**Result**	**Remarks**	**Reference**
		Erythema	Oedema				
Albinos NZ rabbit 3 females	OECD 404 Semi-occlusive, 4h	0.11	0	na	Not irritant		Colas S. 2010

Ocular irritation test:

Species	Method	Average Score (24h, 48h, 72h)				Result	Reversibility yes/no	Remarks	Reference
		Cornea	Iris	Conjunctiva					
				Redness	Chemosis				
Albinos NZ rabbit 3 Males	OECD 405	0	0	0.78	0.22	Not irritant	Redness reversible on day 3 Chemosis reversible on day 2		Colas S. 2010

Sensitisation test:

Species	Method	Result	Remark	Reference
CBA/J mice 4 females/group	Non radioactive cell counting LLNA: 5, 10, 25% (w/w) in dimethylformamide on day 1, 2, 3. Sacrifice on Day 6 and determination of the proliferation of lymphocytes in the draining auricular lymph nodes by cell counting	SI < 1.4: not sensitiser	Not acceptable (method not currently validated)	Colas S. 2010

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)

Short-term toxicity studies

Toxicological data on active substance(s)
(not tested with the preparation)

Toxicological data on non-active substance(s)
(not tested with the preparation)

Further toxicological information

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Directive 1999/45/EC	none
Regulation 1272/2008/EC	none

Annex 6: Safety for professional operators

SORICIDE DB

Date: 12/2011

Exposure assessment

Exposure scenarios for intended uses (Annex IIIB, point 6.6)

Primary exposure of professionals

	Component	CAS	Actual Dermal Total [mg/day]	Actual Dermal Total [mg/kg/d]	Inhalation Exposure [mg/m³]	Model
Sachet not considered: exposure during loading and cleaning (worst case)						
Tier 1 (without gloves)	Difenacoum	56073-07-5	$8.04x10^{-5}$	$1.34x10^{-6}$	negligible	Cefic study
Tier 2 (with gloves; penetration factor: 10%)	Difenacoum	56073-07-5	$8.04 x10^{-6}$	$1.34x10^{-7}$	negligible	Cefic study
Sachet considered: exposure only during cleaning considered (reasonable case)						
Tier 1 (without PPE)	Difenacoum	56073-07-5	$2.01x10^{-6}$	$3.35x10^{-8}$	negligible	Cefic study

Risk assessment

Scenario	Component	CAS	AEL [mg/kg/d]	Absorption [%]		Inhal ext [mg/m3]	Derm syst [mg/kg bw/d]	%AEL	Risk
				inh	derm				
Sachet not considered: exposure during loading and cleaning (worst case)									
Tier 1 (without gloves)	Difenacoum	56073-07-5	$1.1x10^{-6}$	100	0.047	negligible	$1.34x10^{-6}$	122	Unccep table (
Tier 2 (with gloves; penetration factor: 10%)	Difenacoum	56073-07-5	$1.1x10^{-6}$	100	0.047	negligible	$1.34x10^{-7}$	12	Accept able
Sachet considered: exposure only during cleaning considered (reasonable case)									
Tier 1 (without gloves)	Difenacoum	56073-07-5	$1.1x10^{-6}$	100	0.047	negligible	$3.35x10^{-8}$	3	Accept able

Annex 7: Safety for non-professional operators and the general public

SORICIDE DB

Date:12/2011

General information
Formulation Type: wax block
Active substance(s) (incl. content): difenacoum 0.005%
Category
Authorisation number

<Active Substance>

Data base for exposure estimation	
according to	Appendix: Toxicology and metabolism – active substance/CAR

Exposure scenarios for intended uses (Annex IIIB, point 6.6)
Primary exposure: non-professional use
Secondary exposure, acute: child ingesting bait
Secondary exposure, chronic: none

Conclusion:
Exposure of non-professionals and the general public to the biocidal product containing difenacoum as active substance is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

Details for the exposure estimates:

The accidental ingestion of baits poses a risk to infants since the AEL is exceeded when infant ingests more than 0.3 mg of product per day.

Details for the exposure estimates:

	Component	CAS	Actual Dermal Total [mg/day]	Actual Dermal Total [mg/kg/d]	Inhalation Exposure [mg/m³]	Model
Sachet not considered: exposure during loading and cleaning (worst case)						
Non professional	Difenacoum	56073-07-5	$7.20x10^{-6}$	$1.20x10^{-7}$	negligible	Cefic study
Sachet considered: exposure only during cleaning considered (reasonable case)						
Non professional	Difenacoum	56073-07-5	$6.72\ x10^{-7}$	$1.12x10^{-8}$	negligible	Cefic study

Risk assessment

Scenario	Component	CAS	AEL [mg/kg/d]	Absorption [%]		Inhalation exposure [mg/m3]	Derm syst [mg/kg bw/d]	Expo %AEL	Risk
				inhalation	dermal				
Sachet not considered: exposure during loading and cleaning (worst case)									
Non-professional	Difenacoum	56073-07-5	$1.1x10^{-6}$	100	0.047	negligible	$1.20x10^{-7}$	11	Acceptable
Sachet considered: exposure only during cleaning considered (reasonable case)									
Non-professional	Difenacoum	56073-07-5	$1.1x10^{-6}$	100	0.047	negligible	$1.12x10^{-8}$	1	Acceptable

Annex 8: Residue behaviour

SORICIDE DB

Date: 12/2011

The intended use descriptions of the SORICIDE DB for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. No further data are required concerning the residue behaviour.

Product Assessment Report

Biocidal product assessment report related to product authorisation under Directive 98/8/EC

CONFIDENTIAL ANNEX

Formulation composition statement

SORICIDE DB

LARC

December 2011

Internal registration/file no:	PB-10-00011
Authorisation/Registration no:	FR-2012-0002 (professional) / FR-2012-0050 (non-professional)
Granting date/entry into force of authorisation/ registration:	23 February 2012
Expiry date of authorisation/ registration:	31/03/2015 except where a decision of the European Commission extend the registration of the active substance
Active ingredient:	DIFENACOUM (CAS 56073-07-5)
Product type:	14 - Rodenticide

Competent Authority in charge of delivering the product authorisation:
French Ministry of Ecology
Department for Nuisance Prevention and Quality of the Environment
Chemical Substances and Preparation Unit
Grande Arche, Paroi Nord
92 055 La Défense cedex – FRANCE
autorisation-biocide@developpement-durable.gouv.fr

Authority in charge of the efficacy and risk assessment:
Anses – French agency for food, environmental and occupational health and safety
Regulated Products Directorate
253 Avenue du Général Leclerc
94 701 Maisons-Alfort Cedex - FRANCE
biocides@anses.fr

Formulation composition statement

Name of the product : SORICIDE DB

Active Substance(s)

	Common Name	Chemical name	CAS number	Contents			Minimum purity
				g/L or g/kg	Other unit	w/w (%)	
1	Difenacoum 2,5% Red 0,5% DB	Premix [1]	-	2	-	0,2	-

Co-formulant(s)

	Common Name	Chemical name	Function	CAS number	Contents			Substance of concern
					g/kg	Other unit	w/w (%)	
2	Paraffin		Carrier	64742-51-4	500		50	No
3	Basonyl Red 555	Premix [1]	Dyestuff	-	0,3		0,03	No
4	Premix Denatonium benzoate 25%	Premix [1]	Bittering agent	-	0,4		0,04	No
5	Monopropylene	propan-1,2-diol	Solvent	57-55-6	20		2	No

[1] *For detailed information on premix composition, please contact the agency in charge of the efficacy and risk assessment (biocides@anses.fr).*

	glycol							
6	Corn oil	NA	Appetent	8001-30-7	80		8	No
7	Sucrose	Alpha-D-Glucopyranoside, beta-D-fructofuranosyl	Appetent	57-50-1	80		8	No
8	Cereal flour	NA	Appetent	-	317,3		31,73	No