Product Assessment Report

Biocidal product assessment report related to addition of a user category under Directive 98/8/EC

NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES

Triplan SA

March 2013

Internal registration/file no:	PB-13-00131 (NYNA D+ BLE), PB-13-00132 (NYNA D+ AVOINE), PB-13-00134 (NYNA D+ CEREALES)
Authorisation/Registration no:	NYNA D+ BLE: FR-2013-0018 (Pro) + FR-2013-1011 (General users) NYNA D+ AVOINE: FR-2013-0019 (Pro) + FR-2013-1012 (General users) NYNA D+ CEREALES: FR-2013-0020 (Pro) + FR-2013-1013 (General users)
Granting date/entry into force of authorisation/ registration:	April 3rd, 2013
Expiry date of authorisation/ registration:	March 31, 2015
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 - Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail
Direction des Produits Réglementés
253 Avenue du Général Leclerc
94 701 Maisons-Alfort Cedex - FRANCE
biocides@anses.fr

1. General information about the product application

Please refer to the product assessment reports related to NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES product authorisation under Directive 98/8/EC.

For full details of the intended uses claimed by the applicant, please see annex 0a.

2. Summary of product assessment

2.1. Identity related issues

Please refer to the product assessment reports related to NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES product authorisation under Directive 98/8/EC.

2.2. Classification, labelling and packaging

2.2.1 Harmonised classification of the biocidal product

No classification is required for NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES.

2.2.2 Labelling of the biocidal product

No labelling is required for NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES.

2.2.3 Packaging of the biocidal product

Primary packaging:

NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES are supplied in white opaque or transparent polyethylene (PE) film sachets (of 25, 50 or 100 g) for professional and non-professional users and in bulk in 20 or 25 kg bags (in several paper layers + PE film) for professional users, only.

Secondary packaging:

The sachets are put in cardboard boxes or in buckets of different capacities (from 400 g to 3 kg for non-professionals and from 5 kg to 20 kg for professionals).

2.3. Physico/chemical properties and analytical methods

The physicochemical properties and analytical methods initially assessed for the first authorization of products NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES can be considered as valid for this application.

2.4. Risk assessment for Physico/chemical properties

NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES are ready-to-use rodenticides. These products are under the form of cereal grains, not highly flammable, not auto-flammable (up to 400°C), not explosive and does not have oxidizing properties.

The information required in the product assessment reports related to NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES product authorisation under Directive 98/8/EC remain unchanged.

2.5. Effectiveness against target organisms

2.5.1 Reminder of the Efficacy data of NYNA D+ BLE

According to the uses claimed by Triplan, NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES are intended to be used to control rodents. The target organisms to be controlled are brown rat *(Rattus norvegicus),* roof rat or house rat (*Rattus rattus)* and, wild and house mouse *(Mus musculus).*

Based on the studies submitted by the applicant, NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES have demonstrated an efficacy against rats and mice at the following application rates :

Rats: (*Rattus norvegicus and Rattus rattus)*

- 200 g grains/secured bait point separated by 5-10 m.

Mice: (*Mus musculus*)

- 40 g grains/secured bait point separated by 1-2 m.

2.5.2 Conclusion

The efficacy initially assessed for the first authorization of products NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES can be considered as valid for this application.

Uses and doses validated for NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES are the following:

Produit	Targets organism	Application rate and intervals	Use area
NYNA D+ BLE **NYNA D+ AVOINE** **NYNA D+ CEREALES** Bait (cereals) containing 0.005% p/p of difenacoum.	Rats (*Rattus norvegicus and Rattus rattus*)	200 grammes/bait point separated by 5 to 10 meters	Indoor in secured bait station
	Mice (*Mus musculus*)	40 grammes/bait point separated by 1 to 2 meters	Indoor in secured bait station

Conditions of use linked to efficacy assessment are detailed in section 3 of this PAR.

2.6. Exposure assessment

Please refer to the product assessment reports related to NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES product authorisation under Directive 98/8/EC.

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. The results of this toxicological assessment can be found in the CAR. The threshold limits and labelling regarding human health risks listed in Annex 4 „Toxicology and metabolism" must be taken into consideration.

2.7.1.2. Toxicology of the substance(s) of concern

Not relevant

2.7.1.3. Toxicology of the biocidal product

The toxicology of the biocidal product was examined appropriately according to standard requirements. The product was / was not a dummy product in the EU- review program for inclusion of the active substance in Annex I of Directive 98/8/EC.

Please refer to the product assessment report related to NYNA D+ BLE product authorisation under Directive 98/8/EC.

Percutaneous absorption

The dermal absorption of difenacoum formulated as pellet bait (containing 0.005% difenacoum) was investigated *in vitro* using human skin. The measured samples were below the limit of detection or quantification, but as a worst case, the corresponding validated LOQ value was used for the calculations of dermal absorption. The percentage of absorbed difenacoum was 0.647% (receptor fluid + epidermis + dermis + stratum corneum). The total recovery of difenacoum was 97.3% when skin discs were exposed to 5 mg/cm^2 of the product (equivalent to 250 ng a.s./cm^2) for 24 hours.

2.7.2 Human exposure assessment

2.7.2.1. Identification of main paths of human exposure towards active substance from its use in biocidal product

Exposure path	Industrial use	Professional use	General public	*via* the environment
Inhalation	Not relevant	Yes	Yes	Negligible
Dermal	Not relevant	Yes	Yes	Negligible
Oral	Not relevant	No	Yes	Negligible

2.7.2.2. Direct exposure as a result of use of the active substance in biocidal product

The biocidal products are ready-to-use rodenticides containing 0.005 % of difenacoum. Baits are packaged in plastic sachets for professional and non-professional users or in bulk for professional users. In the case of plastic sachet, it can be assumed that there is no decanting phase and no exposure is expected during loading in bait points.

2.7.2.2.1 Exposure of professional users

As a worst case, exposure has been assessed considering the products supplied as loose grains at the maximum recommended dose of 200 g for the control of rats. This approach covers the packaging

in sachets. This also covers human exposure during the control of mice, where the recommended doses are lower.

Exposure by inhalation route is relevant **during the decanting of loose grains**. Based on the CEFIC study and taking into account the HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011, the indicative air concentration is 9.62 mg product/m^3.

The following parameters were considered:

- Duration of manipulation: 15 minutes per day (3 minutes per 3 kg decanting; 12.6 kg decanted per day)
- Inhalation rate: 1.25 m^3/hour
- Inhalation absorption: 100 %
- Active substance in product: 0.005 %
- Body weight: 60 kg

Based on these assumptions, the systemic concentration of difenacoum is 2.5 x 10^{-6} mg/kg bw/day without respiratory protection and 2.5 x 10^{-7} mg/kg bw/day when professional wear a respiratory equipement during decanting (protection factor 90%).

Dermal exposure

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the indicative amount of product on fingers/hands **during the decanting** was 93 mg per 3 kg of decanted product, when considering 1 to 4 decanting times per day and 52.3 mg per 3 kg of decanted product when considering more than 4 decanting times per day. Since the quantity of decanted product is 12.6kg (200 g per bait point; 63 loadings), 52.3 mg of product was considered.

The following parameters were taken into account:

- Active substance in product: 0.005%,
- Quantity of decanted product: 12.6 kg for rat (200 g of grains per bait boxes; 63 loading of bait boxes[1])
- Frequency: one manipulation per day,
- Dermal absorption: 0.647%,
- Body weight: 60 kg.

Therefore, the systemic dose of difenacoum on fingers/hands during decanting is 1.2 x 10^{-6} mg/kg bw/day.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the loading** was 2.04 mg for the assessment of more than 4 manipulations per day (the agreed number is 63 manipulations for professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). Therefore, considering 63 manipulations per day, the systemic dose of difenacoum on fingers/hands during loading is 6.9 x 10^{-7} mg/kg bw/day.

[1] HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant), agreed at TMII2010

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 3.79 mg/manipulation for the assessment of more than 4 manipulations per day (the agreed number is 16 cleanings for professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). Therefore, considering 16 cleanings per day, the systemic dose of difenacoum on fingers/hands during cleaning is 3.3 $x10^{-7}$ mg/kg bw/day.

In conclusion, the total systemic dermal exposure is set at 2.2 x 10^{-6} mg/kg bw/day without individual protective equipment and 2.2 x 10^{-6} mg/kg bw/day with gloves.

Total exposure

The total systemic exposure resulting from inhalation and dermal contacts with the product is 4.7 x 10^{-6} mg/kg bw/day without any individual protective equipment. Considering the protection of respiratory equipment during decanting and the protection of gloves during all tasks, the total systemic exposure is 4.7 x 10^{-7} mg/kg bw/day.

The estimations above represent a very worst case when the products are supplied in plastic sachets. In this case, it can be assumed that there is no decanting phase and no exposure is expected during loading in bait points. Therefore, only exposure during cleaning can be considered: 3.3 x 10^{-7} mg a.s/kg bw/day without gloves.

In Annex 6 „Safety for professional operators", the results of the exposure calculations for the active substance and the substance of concern for the professional user are laid out.

Tier	Inhalation exposure	Dermal exposure	Total exposure
PPE	Systemic dose	Systemic dose	Systemic dose
	mg a.i. / kg bw /day	mg a.i. / kg bw /day	mg a.i. / kg bw /day
Task – time frame:	**Scenario (population) – frequency**		
Bulk			
Tier 1: Without PPE	2.5 x 10^{-6}	2.2 x 10^{-6}	4.7 x 10^{-6}
Tier 2: With respiratory protection + gloves	2.5 x 10^{-7}	2.2 x 10^{-7}	4.7 x 10^{-7}
Sachet			
Tier 1: Without PPE	na	3.3 x 10^{-7}	3.3 x 10^{-7}

2.7.2.2.2 Exposure of non-professional users

For non-professional users, considering the available packaging (only in plastic sachet), it can be assumed that there is no decanting phase and no exposure is expected during loading in bait points.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 3.79 mg for the assessment of more than 4 manipulations per day and 4.52 mg for the assessment of up to 4 manipulations per day (the agreed number is 5 cleanings for non-professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). As a worst-case, considering 5 manipulations per day, the amount of product of 4.52 mg is used and therefore, the systemic dose of difenacoum on fingers/hands during cleaning is 1.2×10^{-7} mg/kg bw/day.

In conclusion, the total systemic dermal exposure is set at 1.2×10^{-7} mg/kg bw/day.

In Annex 7 "Safety for non-professional operators and the general public", the results of the exposure calculations for the active substance and the substance of concern for the non-professional user and the general public are laid out.

Tier	Inhalation exposure	Dermal exposure	Total exposure
PPE	Systemic dose	Systemic dose	Systemic dose
	mg a.i. / kg bw /day	mg a.i. / kg bw /day	mg a.i. / kg bw /day
Task – time frame:	**Scenario (population) – frequency**		
Sachet			
Without PPE	na	1.2×10^{-7}	1.2×10^{-7}

2.7.2.3. Indirect exposure as a result of use of the active substance in biocidal product

Exposure of non users, especially infants, could result from the handling of dead rodents or ingesting poison baits.

Handling of dead rodents (adult, child, infant) – acute scenario

Secondary exposure of users and non users could result in the handling of dead rodents. However, this scenario is excluded because it is considered of low relevance due to unrealistic assumptions (TNsG on human exposure (2007)). Exposure due to this senario is considered negligible.

Oral exposure by ingesting bait (infant) – acute scenario

A reverse scenario was calculated. Based on the short-term AEL of 1.1×10^{-6} mg a.s/kg bw/day, a body weight of 10 kg and an oral absorption of 68%, ingestion of more than 0.3 mg of product per day is needed to exceed the AEL.

2.7.2.4. Combined exposure

Not relevant

2.7.3 Risk assessment for human health

2.7.3.1. Risk for direct exposure

Based on the risk assessment of the active substance, a risk for professional users resulting from the intended use is unlikely. Regarding occupational safety, there are no objections against the intended use.

2.7.3.1.1 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).

Based on the risk assessment of the active substance, the risk for professional users resulting from the intended use is acceptable only with respiratory protection during decanting and with gloves during all tasks for the products packaged as loose grains (%AEL is set at 42.8%). The risk is acceptable without any protection equipment for the products in sachet (%AEL is set at 29.7%).

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
Bulk formulation (exposure during decanting, loading and cleaning phases)				
Professional (without PPE)	$1.1x10^{-6}$	4.7×10^{-6}	428	Unacceptable
Professional (with respiratory protection during decanting and gloves during all tasks)	$1.1x10^{-6}$	4.7×10^{-7}	42.8	Acceptable
Sachet formulation (exposure during cleaning phase)				
Professional (without PPE)	$1.1x10^{-6}$	3.3×10^{-7}	29.7	Acceptable

2.7.3.1.2 Non-professional users

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

Based on the risk assessment of the active substance, the risk for non-professional users resulting from the intended use is acceptable without gloves for the products in sachet (%AEL is set at 11.1%).

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
Sachet formulation (exposure during cleaning phase)				
Non-professional (without PPE)	$1.1x10^{-6}$	1.2×10^{-7}	11.1	Acceptable

2.7.3.2. Risk for indirect exposure

Based on a reverse scenario, more than 0.3 mg of product per day should be ingested by infant to exceed the AEL. This indicates that infants are at significant risk of poisoning. Therefore, even if the products contain a bittering agent which reduces the likelihood of ingestion, the baits must be unattainable which do not allow access to children.

Product label ("do not open the sachet") and good practice advise users to prevent access to bait by children and infants.

2.7.3.3. Risk for combined exposure

Not relevant.

2.7.3.4. Summary of risks characterisation of the product for human health

Based on the new study submitted for this application, the risk for operators resulting from the intended uses is acceptable :

- when the product is supplied in bulk : when professionals are wearing protecting gloves and a respiratory protection equipment during decanting of grains ;
- when the product is supplied in sachet : whithout gloves for professional and non professional users.

Finally, there is a significant risk of poisoning for infants, thus, the baits should be unattainable for children.

See also section 3 of this PAR

Specific use restriction and issues accounted for product labelling:

- For professionals : wear protective gloves when handling the product and dead rodents.
- For professionals : wear respiratory protection equipment during decanting of grains in bulk.
- Do not open the sachets.
- Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
- Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
- Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
- Do not place tamper-resistant bait boxes on surfaces in contact with food, feed or drinks and beverages.
- Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes and dead rodents, during and after treatment.
- Remove all bait points after the end of treatment.

2.8. Risk assessment for the environment

The environmental risk assessment initially carried out for the first authorization of products NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES can be considered as valid for this application.

Measures to protect environment are detailed in section 3 of this PAR.

2.9. Measures to protect man, animals and the environment

See Summary of Product Characteristics (SPC).

3. Proposal from authority in charge of the efficacy and 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 efficacy and 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 physicochemical properties and analytical methods, the efficacy, the toxicology and the risk for environment initially assessed for the first authorization of products NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES can be considered as valid for this application.

Based on the new study submitted for this application, the risk for operators resulting from the intended uses is acceptable :

- when the product is supplied in bulk : when professionals are wearing protecting gloves and a respiratory protection equipment during decanting of grains ;
- when the product is supplied in sachet : whithout gloves for professional and non professional users.

Please refer to the product assessment reports related to NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES product authorisation under Directive 98/8/EC for more details.

Risk mitigation measures and conditions of use

Professional users

Conditions of use linked to efficacy assessment

- Adapt the number of bait station to the infestation level.
- Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed.
- Remove all bait points after the end of treatment.
- The amount of bait per bait point and distances between bait points must be respected. Products have always to be used in accordance with the label.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.
- To avoid resistance:

- The treatment has to be alternated with other kinds of active substances having different modes of action.
- Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures.
- 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.
- Do not use the product in areas where resistance is suspected or established.

Recommendations to be taken into account by the applicant

- Adapt the amount of bait per bait point to the validated effective dose.
- The product label has to contain information on resistance management for rodenticides.

Measures to protect man

- Wear protective gloves when handling the product and dead rodents.
- Wear respiratory protection equipment during decanting of grains in bulk.
- Do not open the sachets.
- Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
- Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
- Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
- Do not place tamper-resistant bait boxes on surfaces in contact with food, feed or drinks and beverages.
- Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes and dead rodents, during and after treatment.
- Remove all bait points after the end of treatment.

Measures to protect environment

- Dispose of the tamper-resistant bait boxes, uneaten baits and dead rodents in accordance with local requirements.
- Never wash the tamper-resistant bait boxes with water.
- Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.
- Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes and dead rodents, during and after treatment.
- Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
- Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
- Remove all bait points after the end of treatment.

Non professional users

Conditions of use linked to efficacy assessment

- Adapt the number of bait station to the infestation level.
- Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed.
- Remove all bait points after the end of treatment.
- To avoid resistance:
    - The amount of bait per bait point and distances between bait points must be respected. Products have always to be used in accordance with the label.
    - The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.

Measures to protect man

- Do not open the sachets.
- Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
- Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
- Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
- Do not place tamper-resistant bait boxes on surfaces in contact with food, feed or drinks and beverages.
- Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes and dead rodents, during and after treatment.
- Remove all bait points after the end of treatment.

Measures to protect environment

- Dispose of the tamper-resistant bait boxes, uneaten baits and dead rodents in accordance with local requirements.
- Never wash the tamper-resistant bait boxes with water.
- Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.
- Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes and dead rodents, during and after treatment.
- Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
- Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
- Remove all bait points after the end of treatment.

Directions for safe disposal of the product and its packaging

Directions linked to risk assessment for human health

- Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes and dead rodents, during and after treatment.
- Remove all bait points after the end of treatment.

Directions linked to risk assessment for environment

- Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes and dead rodents, during and after treatment.
- Dispose of the tamper-resistant bait boxes, uneaten baits and dead rodents in accordance with local requirements.
- Never wash the tamper-resistant bait boxes with water.
- 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 bait points after the end of treatment.

Information required post-authorisation

The information required in the product assessment report related to NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES products authorisation under Directive 98/8/EC remain unchanged.

NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES **Type of formulation (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)**	**Dosage validated expressed in g/bait point, for high and low infestation (if**	**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)**	**Individual packaging (yes/no)*** ***for more details please fulfill the column related to primary packaging***	**Primary packaging : type : bulk, individual wrapping…/ nature: bucket, bottle, sachet…/ material: paper, polyethylene…/ sizes**	**Secondary packaging**
NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES **Formulation : grains**	Rats (*Rattus norvegicus* and *Rattus rattus)*	Professional	In the buildings	180-200 g	200 g	4-10 days	Once a week Over a period of 28 days for application	25g/sachet, 50g/sachet, 100g/sachet	secured bait point separated by 5-10 m	Sachets in the secured bait	Yes	Sachet in white opaque or transparent PE film 25 - 100g	Bucket 5 – 18kg Cardboard 10 – 20kg
	Rats (*Rattus norvegic*	Professional	In the buildings	180-200 g	200 g	4-10 day	Once a week Over a	-	secured bait	Bulk in the secure	No	Bag in several paper	-

	us and *Rattus rattus)*					s	period of 28 days for applicatio n		point separate d by 5-10 m	d bait		layers + PE film 20 – 25kg	
	Mice (*Mus musculus*)	Profession al	In the buildings	30- 40 g	40 g	4-10 day s	Once a week Over a period of 28 days for applicatio n	25g/sachet, 50g/sachet, 100g/sachet	secured bait point separate d by 1-2 m	Sachet s in the secure d bait	Yes	Sachet in white opaque or transpare nt PE film 25 - 100g	Bucket 5 – 18kg Cardboar d 10 – 20kg
	Mice (*Mus musculus*)	Profession al	In the buildings	30-40 g	40 g	4-10 day s	Once a week Over a period of 28 days for applicatio n	-	secured bait point separate d by 1-2 m	Bulk in the secure d bait	No	Bag in several paper layers + PE film 20 – 25kg	-
NYNA D+ AVOINE / NYNA D+ CEREALES Formulation :	Rats (*Rattus norvegic us* and *Rattus rattus)*	Non Profession al	In the buildings	180-200 g	20 0 g	4-10 day s	Once a week Over a period of 28 days for applicatio n	25g/sachet, 50g/sachet, 100g/sachet	secured bait point separate d by 5-10 m	Sachet s in the secure d bait	Yes	Sachet in white opaque or transpare nt PE film 25g	Cardboar d 400g Bucket 3kg
												Sachet in white opaque or	Cardboar d 500g

												transparent PE film 50g	Bucket 3kg
												Sachet in white opaque or transparent PE film 100g	Bucket 3kg
	Mice (*Mus musculus*)	Non Professional	In the buildings	30-40 g	40 g	4-10 days	Once a week Over a period of 28 days for application,	25g/sachet, 50g/sachet, 100g/sachet	secured bait point separated by 1-2 m	Sachets in the secured bait	Yes	Sachet in white opaque or transparent PE film 25g	Cardboard 400g
													Bucket 3kg
												Sachet in white opaque or transparent PE film 50g	Cardboard 500g
													Bucket 3kg
												Sachet in white opaque or transparent PE film 100g	Bucket 3kg

Annex 6 : Safety for professional operators

NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES

Date: 07.03.2013

Exposure assessment

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

Primary exposure of professionals

	Component	**CAS**	**Actual Dermal Total [mg/kg/d]**	**Inhalation Exposure [mg/kg/d]**	**Model**
Bulk					
Tier 1: Without PPE	Difenacoum	56073-07-5	2.2×10^{-6}	2.5×10^{-6}	CEFIC study
Tier 2: With respiratory protection and gloves	Difenacoum	56073-07-5	2.2×10^{-7}	2.5×10^{-7}	CEFIC study
Sachet					
Tier 1: Without PPE	Difenacoum	56073-07-5	3.3×10^{-7}	na	CEFIC study

Risk assessment

	Component	**CAS**	**AEL [mg/kg/d]**	**Absorption [%]**		**Inhal [mg/kg/d]**	**Derm [mg/kg/d]**	**Total syst exposure [mg/kg bw/d]**	**% AEL**	**Risk**
				inhalation	dermal					
Bulk										
Tier 1: Without PPE	Difenacoum	56073-07-5	1.1×10^{-6}	100	0.647	2.5×10^{-6}	2.2×10^{-6}	4.7×10^{-6}	428	Unacceptable
Tier 2: With respiratory protection and gloves	Difenacoum	56073-07-5	1.1×10^{-6}	100	0.647	2.5×10^{-7}	2.2×10^{-7}	4.7×10^{-7}	42.8	Acceptable
Sachet										
Tier 1: Without PPE	Difenacoum	56073-07-5	1.1×10^{-6}	100	0.647	na	3.3×10^{-7}	3.3×10^{-7}	29.7	Acceptable

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

NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES

Date: 07.03.2013

General information	
Formulation Type	
Active substance(s) (incl. content)	
Category	
Authorisation number	

<Difenacoum >

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	Infant ingesting bait
Secondary exposure, chronic	None

Conclusion:

Exposure of non-professionals 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.

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/kg/d]**	**Inhalation Exposure [mg/m³]**	**Model**
Without PPE	Difenacoum	56073-07-5	1.2×10^{-8}	na	CEFIC study

Risk assessment

Component	**CAS**	**AEL [mg/kg/d]**	**Absorption [%]**		**Total syst exposure [mg/kg bw/d]**	**% AEL**	**Risk**
			inhalation	dermal			
Difenacoum	56073-07-5	1.1×10^{-6}	100	0.647	1.2×10^{-8}	11.1	Acceptable