

Addendum to the Product Assessment Report

Biocidal product assessment report related to an
extension of use under Regulation 528/2012

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

Triplan SA

February 2015

Internal registration/file no:	BC-BG004021-79 (NYNA D+ BLE), BC-SU004183-22 (NYNA D+ AVOINE), BC-SV004184-18 (NYNA D+ CEREALES)
Authorisation/Registration no:	NYNA D+ BLE : FR-2013-0018 (professional) & FR-2013-1011 (non professional) NYNA D+ AVOINE : FR-2013-0019 (professional) & FR-2013-1012 (non professional) NYNA D+ CEREALES : FR-2013-0020 (professional) & FR-2013-1013 (non professional)
Granting date/entry into force of authorisation/ registration:	April 3, 2013
Expiry date of authorisation/ registration:	August, 31 2020
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
Tour Séquoia
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Authority in charge of the efficacy and risk assessment:
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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

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.

2.3. 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.

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.

2.5. Effectiveness against target organisms

2.5.1 Reminder of the Efficacy data

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
NYNA D+ BLE NYNA D+ AVOINE NYNA D+ CEREALES Bait (cereals) containing 0.005% p/p of difenacoum.	Rats (<i>Rattus norvegicus</i> and <i>Rattus rattus</i>)	200 grams/bait point separated by 5 to 10 meters
	Mice (<i>Mus musculus</i>)	40 grams/bait point separated by 1 to 2 meters

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

2.7.2 Human 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.

2.7.3 Risk assessment for human health

Reminder : 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 : without 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.

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.

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

2.8. Risk assessment for the environment

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.

No studies were conducted with the products NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES for the environment part; therefore the environmental risk assessment has been carried out with data from the CAR of difenacoum. The environmental risk is considered as limited for the use in and around buildings by professional and for indoor use by non-professionals, in strict compliance

with the specific use instructions of rodenticidal baits and the use restrictions to reduce the risk for primary and secondary poisoning.

Nevertheless, the Authority in charge of the efficacy and risk assessment is not able to assess the applicability of the specific use instructions and restrictions for the outdoor applications by non-professionals and the uses by professionals in waste dump and in open areas.

Professional users

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.
- Place the tamper-resistant bait boxes in areas non-labile to floodings and sites sheltered from rain.
- 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

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.
- Place the tamper-resistant bait boxes in areas non-labile to floodings and sites sheltered from rain.
- 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.
- Use only in tamper-resistant bait boxes.
- 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.

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 products NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES have shown a sufficient efficacy for the control of mice (*Mus musculus*) and rats (*Rattus norvegicus* and *Rattus rattus*). Resistant strategies management has to be taken into account and difenacoum must not be used in an area where resistance to this substance is suspected.

The human health and environmental risks were assessed considering that these products are available in sachet for professional and non-professional users and in bulk for professional users and that the cereal grains are loaded in secure bait points.

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 : without gloves for professional and non professional users.

Furthermore, accidental ingestion of baits is at risk to infants. Adequate measures for protection and risk mitigation have to be applied during use to control especially the risk from secondary exposure.

No studies were conducted with these products for the environment part. The environmental risk assessment has been carried out 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 use in and around buildings by professional and for indoor use by non-professionals, in strict compliance with the specific use instructions of rodenticidal baits and the use restrictions to reduce the risk for primary and secondary poisoning.

Nevertheless, the Authority in charge of the efficacy and risk assessment is not able to assess the applicability of the specific use instructions and restrictions for the outdoor applications by non-professionals and the uses by professionals in waste dump and in open areas.

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.
- 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.
- 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.

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 data required in post-authorization pursuant to Article 2 of decisions n° FR-2012-0008 (NYNA D+ BLE ; February 23rd, 2012), n° FR-2012-0005 (NYNA D+ AVOINE ; February 23rd, 2012) and n° FR-2012-0006 (NYNA D+ CEREALES ; February 23rd, 2012) are maintained.

Annex 0a: Practical use of Biocides - PT14

<p>NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES</p> <p>Type of formulation (grains)</p>	<p>Target organism (rat, mice...)*</p>	<p>User category (professional/non professional)*</p>	<p>Area of use (sewers, in and around buildings, indoor only, open areas, waste dumps,</p>	<p>Dosage claimed expressed in g/bait point, for high and low infestation (if appropriate)</p>	<p>Dosage validated expressed in g/bait point, for high and low infestation (if appropriate)</p>	<p>Time delay of the action of the product</p>	<p>Frequency and method of controls</p>	<p>Distance between 2 bait points, for high and low infestation (if appropriate)</p>	<p>Methods of application of the bait (ex: pre-filled secured bait box)</p>	<p>Package details : Individual packaging (yes/no)* *for more details please fulfill the column related to primary packaging and secondary packaging</p>
<p>NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES</p> <p>Formulation : grains</p>	<p>Rats (<i>Rattus norvegicus</i> and <i>Rattus rattus</i>)</p>	<p>Professional</p>	<p>In and around the buildings, open areas, waste dumps and landfills</p>	<p>180-200 g</p>	<p>200 g</p>	<p>3-10 days</p>	<p>Manual application of baits in bait stations</p> <p>Collect of unconsumed bait and dead rodents at the end of each week.</p>	<p>Secured bait point separated by 5-10 m</p>	<p>Bulk or sachets in the secured bait stations</p>	<p>Yes</p>

	Mice (<i>Mus musculus</i>)	Professional	In and around the buildings, open areas, waste dumps and landfills	30- 40 g	40 g	3-10 days	Manual application of baits in bait stations Collect of unconsumed bait and dead rodents at the end of each week.	Secured bait point separated by 1-2 m	Bulk or sachets in the secured bait stations	Yes
NYNA D+ BLE / NYNA D+ AVOINE / NYNA D+ CEREALES Formulation : grains	Rats (<i>Rattus norvegicus</i> and <i>Rattus rattus</i>)	Non Professional	In and around the buildings, open areas	180-200 g	200 g	3-10 days	Once a week Over a period of 28 days for application	secured bait point separated by 5-10 m	Sachets in secured bait stations	Yes
	Mice (<i>Mus musculus</i>)	Non Professional	In and around the buildings, open areas	30-40 g	40 g	3-10 days	Once a week Over a period of 28 days for application	secured bait point separated by 1-2 m	Sachets in secured bait stations	Yes

