

# **Assessment Report of the major change of authorisation for the biocidal product Toxan 25 Granulat (30.10.2017)**

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## **1. Introduction**

The assessment presented in this report has been performed due to the application for the major change of authorisation for the product Toxan 25 Granulat submitted by the applicant. The major change involves a reduction of active substance content in the product from level at 0.004 % w/w to 0.0025 % w/w in the product.

According to Commission Regulation (EU) 2016/1179 the product Toxan 25 Granulat, with the active substance bromadiolone, at a level of 0.0025 % w/w is classified as SPECIFIC TARGET ORGAN TOXICITY AFTER REPEATED EXPOSURE. CATEGORY 2 (STOT RE 2); H373 May cause damage to organs (blood) through prolonged or repeated exposure.

Physical, chemical and technical properties remain valid to the evaluation for the product Toxan Granulat.

The conclusions on physical hazards and methods for detection and identification remain valid to the evaluation for the product Toxan Granulat and no new information has been submitted.

New efficacy data have been provided by the applicant in order to address the reduced content of active ingredient and new recommended dose rate. PL CA has performed the assessment of these studies (for details please refer to point 2).

No new data has been provided, nor new guidance had to be taken into account for the purpose of the risk assessment for human health, animal health and environment. Accordingly, the conclusions of the assessment performed for the biocidal product Toxan Granulat remain valid (please see the Product Assessment Report for the reference product: Toxan Granulat).

## **2. Efficacy against target organisms**

### **Function**

The biocidal product Toxan 25 Granulat will be used as rodenticide (PT 14) for the control of commensal rodent species. Content of active substance (bromadiolone) is 0,0025%.

The product is intended for use indoors and around the buildings and will be used by non-professional users. The product is intended for use indoors (e.g. live-stock buildings), around the buildings and outdoors (e.g. parks, tennis courts, camping sites and other places of the public utility, waste dumps) and will be used by professional users.

### **Organisms to be controlled**

Toxan 25 Granulat is intended to be used against *Rattus norvegicus* (brown rat), *Mus musculus* (house mouse) and *Apodemus agrarius* (field mouse).

### Dose / mode of action

Test organism(s)	Test system	Test conditions	Test results
House mouse ( <i>Mus musculus</i> )	Field test done according to method KES-01/2009 (04.05.16-11.06.16)	<p>The size of rodents population was evaluated by measure of control bait intake at the beginning and the end of the study. 100g FRE 02/16/002 (the same with Toxan 25 Granulat) has been placed into each bait station spaced every 1.5 – 2 meters in infested area. Bait stations were refilled 5 times every 3 days. After 20 days three parameters were tested :</p> <ol style="list-style-type: none"> <li>1) percentage loss of intake control bait,</li> <li>2) percentage loss of intake poison bait and</li> <li>3) percentage of active holes</li> </ol>	<p>The study indicates that:</p> <ol style="list-style-type: none"> <li>1) intake of control bait was reduced 92.0%</li> <li>2) intake of tested bait was reduced 91.7%</li> <li>3) percentage of active holes was reduced to 13.6%</li> </ol>
Brown rat ( <i>Rattus norvegicus</i> )	Field test done according to method KES-01/2009 (04.05.16-11.06.16)	<p>The size of rodents population was evaluated by measure of control bait intake at the beginning and the end of the study. 200g FRE 02/16/002 (the same with Toxan 25 Granulat) has been placed into each bait station located every 10 – 15 meters in infested area. Bait stations were refilled 5 times every 3 days. After 20 days three parameters were tested :</p> <ol style="list-style-type: none"> <li>1) percentage loss of intake control bait,</li> <li>2) percentage loss of intake poison bait and</li> <li>3) percentage of active</li> </ol>	<p>The study indicates that</p> <ol style="list-style-type: none"> <li>1) intake of control bait was reduced 90.0%</li> <li>2) intake of tested bait was reduced 91.7%</li> <li>3) percentage of active holes was reduced to 9.5%</li> </ol>

		holes	
House mouse ( <i>Mus musculus</i> )  Field mouse ( <i>Apodemus agrarius</i> )	Field test done according to method KES-01/2009 (14.12.16-08.02.17)	The size of rodents population was evaluated by measure of control bait intake at the beginning and the end of the study. 50g Toxan 25 Granulat has been placed into each bait station spaced every 1.5 – 2 meters in infested area. Bait stations were refilled 5 times every 3 days. After 20 days three parameters were tested : 1) percentage loss of intake control bait, 2) percentage loss of intake poison bait and 3) percentage of active holes	The study indicates that: 1) intake of control bait was reduced 96.0% 2) intake of tested bait was reduced 91.25% 3) percentage of active holes was reduced to 4.8%
Brown rat ( <i>Rattus norvegicus</i> )	Field test done according to method KES-01/2009 (14.12.16-08.02.17)	The size of rodents population was evaluated by measure of control bait intake at the beginning and the end of the study. 150g Toxan 25 Granulat has been placed into each bait station located every 10 – 15 meters in infested area. Bait stations were refilled 5 times every 3 days. After 20 days three parameters were tested : 1) percentage loss of intake control bait, 2) percentage loss of intake poison bait and 3) percentage of active holes	The study indicates that 1) intake of control bait was reduced 90.8% 2) intake of tested bait was reduced 90.4% 3) percentage of active holes was reduced to 4.3%

Effectiveness data has confirmed that Toxan 25 Granulat is effective in the proposed areas for use, at the recommended dose rate when used as per label recommendations. An evaluation of the field trials provided demonstrated that the product proved to be effective against

infestations of brown rats (*Rattus norvegicus*), house mice (*Mus musculus*) and field mouse (*Aspodemus agrarius*).

### **3. General conclusion**

After evaluation of the new submitted data it can be concluded that ready-to-use product, Toxan 25 Granulat, with the active substance bromadiolone, at a concentration of 0.0025 % w/w may be authorised for use as a rodenticide (Product Type 14) against house mice (*Mus musculus*), field mice (*Apodemus agrarius*) and brown rats (*Rattus norvegicus*). It can be used in and around buildings by non-professional users and in and around buildings, in open areas and on waste dumps by professional users. The product must be used in the tamper-resistant bait stations.