

# Assessment Report for the major change of authorisation for the biocidal product Toxan 25 Ziarno (02.11.2017)

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## 1. Introduce

The assessment presented in this report has been performed due to the application for the major change of authorisation for the product Toxan 25 Ziarno submitted by the applicant. The major change involves a reduction of active substance content in the product from level at 0.005 % w/w to 0.0025% w/w in the product.

According to Commission Regulation (EU) 2016/1179 the product Toxan 25 Ziarno, 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 Ziarno.

The conclusions on physical hazards and methods for detection and identification remain valid to the evaluation for the product Toxan Ziarno 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 Ziarno remain valid (please see the Product Assessment Report for the reference product: Toxan Ziarno).

## 2. Efficacy against target organisms

### Function

The biocidal product Toxan 25 Ziarno 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 to be used: in and around buildings by non-professional and professional users. Additionally, professionals can use Toxan 25 Ziarno in open areas (e.g. parks, tennis courts, camping sites and other places of the public utility) and on the waste dumps.

### Organisms to be controlled

Toxan 25 Ziarno 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
<p>House mouse <i>(Mus musculus)</i></p> <p>Field mouse <i>(Apodemus agrarius)</i></p>	<p>Field test according to method KES-01/2009  (17.03.2017-14.04.2017)</p>	<p>The size of rodents population was evaluated by the measurement of control bait intake at the beginning and the end of the study. 50 g of Toxan 25 Ziarno 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 to 90.0%</li> <li>2) intake of tested bait was reduced to 92.8%</li> <li>3) percentage of active holes was reduced to 4.8%</li> </ol>
<p>Brown rat <i>(Rattus norvegicus)</i></p>	<p>Field test according to method KES-01/2009  (17.03.2017-14.04.2017)</p>	<p>The size of rodents population was evaluated by the measurement of control bait intake at the beginning and the end of the study.</p> <p>150g of Toxan 25 Ziarno 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 holes</li> </ol>	<p>The study indicates that:</p> <ol style="list-style-type: none"> <li>1) intake of control bait was reduced to 91.4%</li> <li>2) intake of tested bait was reduced to 90.4%</li> <li>3) percentage of active holes was reduced to 7.1%</li> </ol>
<p>House mouse <i>(Mus musculus)</i></p>	<p>Field test according to method KES-01/2009  (21.06.2016-17.07.2016)</p>	<p>The size of rodents population was evaluated by the measurement of control bait intake at the beginning and the end of the study. 100 g of FRE 02/16/007 (which is the same as Toxan 25 Ziarno) has been placed into each bait station spaced every 1.5 – 2</p>	<p>The study indicates that:</p> <ol style="list-style-type: none"> <li>1) intake of control bait was reduced to 93.3%</li> <li>2) intake of tested bait was reduced to</li> </ol>

		<p>meters in infested area. Bait stations were refilled 5 times every 3 days. After 20 days three parameters were tested :</p> <p>4) percentage loss of intake control bait,</p> <p>5) percentage loss of intake poison bait and percentage of active holes</p>	<p>91.4%</p> <p>3) percentage of active holes was reduced to 14.3%</p>
<p>Brown rat (<i>Rattus norvegicus</i>)</p>	<p>Field test done according to KES-01/2009  (21.06.2016-17.07.2016)</p>	<p>The size of rodents population was evaluated by the measurement of control bait intake at the beginning and the end of the study.</p> <p>200 g of FRE 02/16/007 (which is the same as Toxan 25 Ziarno) 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> <p>4) percentage loss of intake control bait,</p> <p>5) percentage loss of intake poison bait and percentage of active holes.</p>	<p>The study indicates that:</p> <p>1) intake of control bait was reduced to 92.9%</p> <p>2) intake of tested bait was reduced to 90.0%</p> <p>3) percentage of active holes was reduced to 15.0%</p>

Effectiveness data has confirmed that Toxan 25 Ziarno is effective in the proposed areas for use, at the recommended dose rate when used as per label recommendations. The evaluation of the field trials demonstrated that the product is 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 Ziarno, with the active substance bromadiolone, at a concentration of 0.0025 % w/w may be authorised for use as a rodenticide (ProductType 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.