

## Evaluation Report for Category B, Subcategory 3.4, 3.12 Application

**Application Number:** 2005-4102  
**Application:** Evaluation Report for Category B, Subcategory 3.4, 3.12  
**Product:** Generation Paraffin Block  
**Registration Number:** 27259  
**Active ingredients (a.i.):** Difethialone  
**PMRA Document Number:** 1376978

### Background

Difethialone (DFL) end-use products were first registered in March 2000 for USC# 20 and 32 (structural and various outdoor sites). DFL is a second-generation anticoagulant which is more highly toxic and persistent than the first-generation anticoagulants. Generation Paraffin Block EP (Reg. No. 27259) is a rodenticide product containing 0.0025% difethialone (DFL) that is currently registered for the control of mice and rats indoors and in areas adjacent to home, industrial, commercial, agricultural and public buildings. Each Generation Paraffin Block consists of a 454 g slab which is to be broken into 8 pieces (i.e. 56 grams each). For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label (PMRA #1107615).

### Purpose of Application

The registrant, Liphatech Inc., requested the addition of use directions on the label for the control of rats in sewers. This was not an additional use-site since sewers are included under USC #20, Structural. For this reason, no data were submitted to support this submission.

### Efficacy and Sustainable Assessment

The rationale submitted by the applicant (PMRA #1107588) to support the addition of use directions specific to the control of rats in sewers is acceptable. The use directions for the control of rats in sewer systems is identical to that present on the label of the cited precedent product, Ditrac Blox (0.005% diphacinone; Reg. No. 23558). Although the cited precedent product contains a different active ingredient which is a first generation anticoagulant, the use directions to use wire to hang an entire paraffin block above the high water mark can be extrapolated to the label of Generation Paraffin Block because both labels also indicate to 'maintain an uninterrupted supply of fresh bait for 10 days' and 'replace contaminated or spoiled bait immediately'. Both of these statements direct the user to monitor the consumption of the bait.

## **Health Assessment**

### **Occupational Exposure Assessment**

The applicant has applied to add the following statement: "*In sewer applications, use wire to secure one entire bait block (i.e. 454 g.) above the high water mark.*" to the instruction in the following manner:

Generation Paraffin Block: RATS: Place 3 to 10 pieces of block per placement at intervals of 5 to 10 meters. *In sewer applications, use wire to secure one entire bait block (i.e. 454 g.) above the high water mark.* Maintain an uninterrupted supply of fresh bait for 10 days, or until signs of rat activity cease.

No other changes are proposed to the label, PPE, use-pattern or application rates. Since no changes to the use-pattern was proposed and the only change that was proposed should not result in any increase in occupational or bystander exposure.

### **Environmental Assessment**

On the basis that the proposed use in sewers is considered as an indoor use, difethialone should not pose an environmental risk to non-target organisms. The PMRA, therefore, does not object to the proposed registration of the difethialone end-use product, Generation Paraffin Block EP for use in sewers.

### **Conclusions**

The additional use of Generation Paraffin Block EP for the control of rats in sewers is acceptable regarding the proposed use instructions. In addition, the proposed use of Generation Paraffin Block EP should not pose an increased risk to humans on an occupational and bystander exposure basis and should not pose an environmental risk to non-target organisms.

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