



ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: MAKI PELLET RODENTICIDE
Applicant: LIPHATECH S.A.S.
Product number: 61411
Application number: 40681

Purpose of Application and Description of Use: Registration of a 0.05g/kg bromadiolone pellet bait for the control of rats and mice in and around agricultural, domestic, commercial, public services and industrial buildings.

Active Constituent(s): BROMADIOLONE

Regulatory Decision:

To grant the application subject to the following conditions:

Standard Conditions of Registration/Approval

1. Containers must meet AgVet Code Regulation 18
2. Agricultural products must meet Active Constituents Quality Assurance Requirements
3. Label must contain a Date of Manufacture, Batch Number and Expiry Date no greater than 1 years after the DOM

For full conditions, refer to http://www.apvma.gov.au/advice_summaries/adv_summaries.shtml.

Non-Standard Conditions of Registration/Approval

Nil

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State/External Efficacy Reviewer

Liphatech S.A.S. have applied to register a new rodenticide product for control of rats and mice in and around buildings. The proposed product contains 0.05 g/kg bromadiolone. Demonstration of efficacy was based on evidence of equal acceptance/palatability to an industry standard. The applicant provided two bioequivalence studies that demonstrated that the proposed product was equally palatable to rats and mice as the industry standard.

The first study was conducted overseas on a mixed sex group of 20 individually housed enclosure-bred “wild” strain Norway rats *Rattus norvegicus*. The experiment included two replicates (10 animals in each replicate). Following acclimatisation, the rats were offered a choice between the proposed product and the industry standard for four days. The consumption of each bait was measured each day and a ‘palatability index’ calculated, reflecting the proportion of the diet for each bait. The protocol for the trial followed a standard European Plant protection Organization (EPPO) protocol and was acceptable. Use of palatability indices is also a standard practice in comparing acceptability of baits, foods etc. In the first replicate the palatability index for the proposed product was 0.55 (55% of diet was Maki Pellets) and the palatability index in the second replicate was 0.68 (68% of diet was Maki Pellets). Therefore, in the first replicate there was no preference between the two baits and there was a mild preference for the proposed product in the second replicate.

The second study was also conducted overseas and used a similar protocol to the first (rat) study, but used laboratory-bred house mice *Mus musculus* instead. Animals were housed in groups according to sex and the study used 10 male and 11 female mice. The palatability indices indicated a very strong preference for the proposed product over the reference product (0.96 for males, 0.93 for females, or 0.95 overall). Therefore, mice have a very strong preference for Maki Pellets when offered as an alternative to the industry standard.

The data provided demonstrates that the proposed product is as readily accepted by rats and mice as the industry standard.

Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
15294	S	Berny, Ph	Study on the Palatability of Maki Pellets Versus Australia and Bromakil Pellet in Mice, <i>Mus musculus</i> , Wild Strain	2007	Efficacy and Safety	Efficacy	Applicant	
15293	S	Berny, Ph	Study on the Palatability of Maki Pellets Version Australia Versus Bromakil Pellet in the Rat, <i>Rattus norvegicus</i> , Wild Strain	2007	Efficacy and Safety	Efficacy	Applicant	

* S = Data submitted with the application;

I = Data inherited (that is, referenced) from another application