

Evaluation Report for Category B, Subcategory 1.1 (new site of manufacture by same registrant) and 1.3 (changes in TGAI guarantee) Application

Application Number: 2005-2312
Application: Evaluation Report for Category B, subcategory 1.1 (new site of manufacture by same registrant) and 1.3 (changes in TGAI guarantee)
Product: Difethialone Technical
Registration Number: 26278
Active ingredients (a.i.): Difethialone
PMRA Document Number: 1368194

Background

The original source of Difethialone Technical (PCP 26278) was first registered in 2000.

Purpose of Application

The purpose of this submission is to register a new (replacement) site of manufacture for Difethialone Technical, and to increase the guarantee from 97.6% to 98.6%.

Chemistry Assessment

Common Name: Difethialone
Chemical Name: 3-[3-(4'-bromo[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzothiopyran-2-one

Difethialone Technical has the following properties:

Property	Result
Colour and physical state	whitish-yellow powder
Nominal concentration	98.8%
Odour	not provided
Density	1.36 g/cm ³
Vapour pressure	0.074 mPa
pH	not available as TGAI is extremely insoluble
Solubility in water	0.39 mg/L
n-Octanol/water partition coefficient	log K _{ow} = 5.00

The chemistry requirements for Difethialone Technical have been completed.

Health Assessment

No toxicology review was conducted since results from the chemistry review indicate that the active ingredient produced at both the registered and new site of manufacture of Difethialone Technical are chemically equivalent. Therefore, the health risk profile of Difethialone Technical is expected to be similar to that of the original registered source.

Environmental Assessment

An environmental assessment is not required for this application type.

Value assessment

A value assessment is not required for technical grade active ingredient products.

Conclusions

The PMRA has completed an evaluation of the subject application and has determined that Difethialone Technical is eligible for registration.

References

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