



Evaluation Report for Category B, Subcategory 4.6 Application

Application Number: 2010-3141
Application: Fulfilling conditions of registration on a product with full registration.
Product: Plantskydd Dried Blood Technical Grade Active Ingredient
Registration Number: 27410
Active ingredients (a.i.): Dried blood
PMRA Document Number English PDF: 2040489

Purpose of Application

The purpose of this application was to fulfill the requirement for five batch data, which was a condition of the full registration for Plantskydd Dried Blood Technical Grade Active Ingredient (Registration number 27410).

Chemistry and Health Assessment

Representative microbial contaminant screening data supplied by the applicant in support of Plantskydd Dried Blood Technical Grade Active Ingredient were reviewed from a human health and safety viewpoint. This information database indicated that Plantskydd Dried Blood Technical Grade Active Ingredient does not contain any significant levels of *Escherichia coli*. The registrant, however, must include *E. coli* batch testing in its quality assurance program and ensure that all batches of product containing 10 or more colony forming units of *E. coli* per gram of product are destroyed and discarded.

Environmental and Value Assessment

Environmental and value assessments were not required for this application

Conclusion

The PMRA has completed an assessment of available information for Plantskydd Dried Blood Technical Grade Active Ingredient and has found the information sufficient to fulfill the data requirement of five batch data.

References

1933066 2010, Analytical Results, DACO: 2.13.3 CBI

ISSN: 1911-8082

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