



Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2020-3127
Application: Changes to TGAI Product Chemistry – New Source (site) same registrant
Product: *Streptomyces lydicus* WYEC 108
Registration Number: 28673
Active ingredient (a.i.): *Streptomyces lydicus* strain WYEC 108
PMRA Document Number : 3207089

Purpose of Application

The purpose of this application was to add a new manufacturing method and a manufacturing site for *Streptomyces lydicus* WYEC 108.

Chemistry Assessment

The new manufacturing process and the quality assurance associated with the production of the technical grade active ingredient (TGAI), *Streptomyces lydicus* WYEC 108, at the new site were described in sufficient detail and determined to be acceptable. Acceptable representative potency and microbial contaminant screening data were also submitted to demonstrate that all batches of the TGAI meet the required acceptance criteria for potency and microbial contamination. All batches of the TGAI must conform to the limits outlined in the OECD Issue Paper on Microbial Contaminants for Microbial Pest Control Products.

The potential production of secondary metabolites was adequately addressed.

A review of the submitted information/data indicated that the TGAI manufactured using the new process at the new site is comparable in potency and physical and chemical characteristics to the registered TGAI. No additional information or data are required.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found it sufficient to support the amendments to the registration of *Streptomyces lydicus* WYEC 108 to add a new manufacturing method and a manufacturing site.

References

PMRA Document Number	References
3139134	2020, Waiver Request for Analysis for other unintentional ingredients, DACO: M2.10.3
3139137	2020, Literature review of Streptomyces lydicus WYEC108 and metabolites: Toxicological and persistence studies, DACO: M2.7.2 CBI
3139135	2020, Streptomyces lydicus WYEC 108 Physchem, DACO: M2.12
3139136	2013, The genome of Actinovate, DACO: M2.7.2 CBI
3139133	2020, Streptomyces lydicus WYEC108 manufacturing process, DACO: M2.8 CBI
3139131	2020, Streptomyces lydicus WYEC108 5 batch, DACO: M2.10.1,M2.10.2,M2.8,M2.9.2,M2.9.3 CBI

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