

# **Evaluation Report for Category B, Subcategories 1.1, 1.3 Application**

2018-6668 **Application Number:** 

**Application:** Changes TGAI Prod Chemistry-New Source (site) same registrant

Changes TGAI Prod Chemistry-Specifications

**Product:** Streptomyces lydicus WYEC 108

**Registration Number:** 28673

**Active ingredient (a.i.):** Streptomyces lydicus strain WYEC 108

**PMRA Document Number:** 3011323

### **Purpose of Application**

The purpose of this application was to amend the formulation and register a new manufacturing site and new manufacturing methods for Streptomyces lydicus WYEC 108.

### **Chemistry Assessment**

The results of the potency estimation and microbial contamination analyses, and the new manufacturing methods provided by the applicant support the new manufacturing site, new manufacturing methods, and new formulation of Streptomyces lydicus WYEC 108.

### 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 new manufacturing site, new manufacturing methods, and new formulation of Streptomyces lydicus WYEC 108.

### References

## PMRA Doc.

No.	Reference
2921933	2018, Final Actinovate Soluble Storage Stability NZ 02OCT2018, DACO:
	M2.11 CBI
2921934	2015, Actinovate Soluble Manufacturing Process Trade Secret
	02OCT2018, DACO: M2.8 CBI
2945225	2018, Streptomyces lydicus WYEC 108 (PCP# 28673) and Actinovate SP
	(PCP# 28672), 5 Batch Analysis, DACO: M2.10.2,M2.9.2 CBI
2945226	2018, 18282B Certificate 13Dec2018, DACO: M2.10.2 CBI
2945227	2018, 18282B Results 13Dec2018, DACO: M2.10.2 CBI
2945228	2018, 18289C Certificate 13Dec2018, DACO:
	1 Canada

# M2.10.2 CBI

2945229	2018, 18289C Results 13Dec2018, DACO: M2.10.2 CBI
2945230	2018, 18296B Certificate 13Dec2018, DACO: M2.10.2 CBI
2945231	2018, 18296B Results 13Dec2018, DACO: M2.10.2 CBI
2945232	2018, 18303A Certificate 13Dec2018, DACO: M2.10.2 CBI
2945233	2018, 18303A Results 13Dec2018, DACO: M2.10.2 CBI
2945234	2018, 18317A Certificate 13Dec2018, DACO: M2.10.2 CBI
2945235	2018, 18317A Results 13Dec2018, DACO: M2.10.2 CBI

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