

## Evaluation Report for Category B, Subcategory B.1.1 Application

**Application Number:** 2016-3185  
**Application:** Changes to TGAI Product Chemistry-New site, same registrant  
**Product:** *Aureobasidium pullulans* DSM 14941  
**Registration Number:** 30553  
**Active ingredients (a.i.):** *Aureobasidium pullulans* DSM 14941  
**PMRA Document Number:** 2709228

### Background

*Aureobasidium pullulans* DSM 14941 is currently fully registered. It was first registered as a technical grade active ingredient (TGAI) in Canada in 2012.

### Purpose of Application

The purpose of this submission is to register new formulating sites for the TGAI product *Aureobasidium pullulans* DSM 14941.

### Chemistry Assessment

Sufficient batch analysis data for microbial contamination analysis and potency estimation were submitted to support the registration of the new manufacturing locations and formulating sites for *Aureobasidium pullulans* DSM 14941.

### Health, Environmental and Value Assessments

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

### Conclusion

The PMRA has conducted a review of the information provided in support of this application. Based on the results of this review, registration of the new formulating sites is supported.

## References

<b>PMRA Document Number</b>	<b>Reference</b>
2652309	2012, Optimization of the production process of <i>Aureobasidium pullulans</i> strains DSM 14940 and 14941, DACO: M2.8 CBI
2652310	2013, Certificate of analysis, DACO: M2.9.2, M2.9.3 CBI
2652311	2009, Certificate of analysis, DACO: M2.9.2, M2.9.3 CBI
2652312	2009, Contamination of CF10 and CF40 with yeasts, DACO: M2.9.2, M2.9.3 CBI
2652313	2013, Certificate of analysis, DACO: M2.9.2, M2.9.3 CBI

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