

Evaluation Report for Category B, Subcategory B.1.1 Application

Application Number: 2016-3184
Application: Changes to TGAI Product Chemistry-New site, same registrant
Product: *Aureobasidium pullulans* DSM 14940
Registration Number: 30554
Active ingredients (a.i.): *Aureobasidium pullulans* DSM 14940
PMRA Document Number: 2709224

Background

Aureobasidium pullulans DSM 14940 is currently fully registered. It was first registered in Canada as a technical grade active ingredient (TGAI) in 2012.

Purpose of Application

The purpose of this submission is to register new manufacturing sites for the TGAI product *Aureobasidium pullulans* DSM 14940.

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 14940.

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 manufacturing sites for *Aureobasidium pullulans* DSM 14940 is supported.

References

PMRA Document Number	Reference
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

ISSN: 1911-8082

8 Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2016

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.