



ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: MYCOFIX PLUS BBSH
Applicant: BIOMIN (AUSTRALIA) PTY LTD
Product number: 59620
Application number: 45156

Purpose of Application and Description of Use: Registration of a 5x10¹² cfu/kg powder product for management of trichothecenes, aflatoxins and fumosins in feed for pigs and poultry.

Active Constituent(s): BENTONITE
EUBACTERIUM SP. STRAIN BBSH 797

Regulatory Decision:

To grant the application subject to the following conditions:

Standard Conditions of Registration/Approval

1. Containers must meet AgVet Code Regulation 18
2. Product must not be supplied without meeting GMP Requirements
3. Label must contain an Expiry Date and Batch Number

For full conditions, refer to Standard Conditions for Applications on the APVMA website.

Non-Standard Conditions of Registration/Approval

4. This product can only be supplied subject to the biosecurity requirements of the Department of Agriculture.
5. The registrant can only supply, or cause this product to be supplied, where the Department of Agriculture has issued a permit for the importation of the product into Australia.
6. The registrant must continue to hold an import permit issued by Department of Agriculture's Biological Imports Program for the product.

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Australian Government Department of Health and Ageing, Office of Chemical Safety

The Office of Chemical Safety (OCS) in the Department of Health and Ageing has conducted a risk assessment on the product and concluded that it can be used safely.

The active constituent, Biomin BBSH797, is of low oral toxicity, moderate acute inhalation toxicity and is unlikely to be genotoxic. Some deficiencies in the submitted dataset were considered acceptable; *Eubacterium* sp. strain DSM 11798 is an obligate anaerobe and hence testing for pathogenicity via inhalation and other routes is problematic as the organism is unlikely to survive the test procedures. There was no evidence of pathogenicity or infectivity for this microorganism in any of the submitted studies in the usual test species. The conclusion, based on weight of evidence, is that there are no concerns regarding the infectivity and pathogenicity of *Eubacterium* sp. strain DSM 11798 in humans.

On the basis of the data available, the use of the product, Mycofix Plus BBSH, will present minimal hazards in the preparation and dispensation of treated feed. A limited array of PPE will be required to protect from prolonged contact with skin, eyes and respiratory mucosa.

First aid instructions and safety directions are required and are included on the label.

Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
21627	S	V Thiss	Determination of the skin sensitisation of Biomin BBSH	July 2005	Toxicology	Acute eye irritation studies, product	Applicant	

63132	S	Hargitai, J	Biomin BBSH797 in vitro mammalian chromosome aberration test.	2011	Toxicology	Acute oral studies, active	Applicant	
63129	S	Tavaszi, J	Acute oral toxicity study of test item Biomin BBSH 797 in rats.	2011	Toxicology	Acute oral studies, active	Applicant	
63134	S	Torok-Batho, M	Mammalian Erythrocyte Micro Nucleus Test in bone marrow cells of mouse with Biomin BBSH797.	2010	Toxicology	Genotoxicity (mutagenicity) Studies	Applicant	
63130	S	Hargitai, J	The testing of Biomin BBSH797 with bacterial reverse mutation assay.	2009	Toxicology	Genotoxicity (mutagenicity) Studies	Applicant	
63133	S	Schatzmayr, D	Toxicological studies of Biomin BBSH797 official statement by Biomin (Arguments against requirement for a pathogenicity study on Biomin BBSH797)	Dec 2011	Toxicology	Other information	Applicant	
21628	S	Kazar and Zeljenkova	Sub-chronic oral toxicity: rodent. 90 day study of oral toxicity of Eubacterium sp in rats according to OECD guideline 408.	December 2006	Toxicology	Sub-chronic studies	Applicant	

* S = Data submitted with the application

I = Data inherited (that is, referenced) from another application