

Evaluation Report for Category B, Subcategory B1.1 Application

Application Number: 2014-3942
Application: B.1.1 - New Source Same Registrant
Product: Taegro Technical B
Registration Number: 31864
Active ingredients (a.i.): *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24
PMRA Document Number : 2536802

Purpose of Application

The purpose of this application was to register a new source of a registered product, Taegro Technical B. The new source product is based on the similarity to the currently registered product Taegro Technical (Reg. No. 30719).

Taegro Technical B and Taegro Technical contain the same active ingredient (*Bacillus subtilis* var. *amyloliquefaciens* strain FZB24) in the same concentration but are manufactured using slightly different methods.

Chemistry Assessment

The product characterization data for Taegro Technical B were deemed adequate to assess the potential human health and environmental risks. Taegro Technical B was characterized by the analyses of a sufficient number of batches. The storage stability data were sufficient to support a shelf life of 1 year when stored at 4–35°C.

Health Assessments

Waiver rationales and new studies were submitted in support of Taegro Technical B. These studies included acute oral infectivity and toxicity, dermal toxicity, dermal irritation and eye irritation studies for Taegro Technical B. Taegro Technical B was of slight toxicity via the oral route in mice ($LD_{50} > 1.98 \times 10^8$ CFU/animal), low toxicity to the rat via the dermal route ($LD_{50} > 2000$ mg/kg bw), slightly irritating to the skin of rabbits (Maximum Average Score or MAS=1.0/8) and minimally irritating to the eye of rabbits (MAS=0/110). The MPCA was not pathogenic in acute oral infectivity and toxicity testing. Acute pulmonary and intravenous infectivity/toxicity testing was waived.

The differences in the manufacturing processes for Taegro Technical B over the existing Taegro Technical product are minimal. The change in the manufacturing method for the Taegro Technical B should not result in differences in potential occupational or bystander exposure over the existing manufacturing process for Taegro Technical. No unacceptable risk is expected when workers follow label directions and wear personal protective equipment as required on the label.

Based on all the available data, negligible to no risk is expected for the general population, including infants and children, or animals.

Environmental Assessment

Waiver rationales were submitted in lieu of avian oral, wild mammal, freshwater fish, terrestrial arthropod, honeybee, aquatic arthropod, terrestrial plant and aquatic plant testing based on past testing and the rationale that minimal changes were made to the manufacturing process. Given that *Bacillus subtilis* var. *amyloliquefaciens* is not considered a toxigenic or a pathogenic species and no known toxins are produced by strain FZB24, the minimal changes in manufacturing processes are not likely to significantly impact the environmental toxicology of Taegro Technical B.

Value Assessment

Value assessment not required for this application.

Conclusion

PMRA has reviewed information provided in support of the registration of the subject product as described above. Based on this review, the subject product is acceptable for full registration.

References

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- 2457790 2000, Use of *Bacillus subtilis* as biocontrol agent, DACO: M2.7.2
- 2457791 1999, Growth Parameters of *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24 at various temperatures, DACO: M2.7.2
- 2457794 1991, On the safety of *Bacillus subtilis* and *B. amyloliquefaciens* a review, DACO: M2.7.2
- 2457796 2014, 5 batch for Taegro Technical B, DACO: M2.10.1, M2.10.2, M2.8, M2.9.2, M2.9.3 CBI
- 2457798 2014, Taegro Technical B Manufacturing Process, DACO: M2.8 CBI
- 2457803 2014, Waiver Request for Analysis for other intentional ingredients, DACO: M2.10.3
- 2457805 2013, Storage Stability Study for Taegro Technical B, DACO: M2.11 CBI
- 2457808 2014, Determination of color physical state odor pH and true density of Taegro Technical B, DACO: M2.12
- 2457809 2014, Summary of Infectivity Pathogenicity and Toxicity, DACO: M4.2.1
- 2457810 2014, Acute Oral toxicity/pathogenicity study of taegro technical in mice, DACO: M4.2.2
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2457819	2014, Waiver Request for Avian Oral Testing, DACO: M9.2.1
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2457831	2014, Waiver request for terrestrial plants testing requirements, DACO: M9.8.1
2457833	2014, Waiver request for aquatic plants testing requirements, DACO: M9.8.2
2457853	2013, 5 batch analysis for Taegro 2, DACO: M2.10.1, M2.10.2, M2.8, M2.9.2, M2.9.3 CBI
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