

**TSCA Section 5(a)(3)(C) Determination for Microbial Commercial Activity Notice
(MCAN) J-16-0006**

Number: J-16-0006

TSCA Section 5(a)(3) Determination: Microorganism not likely to present an unreasonable risk (5(a)(3)(C))

Chemical Name:

Generic: *Trichoderma reesei* modified

Assessed Conditions of Use (intended, known, or reasonably foreseen)¹:

Intended use(s) (generic): Enzyme Production

Known and reasonably foreseen use(s): Enzyme production under submerged standard industrial fermentation operations

Summary: The microorganism is not likely to present an unreasonable risk based on low human health hazard and low environmental hazard associated with the recipient microorganism and introduced genetic material. *T. reesei* is not pathogenic to humans or animals and has a long history of safe use for production of enzymes. The introduced genetic modifications pose low concern for health and environmental hazard, do not include antibiotic resistance markers, and do not provide a growth advantage over the parental strain.

Human Health Hazard²: Human health hazard is relevant to whether a new microorganism is likely to present an unreasonable risk because the significance of the risk is dependent upon both the hazard (or pathogenicity/toxicity) of the microorganism and the extent of exposure to the microorganism. EPA estimated the human health hazard of this microorganism based on data for the recipient parental strain as well as the genetic modifications. There is low concern for human health hazard for the microorganism based on the recipient strain not being a human pathogen and the introduced genetic material encoding for common enzymes found in many organisms including humans, rodents, and yeasts. Although *T. reesei* is known to produce the secondary metabolite paracelsin, under submerged standard industrial fermentation operations, paracelsin is not expected to be produced.

Environmental Hazard³: Environmental hazard is relevant to whether a new microorganism is likely to present unreasonable risks because the significance of the risk is dependent upon both the hazard (or pathogenicity/toxicity) of the microorganism and the extent of exposure to the microorganism. EPA estimated the environmental hazard of this microorganism based on data

¹ Intended uses are those identified in the section 5(a) notification. EPA identifies “known” and “reasonably foreseen” uses of the new microorganism based on evidence of current use of the new microorganism outside the United States and evidence of the current uses of microorganisms that are structurally analogous to the new microorganism. EPA identifies uses based on searches of internal CBI EPA MCAN databases (containing use information on analog microorganisms), other U.S. government public sources, and Internet searches.

² A microorganism is considered to have low human health hazard if it is not known to be a frank human pathogen that causes disease in healthy adults, and/or animal studies have demonstrated a lack of pathogenicity or toxicity; a microorganism is considered to have high human health hazard if there is evidence of adverse effects in humans or conclusive evidence of severe effects in animal studies. In the absence of animal data on a microorganism, EPA may use other data or information obtained through literature searches.

³ A microorganism is considered to be of low ecological hazard if it is not known to be an animal or plant pathogen, and the genetic modifications do not impart pathogenic or toxigenic traits, and the introduced genetic material does not provide a selective growth advantage in outcompeting indigenous microbial communities in the environment.

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for the recipient parental strain as well as information on the genetic modifications. There is low concern for environmental hazard for the microorganism based on the recipient strain not being an animal or plant pathogen and the introduced genetic material encoding for common enzymes found in many organisms including humans, rodents, and yeasts. Also, the deletion of certain genes from the parental strain in construction of the new microorganism lessens its ability to survive in the environment.

Potential Exposures: The exposure to a new microorganism is potentially relevant to whether a new microorganism is likely to present unreasonable risks because the significance of the risk is dependent upon both the hazard (or pathogenicity/toxicity) of the microorganism and the nature and extent of exposure to the substance. However, in this case EPA did not estimate the exposure because EPA determined that the microorganism presents both low human health hazard and low environmental hazard. Due to low hazard, EPA believes that this microorganism would be unlikely to present an unreasonable risk even if exposures were high. Members of the genus *Trichoderma* are ubiquitous in the environment.

Potentially Exposed or Susceptible Subpopulation(s): Workers are potentially exposed. Given the low hazard of this microorganism, EPA finds that this microorganism is not likely to present unreasonable risk to workers.

9/2/2016

Date:

/s/

Director, Office of Pollution Prevention and Toxics