

TSCA Section 5(a)(3)(C) Determination for Microbial Commercial Activity Notices (MCANs) J-16-0036, J-16-0037, J-16-0038, J-16-0039, J-16-0040, and J-16-0041

Numbers: J-16-0036, J-16-0037, J-16-0038, J-16-0039, J-16-0040, and J-16-0041

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

Chemical Name:

Generic: Biofuel producing modified microorganism(s), with chromosomally-borne modifications

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

Intended use(s) (generic): Production of Biofuels

Known and reasonably foreseen use(s): Production of Biofuels

Summary: The microorganisms are 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. The recipient microorganism is not pathogenic to humans or animals and has an extensive history of safe use. The introduced genetic modifications pose low concern for health and environmental hazard and do not include antibiotic resistance markers.

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 (e.g., pathogenicity/toxicity) of the microorganism and the extent of exposure to the microorganism. EPA estimated the human health hazard of these microorganisms based on data for the recipient parental strain as well as the genetic modifications. There is low concern for human health hazard for the microorganisms based on the recipient strain not being a human pathogen and the introduced genetic material encoding for common enzymes found in numerous organisms.

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 these microorganisms based on data for the recipient parental strain as well as information on the genetic modifications. There is low concern for environmental hazard for the microorganisms based on the

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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recipient strain not being an animal or plant pathogen and the introduced genetic material encoding for common enzymes found in numerous organisms.

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 (e.g., 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 microorganisms present both low human health hazard and low environmental hazard. Due to low hazard, EPA believes that these microorganisms would be unlikely to present an unreasonable risk even if exposures were high.

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.

12/1/2016
Date: _____

_____/s/_____
Director, Chemical Control Division