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Environmental Risk Assessment

BIMZELX®

Introduction

The Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use (EMA/CHMP/SWP/4447/00 dated 01 June 2006 and EMA/CHMP/SWP/4447/00 Rev. 1 dated 15 November 2018), states that peptides and proteins are exempted of ecotoxicity and environmental fate studies because they are unlikely to result in significant risk to the environment.

Bimekizumab is an engineered, humanized, full-length monoclonal antibody and does not contain non-natural amino acids or modifications. It is expected to be subject to the same in vivo degradation pathways as natural proteins and to have the same environmental impact as naturally occurring human antibodies. The excretion of monoclonal antibodies is generally thought to be mediated by non-specific or target mediated uptake by cells followed by lysosomal degradation with no appreciable excretion of intact bimekizumab by the liver or kidney (Brady and Webster, 2012, Lobo, et al, 2004, and Braeckman, 1997).

No environmental concerns are apparent for the bimekizumab drug product. Bimekizumab is unlikely to represent a risk for the environment following its prescribed usage in patients.