Inspired by patients.
Driven by science.

Environmental Risk Assessment
RYSTIGGO®

Introduction

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

Rozanolixizumab, the active ingredient, is an humanized monoclonal antibody. Antibodies are naturally occurring products (i.e., proteins) and are not expected to pose any risk to the environment. Because of their molecular size, elimination of monoclonal antibodies through the kidney is considered insignificant. Monoclonal antibodies are mainly metabolized and eliminated through proteolytic degradation that results in smaller peptides and amino acids. Furthermore, biodegradability and acute toxicity tests with some monoclonal antibodies and other proteins or peptide active pharmaceutical substances showed ready biodegradability and a very low risk to the environment.

Considering the suggested rapid biodegradability and the suggested low excretion, Rozanolixizumab is not expected to pose any risk to the environment.