



Inspired by **patients**.
Driven by **science**.

Environmental Risk Assessment

EVENTITY®

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.

Romosozumab, the active ingredient, is a humanized monoclonal antibody. It is expected to be subject to the same degradation pathways as natural naturally occurring human antibodies.

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