Environmental risk assessment data
Palivizumab

Version 2 – October 2023

Mode of action

Humanized monoclonal antibody (IgG1k)

Environmental risk summary

As per EU EMA guideline for environmental risk assessment of pharmaceuticals (Ref. 1), ecotoxicity and environmental fate studies are not required for vitamins, electrolytes, amino acids, peptides, proteins, carbohydrates, lipids, vaccines and herbal medicinal products because they are unlikely to result in significant risk to the environment. Monoclonal antibodies are considered naturally occurring products (i.e., they are proteins) and therefore susceptible to chemical, physical and biological degradation and are not expected to remain stable or biologically active in the environment.

References

1. Committee for Medicinal Products for Human Use (CHMP); Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use. 1 June 2006, EMEA/CPMP/SWP/4447/00 corr 2.

For more information on how we prepare our environmental risk summary documents, please see: https://www.astrazeneca.com/content/dam/az/PDF/Sustainability/Environmental_risk_data_relating_to_our_medicines.pdf