Inspired by patients.
Driven by science.

Environmental Risk Assessment
XYREM®

Introduction

Sodium oxybate, the active ingredient, is the sodium salt of γ-hydroxybutyric acid, an endogenous neurotransmitter present in several tissues of a lot of animal species – including humans – and in some plants. The sodium salt is expected to be fully hydrolized in the gut and/or in the blood stream of humans, which results in the liberation of a sodium ion on one end, and the active moeity of the product γ-hydroxybutyrate on the other. Both products correspond to endogenous substances.

Gamma-hydroxybutyrate is metabolized into molecules that are otherwise well-known as being widely spread amongst living organisms, such as for instance succinic acid. The main end product of biotransformation of the compound is carbon dioxyde that accounts for 80 % of radioactivity after administration of radiolabelled sodium oxybate.

To conclude, sodium oxybate is qualitatively equivalent to an endogenous biological compound that is metabolized into harmless and well-known molecules. Quantitatively, due to the very widespread availability of γ-hydroxybutyric acid in nature, and the even more widespread availability of its intermediate and end products resulting from biotransformation, the increased amount of XYREM® will unlikely represent a significant increase in the proportion of the already existing amount of those molecules in the environment.