

To whom it may concern

Justification for Absence of Environmental Risk Assessment

Travoprost/Timolol 40 mcg/ml + 5 mg/ml eye drops, solution is the generic copy of other product of similar composition already existing on the market more than 10 years.

The applicant herewith states that the product is intended to substitute for other identical products on the market. The product does not contain any component which results in additional hazard to the environment during storage, distribution, use and disposal.

Based on the assumption that this generic product is intended to substitute for other identical products on the market, the approval of the referred product should not result in an increase of the total quantity of Travoprost / Timolol released into the environment. Therefore it should not result in increase of risk to the environment during storage, distribution, use and disposal.

Athens, 01/09/2016

Head of Corporate Quality Management

Senior Vice President of Research & Industrial Operations

Module 1.6.2 GMO

Not applicable