

## **DECLARATION OF RESIDUAL SOLVENTS**

We, Farmadria - Avena Lab, as the distributor, assure and confirm on behalf of the manufacturer that our Trihydroxystearin does not contain, nor is it processed using, any solvents of the three classes mentioned in: (Class – 1, Class – 2, Class – 3) listed in the European Pharmacopeia's "Guidelines for Residual Solvents (CPMP/ICH/283/95) (According to ICH guidelines Q3C)." Hexane is a Class-2 solvent.

Furthermore, we declare that our Trihydroxystearin is of the highest purity and hexane-free. The manufacturer does not routinely analyze this product or the raw materials for the presence of these solvents. However, this declaration is based on the knowledge of the manufacturing process and the raw materials utilized.

## **IZJAVA O PREOSTALIM RASTVARAČIMA**

Mi, Farmadria - Avena Lab, kao distributer, u ime proizvođača osiguravamo i potvrđujemo da naš Trihydroxystearin ne sadrži, niti se prerađuje koristeći bilo koje rastvarače iz tri klase navedene u: (Klasa – 1, Klasa – 2, Klasa – 3) navedene u Evropskoj farmakopeji "Smernice za preostale rastvarače (CPMP/ICH/283/95) (prema ICH smernicama Q3C)." Heksan je rastvarač klase 2.

Dalje, izjavljujemo da je naš Trihydroxystearin najviše čistoće i bez heksana. Proizvođač rutinski ne analizira ovaj proizvod ili sirovine za prisustvo ovih rastvarača. Međutim, ova izjava se zasniva na poznavanju procesa proizvodnje i korišćenih sirovina.

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