

Government of Upper Bavaria - Central Authority for Supervision of Medicinal Products in Bavaria (GMP/GCP)

Union Format for Registration of Manufacturer, Importer or Distributor of Active Substances to be used as Starting Materials in Medicinal Products for Human Use

1. Registration Number : DE_BY_04_Reg_2019_0005
2. Name or corporate name of registrant : Denk Ingredients GmbH
3. Permanent or legal address of registrant : Neherstr. 9, Muenchen, 81675, Germany
4. Address(es) of site(s) where registered activities take place : Neherstr. 9, München, 81675, Germany
5. National legal basis of registration : § 64 Abs. 3g German Drug Law
6. Name of responsible officer of the competent authority of the member state validating the registration : Confidential
7. Signature :
8. Date : 2020-01-24

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in the Union database or with the validating authority.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site: Denk Ingredients GmbH, Neherstr. 9, München, 81675, Germany

2. IMPORTATION AND DISTRIBUTION OPERATIONS			
A	Importation		
	Active Substance	3rd Country Manufacturer	3rd Country Distributor
	List of APIs is available at the NCA (DE_BY_04)		
B	Distribution		
	List of API is available at the NCA (DE_BY_04_Reg_2019_0005)		

Any restrictions or clarifying remarks to the scope of these registered operations (for all users) : Registered activities cover the import and the distribution of APIs. The list of relevant APIs has been submitted to the national competent authority, but is not mentioned in the API Registration.

Storage: Unitax-Pharmalogistik GmbH, An den Gehren 1, 12529 Schönefeld (Germany)

Loxess Pharma GmbH, Oberheisinger Str. 11, 93073 Neutraubling (Germany)

Die registrierte Tätigkeit umfasst die Einfuhr und den Handel mit Wirkstoffen. Um welche Wirkstoffe es sich handelt, ist der zuständigen Behörde bekannt. Die Auflistung der Wirkstoffe unterbleibt.

Lagerung: Unitax-Pharmalogistik GmbH, An den Gehren 1, 12529 Schönefeld

Loxess Pharma GmbH, Oberheisinger Str. 11, 93073 Neutraubling