

Landesamt für soziale Dienste Schleswig-Holstein

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_SH_01_Reg_2018_0003
2. Name or corporate name of registrant : Inter-Harz GmbH
3. Permanent or legal address of registrant : Rostock-Koppel 10, Klein Offenseth-Sparrieshoop, Schleswig-Holstein, 25365, Germany
4. Address(es) of site(s) where registered activities take place : Rostock-Koppel 10, Klein Offenseth-Sparrieshoop, Schleswig-Holstein, 25365, Germany
5. National legal basis of registration : Section 64 (3g) German Drug Law (Arzneimittelgesetz)
6. Name of responsible officer of the competent authority of the member state validating the registration : Confidential
7. Signature :
8. Date : 2018-03-02

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: Inter-Harz GmbH, Rostock-Koppel 10, Klein Offenseth-Sparrieshoop, Schleswig-Holstein, 25365, Germany

2. IMPORTATION AND DISTRIBUTION OPERATIONS			
A	Importation		
	Active Substance	3rd Country Manufacturer	3rd Country Distributor
	List of APIs is available at the NCA (API_001_SH)		
B	Distribution		
	List of APIs is available at the NCA (API_001_SH)		

Any restrictions or clarifying remarks to the scope of these registered operations (for all users) : 2.A Importation Operations:

Registered activities cover the import of APIs.

The list of relevant APIs has been submitted to the national competent authority, but is not mentioned in the API Registration.

2.B Distribution Operations:

Registered activities cover 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.

2.A Einfuhrtätigkeiten:

Die registrierte Tätigkeit umfasst die Einfuhr von Wirkstoffen.

Um welche Wirkstoffe es sich handelt, ist der zuständigen Behörde bekannt. Die Auflistung der Wirkstoffe unterbleibt.

2.B Handelstätigkeiten:

Die registrierte Tätigkeit umfasst den Handel mit Wirkstoffen.

Um welche Wirkstoffe es sich handelt, ist der zuständigen Behörde bekannt. Die Auflistung der Wirkstoffe unterbleibt.