

National Agency For The Safety Of Medicine And Health Products

Certificate No: 23MPP060D01

CERTIFICATE OF GDP COMPLIANCE OF A DISTRIBUTOR OF ACTIVE SUBSTANCES FOR USE AS STARTING MATERIALS

Issued following an inspection in accordance with Art. 111(1) of Directive 2001/83/EC and Art. 123(6) of regulation (EU) 2019/6

The competent authority of France confirms the following:

The active substance distributor (API): IMCD France S.A.S.

Site address: Immeuble New Corner, 2 Avenue Du Stade De France, St Denis, 93210

OMS Identifiers: (ORG-100035229 / LOC-100080051)

has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC and Art. 123(6) of regulation (EU) 2019/6

Scope of certificate: Human Active Substances, Veterinary Active Substances

From the knowledge gained during inspection of this active substance distributor, the latest of which was conducted on 2023-08-31, it is considered that it complies with the principles of Good Distribution Practice for active substances referred to in Article 47 of Directive 2001/83/EC and in Article 95 (8) of Regulation (EU) 2019/6.

This certificate reflects the status of the site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However this period of validity may be reduced using regulatory risk management principles, by an entry in the Restrictions or Clarifying Remarks field.

The authenticity of this certificate may be verified in the Union database. If it does not appear please contact the issuing authority.

Any restrictions or clarifying remarks related to the scope of this certificate(For All Users):

Signatory : Mrs Linda Gallais, head of starting materials inspection department --- The ANSM does not issue hard copies of good practices certificates

2023-11-28

Name and signature of the authorised person of the Competent Authority of France

EUROPEAN GMP

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