

Certificate No: SE-H-API-25-089174

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

The competent authority of Sweden confirms the following:

The active substance distributor (API): AAK Sweden AB
Site address: Vastra Kajen, Karlshamn, 374 82, Sweden
OMS Identifiers: (ORG-100021753 / LOC-100057679)

has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC and in connection with registration no* SE-H-REG-23-020996

Scope of certificate: Human Active Substances

From the knowledge gained during inspection of this active substance distributor, the latest of which was conducted on 2025-11-20, 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.

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.

2026-02-12

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



Mr Bengt Berglund
Swedish Medical Products Agency
Tel: +46 18 174600
bengt.berglund@lakemedelsverket.se

