SPECIFICATION

HEDINGER 1843 A pure decision.

Disodium Edetate Ph. Eur.* / USP*
VERSENE** NA Chelating Agent

Product code: 214

Testing specifications: Ph. Eur.* / USP* / LSM 214*
The material meets all requirements of Ph. Eur.*, USP*

Parameter	Ph. Eur.*		USP*	
	Specification	Method	Specification	Method
Characters	White or almost white crystalline powder, soluble in water	Ph. Eur.*	–	–
Assay	98.5 – 101.0%	Ph. Eur.*	99.0 – 101.0%	USP*
Identification	A / B / D	Ph. Eur.*	A / B / C	USP*
Appearance of solution	clear / colourless	Ph. Eur.*	–	–
pH	4.0 – 5.5	Ph. Eur.*	4.0 – 6.0	USP*
Limit of nitrilotriacetic acid[1]	≤ 0.1% (Impurity A)	Ph. Eur.*	≤ 0.1%	USP*
Iron	≤ 80 ppm	Ph. Eur.*	–	–
Loss on Drying	–	–	8.7 – 11.4%	USP*
Calcium	–	–	conforms	USP*

[1]Limit of nitrilotriacetic acid is only analysed according to USP*

Quality Assurance and Quality Control	
Process/Operation	**Standard / Requirement**
Production at chemical manufacturer	ISO 9001*
Final manufacturing steps and supplier	IPEC PQG – GMP Guidelines for Pharmaceutical Excipients* & IPEC GDP Guideline*
Analytical quality control at final manufacturer	Full analysis of specification for each batch in a GMP qualified laboratory (in compliance with EU-GMP Part I, Chapter 6*)
Batch release at final manufacturer	Qualified Person according to EU-GMP (2001/83/EC; Articles 48 & 49)
Packaging at final manufacturer	Grade D (100,000) clean room according to GMP [EU-GMP Part I Annex 1 (classification and operating conditions), US cGMP (as applicable)]

Storage: It is recommended to store the material in well closed containers and protected from light.

Shelf-life: 36 months from date of manufacture
The specified shelf-life relates to originally closed containers.

Chemical manufacturer and manufacturing site: The Dow Chemical Company, Freeport, Texas, USA

Manufacturing process: synthetic, key raw material: EDTA acid

Final manufacturing steps and supplier: Aug. Hedinger GmbH & Co. KG, 06179 Teutschenthal, Germany

*current version
**Trademark of The Dow Chemical Company

Effective date: 21.10.2026
Supersedes version from: 26.07.2021

SPECIFICATION

Disodium Edetate Ph. Eur.* / USP*
VERSENE** NA Chelating Agent

Product code: 214

Testing specifications: Ph. Eur.* / USP* / LSM 214*
The material meets all requirements of Ph. Eur.*, USP*

Regulatory Compliance

The material is stored, repacked, tested and released at Aug. Hedinger GmbH & Co. KG according to IPEC PQG – GMP Guidelines for Pharmaceutical Excipients.

Batch certification:

Every batch is analysed according to all parameters of this specification. The Certificate of Analysis (CoA) provides all results including analysis date and date of manufacture. All CoAs are signed by a Qualified Person according to EU-GMP or a responsible QA/QC-Manager.

*current version
**Trademark of The Dow Chemical Company

Compiled by: 22.09.2026	Approved by: 22.09.2026	Released by: 25.09 2026	Effective:	Supersedes:
Dr. Katja Teufel QA-Manager	Dr. Stefan Heß QA- Manager	Elisabeth Bartel Qualified Person (GMP)	21.10.2026	26.07.2021