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.* and USP*

Parameter	Ph. Eur.*		USP*	
	Specification	Test Method	Specification	Test Method
Characters	White cristall. 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.*	-	-
Heavy Metals	-	-	≤ 50 ppm	USP*
Loss on Drying	-	-	8.7 – 11.4 %	USP*
Calcium	-	-	conforms	USP*

Shelf life: 24 months
Manufacturer: The Dow Chemical Company
Manufacturing Site: USA, Freeport, Texas
Storage conditions: protected from light in well closed containers

Residual Solvents (Ph. Eur.* 5.4 / USP* <467> / ICH Q3C):
No organic solvents are used in the manufacture or as raw materials. The raw materials used to manufacture Versene** NA also do not incorporate solvents. This includes the class 1, 2 and 3 solvents listed in ICH Q3C.

Elemental Impurities (Ph. Eur.* 5.20 / ICH Q3D)
At least three independent batches have been analysed for elemental impurities according to guideline ICH Q3D. All determined values of elemental impurities were below the level of 30% of the permitted concentrations for parenteral application according to table A.2.2 of the guideline ICH Q3D. More detailed information is available upon request.

Batch certification:
Every batch is analyzed according to all parameters of this specification[1]. The certificate of analysis (CoA) provides all results like above plus analysis date, date of manufacture and residual solvents statement. All CoAs are signed by a Qualified Person according to GMP or a responsible QA/QC-Manager.

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

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Dr. Philipp Hoch QA/QC-Manager	Dr. Katja Teufel QC-Manager	Dr. Frank Milek Qualified Person (GMP)	15.07.2019	01.01.2017