HEDINGER 1843 A pure decision.

SPECIFICATION

White spirit, Petroleum spirit 40/65
(Benzin DAB 2022)

Testing specifications: DAB 2022; LSM 028
The material meets all requirements of DAB 2022 **Product code: 028**

Parameter	Specification DAB 2022	Test method
Identification	A / B / C	DAB 2022
Appearance	conforms	DAB 2022
Acidity or alkalinity	conforms	DAB 2022
Relative density d_{20}^{20}	0.642 – 0.656	DAB 2022
Refractive index	1.362 – 1.368	DAB 2022
Distillation range	min. 75% (V/V) at 40 – 60 °C	DAB 2022
Sulfuric compounds, reducing substances	conforms	DAB 2022
Non-volatile substances	conforms	DAB 2022
n-Hexane	≤ 2% (V/V)	GC, LSM 028
Benzene	≤ 10 ppm (V/V)	GC, LSM 028
Reaction with sulfuric acid	conforms	DAB 2022
Non-volatile matter	≤ 0.001% (m/V)	DAB 2022

Quality Assurance and Quality Control	
Process/Operation	**Standard / Requirement**
Production at original manufacturer	ISO 9001:2015
Supply chain	EXCiPACT GMP / GDP
Analytical quality control	Full analysis of specification for each batch in a GMP qualified laboratory
Batch release	Qualified Person according to EU-GMP (2001/83/EC; Articles 48 & 49)
Packaging	Grade D (100,000) clean room according to GMP [EU-GMP Part I Annex 1 (classification and operating conditions), US cGMP]

Packaging and storage: Preserve in tight containers and prevent exposure to excessive heat.
Protect from direct sunlight.

Shelf life in originally sealed containers: 48 months from date of release in containers ≤ 20 l / 20 kg
24 months from date of release in containers > 20 l / 20 kg

Manufacturer and manufacturing site: Shell Chemicals Europe B.V., Rotterdam (Netherlands)

Compiled by: 30.09.2022	Approved by: 30.09.2022	Released by: 30.09.2022	Effective:	Supersedes:
Elisabeth Bartel Qualified Person (GMP), QK	Dr. Stefan Heß QA-Manager	Dr. Frank Milek Qualified Person (GMP)	01.10.2022	01.01.2006

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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.

Allergens:

Allergens listed in Regulation (EU) No 1169/2011 Annex II are not used during the manufacture, are not intentionally added or known to be present in the product.

Batch certification:

Every batch is analysed according to all parameters of this specification. The Certificate of Analysis (CoA) provides all results above including date of analytical release, date of manufacture and elemental impurities statement. All CoAs are signed by a qualified person according to EU-GMP or a responsible QA/QC-manager.

Elemental impurities (Ph. Eur.* 5.20 / USP* <232> / 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.

Nitrosamines:

Nitrosamines, nitrites, nitrates, nitrosating agents, secondary and tertiary amines, primary amines, amides or ammonium salts are not expected to be present in the finished product. More detailed information is available upon request.

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Elisabeth Bartel Qualified Person (GMP), QK	Dr. Stefan Heß QA-Manager	Dr. Frank Milek Qualified Person (GMP)	01.10.2022	01.01.2006