

Safety Data Sheet (1907/2006/EC)

Material: 60076688

**HDK® N20PHARMA
HYDROPHILIC PYROGENIC SILICA**

Version: 2.7 (GB)

Date of print: 26.12.2021

Date of last alteration: 24.08.2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Commercial product name: HDK® N20PHARMA
HYDROPHILIC PYROGENIC SILICA

CAS No.: 112945-52-5

REACH registration number: 01-2119379499-16-0001

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of substance / preparation:
Industrial.
Auxiliary agent for: medicine .

1.3 Details of the supplier of the safety data sheet

Manufacturer/distributor: Wacker Chemie AG
Street/POB-No.: Hanns-Seidel-Platz 4
State/postal code/city: D 81737 München
Telephone: +49 89 6279-0
Telefax: +49 89 6279-1770

Information about the Safety Data Sheet: Telephone +49 8677 83-4888
Telefax +49 8677 886-9722
eMail WLCP-MSDS@wacker.com

1.4 Emergency telephone number

Emergency Information: **+44 1273 289451**

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture**

Classification according to Regulation (EC) No. 1272/2008:
Not a hazardous substance or mixture.

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008:
No labeling according to GHS required.

2.3 Other hazards

No data available.

SECTION 3: Composition/information on ingredients**3.1 Substances****3.1.1 Chemical characteristics**

CAS No.: 112945-52-5
Pyrogenic micro-dispersed silica, synthetic X-ray amorphous silicon dioxide (SiO₂)

3.1.2 Hazardous ingredients

This material does not contain any ingredients above the permitted limit(s).

This product does not contain substances of very high concern (Regulation (EC) No 1907/2006 (REACH), Article 57) in amounts above ≥ 0.1%.

3.2 Mixtures

not applicable

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SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

In case of accident or if you feel unwell seek medical advice (show label or SDS where possible).

After contact with the eyes:

Rinse immediately with plenty of water. Seek medical advice in case of continuous irritation.

After contact with the skin:

Wash with plenty of water or water and soap. In the event of a visible skin change or other complaints, seek medical advice (show label or SDS where possible).

After inhalation:

Provide fresh air.

After swallowing:

Give several small portions of water to drink. Do not induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Any relevant information can be found in other parts of this section.

4.3 Indication of any immediate medical attention and special treatment needed

Further toxicology information in section 11 must be observed.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

not applicable

Extinguishing media which must not be used for safety reasons:

not applicable

5.2 Special hazards arising from the substance or mixture

Ambient fire may lead to hazardous fumes. Exposure to combustion products may be a health hazard! Hazardous combustion products: toxic and very toxic fumes .

5.3 Advice for firefighters

Special protective equipment for fire fighting:

Use respiratory protection independent of recirculated air. Keep unprotected persons away.

General information:

Product does not burn. Use extinguishing measures appropriate to the source of the fire.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Secure the area. Wear personal protection equipment (see section 8). Keep unprotected persons away. Avoid dust formation. Do not breathe dust. Avoid contact with eyes and skin.

6.2 Environmental precautions

Prevent material from entering surface waters, drains or sewers and soil. Close leak if possible without risk. Cover any spilled material in accordance with regulations to prevent dispersal by wind. Retain contaminated water/extinguishing water. Dispose of in prescribed marked containers. Inform authorities if substance leaks into surface waters, sewerage or ground.

6.3 Methods and material for containment and cleaning up

Damp down dust and fill into containers. Avoid dust formation.

6.4 Reference to other sections

Relevant information in other sections has to be considered. This applies in particular for information given on personal protective equipment (section 8) and on disposal (section 13).

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SECTION 7: Handling and storage**7.1 Precautions for safe handling****Precautions for safe handling:**

Avoid dust formation. Observe information in section 8.

Precautions against fire and explosion:

Electrostatic discharge possible during transport and processing. Take precautionary measures against electrostatic charging. Ensure all parts of equipment are well earthed. Use inert gas when working with combustible and explosive liquids. Avoid dust deposit, remove dust regularly.

7.2 Conditions for safe storage, including any incompatibilities**Conditions for storage rooms and vessels:**

Observe local/state/federal regulations.

Advice for storage of incompatible materials:

Observe local/state/federal regulations.

Further information for storage:

Keep container dry and tightly closed.

7.3 Specific end use(s)

No data available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Maximum airborne concentrations at the workplace:**

CAS No.	Substance	Type	mg/m ³	ppm	Dust fract.	Fibre/m ³
7631-86-9	Silica, amorphous	TLV_GB	2,4		Respirable dust/mist	
7631-86-9	Silica, amorphous	TLV_GB	6,0		Inhalable dust/mist	

Re Silica, amorphous: The exposure limits given for CAS-No. 7631-86-9 cover all types of synthetic amorphous silica.

Derived No-Effect Level (DNEL):**Silica, amorphous**

Area of use:	Value:
Worker; by inhalation; local (long term)	4 mg/m ³ The given value corresponds to the German occupational exposure limit.

Predicted No Effect Concentration (PNEC):**Silica, amorphous**

Area of use:	Value:
Secondary poisoning	60000 mg/kg food NOEC value

8.2 Exposure controls**8.2.1 Exposure in the work place limited and controlled****General protection and hygiene measures:**

Observe standard industrial hygiene practices for the handling of chemical substances. Do not breathe dust. Avoid contact with eyes and skin. Application of skin cream recommended to ensure optimum protection of skin. Do not eat, drink or smoke when handling.

Personal protection equipment:**Respiratory protection**

Respirator must be worn if exposed to dust.

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If inhalative exposure above the occupational exposure limit cannot be excluded, adequate respiratory protection equipment must be used.

Suitable respiratory equipment: Filtering half-face mask, according to acknowledged standards such as EN 149.

Recommended Filter type: FFP1 or equivalent filter, according to acknowledged standards such as EN 149

Observe the equipment manufacturer's information and wear time limits for respirators.

Eye protection

Recommendation: protective goggles . In case of dust formation: tight fitting protective goggles .

Hand protection

Use of protective gloves is recommended when handling the material.

Recommended glove types: Rubber gloves

thickness of the material: > 1 mm

Breakthrough time: > 480 min

Recommended glove types: Protective gloves made of nitrile rubber

thickness of the material: > 0,1 mm

Breakthrough time: > 480 min

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. Note that, due to the numerous external influences (such as temperature), a chemically resistant protective glove in daily use may have a service life that is considerably shorter than the measured break through time.

Skin protection

antistatic working shoes .

8.2.2 Exposure to the environment limited and controlled

Prevent material from entering surface waters, drains or sewers and soil. Can be removed mechanically from waste water.

8.3 Further information for system design and engineering measures

Observe information in section 7. Observe national regulatory requirements.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Property:	Value:	Method:
Appearance		
Physical state	solid	
Form	powder	
Colour	white	
Odour		
Odour	odourless	
Odour limit		
Odour limit	no data available	
pH-Value		
pH-Value	3,8 - 4,3	(DIN EN ISO 787-9)
Melting point/freezing point		
Melting point / melting range	1700 °C at 1013 hPa	
Initial boiling point and boiling range		
Boiling point / boiling range	not applicable	
Flash point		
Flash point	not applicable	
Evaporation rate		
Evaporation rate	no data available	
Upper/lower flammability or explosive limits		
Lower explosion limit (LEL)	not applicable	
Upper explosion limit (UEL)	not applicable	

Safety Data Sheet (1907/2006/EC)

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Vapour pressure

Vapour pressure.....: not applicable

Solubility(ies)

Water solubility / miscibility.....: virtually insoluble at 20 °C

Vapour density

Relative gas/vapour density: No data known.

Relative Density

Relative Density: 2,2 (20 °C) (DIN 51757)

(Water / 4 °C = 1,00)

Density: 2,2 g/cm³ (20 °C) (DIN 51757)

Bulk density: 20 - 130 kg/m³

Partition coefficient: n-octanol/water

Partition coefficient: n-octanol/water.....: No data known.

Auto-ignition temperature

Ignition temperature: not applicable

Viscosity

Viscosity (dynamic): not applicable

Explosive properties (disturbed dust)

Dust explosion class.....: No danger of dust explosion according to German VDI 2263.

Molecular mass

Molecular mass: no data available

9.2 Other information

No data available.

SECTION 10: Stability and reactivity

10.1 – 10.3 Reactivity; Chemical stability; Possibility of hazardous reactions

If stored and handled in accordance with standard industrial practices no hazardous reactions are known.

Relevant information can possibly be found in other parts of this section.

10.4 Conditions to avoid

Moisture.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

If stored and handled properly: none known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

11.1.1 Acute toxicity

Assessment:

Based on the available data acute toxic effects are not expected after single oral exposure. Based on the available data acute toxic effects are not expected after single dermal exposure. Based on the available data acute toxic effects are not expected after short-term inhalative exposure.

Product details:

Route of exposure	Result/Effect	Species/Test system	Source
Oral	LD50: > 5000 mg/kg	Rat	literature
dermal	LD50: > 5000 mg/kg	Rabbit	literature
by inhalation (dust)	LC50: > 0,139 mg/l; 4 h At the technically highest possible concentration no mortality in animal test.	Rat	literature

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11.1.2 Skin corrosion/irritation**Assessment:**

Based on the available data a clinically relevant skin irritation hazard is not expected.

Product details:

Result/Effect	Species/Test system	Source
No skin irritation	Rabbit	literature

11.1.3 Serious eye damage / eye irritation**Assessment:**

Based on the available data a clinically relevant eye irritation hazard is not expected.

Product details:

Result/Effect	Species/Test system	Source
No eye irritation	Rabbit	literature

11.1.4 Respiratory or skin sensitization**Assessment:**

During several years of handling this material, there were no indications of a skin-sensitizing potential.

11.1.5 Germ cell mutagenicity**Assessment:**

According to our present state of knowledge not mutagenic.

11.1.6 Carcinogenicity**Assessment:**

Animal tests have not revealed any carcinogenic effects.

11.1.7 Reproductive toxicity**Assessment:**

In animal experiments there have not been any indications of reproduction toxicity.

11.1.8 Specific target organ toxicity (single exposure)**Assessment:**

For this endpoint no toxicological test data is available for the whole product.

11.1.9 Specific target organ toxicity (repeated exposure)**Assessment:**

Changes in the lungs (inflammatory processes) observed in animal experiments after chronic inhalative exposure were reversible; no indication of silicosis.

11.1.10 Aspiration hazard**Assessment:**

For this endpoint no toxicological test data is available for the whole product.

11.1.11 Further toxicological information

By handling the product for many years no damage to health was observed.

SECTION 12: Ecological information**12.1 Toxicity****Assessment:**

No expected damaging effects to aquatic organisms. According to current knowledge adverse effects on water purification plants are not expected.

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Product details:

Result/Effect	Species/Test system	Source
LC50: > 10000 mg/l	zebra fish (Danio rerio) (96 h)	literature
EC50: > 10000 mg/l	Daphnia magna (24 h)	literature

12.2 Persistence and degradability**Assessment:**

The substance is degradable in abiotic processes.

12.3 Bioaccumulative potential**Assessment:**

No adverse effects expected.

12.4 Mobility in soil**Assessment:**

No adverse effects expected.

12.5 Results of PBT and vPvB assessment

No data available.

12.6 Other adverse effects

none known

12.7 Additional information

Insoluble in water.

SECTION 13: Disposal considerations**13.1 Waste treatment methods****13.1.1 Material****Recommendation:**

Material that cannot be used, reprocessed or recycled should be disposed of in accordance with Federal, State, and local regulations at an approved facility. Depending on the regulations, waste treatment methods may include, e.g., landfill or incineration.

13.1.2 Uncleaned packaging**Recommendation:**

Completely discharge containers (no tear drops, no powder rest, scraped carefully). Containers may be recycled or re-used. Observe local/state/federal regulations. Uncleaned packaging should be treated with the same precautions as the material.

13.1.3 Waste Disposal Legislation Ref.No.(EC)

It is not possible to determine a waste code for this product in accordance with the European Waste Catalogue (EWC) since it is only possible to classify it according to how it is used by the customer. The waste code is to be determined within the EU in liaison with the waste-disposal operator.

SECTION 14: Transport information**14.1 – 14.4 UN number; UN proper shipping name; Transport hazard class(es); Packing group****Road ADR:**

Valuation: Not regulated for transport

Railway RID:

Valuation: Not regulated for transport

Transport by sea IMDG-Code:

Valuation: Not regulated for transport

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Air transport ICAO-TI/IATA-DGR:

Valuation: Not regulated for transport

14.5 Environmental hazards

Hazardous to the environment: no

14.6 Special precautions for user

Relevant information in other sections has to be considered.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Bulk transport in tankers is not intended.

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

National and local regulations must be observed.

For information on labelling please refer to section 2 of this document.

Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances (Seveso III):

Not applicable

Relevant regulations:

SI 2002/1689: CHIP Regulations 2002

SI 2002/2677: COSHH Regulations 2002

SI 1999/3242: Management of Health & Safety at Work Regulations 1999

Health & Safety at Work Act 1974

SI 1993/1643: Environmental Protection Act 1993 & Subsidiary Regulations.

Other national and local measures relating to the workplace, pollution control, environmental protection and waste control.

Other specifications, restrictions and prohibitions:

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

15.2 Chemical safety assessment

For this product, a chemical safety assessment according to (EC) regulation 1907/2006 (REACH) has been carried out.

15.3 Details of international registration status

Relevant information about individual substance inventories, where available, is given below.

Japan.....	: ENCS (Handbook of Existing and New Chemical Substances): This product is listed in, or complies with, the substance inventory.
Australia	: AICS (Australian Inventory of Chemical Substances): This product is listed in, or complies with, the substance inventory.
China	: IECSC (Inventory of Existing Chemical Substances in China): This product is listed in, or complies with, the substance inventory.
Canada.....	: DSL (Domestic Substance List): This product is listed in, or complies with, the substance inventory.
Philippines	: PICCS (Philippine Inventory of Chemicals and Chemical Substances): This product is listed in, or complies with, the substance inventory.
United States of America (USA)	: TSCA (Toxic Substance Control Act Chemical Substance Inventory): All components of this product are listed as active or are in compliance with the substance inventory.
Taiwan.....	: TCSI (Taiwan Chemical Substance Inventory): This product is listed in, or complies with, the substance inventory. General note: The Taiwanese chemicals regulation requires a phase 1 registration for TCSI-listed or TCSI-compliant substances if imports to Taiwan or manufacturing in Taiwan exceed the trigger quantity of 100 kg/a (for mixtures to be calculated per each ingredient). It is the duty of the importing/manufacturing legal entity to take care of this obligation.

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European Economic Area (EEA) : **REACH** (Regulation (EC) No 1907/2006):
General note: the registration obligations for substances imported into the EEA or
manufactured within the EEA by the supplier mentioned in section 1 are fulfilled by
the said supplier. The registration obligations for substances imported into the EEA
by customers or other downstream users must be fulfilled by the latter.

South Korea (Republic of Korea)..... : **AREC** (Act on Registration and Evaluation of Chemicals; "K-REACH"):
Please approach your regular WACKER contact for more detailed information.

SECTION 16: Other information**16.1 Material**

The details in this document are based on the state of our knowledge at the time of revision. They do not constitute an assurance of the described product properties in terms of statutory warranty requirements.

The providing of this document to a recipient does not relieve the recipient of his or her responsibility toward compliance with all laws and stipulations applicable to the product. This applies in particular to the further sale or distribution of the product or substances or items containing the product, in other jurisdictions and with regard to the protection of third-party intellectual property rights. If the described product is processed or mixed with other substances or materials, the details stated in this document cannot be conferred to the resultant new product unless this has been expressly mentioned. If the product is repackaged, the recipient is obligated to additionally provide the required safety-related information.

WACKER restricts the use of its products inside the human body or in contact with bodily fluids and mucosa. For further details please review our Health Care Policy on www.wacker.com. WACKER may cancel any delivery obligation(s) if the Health Care Policy is not observed.

16.2 Further information:

Commas appearing in numerical data denote a decimal point. Vertical lines in the left-hand margin indicate changes compared with the previous version. This version supersedes all previous versions.

- End of Safety Data Sheet -