

Material: 60105852 HDK® N20P PHARMA

HYDROPHILIC PYROGENIC SILICA

Version: 1.1 (US) Date of print: 12/26/2021 Date of last alteration: 11/16/2019

1. Product and company identification

1.1 Identification of the substance or preparation:

Commercial product name: HDK® N20P PHARMA

HYDROPHILIC PYROGENIC SILICA

Use of substance / preparation Industrial.

Auxiliary agent for: medicine

1.2 Company/undertaking identification:

Manufacturer/distributor: Wacker Chemie AG

Hanns-Seidel-Platz 4 81737 München

Customer information: Germany

Wacker Chemical Corporation

3301 Sutton Road

Adrian, Michigan 49221-9397

USA InfoLine:

Tel (517) 264-8240 Hours of operation:

Monday - Friday, 8 am to 5 pm (eastern standard time)

Corporate website: www.wacker.com

Emergency telephone no. (24h): (517) 264-8500

Transportation emergency: (800) 424-9300 (CHEMTREC, USA)

(703) 527-3887 (CHEMTREC, international)

This SDS was prepared by the Regulatory Affairs and Product Safety Department (RAPS) of Wacker Chemical Corporation.

2. Hazards identification

2.1 Classification of the substance or mixture

Classification (GHS):

Not a hazardous substance or mixture.

2.2 Label elements

Labelling (GHS):

No labeling according to GHS required.

2.3 Other hazards

No data available.

3. Composition/information on ingredients

3.1 Chemical characterization (substance)

CAS No.	Chemical characteristics
	Pyrogenic micro-dispersed silica, synthetic X-ray amorphous silicon dioxide (SiO2)

3.2 Information on ingredients:

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

Substances listed in the Subsections "HAPS" and "California Proposition 65 Carcinogens / Reproductive Toxins" that are not listed in this section are only present at quantities below 0.1% for California Proposition 65 listed toxins or below 1% for non-carcinogenic HAPS or they are inextricably bound in the product. Specific chemical identities and/or exact percentage (concentration) of the composition may have been withheld as a trade secret.

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



Material: 60105852 HDK® N20P PHARMA

HYDROPHILIC PYROGENIC SILICA

Version: 1.1 (US) Date of print: 12/26/2021 Date of last alteration: 11/16/2019

4. First-aid measures

4.1 General information:

Get medical attention if irritation occurs or if breathing becomes difficult.

4.2 After inhalation

If inhaled, remove to fresh air.

4.3 After contact with the skin

If contact with skin, wash skin with plenty of water or with water and soap.

4.4 After contact with the eyes

If contact with eyes, immediately flush eyes with plenty of water.

4.5 After swallowing

Drink plenty of water. Get medical attention if symptoms occur. Show label if possible.

Fire-fighting measures

5.1 Flammable properties:

Property:	Value:	Method:
Flash point:	not applicable	
Boiling point / boiling range:	not applicable	
Lower explosion limit (LEL):	not applicable	
Upper explosion limit (UEL)	not applicable	
Ignition temperature:	not applicable	

5.2 Fire and explosion hazards:

Material does not burn. Electrostatic charging is possible.

5.3 Recommended extinguishing media:

Use extinguishing measures appropriate to the source of fire.

5.4 Unsuitable extinguishing media:

not applicable

5.5 Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases

5.6 Fire fighting procedures:

Fire fighters should wear full protective clothing including a self-contained breathing apparatus.

6. Accidental release measures

6.1 Precautions:

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.

HAZWOPER PPE Level: D

6.2 Containment:

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.

Spills of material which could reach surface waters must be reported to the United States Coast Guard National Response Center's toll free phone number (800) 424-8802.



Material: 60105852 HDK® N20P PHARMA

HYDROPHILIC PYROGENIC SILICA

Version: 1.1 (US)

Date of print: 12/26/2021

Date of last alteration: 11/16/2019

6.3 Methods for cleaning up

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

7. Handling and storage

7.1 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 Storage

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.

8. Exposure controls and personal protection

8.1 Engineering controls

Ventilation:

Use only with adequate ventilation.

Local exhaust:

In case of dust formation: (To maintain concentration below TLV.) Local exhaust ventilation which meets the requirements of ANSI Z9.2 is recommended to control airborne contaminants at the point of use.

8.2 Associate substances with specific control parameters such as limit values

Maximum airborne concentrations at the workplace:

CAS No.	Substance	Туре	mg/m³	ppm	Dust fract.
7631-86-9	Silica, amorphous	OSHA PEL	0.8		
	Particulates not otherwise classified	ACGIH TWA	10.0		Inhalable dust/mist
	Particulates not otherwise classified	ACGIH TWA	3.0		Respirable dust/mist

Re Silica, amorphous: The exposure limits given for CAS-No. 7631-86-9 cover all types of synthetic amorphous silica; it appears, that there is an error in the OSHA PEL entry for amorphous silica. There should have been a footnote to the Z-3 Table indicating that the percent SiO2 in formula (80 mg/m3 + % SiO2) refers to crystaline silica content and not to amorphous silica. For evaluation of U.S. exposure measurements WACKER recommends use of the current NIOSH REL (6 mg/m3) instead of the old Z-3 Table entry.

Re Particulates not otherwise classified: The value is for particulate matter containing no asbestos and < 1% crystalline silica (ACGIH).

8.3 Personal protection equipment (PPE)

Respiratory protection:

In case of dust formation: A NIOSH approved particulate respirator with a P95 or higher rating.

Hand protection:

Recommendation: rubber gloves.

Eye protection:

Recommendation: Safety glasses with side shields or chemical safety goggles.



Material: 60105852 HDK® N20P PHARMA

HYDROPHILIC PYROGENIC SILICA

Version: 1.1 (US) Date of print: 12/26/2021 Date of last alteration: 11/16/2019

Other protective clothing or equipment:

Barrier cream may be used to prevent dryness of skin.

8.4 General hygiene and protection measures:

Do not breathe dust/vapor/mist/gas/aerosol. Wash thoroughly after handling.

Physical and chemical properties

9.1 Appearance

Physical state solid
Form powder
Colour white
Odour odourless

9.2 Safety parameters

Value: Method: Melting point / melting range 1700 °C (3092 °F) at 1013 hPa (-) Boiling point / boiling range not applicable Flash point..... not applicable Ignition temperature not applicable Lower explosion limit (LEL) not applicable Upper explosion limit (UEL)..... not applicable Vapour pressure..... not applicable Density ca. 2.2 g/cm³ at 20 °C (68 °F) (DIN 51757) Bulk density..... ca. 70 kg/m³ (-) Water solubility / miscibility.....: virtually insoluble pH-Value 3.8 - 4.3 (40 g/l H₂O) (DIN EN ISO 787-9)

Viscosity (dynamic) not applicable

9.3 Further information

Odour limit.....: no data available Thermal decomposition....: no data available

disturbed dust

2263.

10. Stability and reactivity

10.1 General information:

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

10.2 Conditions to avoid

moisture.

10.3 Materials to avoid

none known

10.4 Hazardous decomposition products

If stored and handled properly: none known.

10.5 Further information:

Hazardous polymerization cannot occur.

11. Toxicological information

11.1 Information on toxicological effects



Material: 60105852 HDK® N20P PHARMA

HYDROPHILIC PYROGENIC SILICA

Version: 1.1 (US) Date of print: 12/26/2021 Date of last alteration: 11/16/2019

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 exposu	ure Result/Effect	Species/Test system	Source
Oral	LD50: > 5000 mg/kg	Rat	literature
dermal	LD50: > 5000 mg/kg	Rabbit	literature
by inhalation	LC50: > 0.139 mg/l; 4 h	Rat	literature
(dust)	At the technically highest possible concentration no		
	mortality in animal test.		

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
not irritating	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
not irritating	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.

Page: 5/9



Material: 60105852 HDK® N20P PHARMA

HYDROPHILIC PYROGENIC SILICA

Version: 1.1 (US)

Date of print: 12/26/2021

Date of last alteration: 11/16/2019

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

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP. No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

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

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.

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.

13. Disposal considerations

13.1 Product disposal

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.



Material: 60105852 HDK® N20P PHARMA

HYDROPHILIC PYROGENIC SILICA

Version: 1.1 (US) Date of print: 12/26/2021 Date of last alteration: 11/16/2019

13.2 Packaging disposal

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.

14. Transport information

14.1 US DOT & CANADA TDG SURFACE

Valuation Not regulated for transport

14.2 Transport by sea IMDG-Code

Valuation Not regulated for transport

14.3 Air transport ICAO-TI/IATA-DGR

Valuation Not regulated for transport

15. Regulatory information

15.1 U.S. Federal regulations

TSCA 12(b) Export Notification:

This material does not contain reportable amounts of any TSCA 12(b) listed chemicals.

CERCLA Regulated Chemicals:

This material does not contain any CERCLA regulated chemicals.

SARA 302 EHS Chemicals:

This material does not contain any SARA extremely hazardous substances.

SARA 311/312 Hazard Class:

This product does not present any SARA 311/312 hazards.

SARA 313 Chemicals:

This material does not contain any SARA 313 chemicals above de minimus levels.

HAPS (Hazardous Air Pollutants):

This material does not contain any hazardous air pollutants.

15.2 U.S. State regulations

California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986):

This material does not contain any chemicals known to the State of California to cause cancer.

This material does not contain any chemicals known to the State of California to cause reproductive effects.

Massachusetts Substance List:

112945-52-5 Silica, amorphous, fumed

New Jersey Right-to-Know Hazardous Substance List:

112945-52-5 Silica, amorphous, fumed

Pennsylvania Right-to-Know Hazardous Substance List:

112945-52-5 Silica, amorphous, fumed

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.

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.

Page: 7/9



Material: 60105852 HDK® N20P PHARMA HYDROPHILIC PYROGENIC SILICA

Version: 1.1 (US) Date of print: 12/26/2021 Date of last alteration: 11/16/2019

Canada: DSL (Domestic Substance List):

This product is listed in, or complies with, the substance inventory.

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.

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.

European Economic Area (EEA)...... : REACH (Regulation (EC) No 1907/2006):

REACH registration number: 01-2119379499-16-0001

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. AREC (Act on Registration and Evaluation of Chemicals; "K-REACH"):

General note: in case of registration obligations for substances or polymers imported into Korea or manufactured within Korea these are fulfilled by the supplier mentioned in section 1. The registration obligations for substances or polymers imported into Korea by customers or other downstream users must be fulfilled by

the latter.

16. Other information

16.1 Additional information:

This Safety Data Sheet (SDS) meets the requirements of the Federal OSHA Hazard Communication Standard (29 CFR 1910.1200). This information relates to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is to the best of our knowledge and belief accurate and reliable as of the date compiled. However, no representation, warranty or guarantee expressed or implied, is made as to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability and completeness of such information for his own particular use. We do not accept liability for any loss or damage that may occur from the use of this information. Nothing herein shall be construed as a recommendation for uses which infringe valid patents or as extending a license under valid patents. This SDS provides selected regulatory information on this product, including its components. This is not intended to include all regulations. It is the responsibility of the user to know and comply with all applicable rules, regulations and laws relating to the product being used.

Vertical lines in the left-hand margin indicate changes compared with the previous version.

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.

Glossary of Terms: 16.2

ACGIH - American Conference of Governmental Industrial ppm - Parts per Million

Hygienists

South Korea (Republic of Korea):

DOT - Department of Transportation

hPa - Hectopascals

mPa*s - Milli Pascal-Seconds

OSHA - Occupational Safety and Health Administration

PEL - Permissible Exposure Limit

SARA - Superfund Amendments and Reauthorization Act

STEL - Short Term Exposure Limit TSCA - Toxic Substances Control Act

TWA - Time Weighted Average

WHMIS - Canadian Workplace Hazardous Materials

Identification System

Flash point determination methods Common name

ASTM D92, DIN 51376, ISO 2592 Cleveland open cup

ASTM D93, DIN 51758, ISO 2719 Pensky-Martens closed cup ASTM D3278, DIN 55680, ISO 3679 Setaflash or Rapid closed cup



Material: 60105852 HDK® N20P PHARMA

HYDROPHILIC PYROGENIC SILICA

Version: 1.1 (US)

Date of print: 12/26/2021

Date of last alteration: 11/16/2019

DIN 51755...... Abel-Pensky closed cup

16.3 Conversion table:

Pressure:..... 1 hPa * 0.75 = 1 mm Hg = 1 torr; 1 bar = 1000 hPa

Viscosity: 1 mPa*s = 1 centipoise (cP)