

Safety Data Sheet

according to Regulation (EC) No 1907/2006 (REACH)

Version: 001

Release date : 10-10-04

Revision date :

Print date: 10-10-04

JRS PHARMA
GMBH & CO. KG



**THE EXCIPIENT
FAMILY**

A Member of the JRS Group

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1 Identification of the substance or preparation: Cellulose

Identification on the label/trade name: VIVAPUR® Type 12

Additional identification: N/A

REACH Registration-No:

According to REACH article 2, the substance does not require registration.

1.2 Use of the substance/preparation:

Product categories (PC): Pharmaceuticals (PC29), other products (PC0).

1.2.1 Identified uses:

Remark:

It is not required to list the identified uses because preparations do not require registration according to REACH.

1.2.2 Uses advised against: N/A

1.3 Company/undertaking identification:

Supplier (manufacturer/importer/downstream user/distributor):

JRS PHARMA GMBH + CO.KG

Holzmuehle 1

D-73494 Rosenberg

Telephone: + 49 (0)7967 152 0

Telefax: + 49 (0)7967 152 222

e-mail: info@jrs.de

Manufacturer:

Microcellulose Weissenborn GmbH & Co.KG

A member of the JRS Group

Freiberger Strasse 7

D-09600 Weissenborn

E-Mail (competent person): reach-beauftragter@jrs.de

Information contact: +49 (0)7967 152 0

National contact:

1.4 EMERGENCY TELEPHONE: +49 (0)7967 152 199

2. HAZARDS IDENTIFICATION

2.1 Hazards description: VIVAPUR® Type 12 is not classified as dangerous according to directive 67/548/EEC, directive 1999/45/EC and directive 1272/2008/EC (CLP).

2.1.1 Classification: N/A

2.1.2 Additional hints: Full text of H-, P-, R- and S-phrases: see section 15 and 16.

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2.2 Information pertaining to special dangers for human and environment:

Adverse physicochemical effects: Capable of causing dust explosions.

Adverse human health effects and symptoms: N/A

Adverse environmental effects: N/A

Other adverse hazards: Substance is combustible.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance related information:

Microcrystalline Cellulose

100 %

CAS-No.: 9004-34-6

EC-No.: 232-674-9

Index-No.: N/A

REACH registration No.:

According to REACH article 2, the substance does not require registration.

Stabilizers: N/A

Hazardous Impurities: N/A

3.2 Additional hints: N/A

4. FIRST AID MEASURES

4.1 General information:

The substance is not classified as not dangerous. A mechanical irritation of the respiratory tract and of the eye surface by product dust may be possible.

4.2 In case of inhalation: Provide fresh air.

4.3 In case of skin contact: N/A

4.4 In case of eye contact: Rinse immediately carefully and thoroughly with eye-bath or water.

4.5 If major quantity of dust is swallowed or inhaled, immediately drink: water.

4.6 Self-protection of the first aider: N/A

4.7 Information to physician:

Symptoms: N/A

Hazards: N/A

Treatment: N/A

5. FIRE-FIGHTING MEASURES

5.1 Suitable extinguishing media: water, CO₂, foam, dry extinguishing powder.

5.2 Extinguishing media which must not be used for safety reasons: N/A

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

Raising of dust may cause a dust explosion.

Gases created during burning: carbon monoxide and carbon dioxide.

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5.4 Special protective equipment for fire-fighters:

Use independent breathing apparatus.

5.5 Additional information: Fire class: No data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions:

Wear breathing apparatus if exposed to vapours/dusts/aerosols.
Refer to protective measures in section 7 and 8.

6.2 Environmental precautions: N/A

6.3 Methods for cleaning up:

Take up mechanically.
Avoid generation of dust.

6.4 Additional information: N/A

7. HANDLING AND STORAGE

7.1 Handling

7.1.1 Advices on safe handling: Avoid generation of dust if handled uncovered.

Safety measures:

If handled uncovered, arrangements with local exhaust ventilation should be used if possible.

It is recommended to design all work processes always so that the following is excluded:
Inhalation of dust/particles.

Technical measures:

Measures to prevent aerosol and dust generation:

During filling, metering and sampling should be used if possible:

Devices with local exhaust.

Dust should be exhausted directly at the point of origin.

Measures for environmental protection: N/A

Specific requirements or handling rules:

Not avoidable dust deposition must be taken up periodically.

Use approved vacuum cleaners or special ventilation for dust explosion endangered areas.

Blow-off for cleaning is forbidden.

7.1.2 Precautions against fire and explosion:

The substance is: Combustible.

Dust explosive, Dust explosion category: ST1.

Make fire-fighting equipment available.

Keep away from sources of heat (e.g. hot surfaces, sparks and open flames).

7.1.3 Further information:

Is there a possibility for a dust explosion measurements according to
"Directive for Explosion Protection" may be necessary.

7.2 Storage

Safety Data Sheet

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7.2.1 Technical measures and storage conditions: N/A

7.2.2 Packaging materials: N/A

7.2.3 Requirements for storage rooms and vessels: N/A

7.2.4 Hints on storage assembly: N/A

7.2.5 Further information on storage conditions:

Protect against: humidity

Storage temperature: N/A

Relative humidity (%): N/A

Shelf life: minimum 4 years

Maximum shelf life: N/A

Storage class VCI: 11

7.3 Specific uses:

Recommendations: N/A

Industrial sector specific solutions: N/A

8. EXPOSURE CONTROLS/ PERSONAL PROTECTION

8.1 Exposure limit values:

8.1.1 Components with occupational exposure limits resp. Biological occupational exposure limits requiring monitoring:

900-4-34-6

Microcrystalline Cellulose

100 %

8.1.1.1 Occupational exposure limits:

Air limit values:

Limit value type (country of origin)	Substance name	EC-No	CAS-No	Occupational Exposure limit value		Recommended monitoring procedures	Peak limitation	Source
				Long term	Short term			
Limit(B)	Cellulose	232-647-9	9004-34-6	10 mg/m ³				GESTIS
Limit(CAN)	Cellulose	232-647-9	9004-34-6	10 mg/m ³				GESTIS
Limit(F)	Cellulose	232-647-9	9004-34-6	10 mg/m ³ inhalable aerosol				GESTIS
Limit(E)	Cellulose	232-647-9	9004-34-6	10 mg/m ³ Inhalable Aerosol				GESTIS
Limit(CH)	Cellulose	232-647-9	9004-34-6	3 mg/m ³ Breathable Aerosol				GESTIS
Limit(USA)	Cellulose	232-647-9	9004-34-6	15 mg/m ³ Total dust 5 mg/m ³ Breathable dust				GESTIS
Limit(GB)	Cellulose	232-647-9	9004-34-6	10 mg/m ³ Inhalable Aerosol 4 mg/m ³ Breathable aerosol	20 mg/m ³ Inhalable Aerosol			GESTIS

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Biological limit values: No data available

8.1.1.2 Additional exposure limits under the conditions of use: No data available

8.1.1.3 DNEL/DMEL and PNEC-values: No data available

8.2 Exposure controls

8.2.1 Occupational exposure controls:

Product related measures to prevent exposure: N/A

Instructively measures to prevent exposure: N/A

Organizational measures to prevent exposure: N/A

Technical measures to prevent exposure:

Use closed equipment if possible.

Use suitable ventilation.

Personal protection equipment:

Respiratory protection necessary at: dust formation

Suitable respiratory protection apparatus:

Full-/Half-/quarter-face masks (DIN EN 136/140): P1 or P2

Filtering Half-face mask (DIN EN 149) FFP1 or FFP2

Half-face mask or quarter facepiece: maximum use concentration for substances with exposure

limits: P1 filter: up to a max. of 4 times the exposure limit. P2 filter: up to a max. of 10 times the exposure limit. P3 filter: up to a max. of 30 times the exposure limit.

Observe the wear time limits according GefStoffV in combination with the rules for using respiratory protection apparatus (BGR 190).

Breathing apparatus: independent equipment.

Use at concentrations exceeding the limit of particle masks, at oxygen contents lower than 17 Vol.% or at unclear conditions.

Hand protection: not required

Eye protection: Dust protection eye glasses.

Body protection: not required

General health and safety measures:

Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500.

8.2.2 Environmental exposure controls:

Product related measures to prevent exposure: N/A

Instructively measures to prevent exposure: N/A

Organizational measures to prevent exposure: N/A

Technical measures to prevent exposure:

See section 7. No additional measures necessary.

8.2.3. Consumer exposure controls:

Measures related to consumer uses of the substance

(as such or in preparations): N/A

Measures related to the service life of the substance in articles: N/A

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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Appearance

Physical state: powder

Colour: white

Odour: odourless

9.2 Important health, safety and environmental information

9.2.1. Safety relevant basic data:

pH (20 °C):	5 – 7
Melting point/range (°C):	N/A
Boiling point/range (°C):	N/A
Flash point (°C):	N/A
Ignition temperature (°C):	approx. 500 (Godber-Greenwald)
Vapour pressure (°C):	N/A
Density (g/cm ³):	approx. 1.5
Bulk density (kg/m ³):	300 – 360
Water solubility (20 °C in g/l):	insoluble
Partition coefficient: n-Octanol/Water (log Po/w)	N/A
Viscosity, dynamic (mPa·s):	N/A
Dust explosion hazard:	Capable of causing dust explosions.
Explosion limits (g/m ³):	
lower:	no data available
upper:	no data available

9.2.2 Substance group relevant properties:

Explosives: N/A
Flammable gases: N/A
Flammable aerosols: N/A
Oxidizing gases: N/A
Gases under pressure: N/A
Flammable liquids: N/A
Flammable solids: N/A
Self-reactive substances and mixtures: N/A
Pyrophoric liquids: N/A
Pyrophoric solids: N/A
Self-heating substances and mixtures: N/A
Substances or mixtures which, in contact with water emit flammable gases:
N/A
Oxidizing liquids: N/A
Oxidizing solids: N/A
Organic peroxides: N/A
Metal corrosion: N/A

9.3. Other information: N/A

10. STABILITY AND REACTIVITY

10.1 Conditions to avoid:

Temperatures above 200 °C.
Open ignition sources.

10.2 Materials to avoid: N/A

10.3 Hazardous decomposition products: Combustion gases: carbon monoxide and carbon dioxide.

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11. TOXICOLOGICAL INFORMATION

11.1 Toxicokinetics, metabolism and distribution

Non-human toxicological data: No data available

Human toxicological data: No data available

11.2. Acute effects (toxicity tests):

	Effect dose	Species	Method	Remark
Acute oral toxicity	LD50 : > 3,000 mg/kg	Rat		Bibliography
Acute dermal toxicity				N/A
Acute inhalative toxicity				N/A

Specific Target Organ Toxicity (STOT) after single exposure: N/A

Specific symptoms in animal studies:

In case of ingestion: no data available

In case of skin contact: no data available

In case of inhalation: no data available

In case of eye contact: no data available

Irritant and corrosive effects: N/A

Irritation to respiratory tract: No data available

Acid/base reserve (buffer capacity for mixtures with extreme pH values):

N/A

Sensitization:

In case of skin contact: No data available

In case of inhalation: No data available

Repeated dose toxicity (sub-acute, sub-chronic, chronic): N/A

Specific Target Organ Toxicity (STOT) after repeated exposure: N/A

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):

N/A

Summarized evaluation of the CMR properties: N/A

11.3. Experience made in practice:

Observations relevant to classification: N/A

Other observations: Mechanical irritation of the mucous membranes of the eyes and of the pharyngeal cavity possible.

11.4 General remarks: N/A

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity: No data available

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12.2 Mobility

Known or predicted distribution to environmental compartments:

Surface tension: N/A

Adsorption/Desorption: N/A

12.3 Persistence and degradability

Abiotic degradation: No data available

Physico- and photo-chemical elimination

Biodegradation: No data available

Bioaccumulative potential

Partition coefficient n-octanol/water ($\log P_{ow}$) : N/A

Bioconcentration factor (BCF): N/A

Long-term-Ecotoxicity : No data available

12.4 Results of PBT assessments: N/A

12.5 Other adverse effects: N/A

12.6 Further ecological information: N/A

13. DISPOSAL CONSIDERATIONS

13.1 Appropriate disposal / Product:

Dispose of waste according to applicable local, state, and federal regulations.

13.2 List of proposed waste codes/waste designations in accordance with EWC:

Waste code product: 03 03 99

Waste name:waste n. o. s.

13.3 Appropriate packaging material:

Non-contaminated and completely emptied packages may be recycled.

13.4 Additional information:

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

14. TRANSPORT INFORMATION

14.1 Land transport (ADR/RID/GGVSE):

Official transport designation: N/A

Class: N/A

Classification code: N/A

Hazard label: N/A

UN-No.: N/A

Packing group: N/A

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Hazard sign: N/A
Tunnel restriction code: N/A
Special provisions: N/A

14.2 Sea transport (IMDG-Code/GGVSee):

Proper shipping name: N/A
Class: N/A
UN-No.: N/A
Packing group: N/A
EmS: N/A
Marine pollutant: No
Special provisions: N/A

14.3 Air transport (ICAO-IATA/DGR):

Proper shipping name: N/A
Class: N/A
UN-No.: N/A
Packing group: N/A
Special provisions: N/A

15. REGULATORY INFORMATION

15.1 EU regulations:

Chemical Safety Assessment:

For this substance a chemical safety assessment has not been carried out.

Labelling (Regulation (EC) No 1272/2008): N/A

Hazard components for labeling: N/A

Signal words: N/A

Hazard pictograms: N/A

Hazard statements: N/A

Precautionary statements: P210 "Keep away from heat, sparks, open flames and hot surfaces"

P240 "Ground container and receiving equipment"

P241 "Use explosion-proof equipment"

P280 "Wear eye protection" (see section 8)

Supplemental Hazard Information (EU): N/A

Special rules for supplemental label elements for certain mixtures:
N/A

Authorizations and/or restrictions on use:

Authorizations: N/A

Restrictions on use: N/A

Other EU regulations:

Directive 94/9/EC

Directive 1999/92/EC

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15.2 National regulations (Germany):

Restrictions of occupation: N/A

Störfallverordnung (12. BImSchV): N/A

Water Hazard Class (WGK):

Non-hazardous to water (nwg) according to VwVws, Annex 1, ID-No. 756.

Technische Anleitung Luft (TA-Luft):

Chapter 5.2.5 Organic substances, dust shaped.

The dust shaped particles in waste gas are not allowed to exceed the limits:

Mass stream: 0.10 kg/h

or

Mass concentration: 20 mg/m³

Other regulations, restrictions and prohibition regulations:

TRGS 500 "Schutzmaßnahmen"

TRGS 515 "Lagern brandfördernder Stoffe in Verpackungen und ortsbeweglichen Behältern"

TRGS 900 "Arbeitsplatzgrenzwerte"

BGR 189 (ZH 1/700): "Einsatz von Schutzkleidung"

BGR 190 "Benutzung von Atemschutzgeräten"

16. OTHER INFORMATION

16.1 Relevant H-, P-, R – and S-phrases (number and full text):

P210 "Keep away from heat, sparks, open flames and hot surfaces"

P240 "Ground container and receiving equipment"

P241 "Use explosion-proof equipment"

P280 "Wear eye protection" (see section 8)

16.2 Training instructions: N/A

16.3 Uses and exposure categories (overview):

Exposure	Industrial use	Professional Use	Consumer use
Human, oral, short term:	+	+	+
Human, oral, long term/repeated:	0	0	0
Human, dermal, short term:	+	+	+
Human, dermal, long term/repeated:	0	0	0
Human, inhalative, short term:	-	-	-
Human, inhalative, long term/repeated:	-	-	-
Environment, water, short term/single:	+	+	+
Environment, water, continuous:	0	0	0

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Environment, air, short term/single:	+	+	+
Environment, air, continuous:	0	0	0
Environment, soil, short term/single:	+	+	+
Environment, soil, continuous:	0	0	0

Supported use (+)

Unsupported use (-)

not identified use (0)

16.4 Further information:

| = data have been changed

16.5 Data sources :

GESTIS-substances database

TRGS 900

Directive 67/548/EC

Directive 1999/45/EC

Regulation 1272/2008/EC

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet can not necessarily be transferred to the new product.