

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

PROSOLV SMCC xx

Silicified microcrystalline Cellulose

Scope:

PROSOLV SMCC 50	PROSOLV SMCC 90 LM
PROSOLV SMCC 50 LD	PROSOLV SMCC HD 90
PROSOLV SMCC 50 LM	PROSOLV SMCC HD 90 LM
PROSOLV SMCC 90	

CAS No.: not relevant
EC No.: not relevant
INDEX No.: not relevant
REACH No.: do not require registration

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

Relevant identified uses: The product is intended for professional use.
Uses advised against: not relevant

1.3. Details of the supplier of the safety data sheet

Manufacturer

Microcellulose Weißenborn
A Member of the JRS Group
Freiberger Straße 7
D 09600 Weißenborn
Germany

JRS PHARMA LP
A Member of the JRS Group
801 First Street SW
Cedar Rapids, IA; 52404
USA

JRS PHARMA OY
A Member of the JRS Group
Maitotie 4
15560 Nastola
Finland

Supplier

JRS PHARMA GMBH + CO. KG
A Member of the JRS Group
Holzmühle 1
D 73494 Rosenberg
Germany

Telephone: +49 7967 152 0
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Information contact

Information

Information telephone: +49 7967 152 0
Information telefax: +49 7967 152 222
E-mail (competent person): reach-beauftragter@jrs.de
Website: www.jrspharma.de

1.4. Emergency telephone number

Telephone: +49 7967 152 199

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008 (CLP): not relevant

2.2. Label elements

Classification according to Regulation (EC) No. 1272/2008 [CLP]

not relevant

2.3. Other hazards

This material is combustible, but will not ignite readily.

In case of fire may be liberated: Carbon monoxide. Carbon dioxide.

Danger of dust explosion.

Damage can be caused through mechanical influence of the product (eg. sticking).

SECTION 3: Composition / information on ingredients

3.1. Substances

not relevant

3.2. Mixtures

Composition/information on ingredients

Substance:	EC-no.:	CAS-No.:	INDEX no.:	REACH-no.:	Concentration:	Classification: EC 1272/2008(CLP):
Microcrystalline Cellulose	232-674-9	9004-34-6	not relevant	not relevant	≥ 98 %	not relevant
Silica, amorphous	601-214-2	112926-00-8	not relevant	not relevant	≤ 2 %	not relevant

Substance with a common (EC) occupational exposure limit value

not relevant

(Full text of H- and EUH-phrases: see section 16.)

Additional information

The substance does not require registration according to REACH.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information: When in doubt or if symptoms are observed, get medical advice.

Following inhalation: Provide fresh air.

Following skin contact: not relevant

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water.
In case of eye irritation consult an ophthalmologist.

After ingestion: not relevant

Self-protection of the first aider: not relevant

4.2. Most important symptoms and effects, both acute and delayed

Symptoms: No known symptoms to date.

Nature of Hazard: not relevant

4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor: Treat symptomatically.

Special treatment: Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: Water. Foam. Extinguishing powder. Carbon dioxide. Sand.

Unsuitable extinguishing media: High power water jet.

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Carbon monoxide. Carbon dioxide.

5.3. Advice for firefighters

General information

Danger of dust explosion.

Special protective equipment for firefighters:

In case of fire: Wear self-contained breathing apparatus.

Additional information

Fire class A (Fires of solids, mainly organic nature, which normally burn down under glow forming).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:

Avoid generation of dust.

For emergency responders:

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

Avoid generation of dust.

See protective measures under point 7 and 8.

6.2. Environmental precautions

No special environmental measures are necessary.

6.3. Methods and material for containment and cleaning up

Take up mechanically.

Avoid generation of dust.

Do not use a dry brush as dust clouds or static can be created.

6.4. Reference to other sections

Disposal: see section 13.

Personal protection equipment: see section 8.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advices on safe handling

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

Technical measures

Measures to prevent aerosol and dust generation:

Provide adequate ventilation as well as local exhaustion at critical locations.

Dust should be exhausted directly at the point of origin.

Precautions against fire and explosion

The product is: Combustible.
 Danger of dust explosion.
 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
 Have fire-extinguishers in readiness before opening containers.

Additional information

Recommendations for handling:

- 210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. -No smoking.
- 240 Ground/bond container and receiving equipment.
- 241 Use explosion-proof electrical/ventilating/lighting equipment.
- 280 Wear protective gloves/protective clothing/eye protection/face protection.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

not relevant

Packaging materials

not relevant

Requirements for storage rooms and vessels

not relevant

Hints on joint storage

Storage class: 11 Combustible solids.

Further information on storage conditions

Protect against: Humidity
 Storage temperature: not relevant
 Relative air humidity (%): not relevant
 Storage stability: at least 5 years
 Maximum storage period (time): not relevant

7.3. Specific end use(s)

not relevant

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit value

Substance:	CAS-No.:	Source:	Long-term occupational exposure limit value:	Short-term occupational exposure limit value:	Remark:
Microcrystalline Cellulose	9004-34-6	GESTIS	10 mg/m ³		OEL AU
Microcrystalline Cellulose	9004-34-6	GESTIS	10 mg/m ³		OEL CA - Ontario
Microcrystalline Cellulose	9004-34-6	GESTIS	10 mg/m ³ inhalable aerosol 4 mg/m ³ respirable aerosol		OEL GB
Microcrystalline Cellulose	9004-34-6	GESTIS	10 mg/m ³ Inhalable fraction 4 mg/m ³ respirable fraction		OEL IE
Microcrystalline Cellulose	9004-34-6	GESTIS	10 mg/m ³		OEL NZ
Microcrystalline Cellulose	9004-34-6	GESTIS	10 mg/m ³ total dust 5 mg/m ³ respirable aerosol		OEL US - NIOSH
Microcrystalline Cellulose	9004-34-6	GESTIS	15 mg/m ³ total dust 5 mg/m ³ respirable dust		OEL US - OSHA
Silica, amorphous	112926-00-8	GESTIS	2 mg/m ³		OEL AU
Silica, amorphous	112926-00-8	GESTIS	10 mg/m ³		OEL CA - Ontario

Silica, amorphous	112926-00-8	GESTIS	6 mg/m ³ inhalable aerosol 2.4 mg/m ³ respirable aerosol		OEL GB
Silica, amorphous	112926-00-8	GESTIS	6 mg/m ³ inhalable fraction 2.4 mg/m ³ respirable fraction		OEL IE
Silica, amorphous	112926-00-8	GESTIS	1 mg/m ³		OEL NZ
Silica, amorphous	112926-00-8	GESTIS	80 mg/m ³ silica total dust		OEL US - OSHA

Substance with a common (EC) occupational exposure limit value

not relevant

DNEL Value

not relevant

PNEC Value

not relevant

Risk management measures according to used control banding approach

not relevant

Additional information

not relevant

8.2. Exposure controls

Occupational exposure controls

If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.

General protection and hygiene measures

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

Personal protection equipment

Respiratory protection necessary at: Dust formation.

Respiratory protection

Suitable respiratory protection apparatus: Filtering Half-face mask (DIN EN 149)

Half-face mask or quarter face piece: 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.

The filter class must be suitable for the maximum contaminant concentration

(gas/vapour/aerosol/particulates) that may arise when handling the product.

If the concentration is exceeded, self-contained breathing apparatus must be used!

Hand protection

Hand protection is not required

Eye/face protection

Dust protection eye glasses

Body protection

not applicable

Environmental exposure controls

See chapter 7. No additional measures necessary.

Consumer exposure controls

not relevant

Exposure Scenario

not relevant

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Powder
Colour: white
Odour: odourless
Odour threshold: not relevant

Safety relevant basis data

Parameter			Unit	Remark
Density:	~	1.5	g/cm ³	
Bulk density:		200 - 500	g/L	
pH:		5.0 - 7.0		
Melting point/freezing point:				not applicable
Initial boiling point and boiling range:				not applicable
Flash point:				not determined
Flammability (solid, gas):				combustible
Explosivity:				Dust explosive
Lower explosion limit:		30	g/m ³	
Upper explosion limit:		11 000	g/m ³	
Ignition temperature:				not determined
Decomposition temperature:	~	200	°C	
Oxidizing potential:				not oxidizing
Vapour pressure:				not applicable
Vapour density:				not applicable
Evaporation rate:				not applicable
Water solubility:				insoluble
Fat solubility:				insoluble
Soluble in:				not relevant
Partition coefficient:				
n-octanol/water:				not applicable
Viscosity:				not applicable
Solvent separation test:				not applicable
Solvent content:				not relevant

9.2. Other information

Dust explosion category: St 1
 Minimum ignition energy in mJ: > 30
 Minimum ignition temperature of a dust cloud (C°): ≥ 400
 Flammability and burning behaviour of dust layers: combustion rate (BZ) 5
 Minimum ignition temperature of a 5 mm dust layer (glowing temperature): ≥ 330 °C
 Maximum explosion pressure in bar: ≤ 9.5
 KSt-value in bar m s⁻¹: ≤ 200

The product has not been tested.
 The statement is derived from products of similar composition.

SECTION 10: Stability and reactivity

10.1. Reactivity

not relevant

10.2. Chemical stability

not relevant

10.3. Possibility of hazardous reactions

not relevant

10.4. Conditions to avoid

Decomposition takes place from temperatures above: ~ 200 °C

10.5. Incompatible materials

not relevant

10.6. Hazardous decomposition products

In case of fire may be liberated: Carbon monoxide. Carbon dioxide.

Additional information

not relevant

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

not relevant

Specific symptoms in laboratory animals

not relevant

Irritation and etching

Irritant effect on the skin

Not an irritant.

Irritant effect on the eye

Not an irritant.

Irritant effect on the respiratory tract

Not an irritant.

Caustic effect

not corrosive

Sensitization

not sensitising.

Repeated dose toxicity (sub-acute, sub chronic, chronic)

not relevant

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity

not relevant

Germ cell mutagenicity

not relevant

Reproductive toxicity

not relevant

General remarks

Damage can be caused through mechanical influence of the product (eg. sticking).

Practical experience/human evidence

not relevant

Other observations

not relevant

Other information

not relevant

SECTION 12: Ecological information

12.1. Toxicity

Eco toxicity

not relevant

12.2. Persistence and degradability

not persistent.

12.3. Bio accumulative potential

No indication of bioaccumulation potential.

12.4. Mobility in soil

not relevant

12.5. Results of PBT and vPvB assessment

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

12.6. Other adverse effects

not relevant

Further ecological information

According to the present state of knowledge negative ecological effects are not expected.

Further details

not relevant

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Appropriate disposal/Product

Dispose of waste according to applicable legislation.

Appropriate disposal / Package

Completely emptied packages can be recycled.

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

Waste code product: 03 03 99 - wastes not otherwise specified

Waste code packaging: 15 01 06 - mixed packaging

Remark

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

SECTION 14: Transport information

14.1. UN number

not relevant

14.2. UN proper shipping name

not relevant

14.3. Transport hazard class(es)

not relevant

14.4. Packing group

not relevant

14.5. Environmental hazards

not relevant

14.6. Special precautions for user

Land transport (ADR/RID)

Remark: No dangerous good in sense of this transport regulation.

Sea transport (IMDG)

Remark: No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI / IATA-DGR)

Remark: No dangerous good in sense of this transport regulation.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Remark: not relevant

SECTION 15: Regulatory information

Labelling

Hazardous component(s) for labelling

not relevant

Special labelling of particular preparations

not relevant

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU legislation

Information according to 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline).

not relevant

Regulation (EC) No 2037/2000 concerning materials, which cause damage to the ozone layer.

not relevant

Regulation (EC) No. 648/2004 (Detergents regulation)

not relevant

National regulations

Observe in addition any national regulations!

Restrictions of occupation

not relevant

Storage class

11 Combustible solids.

Water hazard class (WGK)

non-hazardous to water (nwg)

Other regulations, restrictions and prohibition regulations

not relevant

15.2. Chemical Safety Assessment

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

SECTION 16: Other information

Relevant H- and EUH-phrases (Number and full text)

not relevant

Training advice

not relevant

Recommended restrictions of use

not relevant

Further remarks

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 is not necessarily valid for the new made-up material.

Documentation of changes

| Data changed compared with the previous version

Key literature references and sources for data

Data arise from reference works and literature.

GESTIS- substances data base

Regulation (EC) 1272/2008 [CLP]

Abbreviations and acronyms

EWC = European Waste Catalogue