



Certificate of Analysis

CHEMICAL MARKETING CONCEPTS
COA
194 PICKETT DISTRICT RD
NEW MILFORD CT 06776

Customer Order: REPL US W16 109
6
Shipped Quantity: 1.000 DR
Shipped From: ASI US HOPEWELL PLT
Order Number: 8700814/000010
Delivery: 852512405/000010
Date Shipped: June 10, 2022
Sold To Number: 640985

KLUCCEL LF PHARM DRUM 45.36KG
Klucel (TM) LF PHARM Hydroxypropylcellulose
Ashland Material Number: 424851

Characteristics	Specification	Batch: 22 92 f; Results
Loss on Drying, as packaged, %, < 31 >	0.0 - 5.0	1.2
Moles of Substitution, NF	2.0 - 4.1	3.2
Hydroxypropoxy Groups, %, t-F	53.4 - 80.5	74.1
Viscosity, Water, (1030) 25 °C, cps, USP < 912 >	75 - 150	110
pH, USP < 791 >	5.0 - 8.0	5.7
PSI - total thru 30, %, USP < 786 > Airjet	85.0 - 100.0	96.9
FSZ - on 20 and above, %, < 786 > Airjet	0.0 - 1.0	0.1
PSZC - on 30 and above, %, < 786 > Airjet	0.0 - 15.0	3.1
Residue on Ignition, %, USP < 281 >	0.0 - 0.8	0.3
Sulfate, %, < or= 0.6%, NF	PASS	PASS
Viscosity, 10 Sec-1, 20 °C, cps, E? < 2.2.10 >	75 - 140	118
Date of Manufacture		May 16, 2022
Re-test Date		Msy 16, 2022
Shipped Quantity		1.000 DR

Note:

KLUCCEL LF PHARM and LXF PHARM products have a nominal viscosity based on the EP monograph of 100 cps and a nominal viscosity based on the USP NF of 110 cps

Certified range data below are based on intermittent testing.

Lead, ppm - not more than 2

Heavy metals, ppm - not more than 20

The quality of the above lot conforms to the monograph for Hydroxypropyl Cellulose in the Pharmacopoeia of the NF, Ph.Eur. and JP current editions.

GM? Compliance: Manufactured in a dedicated facility using current: IPEC-PQG GM? excipients.

RESIDUAL SOLVENTS: Meets requirements of USP <467> and ICH Q3C.
Identification Testing: Meets requirements of Nf, Ph. Eur. and JP.

Printed: June 10, 2022

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" ;CSL : \ ' , 'EAR: ")HUM 4 S. 35yc:
X...;eel (:"t) LF PH.D. "i Hydroxypropylcellulose
;g;:lar.d Mat.eria Number: 42485.

Batch: 229262

Characteristics

Specification

Results

=7[S :INTERVAL: We recomenj Klucel be periodically retes:ed for viscosity and moisture to
st...:P coroliance to specifcation. Klucel EL, E, L, IP, NUTRA types should be retested 3
t=s afldr the date of manufacture and at 1 year intervals after cjereafter. Klucel J, G,
...: "FKG-J;" types should be -e:ted 2 years after the date of manufacture and a: 1 year
v3_s thereeater.
e;r. : used within 3 years of Date of manufacture.

re:u s;IO:1 eco'e are fLOID .actual lot. analysis.

This COA is printed frQ a secure
computer syste ensuring the batch
was properly released by the
Quality Department and is
valid without signature.

Manufactured by:

...:..ld S;ECi>LTY INGREDIEN:' G. P.
AFFILIATE OF ASHLAND
...: H C;ES ROAD
...:rNE:L n 2386C

...

Contact:

...:SS.. C' KARELA
[',Jr>=: 614 730 2072
...:..: MJOFARRA@A.3LAND.COM

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SAFETY DATA SHEET

Revision Date: 05/14/2020

Print Date: 10/18/2021

SOS Number: R0702828

Version 1.7

Klucel™ LF PHARM Hydroxypropylcellulose
™ Trademark, Ashland or its subsidiaries, registered
in various countries
424851

29 CFR 1910.1200 (OSHA HazCom 2012)

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product Identifier

Trade name

Klucel™ LF PHARM
Hydroxypropylcellulose
™ Trademark, Ashland or its subsidiaries, registered in
various countries

Substance name

HYOROXYPROPYLCELLULOSE

Substance No.

EC-No.

618-388-0

CAS-No.

9004-64-2

Relevant identified uses of the substance or mixture and uses advised against
Recommended use : Pharmaceutical

Details of the supplier of the safety data
sheet

Ashland

P.O. Box 2219

Columbus, OH 43216

United States of America (USA)

1-614-790-3333

Emergency telephone number

1-800-ASH LAND (1-800-274-5263)

Regulatory information

1-614-790-3333 (customer service)

Product Information

1-614-790-3333

EHSProductSafety@ashland.com

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Combustible Dust

GHS label elements

Signal Word

Warning

Hazard Statements

May form combustible dust concentrations in air.



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Precautionary Statements

Prevention:

Keep dust mixtures away from ignition sources.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

Substance

Chemical nature

organic

Hazardous components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

General advice

No hazards which require special first aid measures.

If inhaled

If breathed in. move person into fresh air.

If unconscious. place in recovery position and seek medical advice.

If symptoms persist. call a physician.

In case of skin contact

First aid is not normally required. However, it is recommended that exposed areas be cleaned by washing with soap and water.

In case of eye contact

Remove contact lenses.

Protect unharmed eye.

If swallowed

Do not give milk or alcoholic beverages.

Never give anything by mouth to an unconscious person.

If symptoms persist. call a physician.

Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see Section 2.2) and/or Section 11.

Notes to physician

No hazards which require special first aid measures.

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SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water spray Foam
Hazardous combustion products	Carbon dioxide (CO2) Carbon monoxide
Specific extinguishing methods	
	Product is compatible with standard fire-fighting agents.
Further information	Standard procedure for chemical fires.
Special protective equipment for firefighters	In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	Avoid dust formation. Avoid breathing dust. Material can create slippery conditions. Persons not wearing protective equipment should be excluded from area of spill until clean-up has been completed.
Environmental precautions	Prevent further leakage or spillage if safe to do so.
Methods and materials for containment and cleaning up	Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.
Other information	Comply with all applicable federal, state, and local regulations.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling	Avoid dust formation. Ensure all equipment is electrically grounded and bonded before beginning transfer operations. The material can accumulate static charge and can therefore cause electrical ignition of flammable atmospheres. Smoking, eating and drinking should be prohibited in the
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application area.

For personal protection see section 8.

Maintain good housekeeping. Do not permit dust layers to accumulate, for example, on floors, ledges, and equipment, in order to avoid any potential for dust explosion hazards.

For further guidance on prevention of dust explosions, refer to National Fire Protection Association (NFPA) 654: "Standard for the Prevention of Fire and Dust Explosions, from the Manufacturing, Processing and Handling of Combustible Particulate Solids".

Conditions for sale storage

No smoking.

Materials to avoid

No materials to be especially mentioned.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures

Provide appropriate exhaust ventilation at places where dust is formed.

General room ventilation should be adequate for normal conditions of use. However, if unusual operating conditions exist, provide sufficient mechanical (general and/or local exhaust) ventilation to maintain exposure below exposure guidelines (if applicable) or below levels that cause known, suspected or apparent adverse effects.

Personal protective equipment

Respiratory protection

In the case of dust or aerosol formation use respirator with an approved filter within the capabilities of the respirator/filter combination.

Where concentrations are above recommended limits or are unknown, or a cartridge type respirator is not adequate, wear a positive-pressure supplied-air respirator.

Hand protection

Material

butyl-rubber

Break through time

480 min

Glove thickness

> 0.5 mm

Remarks

The exact break through time can be obtained from the protective glove producer and this has to be observed. Gloves

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Revision D
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SDS Number: RC212628
Version: 1.17

should be discarded and replaced if there is any indication of degradation or chemical breakthrough.

Eye protection	Safety glasses
Skin and body protection	Wear as appropriate: Safety shoes Wear resistant gloves (consult your safety equipment supplier).
Hygiene measures	Avoid breathing dust.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	granules, powder
Physical state	solid
Colour	off-white
Odour	odourless
Odour Threshold	Not applicable
pH	5-8 Concentration: 2 % (as aqueous solution)
Softening point	212 - 302 °F / 100 - 150 °C
Boiling point/boiling range	not determined
Flash point	Not applicable
Evaporation rate	Not applicable
Flammability (solid, gas)	not determined
Upper explosion limit	Upper explosion limit not determined
Lower explosion limit	30 g/m3
Vapour pressure	Not applicable
Relative vapour density	Not applicable



IDENTIFICATION SHEET

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Relative density	No data available
Density	> 1 g/cm ³
Bulk density	500 - 900 kg/m ³
Solubility(ies)	
Water solubility	Insoluble > 45 °C
Solubility in other solvents	No data available
Partition coefficient n-octanol/water	not determined
Auto-ignition temperature	420 °C
Thermal decomposition	No data available
Viscosity	
Viscosity, dynamic	Not applicable
Viscosity, kinematic	Not applicable
Oxidizing properties	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	No decomposition if stored and applied as directed.
Chemical stability	Stable under recommended storage conditions.
Possibility of hazardous reactions	Dust may form explosive mixture in air.
Conditions to avoid	Keep away from heat, flame, sparks and other ignition sources.
Hazardous decomposition products	Carbon monoxide Carbon dioxide (CO ₂)

SECTION 11. TOXICOLOGICAL INFORMATION