

SAFETY DATA SHEET

Creation Date 27-Jan-2015 Revision Date 25-Mar-2024 Revision Number 2

1. Identification

Product Name Celite hyflo supercel, for GMP use for Z25418

Cat No.: R19220

Synonyms Infusorial earth

Recommended Use Laboratory chemicals.

Uses advised against Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company

Thermo Fisher Scientific Chemicals, Inc. 30 Bond Street Ward Hill, MA 01835-8099

Tel: 800-343-0660 Fax: 800-322-4757

Emergency Telephone Number

For information **US** call: 001-800-227-6701 / **Europe** call: +32 14 57 52 11 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No. **US**:001-800-424-9300 / **Europe**:001-703-527-3887

2. Hazard(s) identification

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Serious Eye Damage/Eye Irritation Category 2
Carcinogenicity Category 1A
Specific target organ toxicity (single exposure) Category 3

Target Organs - Respiratory system.

Specific target organ toxicity - (repeated exposure) Category 1

Target Organs - Lungs.

Label Elements

Signal Word

Danger

Hazard Statements

Causes serious eye irritation

May cause respiratory irritation

May cause cancer

Causes damage to organs through prolonged or repeated exposure



Precautionary Statements

Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Use personal protective equipment as required

Wash face, hands and any exposed skin thoroughly after handling

Wear eye/face protection

Do not breathe dust/fume/gas/mist/vapors/spray

Do not eat, drink or smoke when using this product

Use only outdoors or in a well-ventilated area

Response

IF exposed or concerned: Get medical attention/advice

Inhalation

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

Eyes

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing If eye irritation persists: Get medical advice/attention

Storage

Store locked up

Store in a well-ventilated place. Keep container tightly closed

Disposal

Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

WARNING. Cancer - https://www.p65warnings.ca.gov/.

3. Composition/Information on Ingredients

Component	CAS No	Weight %
Silica, amorphous, diatomaceous earth	68855-54-9	56
Silica, cristobalite	14464-46-1	< 40
Quartz	14808-60-7	< 4

4. First-aid measures

General Advice If symptoms persist, call a physician.

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists,

call a physician.

Inhalation Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if

symptoms occur.

Revision Date 25-Mar-2024

Ingestion Clean mouth with water and drink afterwards plenty of water. Get medical attention if

symptoms occur.

Most important symptoms and

effects

None reasonably foreseeable.

Notes to Physician Treat symptomatically

5. Fire-fighting measures

Suitable Extinguishing Media Substance is nonflammable; use agent most appropriate to extinguish surrounding fire.

Unsuitable Extinguishing Media No information available

Flash Point Not applicable

Method - No information available

Autoignition Temperature

Explosion Limits

No information available

Upper No data available
Lower No data available
Sensitivity to Mechanical Impact No information available
Sensitivity to Static Discharge No information available

Specific Hazards Arising from the Chemical

Non-combustible. None reasonably foreseeable.

Hazardous Combustion Products

None under normal use conditions.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

Health	Flammability	Instability	Physical hazards
2	0	0	N/A

6. Accidental release measures

Personal Precautions Use personal protective equipment as required. Ensure adequate ventilation. Avoid dust

formation.

Environmental Precautions Should not be released into the environment.

Methods for Containment and Clean Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed

Up containers for disposal.

	7. Handling and storage
Handling	Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid dust formation. Avoid ingestion and inhalation. Do not get in eyes, on skin, or on clothing.
Storago	Keen containers tightly closed in a dry cool and well-ventilated place. Incompatible

Storage. Keep containers tightly closed in a dry, cool and well-ventilated place. Incompatible

Materials. None known.

8. Exposure controls / personal protection

Exposure Guidelines

Component	ACGIH TLV	OSHA PEL	NIOSH	Mexico OEL (TWA)
Silica, cristobalite	Silica, cristobalite TWA: 0.025 mg/m ³		IDLH: 25 mg/m ³	TWA: 0.025 mg/m ³
	_	TWA: 50 μg/m ³	TWA: 0.05 mg/m ³	_
Quartz	TWA: 0.025 mg/m ³	(Vacated) TWA: 0.1 mg/m ³	IDLH: 50 mg/m ³	TWA: 0.025 mg/m ³
	_	TWA: 50 μg/m ³	TWA: 0.05 mg/m ³	-

Legend

ACGIH - American Conference of Governmental Industrial Hygienists

OSHA - Occupational Safety and Health Administration

NIOSH: NIOSH - National Institute for Occupational Safety and Health

Engineering Measures Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations

and safety showers are close to the workstation location.

Personal Protective Equipment

Eye/face Protection Wear appropriate protective eyeglasses or chemical safety goggles as described by

OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard

EN166.

Skin and body protectionWear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard

EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Recommended Filter type: Particulates filter conforming to EN 143.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Physical StateSolidAppearanceLight greyOdorOdorless

Odor Threshold No information available

pH 5 - 10

Melting Point/Range1710 °C / 3110 °FBoiling Point/Range2230 °C / 4046 °FFlash PointNot applicableEvaporation RateNot applicable

Flammability (solid,gas) No information available

Flammability or explosive limits

UpperNo data availableLowerNo data availableVapor Pressure10 mmHg @ 1732 °CVapor DensityNot applicable

Specific Gravity
1.9 - 2.35
Solubility
Insoluble in water
Partition coefficient; n-octanol/water
Autoignition Temperature
Decomposition Temperature
No information available
No information available

Decomposition TemperatureNo informationViscosityNot applicable

Molecular Formula SiO2
Molecular Weight 60.0843

10. Stability and reactivity

Reactive Hazard None known, based on information available

Stability Stable under normal conditions.

Conditions to Avoid Avoid dust formation.

Incompatible Materials None known

Hazardous Decomposition Products None under normal use conditions

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

11. Toxicological information

Acute Toxicity

Product Information No acute toxicity information is available for this product

Oral LD50 Based on ATE data, the classification criteria are not met. ATE > 2000 mg/kg. **Dermal LD50** Based on ATE data, the classification criteria are not met. ATE > 2000 mg/kg. Mist LC50 Based on ATE data, the classification criteria are not met. ATE > 5 mg/l.

Component Information

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Silica, amorphous, diatomaceous	Not listed	Not listed	LC50 > 2.6 mg/L (Rat) 4 h
earth			

Toxicologically Synergistic

No information available

Products

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritating to eyes and respiratory system Irritation

Sensitization No information available

The table below indicates whether each agency has listed any ingredient as a carcinogen. Carcinogenicity

Component	CAS No	IARC	NTP	ACGIH	OSHA	Mexico
Silica, amorphous,	68855-54-9	Not listed				
diatomaceous earth						
Silica, cristobalite	14464-46-1	Group 1	Known	A2	X	A2
Quartz	14808-60-7	Group 1	Known	A2	Х	A2

IARC (International Agency for Research on Cancer)

NTP: (National Toxicity Program)

IARC (International Agency for Research on Cancer)

Group 1 - Carcinogenic to Humans

Group 2A - Probably Carcinogenic to Humans Group 2B - Possibly Carcinogenic to Humans

NTP: (National Toxicity Program)

Known - Known Carcinogen

Reasonably Anticipated - Reasonably Anticipated to be a Human

Carcinogen A1 - Known Human Carcinogen

ACGIH: (American Conference of Governmental Industrial

Hygienists)

A2 - Suspected Human Carcinogen

A3 - Animal Carcinogen

ACGIH: (American Conference of Governmental Industrial Hygienists)

No information available **Mutagenic Effects**

No information available. **Reproductive Effects**

Developmental Effects No information available.

Teratogenicity No information available.

Respiratory system STOT - single exposure

STOT - repeated exposure Lungs

Celite hyflo supercel, for GMP use for Z25418

Aspiration hazard No information available

Symptoms / effects,both acute and No information available

delayed

Endocrine Disruptor Information No information available

Other Adverse Effects The toxicological properties have not been fully investigated.

No information available.

12. Ecological information

Ecotoxicity

.

Persistence and Degradability No information available

Mobility No information available.

13. Disposal considerations

Waste Disposal Methods Chemical waste generators must determine whether a discarded chemical is classified as a

hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

14. Transport information

DOTNot regulatedTDGNot regulatedIATANot regulatedIMDG/IMONot regulated

15. Regulatory information

United States of America Inventory

Bioaccumulation/ Accumulation

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags
Silica, amorphous, diatomaceous earth	68855-54-9	X	ACTIVE	-
Silica, cristobalite	14464-46-1	X	ACTIVE	-
Quartz	14808-60-7	X	ACTIVE	-

Legend:

TSCA US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

TSCA - Per 40 CFR 751, Regulation of Certain Chemical Substances & Mixtures, Under TSCA Section 6(h) (PBT)

Not applicable

TSCA 12(b) - Notices of Export

Not applicable

International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Silica, amorphous, diatomaceous	68855-54-9	Х	-	272-489-0	Х	Х	Х	Х	Х	KE-21796
earth										

^{&#}x27;-' - Not Listed

Celite hyflo supercel, for GMP use for Z25418

Silica, cristobalite	14464-46-1	Χ	-	238-455-4	Χ	Χ	Χ	Χ	Х	KE-09017
Quartz	14808-60-7	Х	-	238-878-4	Χ	Х	Х	Х	Х	KE-29983

KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

U.S. Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA - Occupational Safety and

Health Administration

Not applicable

Component	Specifically Regulated Chemicals	Highly Hazardous Chemicals
Silica, cristobalite	50 μg/m³ TWA	-
	25 μg/m³ Action Level	
Quartz	50 μg/m³ TWA	-
	25 ug/m ³ Action Level	

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

California Proposition 65

This product contains the following Proposition 65 chemicals.

Component	CAS No	California Prop. 65	Prop 65 NSRL	Category
Silica, cristobalite	14464-46-1	Carcinogen	-	Carcinogen
Quartz	14808-60-7	Carcinogen	-	Carcinogen

U.S. State Right-to-Know Regulations

Component	Massachusetts	New Jersey	Pennsylvania	Illinois	Rhode Island
Silica, amorphous, diatomaceous earth	-	-	Х	-	-
Silica, cristobalite	X	X	X	X	-
Quartz	X	X	Х	X	Х

U.S. Department of Transportation

Reportable Quantity (RQ): N
DOT Marine Pollutant N
DOT Severe Marine Pollutant N

U.S. Department of Homeland

Security

This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade No information available

Authorisation/Restrictions according to EU REACH

Not applicable

Component	CAS No	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization		REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
Silica, amorphous, diatomaceous earth	68855-54-9	-	-	-
Silica, cristobalite	14464-46-1	-	-	-
Quartz	14808-60-7	-	-	-

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

Component	CAS No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
Silica, amorphous,	68855-54-9	Listed	Not applicable	Not applicable	Not applicable
diatomaceous earth					
Silica, cristobalite	14464-46-1	Listed	Not applicable	Not applicable	Not applicable
Quartz	14808-60-7	Listed	Not applicable	Not applicable	Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)? Not applicable

Other International Regulations

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
Silica, amorphous, diatomaceous earth	68855-54-9	Not applicable	Not applicable	Not applicable	Not applicable
Silica, cristobalite	14464-46-1	Not applicable	Not applicable	Not applicable	Not applicable
Quartz	14808-60-7	Not applicable	Not applicable	Not applicable	Not applicable

16. Other information

Prepared By Health, Safety and Environmental Department

Email: chem.techinfo@thermofisher.com

www.thermofisher.com

 Creation Date
 27-Jan-2015

 Revision Date
 25-Mar-2024

 Print Date
 25-Mar-2024

Revision Summary New emergency telephone response service provider.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of SDS