1. IDENTIFICATION OF THE PRODUCTS AND OF THE COMPANY

1.1. Product identifier

Product form	:	Substance
Trade name	:	Saffil
Chemical name	:	Polycrystalline wools (PCW)
EC no	:	614-074-2
CAS No	:	675106-31-7
REACH registration No	:	01-2119456884-25-0000

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

1.2.1. Relevant identified uses

Use of the substance/mixture : For industrial use within high temperature applications

1.2.2. Uses advised against

No additional information available

1.3. Identification of the company

INSULCON B.V.
The Netherlands
Tel. : +31 (0)167-565750
www.insulcon.com
info@insulcon.com

INSULCON N.V.
Belgium
Tel. : + 32 (0)3 711.02.78

INSULCON GMBH
Germany
Tel.: + 49 (0) 2131-408548-0

2. HAZARD IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
Not classified

Adverse physicochemical, human health and environmental effects
To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]
No labelling applicable

2.3. Other hazards

Other hazards which do not result in classification:
May cause mechanical irritation to the skin, eyes and respiratory system.

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

The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

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3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Substance

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Polycrystalline wools (PCW)	(CAS No) 675106-31-7 (EC no) 614-074-2 (REACH-no) 01-2119456884-25-0000	-	Not classified

Comments:
PCW can also be identified by a combination of CAS Numbers: 1344-28-1 (fibrous forms of Aluminium Oxide), 7631-86-9 (Silica, non-crystalline), or 1302-93-8 (Mullite)

Full text of H-statements : see section 16

3.2. Mixture

Not applicable

4. FIRST AID MEASURES

4.1. Description of first aid measures

First-aid measures general: When in doubt or if symptoms are observed, get medical advice.

First-aid measures after inhalation: Move to fresh air.

First-aid measures after skin contact: Gently wash with plenty of soap and water. Take off contaminated clothing and wash it before reuse.

First-aid measures after eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

First-aid measures after ingestion: Rinse mouth. Do not induce vomiting.

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

Symptoms/effects after inhalation: Irritating to the respiratory system and mucous membranes. mechanical irritation.

Symptoms/effects after skin contact: May cause slight temporary irritation. mechanical irritation.

Symptoms/effects after eye contact: May cause slight temporary irritation to ocular mucous membranes. mechanical irritation.

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

Treat symptomatically.

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5. FIRE FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media	:	The product is not flammable. Use extinguishing media appropriate for surrounding fire. Foam. Dry powder. Carbon dioxide. Water spray.
Unsuitable extinguishing media	:	Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	:	Non-flammable.
Explosion hazard	:	Product is not explosive.
Hazardous decomposition products in case of fire:		None.

5.3. Advice for firefighters

Firefighting instructions	:	Prevent firefighting water from entering the environment.
Protection during firefighting	:	Do not enter fire area without proper protective equipment, including respiratory protection.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

General measures	Avoid dust formation. Do not breathe dust. Avoid contact with skin and eyes.

6.1.1. For non-emergency personnel

Protective equipment	Concerning personal protective equipment to use, see section 8.
Emergency procedures	Manipulations are to be done only by qualified and authorised persons.

6.1.2. For emergency responders

Protective equipment	Ensure adequate ventilation. Concerning personal protective equipment to use, see section 8.

6.2. Environmental precautions

Avoid sub-soil penetration. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Minimise generation of dust. Dust can be vacuumed with a vacuum cleaner containing a HEPA (High Efficiency Particulate Air) filter.
Other information	Disposal must be done according to official regulations.

6.4. Reference to other sections

See section 7. See Section 8. See Section 13.

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7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Additional hazards when processed	Extraction to remove dust at its source.
Precautions for safe handling	Obtain special instructions before use. Ensure good ventilation of the work station. Use personal protective equipment as required. Do not breathe dust. Avoid contact with skin and eyes. Do not eat, drink or smoke when using this product. Clean contaminated areas thoroughly.
Hygiene measures	Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	Product must only be kept in the original packaging. Store tightly closed in a dry and cool place.
Information about storage in one common storage facility	Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

For professional users only. See Section 8.

8. EXPOSURE CONTROL / PERSONAL PROTECTION

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Polycrystalline wools (PCW) (675106-31-7)	
United Kingdom - Occupational Exposure Limits	
Local name	MMMF (Machine-made mineral fibre)
WEL TWA (OEL TWA) [1]	5 mg/m³ (except for refractory ceramic fibres and special purpose fibres)
WEL TWA (OEL TWA) [2]	2 fibers/ml (except for refractory ceramic fibres and special purpose fibres)
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

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8.1.4. DNEL and PNEC
No additional information available

8.1.5. Control banding
No additional information available

8.2. Exposure controls
8.2.1. Appropriate engineering controls
Appropriate engineering controls:
Ensure good ventilation of the work station.

8.2.2. Personal protection equipment
8.2.2.1. Eye and face protection
Eye protection:
Safety glasses with side shields. EN 166

8.2.2.2. Skin protection
Skin and body protection:
Wear proper protective equipment

Hand protection:
Leather protective gloves

8.2.2.3. Respiratory protection
Respiratory protection:
Dust production: dust mask with filter type P2

8.2.2.4. Thermal hazards
No additional information available

8.2.3. Environmental exposure controls
Environmental exposure controls: Avoid release to the environment.

Other information:
Do not eat, drink or smoke when using this product. Do not take working clothes home. Wash contaminated clothing before reuse. Separate working clothes from town clothes. Launder separately.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Appearance	:	Fibres.
Colour	:	white.
Odour	:	odourless.
Odour threshold	:	No data available

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pH	:	Not applicable

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Relative evaporation rate (butylacetate=1):		No data available
Melting point	:	> 1800 °C
Freezing point	:	No data available
Boiling point	:	Not applicable
Flash point	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	No data available
Vapour pressure	:	Not applicable
Vapour pressure at 50°C	:	Not available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Density	:	3 - 3.5 g/cm³
Solubility	:	Water: < 1 mg/l
Log Pow	:	No data available
Log Kow	:	Not applicable
Viscosity, kinematic	:	Not applicable
Viscosity, dynamic	:	Not applicable
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	No data available
Particle size	:	Not available
Particle size distribution	:	Not available
Particle shape	:	Not available
Particle aspect ratio	:	Not available
Particle aggregation state	:	Not available
Particle agglomeration state	:	Not available
Particle specific surface area	:	Not available
Particle dustiness	:	Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other information

Other properties:

Length weighted geometric mean diameter of fibres contained in the product: 3-4 µm.

10. STABILITY AND REACTIVITY

10.1. Reactivity

Stable under normal conditions of use.

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known.

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10.4. Conditions to avoid

No additional information available.

10.5. Incompatible materials

None.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity (oral)	:	Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	:	Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	:	Not classified (Based on available data, the classification criteria are not met)

Polycrystalline wools (PCW) (675106-31-7)	
LD50 oral rat	> 4000 mg/kg bodyweight (OECD 407 method)

Skin corrosion/irritation	:	Not classified (Based on available data, the classification criteria are not met) pH: Not applicable
Additional information	:	(OECD 404 method)
Serious eye damage/irritation	:	Not classified (Based on available data, the classification criteria are not met) pH: Not applicable
Additional information	:	(OECD 492 method)
Respiratory or skin sensitisation	:	Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	:	Not classified (Based on available data, the classification criteria are not met) (OECD 471 method) (OECD 487 method)
Carcinogenicity	:	Not classified (Based on available data, the classification criteria are not met) (OECD 451 method)
Reproductive toxicity	:	Not classified (Based on available data, the classification criteria are not met)

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Specific target organ toxicity (single exposure):		Not classified (Based on available data, the classification criteria are not met)
Specific target organ toxicity (repeated exposure):		Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	:	Not classified (Not relevant)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Other information

Chronic effects: Lifetime rat inhalation studies of polycrystalline fiber show that at the maximum dose level tested, there was no evidence of lung cancer, lung fibrosis or any other significant adverse effect. Intraperitoneal, intratracheal and intrapleural studies in rats, together with two in vitro tests, have all shown negative results. Despite some study limitations, it is important to note the consistent lack of carcinogenic response in animal studies.

In 1988, the International Agency for Research on Cancer (IARC) considered the carcinogenicity of several groups of fibers. One grouping they considered was a poorly defined collection of disparate fiber types [polycrystalline fiber, refractory ceramic fiber (referred to as RCF) and single crystal whiskers] into a broad, single category they termed “ceramic fibers”. The IARC monograph clearly indicated that test data specific to polycrystalline fibers were negative, but according to the IARC classification principles, positive results with other fiber types led to the conclusion that all fibers in the group should be considered as possible human carcinogens (IARC Category 2B). In a subsequent monograph on MMVF (2002), IARC did not specifically re-evaluate polycrystalline fiber. The Annual Report on Carcinogens prepared by the National Toxicology Program (NTP), (latest edition) classified “ceramic fibers (respirable size)” as reasonably anticipated to be carcinogens.

As produced most polycrystalline fibers, including Saffil, have fiber diameters too large to be respirable. Numerous scientific studies suggest that the potential toxicity of a respirable fiber is directly related to bio-persistence (the length of time it take for the fiber to clear the lung). Based on limited in-vitro laboratory analysis, which measure the dissolution rate of fibers in simulated lung fluid, polycrystalline fibers are known to be relatively durable. Data from respiratory surveillance studies are not available for PCW workers. In a small cohort of workers exposed to PCW with historical co-exposures to RCF and other fibers, there was no evidence of interstitial lung disease on chest x-rays nor an accelerated rate of loss of lung function on pulmonary function testing. Symptom responses could not be attributed to or excluded from exposure to PCW as a consequence of the prior fiber exposures.

12. ECOLOGICAL INFORMATION

12.1. Toxicity

Hazardous to the aquatic environment, short–term (acute):

Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long–term (chronic)

Not classified (Based on available data, the classification criteria are not met)

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12.2. Persistence and degradability

Polycrystalline wools (PCW) (675106-31-7)	
Persistence and degradability	Not applicable.

12.3. Bioaccumulative potential

Polycrystalline wools (PCW) (675106-31-7)	
Bioaccumulative potential	Not applicable.

12.4. Mobility in soil

Polycrystalline wools (PCW) (675106-31-7)	
Ecology - soil	Not applicable.

12.5. Results of PBT and vPvB assessment

Polycrystalline wools (PCW) (675106-31-7)
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste treatment methods : European waste catalogue.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

European List of Waste (LoW) code : 17 06 04 - insulation materials other than those mentioned in 17 06 01 and 17 06 03.

14. TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / AND

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				

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Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport	:	Not applicable
Transport by sea	:	Not applicable
Air transport	:	Not applicable
Inland waterway transport	:	Not applicable
Rail transport	:	Not applicable

14.7. Transport in bulk according to IMO instruments

Not applicable

15. REGULATORY INFORMATION

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

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Drug Precursors Regulation (273/2004)
Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations
No additional information available

15.2. Chemical safety assessment
A chemical safety assessment has been carried out

16. OTHER INFORMATION

Abbreviations and acronyms:	
ADN	Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DNEL	Derived-No Effect Level
IATA	International Air Transport Association
IMDG	International Maritime Code for Dangerous Goods
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
PBT	Persistent Bioaccumulative Toxic
vPvB	Very Persistent and Very Bioaccumulative
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
DMEL	Derived Minimal Effect level
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
LC50	Median lethal concentration
LD50	Median lethal dose

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LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PNEC	Predicted No-Effect Concentration
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit

Data sources:
Information provided by the manufacturer. European Chemicals Agency, http://echa.europa.eu/.

Other information:
. CARE PROGRAMME
ECFIA, representing the high temperature insulation wool (HTIW) industry, has undertaken an extensive industrial hygiene programme to provide assistance to the users of all products containing HTIW.
The objectives are twofold:

- to monitor workplace dust concentrations at both manufacturers' and customers' premises.
- to document manufacturing and use of HTIW products from an industrial hygiene perspective in order to establish appropriate recommendations to reduce exposures.

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