



**SECTION 1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

<b>Product Formal Name</b>	<b>VOIL</b>
<b>Product Form</b>	Mixture
<b>Product Use</b>	For professional use only. Light Paraffin Oil for use in ART
<b>Manufacturer</b>	<b>VITROMED GmbH – Hans-Knöll-Str. 6 – 07745 Jena – Germany</b>
<b>For Emergency Assistance</b>	<b>Phone</b> +49 3641 5 39 19 76 <b>Mail</b> support@vitromed.com

**SECTION 2 – HAZARDS IDENTIFICATION**

<b>Regulation (EC) No. 1272/2008</b>	Not classified
<b>Potential Acute Health Effects</b>	No additional information available
<b>Potential Chronic Health Effects</b>	No additional information available
<b>Adverse physicochemical, human health and environmental effects</b>	No additional information available
<b>Labelling according to Regulation (EC) No. 1272/2008 [CLP]</b>	No labelling applicable
<b>Other hazards</b>	No additional information available

**SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS**

<b>Substance</b>	Not applicable
<b>Mixture</b>	Classification of substances in the mixture according to Regulation (EC) No. 1272/2008 [CLP]: Not classified
<b>Comments</b>	The mixture does not contain any raw materials of direct animal-origin or materials that have been produced using animal-origin components. Components have not been in contact with material of animal origin during processing and therefore pose no TSE risk.

**SECTION 4 – FIRST AID MEASURES**

<b>Measures general</b>	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
<b>Inhalation</b>	Remove to fresh air. Allow the victim to rest. If breathing becomes difficult, call a physician.
<b>Eyes</b>	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.
<b>Skin</b>	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
<b>Ingestion</b>	Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. <b>Seek medical attention if any discomfort should occur.</b>
<b>Symptoms/effects</b>	Not expected to present a significant hazard under anticipated conditions of normal use.

**SECTION 5 – FIREFIGHTING MEASURES**

<b>Extinguishing Media</b>	Foam. Dry powder. Carbon dioxide. Water spray. Sand.
<b>Special Firefighting Procedure</b>	Do not use a heavy water stream. Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment. Do not enter fire area without proper protective equipment, including respiratory protection.
<b>Unusual Fire and Explosion Hazards</b>	Emits toxic fumes under fire conditions.

**SECTION 6 – ACCIDENTAL RELEASE MEASURES**

# VOIL

Safety Data Sheet

<b>Personal Precautions</b>	Evacuate unnecessary personnel. Equip cleanup crew with proper protection. Ventilate area.
<b>Environmental Precautions</b>	Notify authorities if liquid enters sewers or public waters.
<b>Methods for Cleaning Up</b>	Collect spillage. Store away from other materials.

## SECTION 7 – HANDLING AND STORAGE

<b>Handling</b>	Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.
<b>Storage</b>	Keep only in the original container away from direct (sun)light. Do not freeze. Do not use after expiry date. After opening the container, the product can be used up to 28 days when sterile conditions are maintained and the products are stored at room temperature. Cannot be reesterilized after opening.
<b>Specific Use</b>	See instructions for use delivered with the device.
<b>Incompatible products</b>	Strong bases. Strong acids.
<b>Incompatible materials</b>	Sources of ignition. Direct sunlight.
<b>Storage temperature</b>	15 - 25°C (Storage temperatures between 2 - 15°C are also allowed, but this might cause some turbidity which disappears when the oil is warmed up again.

## SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Exposure Controls (Occupational)</b>	Handle in accordance with good industrial hygiene and safety. Avoid all unnecessary exposure.
<b>Personal protective equipment</b>	Wear fire/flame resistant/retardant clothing.
<b>Skin protection</b>	Complete suit protecting against chemicals, flame retardant antistatic protective clothing. The type of protection must be selected according to the concentration and volume of the dangerous substance at the specific workplace.
<b>Hand protection</b>	Wear protective gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to meet specifications of regulation EU 2016/425 and the standard EN374.
<b>Eye/Face protection</b>	Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).
<b>Respiratory protection</b>	Wear appropriate mask. Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

## SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance and Odor</b>	Colorless transparent liquid, odorless
<b>pH</b>	Not available
<b>Boiling Point</b>	Not available
<b>Flash Point</b>	Not available
<b>Flammability</b>	Non-flammable
<b>Explosive Properties</b>	Not available
<b>Oxidizing Properties</b>	Not available
<b>Vapor Pressure</b>	Not available

# VOIL

Safety Data Sheet

<b>Relative density</b>	< 0.86 g/cm <sup>3</sup> at 25 °C
<b>Solubility</b>	Not soluble in water
<b>Solubility in Water</b>	Insoluble
<b>Viscosity</b>	< 30 cP at 30 °C
<b>Evaporation Rate</b>	Not available

## SECTION 10 – STABILITY AND REACTIVITY

<b>Stability</b>	Stable. Stable after transport (max. 5 days) at elevated temperature (≤ 37°C). Stable for 18 months from date of manufacture.
<b>Conditions to Avoid</b>	Direct (sun)light, extremely high or low temperatures.
<b>Materials to Avoid</b>	Strong acids and bases.
<b>Hazardous Decomposition Products</b>	Carbon monoxide and dioxide. Fume.

## SECTION 11 – TOXICOLOGICAL INFORMATION

<b>Acute toxicity (oral)</b>	Not classified
<b>Acute toxicity (dermal)</b>	Not classified
<b>Acute toxicity (inhalation)</b>	Not classified
<b>Additional information</b>	Extensive data from Mouse Embryo Assays have demonstrated that the medium is not toxic.
<b>Skin corrosion/irritation</b>	Not classified
<b>Additional information</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/irritation</b>	Not classified
<b>Additional information</b>	Based on available data, the classification criteria are not met
<b>Respiratory or skin sensitization</b>	Not classified
<b>Additional information</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	Not classified
<b>Additional information</b>	Based on available data, the classification criteria are not met
<b>Carcinogenicity</b>	Not classified
<b>Additional information</b>	Based on available data, the classification criteria are not met
<b>Reproductive toxicity</b>	Not classified
<b>Additional information</b>	Based on available data, the classification criteria are not met
<b>STOT-single exposure</b>	Not classified
<b>Additional information</b>	Based on available data, the classification criteria are not met
<b>STOT-repeated exposure</b>	Not classified
<b>Additional information</b>	Based on available data, the classification criteria are not met
<b>Aspiration hazard</b>	Not classified
<b>Additional information</b>	Based on available data, the classification criteria are not met
<b>Potential adverse human health effects and symptoms</b>	Based on available data, the classification criteria are not met.

## SECTION 12 – ECOLOGICAL INFORMATION

<b>Hazardous to the aquatic environment, short-term (acute)</b>	Not classified
<b>Hazardous to the aquatic environment, long-term (chronic)</b>	Not classified
<b>Persistence and degradability</b>	Not established
<b>Bioaccumulative potential</b>	Not established
<b>Mobility in soil</b>	No additional information available
<b>Results of PBT and vPvB assessment</b>	No additional information available
<b>Other adverse effects</b>	Avoid release to the environment

## SECTION 13 – DISPOSAL CONSIDERATIONS

<b>Product/Packaging</b>	Dispose in a safe manner in accordance to with local and
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# VOIL

Safety Data Sheet

**disposal recommendations** national regulations and avoid release to the environment.

**Ecology - waste materials** Avoid release to the environment.

## SECTION 14 – TRANSPORT INFORMATION

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

### UN number

UN-No. (ADR)	Not applicable
UN-No. (IMDG)	Not applicable
UN-No. (IATA)	Not applicable
UN-No. (ADN)	Not applicable
UN-No. (RID)	Not applicable

### UN proper shipping name

Proper Shipping Name (ADR)	Not applicable
Proper Shipping Name (IMDG)	Not applicable
Proper Shipping Name (IATA)	Not applicable
Proper Shipping Name (ADN)	Not applicable
Proper Shipping Name (RID)	Not applicable

### Transport hazard class(es)

ADR	Not applicable
IMDG	Not applicable
IATA	Not applicable
ADN	Not applicable
RID	Not applicable

**Dangerous for the environment** No

**Marine pollutant** No

**Other information** supplementary information available

**Overland transport** Not applicable

**Transport by sea** Not applicable

**Air transport** Not applicable

**Inland waterway transport** Not applicable

**Rail transport** Not applicable

## SECTION 15 – REGULATORY INFORMATION

<b>EU-Regulations</b>	Contains no REACH substances with Annex XVII restrictions Contains no substance on the REACH candidate list Contains no REACH Annex XIV substances Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals. Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants ISO 15223-1 & 93/42/EEC
<b>National regulations Germany</b>	Water hazard class (WGK): WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1) Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

This product does not contain any ingredients which have been determined to be health hazardous pursuant to U.S. OSHA regulations, and which comprise 1 % or more (0.1 % for carcinogens) of the mixture.

## SECTION 16 – OTHER INFORMATION

<b>Data sources</b>	REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
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**Other information** None

The information contained herein is furnished without warranty of any kind. Users should consider these data only as a supplement to other information gathered by them and must take independent

## **VOIL**

### Safety Data Sheet

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determinations of the suitability and completeness of information from all other sources to assure proper use and disposal of these materials and the safety and health of employees and customers. VITROMED GmbH shall not be held liable for any damage resulting from handling or from contact with its products.