Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

DIMETICONUM 1000

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Version: 00

MAGIS PHARMA

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name:	Dimethicone 1000 Dimeticonum 1000 Dimeticone 1000 Diméticone 1000 Dimeticon 1000
N° CAS:	9006-65-9
N° EC:	618-433-4

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company:	FRAVER NV Keizershoek 336 2550 Kontich Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):	Not applicable.
Signal word(s):	Not applicable.
Hazard statements:	Not applicable.
Precautionary statements:	Not applicable.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

This product contains dodecamethylcyclohexasiloxane (D6) that has been identified by the Member State Committee of ECHA as fulfilling the vPvB criteria laid down in Annex XIII to Regulation (EC) No 1907/2006. See Section 12 for additional information.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Dimethicone 1000
IUPAC name:	α-Trimethylsilyl-ω-methylpoly[oxy(dimethylsilanediyl)]
Synonyms:	Dimethyl silicone oil Dimethylpolysiloxane
N° CAS:	9006-65-9
N° EC:	618-433-4
Molecular Formula:	$C_6H_{18}OSi_2(C_2H_6OSi)n$

Content:

N° CAS	N° EC	Concentration	Component
63148-62-9	Polymer	≥ 90.0 - ≤100.0 %	Siloxanes and silicones, dimethyl
540-97-6	208-762-8	≥ 0.1 - < 1.0 %	Dodecamethyl cyclohexasiloxane

This poly(dimethylsiloxane) is obtained by hydrolysis and polycondensation of dichlorodimethylsilane and chlorotrimethylsilane. Different grades of dimeticone exist which are distinguished by a number indicating the nominal kinematic viscosity placed after the name.

Their degree of polymerisation (n = 20 to 400) is such that their kinematic viscosities are nominally between 20 $mm^2 \cdot s^{-1}$ and 1300 $mm^2 \cdot s^{-1}$.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	If potential for exposure exists, refer to Section 8 for specific personal protective equipment.
After inhalation:	Move person to fresh air; if symptoms occur, consult a physician.
After skin contact:	Wash off with plenty of water.
After eye contact:	Flush eyes thoroughly with water for several minutes. Remove contact lenses after the initial 1-2 minutes and continue flushing for several additional minutes. If symptoms occur, consult a physician, preferably an ophthalmologist.
After ingestion:	No emergency medical treatment necessary.

4.2 Most important symptoms and effects, both acute and delayed

Aside from the information found under 'Description of first aid measures' (above) and 'Indication of immediate medical attention and special treatment needed' (below), any additional important symptoms and effects are described in Section 11: Toxicology Information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician: No specific antidote. Treatment of exposure should be directed at the control of symptoms and the clinical condition of the patient.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water spray, alcohol-resistant foam, carbon dioxide (CO_2), dry chemical.
Unsuitable extinguishing media:	None known.

5.2 Special hazards arising from the substance/mixture

Hazardous combustion products: Carbon oxides, silicon oxides.

Unusual Fire and Explosion Hazards: Exposure to combustion products may be a hazard to health.

5.3 Advice for firefighters

Surrounding fires:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Protection against fire:	Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.
Hazardous combustion products:	Carbon oxides, silicon oxides.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Follow safe handling advice and personal protective equipment recommendations.

For emergency responders

Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Soak up with inert absorbent material. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the clean-up of releases. You will need to determine which regulations are applicable.

For large spills, containment or other suitable containment should be provided to prevent the material from spreading. If containment material can be pumped, Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Take care to prevent spills, waste and minimize release to the environment. Handle in accordance with good industrial hygiene and safety practice.
Personal protection:	Not available.
Technical protective measures:	Use only with adequate ventilation. See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Handling:	Use only with adequate ventilation

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Keep in properly labelled containers.
Conditions for safe storage, including any incompatibilities:	Store in accordance with the particular national regulations. Do not store with the following product types: Strong oxidizing agents.
Storage – away from:	Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

If exposure limits exist, they are listed below. If no exposure limits are displayed, then no values are applicable.

Derived No Effect Level (Dodecamethyl cyclohexasiloxane)

Workers, acute local effects, inhalation: 6.1 mg/m^3

Workers, long-term systemic effects, inhalation: 11 mg/m^3

Workers, long-term local effects, inhalation: 1.22 mg/m^3

Consumers, acute systemic effects, oral: 1.7 mg/kg bw/day

Consumers, acute local effects, inhalation: 1.5 mg/m^3

Consumers, long-term systemic effects, inhalation: 2.7 mg/m^3

Consumers, long-term systemic effects, oral: 1.7 mg/kg bw/day

Consumers, long-term local effects, inhalation: 0.3 mg/m^3

Predicted No Effect Concentration (Dodecamethyl cyclohexasiloxane)

Fresh water sediment: 2.826 mg/kg

Marine sediment: 0.282 mg/kg

Soil: 3.336 mg/kg

Sewage treatment plant: > 1.0 mg/l

8.2 Exposure controls

Appropriate engineering control

Use local exhaust ventilation, or other engineering controls to maintain airborne levels below exposure limit requirements or guidelines. If there are no applicable exposure limit requirements or guidelines, general ventilation should be sufficient for most operations. Local exhaust ventilation may be necessary for some operations.

Individual protection measures

Eye/face protection:	Use safety glasses (with side shields). Safety glasses (with side shields) should be consistent with EN 166 or equivalent.
Skin protection:	Wear clean, body-covering clothing.
Hand protection:	Use gloves chemically resistant to this material when prolonged or frequently repeated contact could occur. Use chemical resistant gloves classified under Standard EN374: Protective gloves against chemicals and micro-organisms. Examples of preferred glove barrier materials include: Butyl rubber. Neoprene. Nitrile/butadiene rubber ("nitrile" or "NBR"). Ethyl vinyl alcohol laminate ("EVAL"). Polyvinyl alcohol ("PVA"). Polyvinyl chloride ("PVC" or "vinyl"). Viton. Examples of acceptable glove barrier materials include: Natural rubber ("latex"). When prolonged or frequently repeated contact may occur, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended. Glove thickness alone is not a good indicator of the level of protection a glove provides against a chemical substance as this level of protection is also highly dependent on the specific composition of the material that the glove is fabricated from. The thickness of the glove must, depending on model and type of material, generally be more than 0.35 mm to offer sufficient protection for prolonged and frequent contact with the substance. As an exception to this general rule it is known that multilayer laminate gloves may offer prolonged protection at thicknesses less than 0.35 mm. Other glove materials with a thickness of less than 0.35 mm may offer sufficient protection when only brief contact is expected. NOTICE: The selection of a specific glove for a particular application and duration of use in a workplace should also take into account all relevant workplace factors such as, but not limited to: Other chemicals which may be handled, physical requirements (cut/puncture protection, dexterity, thermal protection), potential body reactions to glove materials, as well as the instructions/specifications provided by the glove supplier.
Respiratory protection:	Respiratory protection should be worn when there is a potential to exceed the exposure limit requirements or guidelines. If there are no applicable exposure limit requirements or guidelines, wear respiratory protection when adverse effects, such as respiratory irritation or discomfort, have been experienced, or where indicated by your risk assessment process. For most conditions, no respiratory protection should be needed; however, if material is heated or sprayed, use an approved air-purifying respirator. Use the following CE approved air-purifying respirator: Organic vapour cartridge with a particulate pre-filter, type AP2 (meeting standard EN 14387).
Thermal hazards:	Not determined.

Environmental exposure control

See SECTION 7: Handling and storage and SECTION 13: Disposal considerations for measures to prevent excessive environmental exposure during use and waste disposal.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Clear, colourless liquid of various viscosities.
Odour:	None.
Odour threshold:	Not available.

pH:	Not available.
Melting/freezing point:	Not available.
Initial boiling point:	> 35 °C (760 mmHg)
Boiling range:	Not available.
Flash point:	Closed cup: > 101.1 °C
Evaporation rate:	Not available.
Flammability (solid/gas):	Not applicable.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	0.970
Solubility:	Very slightly soluble or practically insoluble in anhydrous ethanol, miscible with ethyl acetate, with methyl ethyl ketone and with toluene.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Kinematic: 1000 cSt at 2°C
Explosive properties:	Not explosive.
Oxidising properties:	The substance or mixture is not classified as oxidising.

9.2 Other information

NOTE: The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Can react with strong oxidizing agents.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

Oxidising agents.

10.6 Hazardous decomposition products

Formaldehyde.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Acute oral toxicity Very low toxicity if swallowed. Harmful effects not anticipated from swallowing small amounts. Typical for this family of materials. LD_{50}, Rat, > 15,400 mg/kg Acute dermal toxicity Prolonged skin contact is unlikely to result in absorption of harmful amounts. Typical for this family of materials. LD_{50}, Rabbit, > 2,000 mg/kg; No deaths occurred at this concentration. Acute inhalation toxicity Brief exposure (minutes) is not likely to cause adverse effects. Vapour from heated material or mist may cause respiratory irritation. The LC_{50} has not been determined.
Skin corrosion/irritation:	Brief contact is essentially non-irritating to skin.
Serious eye damage/irritation:	Essentially non-irritating to eyes.
Respiratory/skin sensitisation:	For this family of materials, sensitisation studies done in guinea pigs have been negative. For respiratory sensitization: No relevant data found.
Germ cell mutagenicity:	For this family of materials: In vitro genetic toxicity studies were negative.
Carcinogenicity:	For this family of materials: Did not cause cancer in laboratory animals.
Reproductive toxicity:	For this family of materials: In animal studies, did not interfere with reproduction.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Evaluation of available data suggests that this material is not an STOT-SE toxicant.
STOT-repeated exposure:	Based on available data, repeated exposures are not anticipated to cause significant adverse effects.
Aspiration Hazard:	Based on physical properties, not likely to be an aspiration hazard.
Other:	Teratogenicity: For this family of materials: Did not cause birth defects or any other foetal effects in laboratory animals. Components influencing toxicology: Siloxanes and silicones, dimethyl: Acute inhalation toxicity: the LC50 has not been determined. Dodecamethyl cyclohexasiloxane: Acute inhalation toxicity: the LC50 has not been determined.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.

Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Acute toxicity to aquatic invertebrates

Material is not classified as dangerous to aquatic organisms (LC_{50}/EC_{50}/IC_{50}/LL_{50}/EL_{50}) greater than 100 mg/L in most sensitive species).

For this family of materials: EC_{50}, *Daphnia magna* (Water flea), 48h, > 200 mg/l

12.2 Persistence and degradability

Siloxanes and silicones, dimethyl

Biodegradability: The product is not biodegradable.

Dodecamethyl cyclohexasiloxane

Biodegradability: Based on stringent OECD test guidelines, this material cannot be considered as readily biodegradable; however, these results do not necessarily mean that the material is not biodegradable under environmental conditions.

10-day Window: Fail

Biodegradation: 57 %

Exposure time: 28 d

Method: OECD Test Guideline 301B

12.3 Bioaccumulative potential

Siloxanes and silicones, dimethyl

Bioaccumulation: No bioconcentration is expected because of the relatively high molecular weight (MW greater than 1000).

Dodecamethyl cyclohexasiloxane

Bioaccumulation: Bioconcentration potential is low (BCF less than 100 or log Pow greater than 7).

Partition coefficient: n-octanol/water(log Pow): 8.87

12.4 Mobility in soil

Siloxanes and silicones, dimethyl

Expected to be relatively immobile in soil (Koc > 5000).

Dodecamethyl cyclohexasiloxane

Potential for mobility in soil is very high (Koc between 0 and 50).

12.5 Results of PBT and vPvB assessment

Siloxanes and silicones, dimethyl

This substance has not been assessed for persistence, bioaccumulation and toxicity (PBT).

Dodecamethyl cyclohexasiloxane

Dodecamethyl cyclohexasiloxane (D6) meets the current REACh Annex XIII criteria for vPvB. However, D6 does not behave similarly to known PBT/vPvB substances. The weight of scientific evidence from field studies shows that D6 is not biomagnifying in aquatic and terrestrial food webs. D6 in air will degrade by reaction with naturally occurring hydroxyl radicals in the atmosphere. Any D6 in air that does not degrade by reaction with hydroxyl radicals is not expected to deposit from the air to water, to land, or to living organisms.

12.6 Other adverse effects

Siloxanes and silicones, dimethyl

This substance is not on the Montreal Protocol list of substances that deplete the ozone layer.

Dodecamethyl cyclohexasiloxane

This substance is not on the Montreal Protocol list of substances that deplete the ozone layer.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Do not dump into any sewers, on the ground, or into any body of water. This product, when being disposed of in its unused and uncontaminated state, should be treated as a hazardous waste according to EC Directive 2008/98/EC. Any disposal practices must be in compliance with all national and provincial laws and any municipal or local by-laws governing hazardous waste. For used, contaminated and residual materials, additional evaluations may be required.

The definitive assignment of this material to the appropriate EWC group and thus its proper EWC code will depend on the use that is made of this material. Contact the authorised waste disposal services.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not regulated for transport.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not considered environmentally hazardous based on available data. Not considered as marine pollutant based on available data.

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Consult IMO regulations before transporting ocean bulk.

14.8 Additional transport information

This information is not intended to convey all specific regulatory or operational requirements/information relating to this product. Transportation classifications may vary by container volume and may be influenced by regional or country variations in regulations. Additional transportation system information can be obtained through an authorised sales or

customer service representative. It is the responsibility of the transporting organization to follow all applicable laws, regulations and rules relating to the transportation of the material.

SECTION 15: REGULATORY INFORMATION

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

Not applicable.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumalative

16.3 Key literature references/sources for data

European Chemicals Agency.
https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available.

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals

Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

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