



SAFETY DATA SHEET

Based upon Regulation (EC) No 1907/2006, as amended by Regulation (EU) No 2015/830

LIPO CREAM W/O

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : LIPO CREAM W/O
Synonyms : LIPO CRÈME E/H; LIPO CRÈME W/O
Registration number REACH : Not applicable (mixture)
Product type REACH : Mixture

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

1.2.1 Relevant identified uses

This raw material is purchased by a pharmacist and after distribution will be delivered to the patient as such or processed in a magistral or official preparation
External use

1.2.2 Uses advised against

No uses advised against known

1.3. Details of the supplier of the safety data sheet

Supplier of the safety data sheet

Pannoc NV/SA
Lammerdries-oost 23
B-2250 Olen
☎ +32 14 21 70 18
info@pannoc.eu

1.4. Emergency telephone number

During business hours, 8:00-16:30 (CET) :
+32 14 21 70 18

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Not classified as dangerous according to the criteria of Regulation (EC) No 1272/2008

2.2. Label elements

Not classified as dangerous according to the criteria of Regulation (EC) No 1272/2008

Supplemental information

EUH210 Safety data sheet available on request.

2.3. Other hazards

No other hazards known

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name REACH Registration No	CAS No EC No	Conc. (C)	Classification according to CLP	Note	Remark
white mineral oil (petroleum) 01-2119487078-27	8042-47-5 232-455-8	40 %		(2)	Constituent

(2) Substance with a Community workplace exposure limit

SECTION 4: First aid measures

4.1. Description of first aid measures

General:

If you feel unwell, seek medical advice.

After inhalation:

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Remove the victim into fresh air. Respiratory problems: consult a doctor/medical service.

After skin contact:

Rinse with water. Do not apply (chemical) neutralizing agents without medical advice. Take victim to a doctor if irritation persists.

After eye contact:

Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. Do not apply (chemical) neutralizing agents without medical advice. Take victim to an ophthalmologist if irritation persists.

After ingestion:

Rinse mouth with water. Do not apply (chemical) neutralizing agents without medical advice. Consult a doctor/medical service if you feel unwell.

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

4.2.1 Acute symptoms

After inhalation:

No effects known.

After skin contact:

No effects known.

After eye contact:

No effects known.

After ingestion:

No effects known.

4.2.2 Delayed symptoms

No effects known.

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

If applicable and available it will be listed below.

SECTION 5: Firefighting measures

5.1. Extinguishing media

5.1.1 Suitable extinguishing media:

Small fire: Quick-acting ABC powder extinguisher, Quick-acting BC powder extinguisher, Quick-acting class B foam extinguisher, Quick-acting CO2 extinguisher.

Major fire: Class B foam (not alcohol-resistant).

5.1.2 Unsuitable extinguishing media:

Small fire: Water (quick-acting extinguisher, reel); risk of puddle expansion.

Major fire: Water; risk of puddle expansion.

5.2. Special hazards arising from the substance or mixture

Upon combustion: CO and CO2 are formed.

5.3. Advice for firefighters

5.3.1 Instructions:

No specific fire-fighting instructions required.

5.3.2 Special protective equipment for fire-fighters:

Gloves (EN 374). Protective clothing (EN 14605 or EN 13034). Heat/fire exposure: compressed air apparatus (EN 136 + EN 137).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

No naked flames.

6.1.1 Protective equipment for non-emergency personnel

See heading 8.2

6.1.2 Protective equipment for emergency responders

Gloves (EN 374). Protective clothing (EN 14605 or EN 13034).

Suitable protective clothing

See heading 8.2

6.2. Environmental precautions

Contain released product.

6.3. Methods and material for containment and cleaning up

Scoop solid spill into closing containers. Clean contaminated surfaces with a soap solution. Wash clothing and equipment after handling.

6.4. Reference to other sections

See heading 13.

SECTION 7: Handling and storage

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

7.1. Precautions for safe handling

Keep away from naked flames/heat. Observe normal hygiene standards. Keep container tightly closed.

7.2. Conditions for safe storage, including any incompatibilities

7.2.1 Safe storage requirements:

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Storage temperature: 15 °C - 25 °C. Store in a dark area. Meet the legal requirements.

7.2.2 Keep away from:

Heat sources.

7.2.3 Suitable packaging material:

Polypropylene.

7.2.4 Non suitable packaging material:

No data available

7.3. Specific end use(s)

If applicable and available, exposure scenarios are attached in annex. See information supplied by the manufacturer.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 Occupational exposure

a) Occupational exposure limit values

If limit values are applicable and available these will be listed below.

Belgium

Huiles minérales (brouillards)	Time-weighted average exposure limit 8 h	5 mg/m ³
	Short time value	10 mg/m ³

The Netherlands

Olienevel (minerale olie)	Time-weighted average exposure limit 8 h (Public occupational exposure limit value)	5 mg/m ³
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Germany

Weißes Mineralöl (Erdöl)	Time-weighted average exposure limit 8 h (TRGS 900)	5 mg/m ³
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USA (TLV-ACGIH)

Mineral oil, pure, highly and severely refined	Time-weighted average exposure limit 8 h (TLV - Adopted Value)	5 mg/m ³ (I)
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(I): Inhalable fraction

b) National biological limit values

If limit values are applicable and available these will be listed below.

8.1.2 Sampling methods

If applicable and available it will be listed below.

8.1.3 Applicable limit values when using the substance or mixture as intended

If limit values are applicable and available these will be listed below.

8.1.4 Threshold values

DNEL/DMEL - Workers

white mineral oil (petroleum)

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	160 mg/m ³	
	Long-term systemic effects dermal	220 mg/kg bw/day	

DNEL/DMEL - General population

white mineral oil (petroleum)

Effect level (DNEL/DMEL)	Type	Value	Remark
DNEL	Long-term systemic effects inhalation	35 mg/m ³	
	Long-term systemic effects dermal	93 mg/kg bw/day	
	Long-term systemic effects oral	40 mg/kg bw/day	

8.1.5 Control banding

If applicable and available it will be listed below.

8.2. Exposure controls

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

8.2.1 Appropriate engineering controls

Keep away from naked flames/heat.

8.2.2 Individual protection measures, such as personal protective equipment

Observe normal hygiene standards. Do not eat, drink or smoke during work.

a) Respiratory protection:

Respiratory protection not required in normal conditions.

b) Hand protection:

Protective gloves against chemicals (EN 374).

c) Eye protection:

Eye protection not required in normal conditions.

d) Skin protection:

Protective clothing (EN 14605 or EN 13034).

8.2.3 Environmental exposure controls:

See headings 6.2, 6.3 and 13

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical form	Paste
	Ointment
Viscosity	Greasy
Odour	Characteristic odour
Odour threshold	No data available in the literature
Colour	White
Particle size	No data available in the literature
Explosion limits	No data available in the literature
Flammability	Not classified as flammable
Log Kow	Not applicable (mixture)
Dynamic viscosity	200000 mPa.s - 500000 mPa.s ; room temperature
Kinematic viscosity	No data available in the literature
Melting point	No data available in the literature
Boiling point	No data available in the literature
Evaporation rate	No data available in the literature
Relative vapour density	No data available in the literature
Vapour pressure	No data available in the literature
Solubility	No data available in the literature
Relative density	No data available in the literature
Decomposition temperature	No data available in the literature
Auto-ignition temperature	No data available in the literature
Flash point	No data available in the literature
Explosive properties	No chemical group associated with explosive properties
Oxidising properties	No chemical group associated with oxidising properties
pH	2.5 - 4.5

9.2. Other information

Surface tension	No data available in the literature
Absolute density	No data available in the literature

SECTION 10: Stability and reactivity

10.1. Reactivity

Heating increases the fire hazard. Acid reaction.

10.2. Chemical stability

No data available.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Precautionary measures

Keep away from naked flames/heat.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

Upon combustion: CO and CO₂ are formed.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

11.1.1 Test results

Acute toxicity

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No (test)data on the mixture available

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white mineral oil (petroleum)

Route of exposure	Parameter	Method	Value	Exposure time	Species	Value determination	Remark
Oral	LD50	Equivalent to OECD 401	> 5000 mg/kg bw		Rat (male / female)	Read-across	
Dermal	LD50	Equivalent to OECD 402	> 2000 mg/kg bw	24 h	Rabbit (male / female)	Read-across	
Inhalation	LC50	Equivalent to OECD 403	> 5 mg/l air	4 h	Rat (male / female)	Read-across	

Conclusion

Not classified for acute toxicity

Corrosion/irritation

LIPO CREAM W/O

No (test)data on the mixture available

white mineral oil (petroleum)

Route of exposure	Result	Method	Exposure time	Time point	Species	Value determination	Remark
Eye	Not irritating	Equivalent to OECD 405		24; 48; 72 hours	Rabbit	Experimental value	
Skin	Not irritating	Equivalent to OECD 404	24 h	24; 72 hours	Rabbit	Experimental value	

Conclusion

Not classified as irritating to the skin

Not classified as irritating to the eyes

Not classified as irritating to the respiratory system

Respiratory or skin sensitisation

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No (test)data on the mixture available

white mineral oil (petroleum)

Route of exposure	Result	Method	Exposure time	Observation time point	Species	Value determination	Remark
Skin	Not sensitizing	Equivalent to OECD 406		48 hours	Guinea pig (male)	Experimental value	

Conclusion

Not classified as sensitizing for skin

Not classified as sensitizing for inhalation

Specific target organ toxicity

LIPO CREAM W/O

No (test)data on the mixture available

white mineral oil (petroleum)

Route of exposure	Parameter	Method	Value	Organ	Effect	Exposure time	Species	Value determination
Oral	NOEL	Equivalent to OECD 408	> 20000 ppm			90 day(s)	Rat (male / female)	Experimental value
Skin	NOAEL	Equivalent to OECD 411	> 2000			13 weeks (daily)	Rat (male / female)	Experimental value
Inhalation (mist)	NOEL	Equivalent to OECD 412	50 mg/m ³ air			4 weeks (6h / day, 5 days / week)	Rat (male / female)	Experimental value

Conclusion

Not classified for subchronic toxicity

Mutagenicity (in vitro)

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No (test)data on the mixture available

white mineral oil (petroleum)

Result	Method	Test substrate	Effect	Value determination	Remark
Negative	Equivalent to OECD 471	Bacteria (S.typhimurium)		Experimental value	

Mutagenicity (in vivo)

LIPO CREAM W/O

No (test)data on the mixture available

white mineral oil (petroleum)

Result	Method	Exposure time	Test substrate	Organ	Value determination
Negative	Equivalent to OECD 474		Mouse (male / female)		Read-across

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Conclusion

Not classified for mutagenic or genotoxic toxicity

Carcinogenicity

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No (test)data on the mixture available
white mineral oil (petroleum)

Route of exposure	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Oral	NOAEL	OECD 453	> 1200 mg/kg bw/day	24 month(s)	Rat (male / female)			Experimental value

Conclusion

Not classified for carcinogenicity

Reproductive toxicity

LIPO CREAM W/O

No (test)data on the mixture available
white mineral oil (petroleum)

	Parameter	Method	Value	Exposure time	Species	Effect	Organ	Value determination
Developmental toxicity	NOAEL	Equivalent to OECD 414	> 5 ml/kg	20 day(s) - 40 day(s)	Rat	No effect		Experimental value

Conclusion

Not classified for reprotoxic or developmental toxicity

Toxicity other effects

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No (test)data on the mixture available

Chronic effects from short and long-term exposure

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No effects known.

SECTION 12: Ecological information

12.1. Toxicity

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No (test)data on the mixture available
white mineral oil (petroleum)

	Parameter	Method	Value	Duration	Species	Test design	Fresh/salt water	Value determination
Acute toxicity fishes	LL50	OECD 203	> 100 mg/l	96 h	Oncorhynchus mykiss	Static system	Fresh water	Experimental value; Nominal concentration
Acute toxicity crustacea	LL50	OECD 202	> 100 mg/l	48 h	Daphnia magna	Static system	Fresh water	Experimental value; Locomotor effect
Toxicity algae and other aquatic plants	NOEL	OECD 201	≥ 100 mg/l	72 h	Pseudokirchneriella subcapitata	Static system	Fresh water	Weight of evidence; Growth rate

Conclusion

Not classified as dangerous for the environment according to the criteria of Regulation (EC) No 1272/2008

12.2. Persistence and degradability

white mineral oil (petroleum)

Biodegradation water

Method	Value	Duration	Value determination
OECD 301F: Manometric Respirometry Test	31 %; GLP	28 day(s)	Read-across

Conclusion

Contains non readily biodegradable component(s)

12.3. Bioaccumulative potential

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Log Kow

Method	Remark	Value	Temperature	Value determination
	Not applicable (mixture)			

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white mineral oil (petroleum)

Log Kow

Method	Remark	Value	Temperature	Value determination
	No data available			

Conclusion

No straightforward conclusion can be drawn based upon the available numerical values

12.4. Mobility in soil

Contains component(s) with potential for mobility in the soil

Contains component(s) that adsorb(s) into the soil

12.5. Results of PBT and vPvB assessment

Due to insufficient data no statement can be made whether the component(s) fulfil(s) the criteria of PBT and vPvB according to Annex XIII of Regulation (EC) No 1907/2006.

12.6. Other adverse effects

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Greenhouse gases

None of the known components is included in the list of fluorinated greenhouse gases (Regulation (EU) No 517/2014)

Ozone-depleting potential (ODP)

Not classified as dangerous for the ozone layer (Regulation (EC) No 1005/2009)

white mineral oil (petroleum)

Groundwater

Groundwater pollutant

SECTION 13: Disposal considerations

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

13.1. Waste treatment methods

13.1.1 Provisions relating to waste

European Union

Can be considered as non hazardous waste according to Directive 2008/98/EC, as amended by Regulation (EU) No 1357/2014 and Regulation (EU) No 2017/997.

Waste material code (Directive 2008/98/EC, Decision 2000/0532/EC).

07 05 99 (wastes from the MFSU of pharmaceuticals: wastes not otherwise specified). Depending on branch of industry and production process, also other waste codes may be applicable.

13.1.2 Disposal methods

Remove waste in accordance with local and/or national regulations. Do not discharge into drains or the environment. Dispose of at authorized waste collection point.

13.1.3 Packaging/Container

European Union

Waste material code packaging (Directive 2008/98/EC).

15 01 02 (plastic packaging).

SECTION 14: Transport information

Road (ADR), Rail (RID), Inland waterways (ADN), Sea (IMDG/IMSBC), Air (ICAO-TI/IATA-DGR)

14.1. UN number

Transport	Not subject
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14.2. UN proper shipping name

14.3. Transport hazard class(es)

Hazard identification number	
Class	
Classification code	

14.4. Packing group

Packing group	
Labels	

14.5. Environmental hazards

Environmentally hazardous substance mark	no
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14.6. Special precautions for user

Special provisions	
Limited quantities	

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

Annex II of MARPOL 73/78	Not applicable, based on available data
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SECTION 15: Regulatory information

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

European legislation:

VOC content Directive 2010/75/EU

VOC content	Remark
	No data available

European drinking water standards (Directive 98/83/EC)

white mineral oil (petroleum)

Parameter	Parametric value	Note	Reference
Pesticides	0.1 µg/l		Listed in Annex I, Part B, of Directive 98/83/EC on the quality of water intended for human consumption.
Pesticides — Total	0.5 µg/l		Listed in Annex I, Part B, of Directive 98/83/EC on the quality of water intended for human consumption.

National legislation Belgium

LIPO CREAM W/O

No data available

National legislation The Netherlands

LIPO CREAM W/O

Waterbezwaarlijkheid	B (4); Algemene Beoordelingsmethodiek (ABM)
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National legislation France

LIPO CREAM W/O

No data available

National legislation Germany

LIPO CREAM W/O

WGK	1; Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV) - 18. April 2017
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white mineral oil (petroleum)

TA-Luft	5.2.5
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National legislation United Kingdom

LIPO CREAM W/O

No data available

Other relevant data

LIPO CREAM W/O

No data available

white mineral oil (petroleum)

TLV - Carcinogen	Mineral oil, pure, highly and severely refined; A4
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15.2. Chemical safety assessment

No chemical safety assessment has been conducted for the mixture.

SECTION 16: Other information

(*)	INTERNAL CLASSIFICATION BY BIG
ADI	Acceptable daily intake
AOEL	Acceptable operator exposure level
CLP (EU-GHS)	Classification, labelling and packaging (Globally Harmonised System in Europe)
DMEL	Derived Minimal Effect Level
DNEL	Derived No Effect Level
EC50	Effect Concentration 50 %
ErC50	EC50 in terms of reduction of growth rate
LC50	Lethal Concentration 50 %
LD50	Lethal Dose 50 %
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative & Toxic
PNEC	Predicted No Effect Concentration
STP	Sludge Treatment Process
vPvB	very Persistent & very Bioaccumulative

The information in this safety data sheet is based on data and samples provided to BIG. The sheet was written to the best of our ability and according to the state of knowledge at that time. The safety data sheet only constitutes a guideline for the safe handling, use, consumption, storage, transport and disposal of the substances/preparations/mixtures mentioned under point 1. New safety data sheets are written from time to time. Only the most recent versions may be used. Unless indicated otherwise word for word on the safety data sheet, the information does not apply to substances/preparations/mixtures in purer form, mixed with other substances or in processes. The safety data sheet offers

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no quality specification for the substances/preparations/mixtures in question. Compliance with the instructions in this safety data sheet does not release the user from the obligation to take all measures dictated by common sense, regulations and recommendations or which are necessary and/or useful based on the real applicable circumstances. BIG does not guarantee the accuracy or exhaustiveness of the information provided and cannot be held liable for any changes by third parties. This safety data sheet is only to be used within the European Union, Switzerland, Iceland, Norway and Liechtenstein. Any use outside of this area is at your own risk. Use of this safety data sheet is subject to the licence and liability limiting conditions as stated in your BIG licence agreement or when this is failing the general conditions of BIG. All intellectual property rights to this sheet are the property of BIG and its distribution and reproduction are limited. Consult the mentioned agreement/conditions for details.

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