

Material Safety Data Sheet

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

ADEPS LANAE

EN

FORM-06-14-01 (V00)

Page 1/9

Publication: 25/08/2022

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Version: 00



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

1.1 Product identifier

Product name: Wool fat
Adeps lanae
Wolvat
Graisse de laine
Wollwachs

N° CAS: 8006-54-0

N° EC: 232-348-6

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: FAC SECUNDUM ARTEM NV
Oostmalsebaan 1c (unit 5)
2960 Sint-Lenaarts
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 classified.

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

Not available.

Material Safety Data Sheet

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

ADEPS LANAE

EN

FORM-06-14-01 (V00)

Page 2/9

Publication: 25/08/2022

Revision: XX/XX/XXXX

Version: 00



SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Mixture of fatty acids, higher alcohols, free fatty acids and alcohols.

Product name: Wool fat

IUPAC name: Octadecyl hexadecanoate

Synonyms: Lanolin

N° CAS: 8006-54-0

N° EC: 232-348-6

Molecular Formula: $C_{34}H_{68}O_2$

There are no additional ingredients present which, within the current knowledge of the supplier, are classified and contribute to the classification of the substance and hence require reporting in this section.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: In all cases of doubt, or when symptoms persist, seek medical attention.

After inhalation: Fresh air. Get medical attention if symptoms occur.

After skin contact: Flush contaminated skin with plenty of water, wash with soap and rinse thoroughly. Remove contaminated clothing and shoes.

After eye contact: Immediately flush eyes with plenty of water. Check for and remove any contact lenses. Get medical attention if irritation occurs.

After ingestion: Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam, dry chemical powder, carbon dioxide, sand or earth.

Unsuitable extinguishing media: Water with full jet.

5.2 Special hazards arising from the substance/mixture

Avoid contact with oxidizing agents.

5.3 Advice for firefighters

Surrounding fires: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire.

Protection against fire: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus with a full face-piece operated in

Material Safety Data Sheet

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

ADEPS LANAE

EN

FORM-06-14-01 (V00)

Page 3/9

Publication: 25/08/2022

Revision: XX/XX/XXXX

Version: 00



Hazardous combustion products:

positive pressure mode. Clothing for fire-fighters conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

Smoke, CO, CO₂. At high temperatures acrolein may be formed.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

The usual precautions for handling chemicals should be observed. Do not touch or walk through split material. Put on appropriate personal protective equipment.

For emergency responders

The usual precautions for handling chemicals should be observed. Do not touch or walk through split material. Put on appropriate personal protective equipment.

6.2 Environmental precautions

Avoid dispersal of split material and runoff and contact with soil, waterways, drains and sewers.

6.3 Methods and material for containment and cleaning up

Small spill: Stop leak if without risk. Move container from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill: Stop leak if without risk. Move container from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillage into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via licensed waste disposal contractor.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Advice on general occupational hygiene: The usual precautions for handling chemicals should be observed. Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas.

Personal protection:

Not available.

Technical protective measures:

Not available.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Store in original container.

Conditions for safe storage, including any incompatibilities:

Store in original container protected from direct sunlight in a dry, cool and well-ventilated area at a temperature not exceeding 25 °C.

Material Safety Data Sheet

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

ADEPS LANAE

EN

FORM-06-14-01 (V00)

Page 4/9

Publication: 25/08/2022

Revision: XX/XX/XXXX

Version: 00



Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. Lanolin contains max. 200 mg Butylhydroxytoluene (BHT).

Storage – away from:

Store away from incompatible materials and food and drink.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not applicable.

8.2 Exposure controls

Appropriate engineering control

Hygiene measures: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing.

Individual protection measures

Eye/face protection: Safety eyewear.

Skin protection: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Hand protection: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. >8 hours (breakthrough time): neoprene, nitrile, Viton®.

Respiratory protection: Use properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator. Recommended: organic vapour filter.

Thermal hazards: Not determined.

Environmental exposure control

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Yellow, unctuous substance.
When melted, it is a clear or almost clear, yellow liquid.
A solution in light petroleum is opalescent.

Odour: Characteristic odour.

Material Safety Data Sheet

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

EN

FORM-06-14-01 (V00)

Page 5/9

Publication: 25/08/2022

Revision: XX/XX/XXXX

Version: 00

ADEPS LANAE



Odour threshold:	Not available.
pH:	10 g/L water
Melting/freezing point:	Ca. 38 – 44 °C (method: open cup)
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	285 – 295 °C (method: open cup)
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Ca. 0.90 – 0.95 g/cm ³ at 20 °C
Relative density:	Not available.
Solubility:	Slightly soluble in boiling anhydrous ethanol.
Solubility in water:	Practically insoluble in water. Formation of an emulsion at temperatures above the melting point.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Ca. 280 cP at 50 °C Ca. 130 cP at 60 °C
Explosive properties:	Product does not present an explosion hazard.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability

The product is stable.

10.3 Possibility of hazardous reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

See section 7. Avoid contact with oxidizing agents.

Material Safety Data Sheet

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

ADEPS LANAE

EN

FORM-06-14-01 (V00)

Page 6/9

Publication: 25/08/2022

Revision: XX/XX/XXXX

Version: 00



10.6 Hazardous decomposition products

Smoke and irritating vapours when heated to decomposition. At very high temperatures acrolein may be formed.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Acute oral toxicity to rats: LD ₅₀ is greater than the maximum practical dose of 16 g/kg.
Skin corrosion/irritation:	In an individual case allergic reactions may appear if the product is directly used on the skin.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not available.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not classified as hazardous conform EEC Dangerous Substance Directive and Dangerous Preparation Directives. If the product is used properly it will not cause any injuries to health.

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

Not available.

12.2 Persistence and degradability

Product is biodegradable.

12.3 Bioaccumulative potential

Does not accumulate in organisms.

12.4 Mobility in soil

Not available.

Material Safety Data Sheet

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

ADEPS LANAE

EN

FORM-06-14-01 (V00)

Page 7/9

Publication: 25/08/2022

Revision: XX/XX/XXXX

Version: 00



12.5 Results of PBT and vPvB assessment

PBT: No.

vPvB: No.

12.6 Other adverse effects

If it gets into water in form of emulsion BSB5 and CSB may increase.

- CSB-value: 2000 mg/g
- BSB5-value: 700 – 900 mg/g
- AOX-hint: 4,2 mg/100g

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Methods of disposal: Significant quantities of waste product residues should not be disposed of via the foul sewer but processed in a suitable effluent treatment plant. Dispose of surplus and non-recyclable product via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Packaging: The generation of waste should be avoided or minimized wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

EU-disposal code: 13 08 99 oil waste. Classification of waste is in end user's individual authority.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

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

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

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

14.6 Special precautions for user

Not available.

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

Not available.

Material Safety Data Sheet

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

ADEPS LANAE

EN

FORM-06-14-01 (V00)

Page 8/9

Publication: 25/08/2022

Revision: XX/XX/XXXX

Version: 00



14.8 Additional transport information

No hazardous goods according UN, IMO, ADR/RID and IATA/ICAO.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable.

Risk phrases: Not applicable.

Safety phrases: Not applicable.

15.2 Chemical safety assessment

Complete.

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 Bioaccumulative

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

Classification based on the main component.

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

Material Safety Data Sheet

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

ADEPS LANAE

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 25/08/2022

Revision: XX/XX/XXXX

Version: 00



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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