

LUBRICANT GEL FOR HEARING AIDS



SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2020/878)

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

1.1. Product identifier

Product name : LUBRICANT GEL FOR HEARING AIDS

UFI : DA00-V02V-P00J-TK0T

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

GI for ear canal.

Facilitates the fitting of earmolds and prevents skin irritations.

1.3. Details of the supplier of the safety data sheet

Registered company name : MG DEVELOPPEMENT.

Address : 178 rue Negue-Cat - ZAC « Les Portes de l'aéroport ».34130.MAUGUIO.France.

Telephone : +33 (0)4 67 42 95 24. Fax : +33 (0)4 67 42 88 23.

E-mail : contact@mg-dev.fr

<http://www.mg-dev.com>

1.4. Emergency telephone number : +33 (0)1 45 42 59 59.

Association/Organisation : INRS / ORFILA <http://www.centres-antipoison.net>.

Other emergency numbers

MG Développement : +33 (0)4 67 42 95 24 (8h30 - 18h)

National Poisons Information Service of England: <http://npis.org> - NHS 111: dial 111 - National Poisons Information Centre of Ireland: 353 (1) 809 2166 - LUXEMBOURG : (+352) 8002 5500 - European Emergency Number Association (EENA) : 112

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Serious eye damage, Category 1 (Eye Dam. 1, H318).

Hazardous to the aquatic environment - Chronic hazard, Category 3 (Aquatic Chronic 3, H412).

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

2.2. Label elements

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms :



GHS05

Signal Word :

DANGER

Product identifiers :

EC 500-017-8 OCTADECAN-1-OL, ETHOXYLATED

Hazard statements :

H318 Causes serious eye damage.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements - General :

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

Precautionary statements - Prevention :

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statements - Response :

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

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Precautionary statements - Disposal :

P501

Dispose of contents/container at a disposal facility in accordance with local regulations.

2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) $\geq 0.1\%$ published by the European Chemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>

The mixture fulfils neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

The mixture does not contain substances $\geq 0.1\%$ with endocrine disrupting properties in accordance with the criteria of the Delegated Regulation (EU) 2017/2100 of the Commission or Regulation (EU) 2018/605 of the Commission.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS**3.2. Mixtures****Composition :**

Identification	(EC) 1272/2008	Note	%
CAS: 9005-00-9 EC: 500-017-8 OCTADECAN-1-OL, ETHOXYLATED	GHS05, GHS09 Dgr Eye Dam. 1, H318 Aquatic Chronic 2, H411 Aquatic Acute 1, H400 M Acute = 1		2.5 $\leq$ x % < 10
CAS: 56-81-5 EC: 200-289-5 GLYCERINE		[1]	2.5 $\leq$ x % < 10

Specific concentration limits:

Identification	Specific concentration limits	ATE
CAS: 56-81-5 EC: 200-289-5 GLYCERINE		oral: ATE = 12600 mg/kg BW

Information on ingredients :

(Full text of H-phrases: see section 16)

[1] Substance for which maximum workplace exposure limits are available.

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

4.1. description of first aid measures**In the event of splashes or contact with eyes :**

Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.

Regardless of the initial state, refer the patient to an ophthalmologist and show him the label.

In the event of splashes or contact with skin :

Wash the skin thoroughly with soap and water or a recognised cleaner.

In the event of swallowing :

Seek medical attention, showing the label.

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

No data available.

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

No data available.

SECTION 5 : FIREFIGHTING MEASURES

Non-flammable.

5.1. Extinguishing media

No data available.

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

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In the event of a fire, the following may be formed :

- carbon monoxide (CO)
- carbon dioxide (CO₂)

5.3. Advice for firefighters

No data available.

SECTION 6 : ACCIDENTAL RELEASE MEASURES**6.1. Personal precautions, protective equipment and emergency procedures**

Consult the safety measures listed under headings 7 and 8.

For non first aid worker

Avoid any contact with the skin and eyes.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

6.2. Environmental precautions

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Clean preferably with a detergent, do not use solvents.

6.4. Reference to other sections

No data available.

SECTION 7 : HANDLING AND STORAGE

Requirements relating to storage premises apply to all facilities where the mixture is handled.

7.1. Precautions for safe handling

Always wash hands after handling.

Remove and wash contaminated clothing before re-using.

Emergency showers and eye wash stations will be required in facilities where the mixture is handled constantly.

Fire prevention :

Prevent access by unauthorised personnel.

Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Avoid eye contact with this mixture at all times.

Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the mixture is used.

7.2. Conditions for safe storage, including any incompatibilities

No data available.

Storage

Keep out of reach of children.

Packaging

Always keep in packaging made of an identical material to the original.

7.3. Specific end use(s)

No data available.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Control parameters****Occupational exposure limits :**

- ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values, 2010) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
56-81-5	10 mg/m ³				

- Germany - AGW (BAuA - TRGS 900, 08/08/2019) :

CAS	VME :	VME :	Excess	Notes
56-81-5		200 E mg/m ³		2 (I)

- Australia (NOHSC: 3008, 1995) :

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CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
56-81-5	10 mg/m ³			H	

- Belgium (Arrêté du 19/11/2020) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
56-81-5	10 mg/m ³				

- France (INRS - ED984 / 2020-1546) :

CAS	VME-ppm :	VME-mg/m ³ :	VLE-ppm :	VLE-mg/m ³ :	Notes :	TMP No :
56-81-5	-	10	-	-	-	-

- Switzerland (SUVA PRO 2019) :

CAS	VME	VLE	Valeur plafond	Notations
56-81-5	50 ppm	100 ppm		

- UK / WEL (Workplace exposure limits, EH40/2005, Fourth Edition 2020) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
56-81-5	10 mg/m ³				

- USA / OSHA PEL (Occupational Safety and Health Administration, Permissible Exposure Limits) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
56-81-5	15 mg/m ³				

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE) :



Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

- Eye / face protection

Avoid contact with eyes.

Use eye protectors designed to protect against liquid splashes

Before handling, wear safety goggles with protective sides accordance with standard EN166.

In the event of high danger, protect the face with a face shield.

Prescription glasses are not considered as protection.

Individuals wearing contact lenses should wear prescription glasses during work where they may be exposed to irritant vapours.

Provide eyewash stations in facilities where the product is handled constantly.

- Hand protection

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN ISO 374-1.

Gloves must be selected according to the application and duration of use at the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question : other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.

Type of gloves recommended :

- Natural latex

- Nitrile rubber (butadiene-acrylonitrile copolymer rubber (NBR))

- PVC (polyvinyl chloride)

- Butyl Rubber (Isobutylene-isoprene copolymer)

- Body protection

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Physical state :

-

Viscous liquid.

In gel form.

Colour

Unspecified

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Odour

Odour threshold : Not stated.

Freezing point

Freezing point / Freezing range : Not stated.

Boiling point or initial boiling point and boiling range

Boiling point/boiling range : Not relevant.

Flammability

Flammability (solid, gas) : Not stated.

Lower and upper explosion limit

Explosive properties, lower explosivity limit (%) : Not stated.

Explosive properties, upper explosivity limit (%) : Not stated.

Flash point

Flash Point Interval : FP > 100°C.

Auto-ignition temperature

Self-ignition temperature : Not relevant.

Decomposition temperature

Decomposition point/decomposition range : Not relevant.

pH

pH (aqueous solution) : 6 - 6.5

pH : Not stated.

Neutral.

Kinematic viscosity

Viscosity : Not stated.

Solubility

Water solubility : Dilutable.

Fat solubility : Not stated.

Partition coefficient n-octanol/water (log value)

Partition coefficient: n-octanol/water : Not stated.

Vapour pressure

Vapour pressure (50°C) : Not relevant.

Density and/or relative density

Density : 0.98 - 1.02

Relative vapour density

Vapour density : Not stated.

9.2. Other information

No data available.

9.2.1. Information with regard to physical hazard classes

No data available.

9.2.2. Other safety characteristics

No data available.

SECTION 10 : STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Avoid :

- frost

- heat

10.5. Incompatible materials

Keep away from :

- strong oxidising agents

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- strong acids
- strong bases

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

- carbon monoxide (CO)
- carbon dioxide (CO₂)

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

May have irreversible effects on the eyes, such as tissue damage in the eye, or serious physical decay of sight, which is not fully reversible by the end of observation at 21 days.

Serious eye damage is typified by the destruction of cornea, persistent corneal opacity and iritis.

11.1.1. Substances

Acute toxicity :

GLYCERINE (CAS: 56-81-5)

Oral route : LD50 = 12600 mg/kg
Species : Rat

Dermal route : LD50 > 18700 mg/kg
Species : Rabbit

OCTADECAN-1-OL, ETHOXYLATED (CAS: 9005-00-9)

Oral route : LD50 > 5000 mg/kg
Species : Rat
OECD Guideline 401 (Acute Oral Toxicity)

Dermal route : LD50 > 2000 mg/kg

11.1.2. Mixture

No toxicological data available for the mixture.

11.2. Information on other hazards

Monograph(s) from the IARC (International Agency for Research on Cancer) :

CAS 102-71-6 : IARC Group 3 : The agent is not classifiable as to its carcinogenicity to humans.

SECTION 12 : ECOLOGICAL INFORMATION

Harmful to aquatic life with long lasting effects.

The product must not be allowed to run into drains or waterways.

12.1. Toxicity

12.1.1. Substances

GLYCERINE (CAS: 56-81-5)

Fish toxicity : LC50 > 5000 mg/l
Species : Carassius auratus
Duration of exposure : 96 h

Crustacean toxicity : EC50 > 10000 mg/l
Species : Daphnia magna
Duration of exposure : 48 h

Algae toxicity :

OCTADECAN-1-OL, ETHOXYLATED (CAS: 9005-00-9)

Fish toxicity : LC50 > 1 mg/l
Species : Pimephales promelas
Duration of exposure : 96 h

NOEC > 0.1 mg/l
Species : Pimephales promelas

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Crustacean toxicity : NOEC > 0.1 mg/l
Species : Daphnia magna

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

12.2.1. Substances

OCTADECAN-1-OL, ETHOXYLATED (CAS: 9005-00-9)

Biodegradability : Rapidly degradable.

GLYCERINE (CAS: 56-81-5)

Chemical oxygen demand :

DCO = 1.16 g/g

ISO 15705 (Determination of the chemical oxygen demand index (ST-COD) - Small-scale sealed-tube method)

Five-day biochemical oxygen demand :

DBO5 = 0.87

Biodegradability :

Rapidly degradable.
DBO5/DCO = 0.75

12.3. Bioaccumulative potential

12.3.1. Substances

GLYCERINE (CAS: 56-81-5)

Octanol/water partition coefficient : log K_{ow} = -1.76

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Endocrine disrupting properties

No data available.

12.7. Other adverse effects

No data available.

German regulations concerning the classification of hazards for water (WGK, AwSV vom 18/04/2017, KBws) :

WGK 2 : Hazardous for water.

SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

SECTION 14 : TRANSPORT INFORMATION

Exempt from transport classification and labelling.

14.1. UN number or ID number

-

14.2. UN proper shipping name

-

14.3. Transport hazard class(es)

-

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14.4. Packing group

-

14.5. Environmental hazards

-

14.6. Special precautions for user

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SECTION 15: Regulatory information

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

- Classification and labelling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2021/643 (ATP 16)
- EU Regulation No. 1272/2008 amended by EU Regulation No. 2021/849 (ATP 17)

- Container information:

No data available.

- Particular provisions :

No data available.

- German regulations concerning the classification of hazards for water (WGK, AwSV vom 18/04/2017, KBws) :

WGK 2 : Hazardous for water.

15.2. Chemical safety assessment

No data available.

SECTION 16 : OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Wording of the phrases mentioned in section 3 :

H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

Abbreviations :

LD50 : The dose of a test substance resulting in 50% lethality in a given time period.
LC50 : The concentration of a test substance resulting in 50% lethality in a given period.
EC50 : The effective concentration of substance that causes 50% of the maximum response.
NOEC : The concentration with no observed effect.
REACH : Registration, Evaluation, Authorization and Restriction of Chemical Substances.
ATE : Acute Toxicity Estimate
BW : Body Weight
UFI : Unique formulation identifier.
STEL : Short-term exposure limit
TWA : Time Weighted Averages
TMP : French Occupational Illness table
TLV : Threshold Limit Value (exposure)
AEV : Average Exposure Value.
ADR : European agreement concerning the international carriage of dangerous goods by Road.
IMDG : International Maritime Dangerous Goods.
IATA : International Air Transport Association.
ICAO : International Civil Aviation Organisation
RID : Regulations concerning the International carriage of Dangerous goods by rail.
WGK : Wassergefährdungsklasse (Water Hazard Class).
GHS05 : Corrosion
PBT: Persistent, bioaccumulable and toxic.
vPvB : Very persistent, very bioaccumulable.
SVHC : Substances of very high concern.