

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 : EAR SPRAY ODINELL WITHOUT GAS UFI : 5X00-D0WN-U000-FY38

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

Hygiene of the external auditory canal.

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.

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

This mixture does not present a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

2.2. Label elements

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

No labelling requirements for this mixture.

2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) >= 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> = 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: 56-81-5		[1]	1 <= x % < 2.5
EC: 200-289-5			
REACH: 01-2119471987-18			
GLYCEROL			

Information on ingredients :

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

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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 exposure by inhalation :

If inhaled, move the patient into the fresh air and keep warm and at rest.

In the event of splashes or contact with eyes :

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

If there is any redness, pain or visual impairment, consult an ophthalmologist.

In the event of splashes or contact with skin :

Remove contaminated clothing and 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.

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 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.

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.

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) :

						7
CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :	4
56-81-5	10 mg/m3					
- Germany - AG	W (BAuA - TRGS	5 900, 08/08/201	9):		_	
CAS	VME :	VME :	Excess	Notes]	
56-81-5		200 E mg/m ³		2 (I)		
- Australia (NO	HSC: 3008, 1995)	:				
CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :	
56-81-5	10 mg/m3			Η		
- Belgium (Arrê	té du 19/11/2020)	:				_
CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :]
56-81-5	10 mg/m ³					
- France (INRS	- ED984 / 2020-15	546) :				-
CAS	VME-ppm :	VME-mg/m3	: VLE-ppm :	VLE-mg/m3:	Notes :	TMP No
56-81-5	-	10	-	-	-	-
- Switzerland (S	UVAPRO 2019) :					
CAS	VME	VLE	Valeur plafond	Notations]	
56-81-5	50 ppm	100 ppm				
- UK / WEL (W	orkplace exposure		05, Fourth Editi	on 2020) :	_	
CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :]
56-81-5	10 mg/m ³					
- USA / OSHA	PEL (Occupational	l Safety and Hea	lth Administrati	on, Permissible	Exposure Limit	ts) :
CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :	
56-81-5	15 mg/m3				1	1

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 in accordance with standard EN166.

- Hand protection

Wear suitable protective gloves in the event of prolonged or repeated skin contact.

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

SECTION 9.1 III SICAL AND CHEWICAL I KOI EKTIES	
9.1. Information on basic physical and chemical properties	
Physical state	
Physical state :	Fluid liquid.
Colour	
Unspecified	
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 :	Not relevant.
Auto-ignition temperature	
Self-ignition temperature :	Not relevant.
Decomposition temperature	
Decomposition point/decomposition range :	Not relevant.
pH	
pH (aqueous solution) :	Not stated.
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 :	< 1
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.	

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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

10.5. Incompatible materials

Keep away from :

- acids

- oxidising agents

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

No data available.

11.1.1. Substances

No toxicological data available for the substances.

11.1.2. Mixture

No toxicological data available for the mixture.

11.2. Information on other hazards

SECTION 12 : ECOLOGICAL INFORMATION

12.1. Toxicity

12.1.2. Mixtures

12.2. Persistence and degradability

12.2.2. Mixtures

12.3. Bioaccumulative potential

No data available.

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 1 : Slightly 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)
- 14.4. Packing group

14.5. Environmental hazards

14.6. Special precautions for user

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 1 : Slightly hazardous for water.

- Swiss ordinance on the incentive tax on volatile organic compounds : 99-87-6 p-cymène

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.

Abbreviations :

REACH : Registration, Evaluation, Authorization and Restriction of Chemical Substances.

UFI : Unique formulation identifier.

STEL : Short-term exposure limit

TWA : Time Weighted Averages

- TMP : French Occupational Illness table
- TLV : Threshold Limit Value (exposure)

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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 : Wassergefahrdungsklasse (Water Hazard Class).

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.