

MEDICAL DEVICE

SAFETY DATA SHEET

Product name:
PoloDent Orange Solvent Liquid

POLO MB OISTERWIJK BV

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

1.1 Product identifier

Product name: PoloDent® Orange Solvent Liquid
Article number: 16 92 00

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

Use of substance/mixture: Professional use: Orange Solvent Liquid is a skin preserving cleaning solution for the careful removal of plaster and sticking arrears, gypsum, zinc eugenol pastes, alginate and cement remainders on the skin, lacquer and/or plastic-coated surfaces.

1.3 Details of the supplier of the safety data sheet

Company: Polo MB Oisterwijk BV
Laarakkerweg 5
5061 JR Oisterwijk
The Netherlands
www.polodent.com

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]:

Flam.Liq.3: H226
Asp.Tox.1: H304
Aquatic Acute 1: H400
Aquatic Chronic 1: H410
Skin Irrit.2: H315
Skin Sens.1:H317

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]:

Hazard pictograms:



GHS02: Flame
GHS08: Health hazard
GHS09: Environment
GHS07: Exclamation mark

Signal word: Danger

Hazardous components for labeling: Alcohol C9-C16, Ethoxylated
N,N-Didecyl-N-methyl-Poly (oxyethyl) ammonium propionate
N,N-Bis(3-Aminopropyl)-dodecylamine
Cocospropylendiamine-1,5-bis-Guanidinoacetate

Hazard statements: H226 - Flammable liquid and vapour.
H304 - May be fatal if swallowed and enters airways.
H410 - Very toxic to aquatic life with long lasting effects.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.

Precautionary statements: P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241 - Use explosion-proof electrical/ventilating/lighting equipment.
P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P273 - Avoid release to the environment.
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor.
P331 - Do NOT induce vomiting.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local / regional / national / international regulations.

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SECTION 2 (continued): Hazards identification

2.3 Other hazards

PBT/vPvB: This product is not identified as a PBT/vPvB substance.

SECTION 3: Composition/information on ingredients

3.1 Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Hazardous ingredients:

Chemical Name	EINECS No.	CAS No.	PBT / WEL	Percent	Classification (CLP)
FRACTION OF ORANGE, SWEET, EXTRACT	232-433-8	8028-48-6	-	-	-

SECTION 4: First aid measures

4.1 Description of first aid measures

General information: Remove contaminated clothing immediately.

Skin contact: Wash immediately with soap and water and rinse thoroughly. Consult a doctor if skin irritation persists.

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. If symptoms persist, consult a physician.

Ingestion: Rinse mouth and drink plenty of water and fresh air. Immediately call a POISON CENTER or doctor / physician. DO NOT INDUCE VOMITING - Danger of aspiration! Seek immediate medical advice.

Inhalation: Fresh air supply, respiratory donation, if necessary. If symptoms persist, consult a physician. In case of unconsciousness place and transport in stable sideways position.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

Hazards: If swallowed with subsequent vomiting, aspiration into the lungs may occur, which can lead to chemical pneumonia or asphyxiation.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam

Extinguishing media which must not be used for safety reasons: Water in full beam.

5.2 Special hazards arising from the substance or mixture

Can form explosive vapor-air mixtures. Carbon monoxide (CO) and carbon dioxide (CO₂). Under certain fire conditions traces of other toxic substances can not be excluded.

5.3 Advice for firefighters

Special protective equipment: Wear self-contained breathing apparatus.

More information: Cool endangered containers with water spray. Fire residues and contaminated firefighting water must be disposed of in accordance with official regulations. If possible, remove containers from the hazardous area without risk.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Ensure adequate ventilation. Wear personal protective clothing. Keep ignition sources away. Do not breathe fumes. Avoid contact with eyes and skin.

6.2 Environmental precautions

Environmental precautions: Do not discharge into the drains or waterways. Inform respective authorities when entering in waters or the sewerage.

6.3 Methods and material for containment and cleaning up

Clean-up procedures: Ensure adequate ventilation. Absorb with liquid-binding material (sand, kieselguhr, universal binder). Dispose of contaminated material as waste according to item 13.

6.4 Reference to other sections

Reference to other sections: For information on safe handling see Section 7.
 For waste disposal see Section 13.
 For personal protection see Section 8.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Handling requirements: Ensure good ventilation / exhaustion at workplace. Store in a well-closed container in a cool, dry place. Protect from heat and direct sunlight. Use and open container with care. Avoid aerosol formation. Do not breathe aerosol mist. Do not breathe fumes. Avoid contact with eyes and skin.

Information about fire and explosion protection: Vapors may form an explosive mixture with air. In the emptied container, ignitable mixtures can form. Keep ignition sources away - Do not smoke. Take precautionary measures against electrostatic charging.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and containers: Store in the original container. Observe water regulations. Observe regulations for the storage of flammable liquids.

Storage instructions: Keep away from food, drink and animal feeding stuffs. Keep away from oxidizing agents. Observe regulations for the storage of flammable liquids.

Further information on storage conditions: Keep container tightly closed. Store in a cool, dry place. Keep container in a well-ventilated place. Protect from heat and direct sunlight. Recommended storage temperature: 4°C.

Storage class: Classification according to company safety regulations (BetrSichV): Flammable.

7.3 Specific end use(s)

Specific end use(s): No further relevant information available.

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SECTION 8: Exposure controls / personal protection

8.2 Exposure controls

Additional information about design of technical facilities:	No further data; see item 7.
Components with occupational exposure limits to be monitored:	Void
Additional information:	The lists valid during the making were used as basis.
General protection and hygiene measures:	Keep away from food, drink and animal feed. Take off dirty, soaked clothes immediately. Do not breathe gas / fumes / aerosols. Avoid contact with eyes and skin. Do not eat, drink or smoke at work. Wash hands before breaks and after work.
Hand protection:	Gloves - Resistant to solvents.
- Material of gloves	The glove material must be impermeable and resistant to the product / the substance / the preparation. Due to missing tests, no recommendation can be given for the glove material for the product / the preparation / the chemical mixture. Selection of the glove material taking into account breakthrough times, permeation rates and degradation. Glove material: The choice of a suitable glove depends not only on the material, but also on other quality features and varies from manufacturer to manufacturer.
- Penetration time of glove material	The exact break-through time has to be found out by the manufacturer of the protective glove.
Eye protection:	Safety glasses.
Skin protection:	Protective clothing.
Respiratory protection:	Not required for room ventilation.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

State:	Liquid
Colour:	Colourless to yellowish.
Odour:	Characteristic
Melting point/freezing point:	Undetermined
Initial boiling point and boiling range:	160°C
Flash point:	46-50°C
Self-inflammability:	The product is not self-igniting.
Risk of explosion:	The product is not explosive, but formation of explosive / ignitable vapor / air mixtures is possible.
Explosion limits:	
- Lower	No data available.
- Upper	No data available.
Density at 20°C:	0.846 g/cm ³
Solubility in / miscibility with water:	Slightly soluble.
Viscosity, kinematic at 40 ° C:	<7 mm ² /s

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SECTION 10: Stability and reactivity

10.2 Chemical stability

**Thermal decomposition /
 conditions to be avoided:**

Keep ignition sources away, heat, take measures against electrostatic charges.

10.3 Possibility of hazardous reactions

Hazardous reactions:

Formation of ignitable vapor-air mixtures possible. Uncleaned empty containers may contain product gases that form explosive mixtures with air.

10.4 Conditions to avoid

Conditions to avoid:

No further relevant information available.

10.5 Incompatible materials

Materials to avoid:

Strong oxidising agents.

10.6 Hazardous decomposition products

Haz. decomp. products:

Carbon monoxide (CO) and carbon dioxide (CO₂).

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity:

ORANGE, SWEET, EXTRACT

DERMAL	RABBIT	LD50	2000 mg/kg
ORL	RAT	LD50	4400 mg/kg

Primary irritation to the skin:

Irritates the skin and mucous membrane.

Primary irritation to the eyes:

Short-term, reversible irritation.

Sensitization:

May cause sensitization by skin contact.

CMR effects (carcinogenic, mutagenic and toxic for reproduction):

According to current knowledge, no CMR effects are known.

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SECTION 12: Ecological information

12.1 Ecotoxic effects

Remark: Very toxic to fish and aquatic organisms.

General information: Do not allow product to reach ground water, water course or sewage system.
 Water hazard class 1 (self-classification according to VvWwS): slightly water endangering.
 Avoid entering the environment.

12.2 Persistence and degradability

Persistence and degradability: No further relevant information available.

12.3 Bioaccumulative potential

Bioaccumulative potential: No further relevant information available.

12.4 Mobility in soil

Mobility in soil: No further relevant information available.

12.5 Results of PBT and vPvB assessment

Results of PBT and vPvB assessment: This product does not contain any PBT or VPvB substances.

12.6 Other adverse effects

Other adverse effects: No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Disposal operations: Contact a licensed waste disposal company. Dispose of as special waste in compliance with local and national regulations. For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used. Empty containers can be sent to landfill after cleaning, if in compliance with local and national regulations.

SECTION 14: Transport information

14.1 UN number

UN number: UN2319

14.2 UN proper shipping name

- ADR TERPENCARBON WATER MATERIALS, N.A.G. (Orangeterpenes), ENVIRONMENTALLY HARMFUL
 - IMDG TERPENE HYDROCARBONS, N.O.S. (Orange, sweet, extract), MARINE POLLUTANT
 - IATA TERPENE HYDROCARBONS, N.O.S. (Orange, sweet, extract)

14.3 Transport hazard class(es)

Transport class: 3 Flammable liquids

14.4 Packing group

Packing group: III

14.5 Environmental hazards

Environmentally hazardous: Environmentally hazardous substance, liquid; Marine Pollutant

Marine pollutant: Yes; Symbol (fish and tree)

Special labeling (ADR): Symbol (fish and tree)

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SECTION 14 (continued): Transport information

14.6 Special precautions for user

Caution: Flammable liquids
Kemler Number: 30
EmS Code: F-E S-D

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

Not applicable.

ADR:
 - Released quantity (EQ) E1
 - Limited quantity (LQ) 5L
 - Transport category 3
 - Tunnel Category (D/E)

UN "Model Regulation": TERPENCARBON WATER MATERIALS, N.A.G. (Orangeterpenes), ENVIRONMENTALLY HARMFUL, 3, III

SECTION 15: Regulatory information

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

Specific regulations: Not applicable.

15.2 Chemical safety assessment

Chemical safety assessment: A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

SECTION 16: Other information

16.1 Other information

Other information: This safety data sheet is prepared in accordance with Commission Regulation (EU) No 2015/830.

Abbreviations and acronyms: ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 IMDG: International Maritime Code for Dangerous Goods
 IATA: International Air Transport Association
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service (division of the American Chemical Society)

Legal disclaimer: The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy, reliability or completeness. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. It is the user's responsibility to satisfy him/herself as to the suitability of such information for his /her own particular use.