

SECTION 1. Product identification/preparation/company undertaking

1.1. Product identifier:

Product no.: 81840
Trade name: BISICO Gingiform
Trade number: 05400, 05410

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

No further relevant information available.

Application of the substance / the mixture:

Dental-product

1.3. Details of the supplier of the safety data sheet:

BISICO Bielefelder Dentalsilicone GmbH & Co. KG
 Johanneswerkstraße 3
 D-33611 Bielefeld
 Tel.: +49 521 8016800
 Fax: +49 521 8016801
 Email: info@Bisico.de
 responsible for the Safety Data Sheet: Sebastian Zimmermann

1.4. Emergency telephone number:

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 Tel.: +49 521 8016800 (08:00-16:00 PM)
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 S. Zimmermann

SECTION 2. Hazards identification

2.1 Classification of the substance or mixture:

2.1.1 Classification according to Regulation (EC) 1272/2008: void

2.1.2. 67/548/EEC and 1999/45/EC Directives and following amendments and adjustments:

The product does not have to be labeled due to the calculation procedure of the „General classification guideline for preparations of the EU“ in the latest valid version.

2.2 Label elements: -

Labeling according to Regulation (EC) 1272/2008: -

Labeling according to EU guidelines:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body; are exempted from the provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

2.3. Other hazards:**Results of PBT and vPvB assessment:**

PBT: not applicable

vPvB: not applicable

SECTION 3. Composition/Information of Ingredients**3.1. Substances:****3.2. Mixtures:****Chemical characterization:****Description:**

mixture of polydimethyl polymethyl vinyl siloxane, polydimethyl polymethyl hydrogen siloxane and silica

Hazardous components: none**SECTION 4. First-aid measures****4.1. Description of first aid measures:****General information:**

no special measures required

after skin contact:

wash with plenty of water and soap

after eye contact:

rinse with plenty of water and consult a doctor

after swallowing:

If symptoms persist consult a doctor

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

Information not available

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

Information not available

SECTION 5. Fire fighting measures**5.1 Extinguishing media:** CO₂, water**5.2. Special hazards arising from the substance or mixture:**

For more information see chapter 10 "stability and reactivity"

5.3. Advice for firefighters:**Protective equipment:**

no special measures required

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures:

not required

6.2. Environmental precautions:

no special measures required

6.3. Methods and material for containment and cleaning up:

pick up mechanically

Additional information:

-

6.4. Reference to other sections:

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment

See Section 13 for disposal information

SECTION 7. Handling and storage

7.1. Precautions for safe handling:

Information for safe handling:

For dental use only. No special measures required

Recommendation for fire and explosion protection:

No special measures required

7.2. Conditions for safe storage, including any incompatibilities:

Storage:

Requirements at storerooms and containers:

No special measures required

Requirements for storage with other products:

not required

Further information on storage conditions:

none

7.3. Specific end use(s):

No further relevant information available

SECTION 8. Exposure controls/personal protection

8.1. Control parameters:

Components with limits of values to be supervised at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace

Additional information:

The lists valid during the making were used as basis.

8.2. Exposure controls:

Personal protective equipment:

-

General measures of protection and hygiene:

normal hygienic measures

Respiratory protection:

not required

Protection of hands:

not required

Eye protection:

not absolute required

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Appearance:

Form: Paste
Color: Gum colored
Odor: odorless

Value Unit Method

Information on change in the physical state

Melting point/melting range: n.a. °C

Boiling point/boiling range: n.a. °C

Flash point: n.a. °C

Autoignition temperature: n.a.

Danger of explosion: none

Density: 1,40 (20°C) g/cm³

Vapor pressure: n.a. mbar

Viscosity: Paste

pH: neutral

Solubility in/miscibility with: Partially soluble in toluene, petrol ether

Water: insoluble

Content of solvents: none

Organic solvents: -

Water: -

Content of solids: n.a.

9.2. Other information: no information available

SECTION 10. Stability and reactivity

10.1. Reactivity:

10.2. Chemical stability:

Conditions to avoid:

No decomposition if used according to specification

10.3. Possibility of hazardous reactions:

10.4. Conditions to avoid:

10.5. Incompatible materials:

10.6. Hazardous decomposition products: none

SECTION 11. Toxicological information

11.1. Information on toxicological effects:

Acute toxicity: -
Primary irritation: -
skin: no irritating effect
eye: no irritating effect

Additional toxicological information:

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

SECTION 12. Ecological information

12.1. Toxicity: Information not available.
12.2. Persistence and degradability: Information not available.
12.3. Bioaccumulative potential: Information not available.
12.4. Mobility in soil: Information not available.
12.5. Results of PBT and vPvB assessment: **PBT:** not applicable
vPvB: not applicable

12.6. Other adverse effects:

Classification of water endangerment:

WGK 1 (German regulation): slightly hazardous for water

SECTION 13. Disposal consideration

13.1. Waste treatment methods:

Product:

Recommendation:

Small quantities can be disposed of with household waste.

Use proper landfill disposal or incineration in accordance with local, state and federal regulations

Uncleaned packaging:

Recommendation:

Disposal must be made according to official regulations.

SECTION 14. Transport information

14.1 UN-Number ADR, ADN, IMDG, IATA:	Void
14.2 UN proper shipping name ADR, ADN, IMDG, IATA:	Void
14.3 Transport hazard class(es) ADR, ADN, IMDG, IATA Class:	Void
14.4 Packing group ADR, IMDG, IATA:	Void
14.5 Environmental hazards Marine pollutant:	No
14.6 Special precautions for user:	Not applicable.
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:	Not applicable.
UN "Model Regulation":	-

SECTION 15. Regulatory information

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

Classification according to EC-guidelines:

The product is a medical device according to EC-directive 93/42 EEC.

15.2. Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

SECTION 16. Other information:

Changes compared with the previous version: Adaptation according to 1907/2006/EG, Article 31

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.

Preparation by:

S. Zimmermann

Tel.: +49 521 8016800

SECTION 1. Product identification/preparation/company undertaking**1.1 Product identifier**

Product no.: 81850
Product name: BISICO Gingiform Separator
Trade number: 05400, 05410

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

No further relevant information available.

Application of the substance / the mixture:

Separating Agent

1.3. Details of the supplier of the safety data sheet:

BISICO Bielefelder Dentsilicone GmbH & Co. KG
Johanneswerkstraße 3
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Email: info@Bisico.de
responsible for the Safety Data Sheet: Sebastian Zimmermann

1.4. Emergency telephone number:

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SECTION 2. Hazards identification**2.1 Classification of the substance or mixture:****2.1.1 Classification according to Regulation (EC) No 1272/2008:**

Flam. Liq. 1, H224 Extremely flammable liquid and vapor
Repr. 2; H361f; Suspected of damaging fertility or the unborn child
STOT RE 2; H373 May cause damage to organs through prolonged or repeated exposure.
Asp. 1; H304 May be fatal if swallowed and enter airways
Skin Irrit. 2, H315 Causes skin irritation
STOT SE 3; H336 May cause drowsiness or dizziness
Aquatic Chronic 2, H411 Toxic to aquatic life with long lasting effects

2.1.2 Information concerning particular hazards for human and environment:

The product has to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

2.2 Label elements**Labeling according to Regulation (EC) 1272/2008:****Hazard pictograms****Signal word**

Danger

Hazard statements

H224 Extremely flammable liquid and vapor
 H361f; Suspected of damaging fertility or the unborn child
 H373 May cause damage to organs through prolonged or repeated exposure.
 H304 May be fatal if swallowed and enter airways
 H315 Causes skin irritation
 H336 May cause drowsiness or dizziness
 H411 Toxic to aquatic life with long lasting effects

Precautionary statements

P301 + P310 IF SWALLOWED: immediately call a POISON CENTER or doctor/physician
 P331 Do NOT induce vomiting
 P403 Store in a well-ventilated place.
 P210 Keep away from heat/sparks/open flames/hot surfaces. – No smoking.
 P260 Do not breathe dust/fume/gas/mist/vapors/spray
 P281 Use personal protective equipment as required.
 P271 Use only outdoors or in well ventilated areas.

Reduced labeling (≤ 125 ml)

Hazard pictograms

**Signal word**

Danger

Hazard statements

H224 Extremely flammable liquid and vapor
 H304 May be fatal if swallowed and enter airways
 H361f; Suspected of damaging fertility or the unborn child

Precautionary statements

P301 + P310 IF SWALLOWED: immediately call a POISON CENTER or doctor/physician
 P331 Do NOT induce vomiting

2.3 Other hazards**Results of PBT and vPvB assessment**

PBT: not applicable

vPvB: not applicable

SECTION 3. Composition/Information of Ingredients**3.1 Substances:**

not applicable

3.2 Mixtures:**Description:**

Solution of paraffines in hexane

Hazardous components:

CAS 110-54-3; EG 203-777-6	n-hexane	GHS02, GHS07, GHS08, GHS09 H225, H361f, H304, H373, H315, H3396, H411
CAS 75-28-5; EG 200-857-2	isobutane	GHS02, H224
CAS 74-98-6; EG 200-827-9	propane	GHS02, H224

SECTION 4. First-aid measures**4.1 Description of first aid measures:**

General information: Seek medical advice, if symptoms occur, which can be caused by the product

after skin contact: Wash off with plenty of water and soap and rinse thoroughly.

After inhalation: Fresh air. Consult a physician..

After eye contact: Rinse opened eye for several minutes under running water and consult an ophthalmologist..

After swallowing: Rinse out mouth and then drink plenty of water. Caution if victim vomits. Risk of aspiration! Keep airways free. Call a physician immediately.

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

Information not available

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

Information not available

SECTION 5. Fire fighting measures**5.1 Extinguishing media:**

CO₂, powder, sand. Do not use water.

5.2 Special hazards arising from the substance or mixture:

No further relevant information available

5.3 Advice for firefighters:

Protective equipment Wear self-contained respiratory protective equipment

SECTION 6. Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures:**

Do not inhale vapors/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms. Keep away from ignition sources.

6.2 Environmental precautions:

Do not allow to enter drains/surface water/ ground-water.

6.3 Methods for cleaning up:

Absorb with liquid binding material. Forward for disposal. Clean up affected area.

6.4 Reference to other sections:

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment

See Section 13 for disposal information

SECTION 7. Handling and storage**Handling:**

This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

7.1 Precautions for safe handling: Observe normal care for working with chemicals. Keep containers closed. Use only in well ventilated areas. Do not inhale substance. Keep away from heat and direct sunlight.

Information about fire and explosion protection: Keep away from heat and ignition sources, do not smoke. Do not spray on flames or red-hot objects.
Beware: Container is pressurized. Keep away from direct sun exposure and temperatures over 50°C. Do not open by force or throw into fire even after use.

7.2. Conditions for safe storage, including any incompatibilities:

Storage: Store at a cool and dry place. Store tightly closed. Storage temperature 15-25°C (60-80°F).

Requirements at storerooms and containers: Store only in the original containers

Further information on storage conditions:

Store away from food stuffs.

Heat will increase pressure and may lead to the container exploding. Protect from heat and direct sunlight.

7.3. Specific end use(s):

No further relevant information available

SECTION 8. Exposure controls/personal protection**8.1. Control parameters:**

Components with limits of values to be supervised at the workplace:

<u>CAS-No.</u>	<u>name</u>	<u>art</u>	<u>value</u>	<u>unit</u>
[110-54-3]	n-hexane	MAK	50 ml/m ³ , 180mg/m ³	
[75-28-5]	isobutane	MAK	1000 ml/m ³ , 2400mg/m ³	
[74-98-6]	propane	MAK	1000 ml/m ³ , 1800mg/m ³	

Additional information: The lists valid during the making were used as basis

8.2. Exposure controls:**Personal protective equipment:****General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals. Keep away from foodstuffs and beverages. Do not inhale gases/fumes/aerosols.

Hand protection

Protective gloves.

Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection: safety glasses

Respiratory protection: Required, when vapors/aerosols are generated.

SECTION 9. Physical and chemical properties**Information on basic physical and chemical properties****Appearance**

Form:	liquid
Color:	colorless
Odor:	characteristic
	<u>Value Unit Method</u>

Safety relevant basic data

Melting point/melting range:	n.a.
Boiling point/boiling range:	n.d.
Flash point:	ca. -40 °C
Ignition temperature:	Product is not selfigniting
Danger of explosion:	Product is not explosive. However, formation of explosive air/vapor mixtures is possible lower: 1,2 Vol%, upper 10,9 Vol%
Critical values for exposure	
Density:	0.60 (20 °C) g/cm ³
Vapor pressure:	n.a.
pH:	neutral
Solubility in/miscibility with:	miscible with most organic solvents; alcohols
Water:	insoluble
Content of solvents:	
Organic solvents:	n-hexane
9.2. Other information:	no information available

SECTION 10. Stability and reactivity**10.1. Reactivity:****10.2. Chemical stability:****10.3 Possibility of hazardous reactions:** no information available**10.4 Conditions to avoid:** Protect from heat and direct sunlight. Forms explosive gas mixture with air. Danger of containers bursting at temperatures >55°C because of high vapor pressure.**10.5 Incompatible materials:****10.6 Hazardous decomposition products:** No information available.**SECTION 11. Toxicological information****11.1. Information on toxicological effects:****Acute toxicity: (n-hexane)**

LD50 (oral, rat): 28710 mg/kg (n-hexane)

Primary irritation:**skin:** Irritating for skin and mucous membrane.**eye:** Slight irritations possible.**Sensitization:** No sensitizing effect known.**Additional toxicological information:**

If handled in accordance with good industrial hygiene and safety practice and according to specifications no health diseases are reported.

SECTION 12. Ecological information**General information:** Do not allow to enter drains/canalization/ground-water**12.1. Toxicity:** Information not available.**12.2. Persistence and degradability:** Information not available.**12.3. Bioaccumulative potential:** Information not available.**12.4. Mobility in soil:** Information not available.**12.5. Results of PBT and vPvB assessment:** **PBT:** not applicable
vPvB: not applicable**12.6. Other adverse effects:****Classification of water endangerment:** The product contains materials that are harmful for the environment. Toxic for aquatic organisms. WGK=2 (polluting substance).**SECTION 13. Disposal consideration****13.1. Waste treatment methods:****Product:****Recommendation:**

Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

Uncleaned packaging: Packaging that cannot be cleaned are to be disposed of in the same manner as the product.**Recommendation:** Disposal must be made according to official regulations**SECTION 14. Transport information****14.1 UN-Number ADR, ADN, IMDG, IATA:** 1950**14.2 UN proper shipping name ADR, ADN, IMDG, IATA:** AEROSOLS, flammable, 2.1**14.3 Transport hazard class(es) ADR, ADN, IMDG, IATA**
Class:**Land transport ADR/RID and GGVS/GGVE (Germany):**

UN 1950

AEROSOLS, flammable, 2.1

Sea transport IMDG:

UN 1950

AEROSOLS, flammable, 2.1

Air transport ICAO-TI and IATA-DGR:

UN 1950

AEROSOLS, flammable, 2.1

14.4 Packing group ADR, IMDG, IATA: 2.1**14.5 Environmental hazards Marine pollutant:** No**14.6 Special precautions for user:** -**14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** -
UN "Model Regulation":

The transport regulations are cited according to international regulations and in the form applicable in Germany. Possible national deviations in other countries are not considered.

SECTION 15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:****Classification according to EC-guidelines:**

The product has to be labelled according to EC-regulations or the corresponding national regulations.

15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

SECTION 16. Other information:

Changes compared with the previous version: Adaptation according to 1907/2006/EG, Article 31

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.

Preparation by:

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