# SECTION 1. Product identification/preparation/company undertaking

1.1 Product identifier:

Product no.: 83060, 83070, 83080, 83061

Trade name: BISICO Nanofill flow

Trade number: 74060, 74070, 74062, 74061

## 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-filling-material

# 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:

BISICO Bielefelder Dentalsilicone GmbH & Co. KG

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

Fax: +49 521 8016801 S. Zimmermann

# SECTION 2. Hazards identification

# 2.1 Classification of the substance or mixture:

# 2.1.1 Classification according to Regulation (EC) No 1272/2008:



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

# 2.2 Label elements:

# Labelling according to Regulation (EC) No 1272/2008:

The product is classified and labelled according to the CLP regulation.

Hazard pictograms: GHS07

Signal word: Warning

# Hazard-determining components of labelling:

tetramethylene dimethacrylate

## **Hazard statements:**

H317 May cause an allergic skin reaction.

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# Safety Data Sheet according to 1907/2006/EC, Article 31

# **Precautionary statements:**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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

P321 Specific treatment (see on this label).

P363 Wash contaminated clothing before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

# Labelling of packages where the contents do not exceed 125 ml:

Hazard pictograms: GHS07

Signal word: Warning

# Hazard-determining components of labelling:

tetramethylene dimethacrylate

#### **Hazard statements:**

H317 May cause an allergic skin reaction.

#### **Precautionary statements:**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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

P321 Specific treatment (see on this label).

P363 Wash contaminated clothing before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

### 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:

1,4-Butandioldimethacrylate Urethandimethacrylate Bis-GMA

#### **Dangerous components:**

CAS: 2082-81-7

tetramethylene dimethacrylate Skin Sens. 1B, H317

2.5-10%

EINECS: 218-218-1

**Additional information:** For the wording of the listed risk phrases refer to section 16.

### **SECTION 4. First-aid measures**

# 4.1 Description of first aid measures:

general information: No special measures required.

after inhalation: Supply fresh air; consult doctor in case of complaints.

after skin contact: Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

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**after eye contact:** Rinse opened eye for several minutes under running water.

Then consult a doctor.

**after swallowing:** Do not induce vomiting; call for medical help immediately.

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

No further relevant information available.

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

No further relevant information available.

# **SECTION 5. Fire fighting measures**

# 5.1 Extinguishing media:

Suitable extinguishing agents: Foam, Fire-extinguishing powder, Water haze, Carbon dioxide

For safety reasons unsuitable extinguishing agents: Water with full jet.

**5.2 Special hazards arising from the substance or mixture:** No further relevant information available.

# 5.3 Advice for firefighters:

Protective equipment: self-contained respiratory protective device.

## SECTION 6. Accidental release measures

# 6.1 Personal precautions, protective equipment and emergency procedures:

Not required.

# 6.2 Environmental precautions:

Do not allow to enter sewers/ surface or ground water.

# 6.3 Methods for cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

### 6.4 Reference to other sections:

No dangerous substances are released.

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:

Keep receptacles tightly sealed.

# Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

#### 7.2 Conditions for safe storage, including any incompatibilities:

#### Requirements to be met by storerooms and receptacles:

Close container immediately after use and protect product from light incidence.

Storage between 10 °C and 25 °C.

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Information about storage in	one common	storage f	acility:
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Store away from foodstuffs.

### Further information about storage conditions:

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:

# Additional information about design of technical facilities:

No further data; see item 7.

### Ingredients with limit values that require monitoring 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 protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

# Respiratory protection:

Not required.

Protection of hands: Protective gloves and protective skin cream.

# Material of gloves Butyl rubber, BR

# Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

# Eye/face protection:

Not required.

# SECTION 9. Physical and chemical properties

# 9.1. Information on basic physical and chemical properties:

Appearance:

Form: Viscous

Color: According to product specification

Odour: Weak, characteristic

Value Unit Method

pH-value: Not determined

Change in condition

Melting point/Melting range: undetermined

Boiling point/Boiling range: 251 °C

Flash point: 101 °C

Flammability (solid, gaseous): Not applicable.

Ignition temperature: 370 °C

**Decomposition temperature:** Not determined.

**Self-igniting:** Product is not selfigniting.

**Danger of explosion:** Product does not present an explosion hazard.

Explosion limits: not determined

Vapour pressure at 20 °C: not determined

Density at 20 °C: not determined

Relative density: Not determined.

Vapour density: Not determined.

**Density:** Not determined

Relative density Not determined.

Vapour density Not determined.

**Evaporation rate:** Not determined.

Solubility in / Miscibility with

Water at 20 °C: Not miscible or difficult to mix

Partition coefficient (n-octanol/water): Not determined.

Viscosity:

**dynamic:** Not determined **kinematic:** Not determined

Solvent content:

Organic solvents: 0,0 %

**9.2 Other information** No further relevant information available.

# SECTION 10. Stability and reactivity

# 10.1. Reactivity:

#### 10.2. Chemical stability:

### Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

# 10.3 Possibility of hazardous reactions:

Photoreactive

Danger of polymerization

#### 10.4 Conditions to avoid:

No further relevant information available.

# 10.5 Incompatible materials:

In presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.

#### 10.6 Hazardous decomposition products:

No dangerous decomposition products known

# SECTION 11. Toxicological information

#### 11.1. Information on toxicological effects:

# Acute toxicity:

# LD/LC50 values relevant for classification:

tetramethylene dimethacrylate LD-50 oral > 5000 mg/kg (rat)

### Primary irritant effect:

# Skin corrosion/irritation:

tetramethylene dimethacrylate not irritant effect Time: 24h Species: rabbit Method occlusive, FDA Draize

# Serious eye damage/irritation:

tetramethylene dimethacrylate not irritant effect Species: rabbit

Method OECD 405

**Respiratory or skin sensitisation:** Sensitisation possible through skin contact.

# CMR effects (carcinogenity, mutagenicity and toxicity for reproduction):

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT-single exposure: Based on available data, the classification criteria are not met.

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STOT-repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

## **SECTION 12. Ecological information**

12.1 Toxicity:

Acquatic toxicity: No further relevant information available.

**12.2 Persistence and degradability:**No further relevant information available.

**12.3 Bioaccumulative potential:** No further relevant information available.

**12.4 Mobility in soil:** No further relevant information available.

Additional ecological information:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water. Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

12.5 Results of PBT and vPvB assessment: PBT: Not applicable.

vPvB: Not applicable.

**12.6 Other adverse effects:** No further relevant information available.

## **SECTION 13. Disposal consideration**

### 13.1. Waste treatment methods:

#### **Product:**

# Recommendation:

Must be specially treated adhering to official regulations.

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

# European waste catalogue:

08 04 10 waste adhesives and sealants other than those mentioned in 08 04 09

# Uncleaned packaging:

# Recommendation:

Packagings that may not be cleansed are to be disposed of in the same manner as the product.

Recommended cleansing agents: Alcohol

#### 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

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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:

Directive 2012/18/EU:

Named dangerous substances - ANNEX I: None

None of the ingredients is listed.

**National regulations:** 

Technical instructions (air):

Class: III

Share in %: 2,5-10

Waterhazard class: Water hazard class 2 (Self-assessment): hazardous for water.

**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.

#### Relevant phrases:

H317 May cause an allergic skin reaction.

## 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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1 Skin Sens. 1B: Sensitisation - Skin, Hazard Category 1B

# Preparation by:

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