

GDT NANOCOMP NANOHYBRID COMPOSITE

Material safety data sheet (MSDS) Version 1.1 / EN

10/12/2020



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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE

1.1. Product identifier

Product Name Relevant GDT Nanocomp

identified uses Function Composite. Professional use.

or use category Dental materials.

1.2. Uses advised against:No additional information

available.

SECTION 2: DATA ON THE ORGANIZATION-MANUFACTURER OR THE SUPPLIER

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

Company-Name GDT Implants.

Company-Address Yitzhak Ben Zvi 9/64 Beer Sheva, Israel

Contact Yakir Solcman
Phone/Fax +972.54.77.90.282
E-mail info@gdt-Implants.com

2.2. Emergency telephone number:

Phone / Fax +972.54.77.90.282

SECTION 3: HAZARDS IDENTIFICATION

3.1. Classification of the substance ormixture.

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

 Skin Irrit. 2
 H315

 Eye Irrit. 2
 H319

 Skin Sens. 1
 H317

Full text of hazard classes and H-statements - see section 17.

3.2. Label elements.

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

Hazard pictograms (CLP):



GHS07

Signal word (CLP): Warning.



Hazardous ingredients:

7,7,9 (or 7,9,9)-trimethyl-4, 13-dioxo-3, 14-dioxa-5, 12-diazahexadecane-1, 16-diyl bismethacrylate

Hazard statements (CLP):

H315 - Causes skin irritation.

H317 – May cause an allergic skin reaction.

H319 – Causes serious eye irritation.

Precautionary statements (CLP):

P261- Avoid breathing vapours, fume, dust.

P280 – Wear protective gloves.

P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

P333+P313 – If skin irritation or rash occurs:

Get medical advice/attention.

P304+P340 – IF INHALED: remove victim to fresh air and keep at rest in a position comfortable for breathing.

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

P337+P313 – If eye irritation persists:

Get medical advice/attention.

P403+P233 - Store in a well-ventilated place.

Keep container tightly closed.

P405 – Store locked up.

P501 – Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Extra phrases:

The product is seen as a medical device and therefore not subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d).

3.3. Other hazards.

Other hazards not contributing to the classification:

None under normal conditions.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII. This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.



SECTION 4: COMPOSITION/INFORMATION ON INGREDIENTS

4.1. Substances: 4.2. Mixtures:

Not applicable.

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
1,6-Hexanediol dimethacrylate	(CAS No) 6606-59-3 (EC no) 229-551-7 (REACH-no) N/A	5-10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
7,7,9(or 7,9,9)-trimethyl-4, 13- dioxo-3,14-dioxa-5, 12- diazahexadecane-1, 16-diyl bismethacrylate	(CAS No) 72869-86-4 (EC no) 276-957-5 (REACH-no) 01-2119408252-52	5-10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335

Full text of H-statements: see section 17.

SECTION 5: FIRST AID MEASURES

5.1. Description of first aid measures.

First-aid measures general:

In all cases of doubt, or when symptoms persist, seek medical attention.

First-aid measures after inhalation:

Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention if you feel unwell.

First-aid measures after skin contact:

Gently wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

First-aid measures after eye contact:

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention if you feel unwell.

First-aid measures after ingestion:

If swallowed, rinse mouth with water (only if the person is conscious). Call a POISON CENTER or doctor/physician if you feel unwell.



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

Symptoms/injuries after skin Causes skin irritation. May cause an allergic skin

contact: Symptoms/injuries after eye reaction. Causes serious eye irritation.

contact:

5.3. Indication of any immediate medical attention and special treatment needed Treat symptomatically. In all cases of doubt, or when symptoms persist, seek medical attention.

SECTION 6: FIREFIGHTING MEASURES

6.1. Extinguishing media.

Suitable extinguishing media: Use extinguishing media appropriate for surrounding

fire.

Unsuitable extinguishing media: Foam, carbon dioxide (CO₂) and powder.

Do not use a heavy water stream.

6.2. Special hazards arising from the substance or mixture.

Fire hazard: Non flammable.

Explosion hazard: Product is not explosive.

Hazardous decomposition products in

case of fire: Carbon oxides (CO, CO₂). metallic oxide. Nitrogen oxides.

6.3. Advice for firefighters.

Firefighting instructions:

Use water spray or fog for cooling exposed containers.

Protection during firefighting:

Do not enter fire area without proper personal protective

equipment, including respiratory protection.

SECTION 7: ACCIDENTAL RELEASE MEASURES

7.1. Personal precautions, protective equipment and emergency procedures.

General measures:

Use personal protective equipment as required.

Avoid contact with skin and eyes. Do not breathe

vapour. Do not breathe dust.

For non-emergency personnel:

Protective equipment: See Heading 9.

Emergency procedures: Evacuate unnecessary personnel. For emergency responders: No additional information available.



7.2. Environmental precautions.

Avoid release to the environment.

7.3. Methods and material for containment and cleaning up.

For containment: Collect all waste in suitable and label led containers and

dispose according to local legislation.

Methods for cleaning up: Soak up spills with inert solids, such as clay or diatomaceous

earth as soon as possible. On land, sweep or shovel into suitable containers. This material and its container must be disposed of in a safe way, and as per local legislation.

7.4. Reference to other sections: For further information refer to section 13.

SECTION 8: HANDLING AND STORAGE

8.1. Precautions for safe handling.

Do not eat, drink or smoke when using this product.

Precautions for safe handling: Wear personal protective equipment.

Avoid contact with skin and eyes. Do not breathe dust.

Avoid dust formation. Do not breathe vapours.

Do not eat, drink or smoke when using this product.

Hygiene measures: Wash hands and other exposed areas with mild soap and water

before eating, drinking or smoking and when leaving work.

8.2. Conditions for safe storage, including any incompatibilities.

Storage conditions: Keep container tightly closed. Protect from sunlight.

Store in a well-ventilated place. Keep only in original

container. Keep cool. Protect from sunlight.

Incompatible materials: Reducing materials.

Oxidizing substances. Organic peroxides.

8.3. Specific end use(s).

Consult the supplier for further information. For professional use only.



SECTION 9: EXPOSURE CONTROLS/PERSONAL PROTECTION

9.1. Control parameters.

No additional information available.

9.2. Exposure controls.

Appropriate engineering controls: Ensure good ventilation of the work station.

Emergency eye wash fountains should be available in the

immediate vicinity of any potential exposure.

Personal protective equipment: Gloves.

Hand protection: Neoprene or nitrile rubber gloves.



Breakthrough time: 8 (> 480 minutes).

Layer thickness: 0,2-0,4 mm. STANDARD EN 374.

Eye protection: Use splash goggles when eye contact due to splashing is

possible. STANDARD EN 166.

Skin and body protection: Wear suitable protective clothing.

Respiratory protection:

No special respiratory protection equipment is

recommended under normal conditions of use with

adequate ventilation.

Other information:

Do not eat, drink or smoke during use.

SECTION 10: PHYSICAL AND CHEMICAL PROPERTIES

10.1. Information on basic physical and chemical properties

Physical state: Solid.
Appearance: Paste.
Color: Various.
Odour: Fruitv.

Odour No data available. threshold: pH: No data available.



Relative evaporation rate

No data available. (butylacetate=1): No data available. Melting point: No data available. Freezing point: No data available. Boiling point: No data available. Flash point: No data available. Auto-ignition temperature: No data available. Decomposition temperature: Flammability (solid, gas): No data available. No data available. Vapour pressure: Relative vapour density at 20 ° No data available. C: Relative density: No data available.

Density: 1.8-1.9 g/cm³. Insoluble in water.

Solubility: No data available.
Log Pow: No data available.
Viscosity, kinematic: No data available.

Viscosity, dynamic: Product is not explosive.

Explosive properties: Non flammable.

Oxidising properties: No data available.

Explosive limits:

10.2. Other information.

No additional information available.

SECTION 11: STABILITY AND REACTIVITY

11.1. Reactivity.

No data available.

11.2. Chemical stability.

Stable under normal conditions.

11.3. Possibility of hazardous reactions.

No polymerization.

11.4. Conditions to avoid.

Keep away from heat and direct sunlight.

11.5. Incompatible materials.

Oxidizing materials. reducing materials. Organic peroxides.

11.6. Hazardous decomposition products.

No decomposition if stored and used normally.



SECTION 12: TOXICOLOGICAL INFORMATION

12.1. Information on toxicological effects.

Acute toxicity: Not classified.

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/irritation: Causes serious eye irritation.

Respiratory or skin May cause an allergic skin reaction.

sensitisation: Germ cell

mutagenicity: Carcinogenicity:

Reproductive toxicity:

STOT-single exposure:

STOT-repeated exposure:

Aspiration hazard:

Not classified.

Not classified.

Not classified.

Not classified.

SECTION 13: ECOLOGICAL INFORMATION

13.1. Toxicity

Ecology – general: The product is not considered harmful to aquatic organisms nor

to cause long-term adverse effects in the environment.

13.2. Persistence and degradability.

Persistence and degradability: No data available.

7,7,9 (or 7,9,9)-trimethyl-4, 13-dioxo-3, 14-dioxa-5, 12-diazahexadecane-1, 16-diyl bismethacrylate

(72869-86-4)

Bio-degradation: 22 % (OECD 301F method).

13.3. Bio-accumulative potential.

Bio-accumulative potential: No data.

1,6-Hexanediol dimethacrylate (6606-59-3)

Bio-concentration factor (BCF REACH): 2.51

Log Pow: 4.17

7,7,9 (or 7,9,9)-trimethyl-4, 13-dioxo-3, 14-dioxa-5, 12-diazahexadecane-1, 16-diyl bismethacrylate

(72869-86-4)

Bio-concentration factor (BCF REACH): 1.91

Log Pow: 4.69

13.4. Mobility in soil

Ecology – soil: No data.

13.5. Results of PBT and vPvB assessment

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII. This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.



13.6. Other adverse effects

Other adverse effects:

Additional information:

None to our knowledge. No other effects known.

SECTION 14: DISPOSAL CONSIDERATIONS

14.1. Waste treatment methods

Regional legislation (waste): Dispose as hazardous waste.

Waste treatment methods: Recover the product with absorbent material.

Dispose of contents/container in accordance with

licensed collector's sorting instructions.

Waste disposal recommendations: Dispose of contents/container to a hazardous or

special waste collection point.

Ecology – waste materials: Avoid release to the environment.

European List of Waste (LoW) 18 01 06* – chemicals consisting of or containing

code: dangerous substances.

SECTION 15: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA /

ADN 15.1. UN number:Not regulated for transport.

15.2. UN proper shipping name.

15.3. Transport hazard class(es).

15.4. Packing group.

15.5. Environmental hazards:No supplementary information available.

14.6. Special precautions for user.

14.7. Transport in bulk according to

Annex II of MARPOL 73/78 and the IBC Code: Not applicable.



SECTION 16: REGULATORY INFORMATION

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

EU-Regulations:

Contains no REACH substances with Annex XVII restrictions. Contains no substance on the REACH candidate list. Contains no REACH Annex XIV substances.

National regulations:

EC-regulation 2015/830 /EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC.

Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO).

Workplace exposure limits.

16.2. Chemical safety assessment:

No chemical safety assessment has been carried out for the substance or the mixture by the supplier.

SECTION 17: OTHER INFORMATION

17.1. Data sources:

EC-regulation 2015/830 /EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC.

Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO).

Workplace exposure limits.

 Date of issue:
 15/04/2016.

 Revision date:
 10/12/2019.

 Supersedes:
 15/04/2016.

 Version:
 1.1.

Indication of changes: Updated section 1.3.

17.2. Full text of H- and EUH-statements:

Eye Irrit. 2 Serious eye damage/eye irritation, Category 2.

Skin Irrit. 2 Skin corrosion/irritation, Category 2. Skin Sens. Sensitisation — Skin, Category 1.

1 STOT SE Specific target organ toxicity — Single exposure, Category

3 3, Respiratory tract irritation.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

The information in this safety data sheet is based on information from the manufacturer/supplier, present European and national legislation, and presupposes that the product is used within the specified area of application.