

Safety data sheet according to Regulation (EU) 2020/878

Product designation: NOVOtray Liquids

Version: 2024-09-22 Replayed Version: 2021-11-08

Section 1: Identification of the substance/mixture and of the company

1.1 Product identifier

Substance name Trade name: NOVOtray Liquids
Article number starting: F10 / UDI 763029670010P

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

Relevant identified uses:

Mixture for the fabrication of prosthetic restorations

<u>Uses advised against:</u>

All applications that deviate from the identified use

1.3 Details of the supplier providing the safety data sheet

Manufacturer / Supplier

NOVODENT Ets.

Street/PO Box

Industriestrasse 32

Nat. no./Postal code/City

Liechtenstein - 9487 - Bendern

Contact point for technical information

NOVODENT Ets.

Phone / Fax / E-Mail

+423 377 1500 / -09 / E-Mail: msds@novodent.com

1.4 Emergency phone number

+423 377 1500 (Novodent Ets.)

+41 44 251 51 51 oder 145 (Tox-Zentrum)

Section 2: Potential hazards

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Skin.sens. H317, Eye irrit. H319, Skin irrit. H315, respiratory irrit. H335, Liq.2. H225

2.2 Labelling elements

Labelling elements according to Regulation (EC) No 1272/2008

Pictogram:





Signal word: Danger

Hazard-determining components for labelling

contains: Methylmethacrylat

Hazard information:



Safety data sheet according to Regulation (EU) 2020/878

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Version: 2024-09-22 Replayed Version: 2021-11-08

11215	Marriagna alda indestiga
H315	May cause skin irritation
H317	May cause allergic skin reactions
H319	Causes severe eye irritation
H335	May cause respiratory irritation
H225	Highly flammable liquid and vapour

Safety information:

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P101	Keep out of the reach of children.
P280	Wear protective gloves / clothing / eye protection / face protection.
P262	Do not get in eyes, on skin or on clothing.
P261	Avoid breathing dust/fume/gas/mist/vapour/aerosol.
P501	Dispose of contents/container in accordance with local regulations.
P210	Keep away from heat/sparks/open flames/hot surfaces. Do not smoke
P352	Wash/shower skin with wather
P305	In case of contact with eyes:
P351	Take off immediately all contaminated, soaked clothing.
P338	Remove any contact lenses if possible and continue rinsing.

P273 Avoid release into the environment

Further labelling elements

2.3 Other dangers

PBT or vPvB. Indeterminate, mixture. May polymerise on excessive heating.

Section 3: Composition/information on ingredients

3.1 Substances

This product is a mixture as listed under 3.2.

3.2 Mixtures

Substance Name: Methylmethacrylat

CAS-No.: 80-62-6 EC-Nr.: Index-No.: **REACH Registration No.:**

50-95 % Content:

Classification according to Regulation (EC) No 1272/2008: Skin.Sens. H317, respiratory.irrit. H335, Skin.irrit H315, Flam. Liq.2. H225

Substance Name: Butandioldimethacrylat

EC No.: CAS No.: 82339-26-2 Index No.: **REACH Registration No.:**

10-24 % Content:

Classification according to Regulation (EC) No 1272/2008: Skin.irrit. H315, Eye.irrit. H319, Skin.sens. H335, Stot.se 3

Substance Name: Dimetyhl-p-toluidin

EC No.: CAS No.: 99978 **REACH Registration No.:** Index No.:

Content: < 1 %

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

Ak.tox.3.inh.dem.oral H331, Chron.H20.att.3 H4123

(For the wording of the listed hazard statements see section 16 and 2.2)



Safety data sheet according to Regulation (EU) 2020/878

Doc Nr.: SDB-05-4 Creator: QM

Product designation: NOVOtray Liquids

Version: 2024-09-22 Replayed Version: 2021-11-08

Section 4: First aid measures

4.1 Description of the first aid measure

After inhalation

Provide plenty of fresh air and consult a doctor if symptoms persist.

After skin contact

Wash off with soap and water and rinse well. Consult a doctor if skin irritation persists.

Nach Augenkontakt

Remove contact lenses. Rinse immediately under running water for several minutes with the eyelids open. Consult a doctor if symptoms persist.

After swallowing

Rinse out mouth and drink plenty of water. Avoid vomiting and consult a doctor if symptoms persist.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indications for immediate medical help or special treatment

None known.

Section 5: Fire-fighting measures

5.1 Extinguishing agent

Suitable: CO2, extinguishing powder or water spray. In the case of larger fires, use water spray or alcoholresistant foam.

Unsuitable: Full water jet, high-pressure water jet

5.2 Special hazards arising from the substance or mixture

None known.

5.3 Advice for firefighters

In case of fire, cool the container with water spray.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use protective equipment according to section 8.

6.2 Environmental protection measures

Do not allow to enter drains/surface waters/groundwater.

6.3 Methods and material for retention and cleaning

Absorb with liquid-binding materials (sand, diatomaceous earth, acid binders, universal binders, sawdust) and ensure adequate ventilation.



Safety data sheet according to Regulation (EU) 2020/878

Product designation: NOVOtray Liquids

Version: 2024-09-22 Replayed Version: 2021-11-08

6.4 Reference to other sections

Protective measures under point 7 and 8.

Section 7: Handling and storage

7.1 Protective measures for safe handling

Measures to protect against fire and explosions

Avoid skin contact by keeping a safe distance or wearing suitable protective clothing. Avoid wearing suitable protective clothing. Keep away from sources of ignition - do not smoke and take measures against electrostatic charqing.

Measures to prevent dusts and aerosols

Always keep the container closed.

Measures to protect the environment

Prevent product and large quantities of contaminated wash water from entering water and soil. avoid. Cover sewage systems to prevent product from entering the sewage system.

General hygiene measures

Do not eat, drink or smoke in areas where work is being done.

- Wash hands after use.
- Remove contaminated clothing and protective equipment before entering areas where food is being where food is consumed

7.2 Conditions for safe storage taking into account incompatibilities

Information on storage conditions

2 °C - 30 °C | 35.6 °F - 86 °F (because of quality)

Requirements for storage rooms and containers

Store only in the original container in a cool place protected from light. Equipment in the vicinity should be EX protected.

Storage class: 3 highly flammable

7.3 Specific end uses

Industry and sector-specific guidelines

For further information, please refer to our instructions for use

Section 8: Exposure controls / Personal protective equipment

8.1 Parameters to be monitored

Occupational exposure limit values and/or biological limit values Occupational exposure limit values (OELs) Germany



Safety data sheet according to Regulation (EU) 2020/878

Product designation: NOVOtray Liquids

Version: 2024-09-22 Replayed Version: 2021-11-08

Methylmetacrylat CAS 80-62-6				
MAK (Swizerland)	Short-term value 420 E mg/m³ 100 ml/m³ Long-term value 210 E mlg/m³ 50 ml/m³			
MAK (Austria)	Short-term value 420 E mg/m³ 100 ml/m³ Long-term value 210 E mlg/m³ 50 ml/m³			
AGW (Germany)	210 mg/m³ 50ml/m³ 2(I); DFG, EU, Y			

Doc Nr.: SDB-05-4 Creator: OM

8.2 Exposure controls and monitoring

Suitable technical control devices

No further information, see point 7.

Individual protective measures - personal protective equipment

Eye / face protection

Use safety goggles with side shields according to EN 166:2001. In areas of possible exposure risk, provide eye wash facilities and safety showers be provided.

Skin protection

Gloves

Latex gloves are not suitable

Prolonged exposure:

Glove material: Nitrile rubber (NBR)

Layer thickness (mm): Layer thickness 0.56 mm

Penetration time (min.): >480

Short-term exposure:

Glove material: Nitrile rubber (NBR)

Layer thickness (mm): Layer thickness 0.10 mm

Penetration time (min.): >30

Other skin protection

Wear protective gloves. Recommendations are listed below. Other protective materials may be used depending on the user's risk assessment. Skin protection creams can help protect exposed skin, but should not be applied after exposure has occurred.

Respiratory protection



Safety data sheet according to Regulation (EU) 2020/878

Doc Nr.: SDB-05-4 Creator: QM

Product designation: NOVOtray Liquids

Version: 2024-09-22 Replayed Version: 2021-11-08

In case of short or low exposure use respiratory filter device; in case of intensive or prolonged exposure use self-contained breathing apparatus.

Recommended filter device for short-term use:

Filter A1 Filter A2 Filter A3

Heat / cold protection

Observe storage conditions according to GBA. Keep away from light and heat sources.

Limitation and monitoring of environmental exposure

No information available.

Section 9: Physical and chemical properties

9.1 Information on the basic physical and chemical properties

Appearance

- State of aggregation: Liquid

- Colour : Clear light yellow
Smell : Characteristic ester-like
Smell threshold : No data available
pH value : Undetermined
Melting point/freezing point : - 48°C (- 54°F)
Initial boiling point and boiling 101°C (213°F)

range:

Flash point : 10 °C (50 °F) Cleveland Evaporation rate : Not determined Flammability (solid, gas) : No data available

Upper/lower flammability or The product is not explosive

explosion limits:

Vapour pressure : 47 hPa @ 20°C (68°F)

Vapour density: Not applicable

relative density: 0,943 g/cm³ on 20°C (68°F)
Solubility(s): 1,6g/L on 20°C (68°F)
Partition coefficient: Not determined

n-octanol/water: Not determined

Auto-ignition temperature : The product is not self-igniting

Decomposition temperature : Not determined Viscosity : Not determined

explosive properties: None

9.2 Other details

% Volatile substances (wt.%):
Volatile organic compounds:
Solvent content organic:
Not determined
Not determined
Not determined
Not determined

Section 10: Stability and reactivity



Safety data sheet according to Regulation (EU) 2020/878

Product designation: NOVOtray Liquids

2024-09-22 Version: Replayed Version: 2021-11-08

10.1 Reactivity

No dangerous reactions known.

10.2 Chemical stability

The product is chemically stable under normal ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

Formation of explosive gas mixtures with air. Reactions with strong oxidising agents. Polymerisation with evolution of heat.

10.4 Conditions to be avoided

Heating. A range from approx. 15 Kelvin below the flash point is considered critical. Exposure to light.

10.5 Incompatible materials

Avoid initiators that produce free radiacles and contact with peroxides. Rubber and various plastics.

10.6 Hazardous decomposition products

None under normal storage and handling conditions.

Section 11: Toxicological information

11.1 Data on toxicological effects

Irritates the mucous membranes. Oral acute

Dermal Irritates the skin. toxicity

Inhalation Not classified, Based on available data, the classification criteria are not met.

Corrosive/irritant effect on the skin

Irritates the skin and mucous membranes.

Serious eye damage/irritation

No eye irritation

Sensitisation of the

- Respiratory tract Causes sensitisation

- Skin May cause allergic skin reactions.

Germ cell mutagenicity

None

Carcinogenicity

Not classified, Based on available data, the classification criteria are not met.

Reproductive toxicity

Not classified, Based on available data, the classification criteria are not met.

Specific target organ toxicity after a single exposure

Inhalation - May cause respiratory irritation.

Specific target organ toxicity in case of repeated exposure

Not classified, Based on available data, the classification criteria are not met.

Aspiration risk

Not classified, Based on available data, the classification criteria are not met.

TOXICITY DATA

Acute toxicity

Oral	Rat	Akute LD50	7.872 mg/kg	Literature
Dermal	Rabbit	Akute LD50	> 5.000 mg/kg	Literature
Inhalation	Mouse	Sensitisation		Literature

Local effect on skin and eyes

Acute irritation Dermal Rabbit Irritating to skin Literature Acute irritation Mouse (LLNA) Eye No eye irritation Literature

Allergic sensitisation



Safety data sheet according to Regulation (EU) 2020/878

Product designation: NOVOtray Liquids

Version: 2024-09-22 Replayed Version: 2021-11-08

Sensitisation Skin Sensitisation Literature Sensitisation Respiration Sensitisation Literature

Other information

Toxicity data are from studies funded by raw material manufacturers or from generally available literature. Prolonged or repeated skin or mucous membrane contact of non-polymerised material may cause irritation symptoms.

Symptoms and effects (delayed and chronic) with information on routes of exposure. also: information on toxicokinetics, metabolism and distribution

Not classified, Based on available data, the classification criteria are not met.

Section 12: Environmental information

12.1 Toxicity

Water hazard class 1 (list classification): Slightly water-repellent

Do not allow to enter waters or drains.

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Soil mobility

No data available

12.5 Result of the PBT and vPvB assessment

unspecified

12.6 Other harmful effects

No data available

Section 13: Notes on disposal

13.1 Waste treatment process

Treatment of contaminated packaging

Dispose of to a controlled landfill or incineration line in accordance with local regulations.

Waste code according to the List of Wastes Ordinance (AVV)

150110 Hazardous waste

Special precautionary measures

None

Relevant EU or other regulations

No data available



Safety data sheet according to Regulation (EU) 2020/878

Product designation: NOVOtray Liquids

Version: 2024-09-22 Replayed Version: 2021-11-08

Section 14: Transport information

14.1 UN-Number

UN 1247

14.2 Proper UN shipping name

ADR/RID

UN1247 METHYLMETHYCRYLAT MONOMER, STABILIZED

IMDG-Code / ICAO-TI / IATA-DGR

UN1247 METHYLMETHYCRYLAT MONOMER, STABILIZED

14.3 Transport hazard classes ADR/RID

3

Class: Flammable liquid substances

Hazard label: 3

Transport/further information

Limited quantity (LQ)

Excepted quantities (EQ)

Transport category

Tunnel restriction code

Packing group

1L

Code E2

D/E

2

IMDG



Klasse: Flammable liquid substances

Gefahrenzettel: 3

Transport/further information

Limited quantity (LQ)

Excepted quantities (EQ)

Transport category

Tunnel restriction code

1L

Code E2

2

D/E

IATA



Klasse: Flammable liquid substances

Gefahrenzettel: 3

Transport/further information

None

14.4 Packaging group

II (substances with medium danger)

14.5 Environmental hazards

Indicator for environmentally hazardous substances

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: ☐ Yes / ☒ No

Marine Pollutant: \square Yes / \boxtimes No



Doc Nr.: SDB-05-4 Creator: OM Safety data sheet according to Regulation (EU) 2020/878

Product designation: NOVOtray Liquids

Version: 2024-09-22 Replayed Version: 2021-11-08

14.6 Special precautions for the user

Always follow the instructions for use.

14.7 Carriage in bulk in accordance with Annex II of the MARPOL Convention and the IBC Code

Not applicable

Section 15: Legislation

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

Regulation (EC) No 2037/2000 (substances that deplete the ozone layer):

Not applicable

Regulation (EC) No 850/2004 (persistent organic pollutants):

Not applicable

Regulation (EC) No 689/2008 (export and import of dangerous chemicals):

Not applicable

Regulation (EC) No 648/2004 (Detergents Regulation):

Not applicable

Restrictions under Title VIII of Regulation (EC) No 1907/2006:

Not applicable

National regulations

Water hazard class

Water quality class 2 (list classification)

15.2 Chemical Safety Assessment

The mixture has not been subjected to a safety assessment.

Section 16: Other information

Changes compared to the last version

Transfer to new software, toxicological values taken from literature.

Abkürzungen

ADR European Agreement concerning the International Carriage of Dangerous Goods by Road

Ordinance on Installations for the Handling of Substances Hazardous to Water **AwSV BImSchV** Ordinance on the Implementation of the Federal Immission Control Act

Chemical Abstracts Service CAS

DIN Standard of the German Institute for Standardisation

EC Effective concentration **European Community** EG European Standard ΕN

IATA-DGR International Air Transport Association-Dangerous Goods Regulations

International Code for the Construction and Equipment of Ships Carrying Dangerous **IBC Code**

Chemicals in Bulk

ICATO-TI International Civil Aviation Organization-Technical Instructions

Network: 07 - Produkte\07-2 Sicherheitsdatenblätter\07-02-02 NOVODENT Produkte\Vorgabe - Muster



Safety data sheet according to Regulation (EU) 2020/878

Product designation: NOVOtray Liquids

2024-09-22 Version: Replayed Version: 2021-11-08

> IMDG-Code International Maritime Code for Dangerous Goods Standard of the International Standards Organization International Uniform Chemical Information Database **IUCLID**

Lethal concentration LC

Lethal dose LD

Log Kow Partition coefficient between octanol and water

MARPOL Maritime Pollution Convention = Convention for the Prevention of Pollution from Ships

OECD Organisation for Economic Co-operation and Development

PBT Persistent, bioaccumulative, toxic

Regulations concerning the International Carriage of Dangerous Goods by Rail RID

Technical regulations for hazardous substances TRGS

United Nations UN

VOC Volatile Organic Compounds (VOCs) vPvB Very persistent and very bioaccumulative

Administrative regulation on substances hazardous to water **VwVwS**

WGK Water hazard class

References and data sources

Regulations

REACH Regulation (EC) No 1907/2006, as last amended by Regulation (EU) 2018/675 CLP Regulation (EC) No 1272/2008, as last amended by Regulation (EU) 2018/669

Internet

http://www.llv.li/kontakt/3408/amt-fur-umwelt

http://publikationen.dguv.de

http://dguv.de/ifa/stoffdatenbank

http://www.gischem.de

http://echa.europa.eu/en/candidate-list-table

http://www.ncbi.nlm.nih.gov/pubmed/

Methods according to Article 9 of Regulation (EC) No 1272/2008 have been used to assess the information for the purpose of classification

Physical hazards: Evaluation of test data

Health and environmental hazards: Calculation methods

Wording of the hazard statements and/or precautionary statements referred to in section 2 to 15

H315 May cause skin irritation May cause allergic skin reactions H317 H319 Causes severe eye irritation May cause respiratory irritation H335

Training for employees

No special training is required for activities with the above-mentioned product because they are used by dental technicians.

Further information

This product is part of a 2-component system.

This information is without guarantee or warranty. We do not accept any legal responsibility for it.

SDS Manufactured by: NOVODENT Ets., address and contact see point 1.3

Approach with exposure scenarios

Not applicable as no exposure scenarios need to be developed for mixtures.