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

1.1. Product identifier

CL-1

CAS No.: 112-34-5
EC No.: 203-961-6

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

Relevant identified uses: Manufacture.
Uses advised against: Private households (= general public).

1.3. Details of the supplier of the safety data sheet

Manufacturer
pro3dure medical GmbH

Am Burgberg 13
D 58642 Iserlohn

Telephone +49 (0)2374 920050-10
Telefax: +49 (0)274 920050-50

Supplier
pro3dure medical GmbH

Am Burgberg 13
D 58642 Iserlohn

Telephone +49 (0)2374 920050-10
Telefax: +49 (0)274 920050-50

Information contact
pro3dure medical GmbH

Information telephone +49 (0)2374 920050-10
Information telefax +49 (0)2374 920050-50
E-mail (competent person) info@pro3dure.com
Website www.pro3dure.com

1.4. Emergency telephone number

pro3dure medical GmbH
This number is serviced during office hours.

Telephone +49 (0)2374 920050-10

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008:
Eye Irrit. 2, H319

2.2. Label elements

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

GHS07

Signal word: Warning

Hazard statements:
H319 Causes serious eye irritation.
Precautionary statements:
P264 Wash hands thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+313 If eye irritation persists: Get medical advice/attention.

Special labelling of particular preparations:
none

2.3. Other hazards
-

SECTION 3: Composition / information on ingredients

3.1. Substances
not applicable

3.2. Mixtures
not applicable

Composition/information on ingredients

Substance:	CAS-No.:	REACH-no.:	Concentration:	Classification: EC 1272/2008 (CLP):	M, ATE, Note
Butyldiglycol	112-34-5	01-2119475104-44	100	Eye Irrit. 2, H319	M = 0 ATE (dermal) = Kein Wert ermittelbar ATE (oral) = Kein Wert ermittelbar ATE (inhalativ) = Kein Wert ermittelbar

(Full text of H- and EUH-statements: see section 16.)

SECTION 4: First aid measures

4.1. Description of first aid measures
General information: Remove contaminated, saturated clothing immediately.
In case of inhalation: Provide fresh air. Seek medical attention if problems persist.
Following skin contact: After contact with skin, wash immediately with plenty of water and soap. In case of skin irritation, consult a physician.
After eye contact: In case of contact with eyes, rinse immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Subsequently consult an ophthalmologist.
After ingestion: Rinse mouth thoroughly with water. Let water be drunken in little sips (dilution effect).

4.2. Most important symptoms and effects, both acute and delayed
After eye contact

4.3. Indication of any immediate medical attention and special treatment needed
First Aid, decontamination, treatment of symptoms.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	ABC-powder BC-powder alcohol resistant foam Carbon dioxide (CO2)
Unsuitable extinguishing media	Water spray jet Full water jet Excess water

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Carbon dioxide (CO2). Carbon monoxide.

5.3. Advice for firefighters

General information

Move undamaged containers from immediate hazard area if it can be done safely. Use water spray jet to protect personnel and to cool endangered containers. Use water spray jet to protect personnel and to cool endangered containers.

Special protective equipment for fire-fighters:

In case of fire: Wear self-contained breathing apparatus. Wear chemical resistant suit.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Put on protective equipment and keep unprotected persons away.
Avoid contact with skin, eyes and clothing. Do not inhale vapours. Ventilate affected areas thoroughly.
Close leaks, if possible without taking personal risk.

6.2. Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advices on safe handling

When using do not eat, drink, smoke, sniff. Use only in well-ventilated areas. All work processes must always be designed so that the following is as low as possible: Inhalation Inhalation Skin contact

Precautions against fire and explosion:

Usual measures for fire prevention.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed and in a well-ventilated place.

Hints on joint storage

Do not store together with: Oxidizing agent

7.3. Specific end use(s)

Observe instructions for use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

occupational exposure limit value

Substance:	CAS-No.:		Source:	Occupational exposure limit value:[ppm]	Occupational exposure limit value:[mg/m³]	Limitation of exposure peaks:	Remark:

Substance with a common (EC) occupational exposure limit value.

Substance:	CAS-No.:		Source:	Occupational exposure limit value:[ppm]	Occupational exposure limit value:[mg/m³]	Limitation of exposure peaks:	Remark:

DNEL-/PNEC-values
DNEL value

Substance:	CAS-No.:	DNEL/DMEL
Butyldiglycol	112-34-5	population oral long-term, systemic 5 mg/kg bw/day worker dermal long-term, systemic 83 mg/kg bw/day population dermal long-term, systemic 50 mg/kg bw/day worker inhalative short-term, local 101,2 mg/m³ worker inhalative long-term, systemic 67,5 mg/m³ worker inhalative long-term, local 67,5 mg/m³ population inhalative short-term, local 60,7 mg/m³ population inhalative long-term, systemic 40,5 mg/m³ population inhalative long-term, local 40,5 mg/m³

PNEC Value

Substance:	CAS-No.:	PNEC
Butyldiglycol	112-34-5	aquatic, freshwater 1100 µg/l aquatic, marine water 110 µg/l sewage treatment plant 200 mg/l soil 320 µg/kg dw sediment, marine water 440 µg/kg dw sediment, freshwater 4400 µg/kg dw

Additional information
-

8.2. Exposure controls

Occupational exposure controls:
Provide adequate ventilation as well as local exhaustion at critical locations. Technical measures and the application of suitable work processes have priority over personal protection equipment.

General protection and hygiene measures:
When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work. Apply skin care products after work. Wash contaminated clothing prior to re-use.

Personal protection equipment
Only wear fitting, comfortable and clean protective clothing.

Respiratory protection
In case of inadequate ventilation wear respiratory protection.

Hand protection
Suitable material:Tested protective gloves are to be worn: DIN-/EN-Norms:EN ISO 374 Suitable material: NBR (Nitrilkautschuk) / 0,4mm / >480h / -
Unsuitable material:

Eye/face protection

Eye glasses with side protection

Body protection:
lab coat Chemical resistant safety shoes

Environmental exposure controls
refer to chapter 7. No further action is necessary.

Consumer exposure controls
refer to chapter 7. No further action is necessary.

Exposure Scenario:
Skin contact Ingestion

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state:	Liquid
Colour:	colourless
Odour:	ether-like
Odour threshold:	

Safety relevant basis data

parameter	Value	unit	Remark
Melting point/freezing point:	-68	°C	-
Initial boiling point and boiling range:	231	°C	-
Flammability:			No data available
lower flammability or explosive limits:			No data available
Upper flammability or explosive limits:			No data available
Flash point:	100-110	°C	-
Ignition temperature:			No data available
Decomposition temperature:			No data available
pH:			No data available
Kinematic viscosity:			No data available
Water solubility (g/L):			
Partition coefficient: n-octanol/water:			No data available
Vapour pressure:			No data available
Density:			No data available
Relative density:			No data available
Particle properties:			No data available

9.2. Other information

none

SECTION 10: Stability and reactivity

10.1. Reactivity

No known hazardous reactions.

10.2. Chemical stability
Can polymerise exothermically if heated, exposed to air, sunlight or by addition or free radical initiators.

10.3. Possibility of hazardous reactions
Reactions with strong oxidising agents.
Formation of peroxides in the presence of oxygen and light.

10.4. Conditions to avoid
No information available.

10.5. Incompatible materials
Oxidising agent, strong Aluminium Zinc Light metals Strong acid

10.6. Hazardous decomposition products
In case of fire may be liberated: Carbon dioxide. Carbon monoxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects
There are no data available on the mixture itself.

M-factor: none
Acute toxicity (oral): > 2000
Acute toxicity (dermal): > 2000
Acute toxicity (inhalative): -

Acute toxicity

Substance:	CAS-No.:	Toxicological information
Butyldiglycol	112-34-5	LD50 oral (rat) > 2000 mg/kg LD50 dermal (Rabbit) > 2000 mg/kg NOAEL (rat) 250 mg/kg bw/Tag

Skin corrosion/irritation:
Based on available data, the classification criteria are not met.

Serious eye damage/irritation:
Causes serious eye irritation.

Respiratory or skin sensitisation:
May cause an allergic skin reaction.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
Carcinogenicity:
Based on available data, the classification criteria are not met.
Germ cell mutagenicity:
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.

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

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
Butyldiglycol	112-34-5	LC50 (fish, 96 h) > 1000 mg/L EC50 (Daphnia, 48 h) > 1000 mg/L EC50 (algae, 72 h) > 100 mg/L

12.2. Persistence and degradability
There are no data available on the mixture itself.

12.3. Bioaccumulative potential
No information available.

12.4. Mobility in soil
No information available.

12.5. Results of PBT and vPvB assessment
not applicable

12.6 Endocrine disruptive effect
No information available.

12.7. Other adverse effects
No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Appropriate disposal/Product:
Dispose of waste according to applicable legislation.

Appropriate disposal / Package
Can be incinerated together with household waste in compliance with applicable technical regulations following consultation with approved waste disposal management companies and authorities in charge.

List of proposed waste codes / waste designations according to EWC / AVV
According to EAKV, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.

SECTION 14: Transport information

14.1. UN number
UN No.: -

14.2. UN proper shipping name
Land transport (ADR/RID)
-
-

Sea transport (IMDG), Air transport (ICAO-TI / IATA-DGR)
-
-

14.3. Transport hazard class(es)

Hazard label(s) / Label: - **Classification code: / Classification Code:** -

14.4. Packing group

Packing group/ Packing Group: -

14.5. Environmental hazards

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

14.6. Special precautions for user

Land transport (ADR/RID)
transport category: - **tunnel restriction code:** -
Special provisions: - **Limited quantity (LQ):** -

Sea transport (IMDG)
EmS-No: -
Special provisions: - **Limited quantity (LQ):** -

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Remark -

SECTION 15: Regulatory information

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

EU legislation

Information on Regulation (EC) No 166/2006 establishing a European Pollutant Release and Transfer Register:
-

Regulation (EC) No. 1005/2009 on substances that lead to the depletion of the ozone layer:
-

Regulation (EC) No. 648/2004 (Detergents regulation)
-

Regulation (EC) No 850/2004 [POP-Regulation]:
-

Regulation (EU) No 649/2012 on the export and import of dangerous chemicals:
-

Use restriction according to REACH annex XVII, no.::
-

National regulations
Observe in addition any national regulations!

Restrictions of occupation
-

Other regulations, restrictions and prohibition regulations
-

15.2. Chemical Safety Assessment

For this preparation a chemical safety assessment has been carried out. ja
For this substance a chemical safety assessment has been carried out.

SECTION 16: Other information

Relevant H- and EUH-phrases (Number and full text):
Hazard statements

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Training advice
-

Recommended restrictions of use:
refer to chapter 1.

Further remarks:
The information provided in this safety data sheet is correct to the best of our knowledge at the time of printing. The information is intended to provide guidance on the safe handling of the product specified in this safety data sheet during storage, processing, transport and disposal. The information is not transferable to other products. Insofar as the product is mixed, blended or processed with other materials or undergoes treatment, the information in this safety data sheet cannot be transferred to the new material thus produced, unless expressly stated otherwise.

Documentation of changes:
Changes compared to version 1:

1.4	Name of the company inserted
3.2	Classification of the components of the mixture updated
5.1	Extinguishing agent revised
8.1	revised according to 3.2
8.2	revised
10	revised
11.1	revised according to 3.2
12.1	revised according to 3.2
13	revised
16	List of abbreviations introduced.

Key literature references and sources for data
SDB "Butyldiglykol", V5, 14.09.2018, Julius Hoesch GmbH & Co KG

Abbreviations and acronyms

AC: Artikelkategorie (Article Category)
ACGIH: Rat für Arbeitsschutz und Gefahrstoffe, Amerika (American Conference of Government Industrial Hygienists)
ADN: Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf Binnengewässern (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
ADR: Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf der Straße (Accord européen relatif transport des merchandises dangereuses par route)
AGW: Arbeitsplatzgrenzwert
AOX: Adsorbierbare organisch gebundene Halogene (Adsorbable Organic halogen compounds)
Bw: Körpergewicht (Body weight)
CMR: Stoffe klassifiziert als Krebserzeugend, Mutagen oder Reproduktionstoxisch (Carcinogenic, Mutagenic, toxic for Reproduction)
CSR: Stoffsicherheitsbericht (Chemical Safety Report)
DIN: Deutsches Institut für Normung / Deutsche Industrienorm
DNEL: Grenzwert, unterhalb dessen der Stoff keine Wirkung ausübt (Derived No Effect Level)
DPD: Zubereitungsrichtline / Richtline 1999-45-EC (Dangerous Preparations Directive)
DSD: Stoffrichtlinie / Richtlinie 67-548-EC (Dangerous Substances Directive)
DU: Nachgeschalteter Anwender (Downstream User)
EC50: Wirksame Konzentration 50% (Effective Concentration 50%)
ECHA: Europäische Chemikalienagentur
EN: Europäische Norm
EWC/EWL: Europäischer Abfallartenkatalog (European Waste Catalogue)
IATA: Verband für den internationalen Lufttransport (International Air Transport Association)
IBC: Großpackmittel (Intermediate Bulk Container)
ICAO: Internationale Zivilluftfahrt-Organisation (International Civil Aviation Organization)
IMDG Code: Gefahrgutvorschriften für den internationalen Seetransport (International Maritime Dangerous Goods Code)
IMO: Internationale Seeschifffahrts-Organisation (International Maritime Organization)
ISO: Internationale Normungsorganisation (International Standards Organisation)
LC50: Lethale (Tödliche) Konzentration 50%
LD50: Lethale (Tödliche) Dosis 50%
LEV: Lokale Absaugung (Local exhaust ventilation)
MAK: Maximale Arbeitsplatzkonzentration – DFG
n.a.: nicht anwendbar
n.b.: nicht bestimmt
OEL: Arbeitsplatzgrenzwert (Occupational Exposure Limit)
PBT: persistent, bioakkumlierbar, giftig (persistent, bioaccumulative, toxic)
PNEC: Abgeschätzte Nicht-Effekt-Konzentration (Predicted No Effect Concentration)
PPE/PSA: Persönliche Schutzausrüstung (Personal Protective Equipment)
REACH: Registrierung, Bewertung und Zulassung von Chemikalien (Registration, Evaluation and Authorization of Chemicals)
RID: Gefahrgutvorschriften für den Transport mit der Eisenbahn (Règlement International concernant le transport de marchandises dangereuses par chemin de fer)
STEL: Grenzwert für Kurzzeitexposition (Short-term Exposure Limit)
SVHC: Stoff sehr hoher Besorgnis (Substance of Very High Concern)
TLV: Arbeitsplatzgrenzwert (Threshold Limit Value)
VOC: Flüchtige organische Kohlenwasserstoffe (Volatile Organic Compounds)
vPvB: sehr persistent, sehr bioakkumulierbar (very persistent, very bioaccumulative)