

# Safety Data Sheet

according to UK REACH Regulation

## Pufferlösungen ProClin

Revision date: 07.04.2022

Product code:

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

#### 1.1. Product identifier

Pufferlösungen ProClin

#### Further trade names

This SDS covers the following products:  
rekombinante Blutgruppenantigene (rBGA)  
DaraEx  
DaraEx plus  
DaraEx pro  
DaraEx-PC  
Dara-PC

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

##### Use of the substance/mixture

Scientific research and development  
If CE marked: Product for in vitro diagnostic (IVD) applications.

##### Uses advised against

Any non-intended use.

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

Company name:	imusyn GmbH & Co.KG	
Street:	Feodor-Lynen-Str. 5	
Place:	D-30625 30625 Hannover	
Telephone:	+49 511 563585 0	Telefax: +49 511 563585 29
e-mail:	info@imusyn.de	
Responsible Department:	Dr. Gans-Eichler Chemieberatung GmbH Otto-Hahn-Str. 36 D-48161 Münster	e-mail: info@tge-consult.de Tel.: +49(0)2534 6441185 www.tge-consult.de

#### 1.4. Emergency telephone number:

+49 511 563585 0 - Only available during office hours.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### GB CLP Regulation

Skin Sens. 1; H317  
Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

#### 2.2. Label elements

##### GB CLP Regulation

##### Hazard components for labelling

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

**Signal word:** Warning**Pictograms:****Hazard statements**

H317 May cause an allergic skin reaction.

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H412 Harmful to aquatic life with long lasting effects.

### Precautionary statements

P280 Wear protective gloves.  
 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

For information or further instructions, see also section 11 or 12.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

#### Hazardous components

CAS No	Chemical name	Quantity
	EC No	Index No
	REACH No	
	Classification (GB CLP Regulation)	
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	< 0.1 %
	-	613-167-00-5
	Acute Tox. 2, Acute Tox. 2, Acute Tox. 3, Skin Corr. 1C, Eye Dam. 1, Skin Sens. 1A, Aquatic Acute 1, Aquatic Chronic 1; H330 H310 H301 H314 H318 H317 H400 H410 EUH071	

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

#### Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
55965-84-9	-	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	< 0.1 %
		inhalation: ATE = 0,5 mg/l (vapours); inhalation: LC50 = 0,169-0,33 mg/l (dusts or mists); dermal: LD50 = 87,12 mg/kg; oral: LD50 = 53 mg/kg Skin Corr. 1C; H314: >= 0,6 - 100 Skin Irrit. 2; H315: >= 0,06 - < 0,6 Eye Dam. 1; H318: >= 0,6 - 100 Eye Irrit. 2; H319: >= 0,06 - < 0,6 Skin Sens. 1A; H317: >= 0,0015 - 100 M acute; H400: M=100 M chron.; H410: M=100	

#### Further Information

Product does not contain listed SVHC substances > 0,1 % according to Regulation (EC) No. 1907/2006 Article 59 (REACH)

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

#### After inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. In case of respiratory tract irritation, consult a physician.

#### After contact with skin

Gently wash with plenty of soap and water. In case of skin irritation, seek medical treatment.

#### After contact with eyes

Rinse cautiously with water for several minutes. In case of troubles or persistent symptoms, consult an ophthalmologist.

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### After ingestion

Rinse mouth thoroughly with water. Let water be drunk in little sips (dilution effect). Do NOT induce vomiting. In all cases of doubt, or when symptoms persist, seek medical advice.

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

No information available.

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

#### Suitable extinguishing media

Carbon dioxide (CO<sub>2</sub>). Dry extinguishing powder. alcohol resistant foam. Atomized water.

#### Unsuitable extinguishing media

High power water jet.

### 5.2. Special hazards arising from the substance or mixture

Can be released in case of fire: Carbon monoxide. Carbon dioxide (CO<sub>2</sub>).

### 5.3. Advice for firefighters

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

### Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water. Co-ordinate fire-fighting measures to the fire surroundings.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### General advice

Safe handling: see section 7

#### For non-emergency personnel

Wear personal protection equipment (refer to section 8).

#### For emergency responders

No special measures are necessary.

### 6.2. Environmental precautions

Discharge into the environment must be avoided.

### 6.3. Methods and material for containment and cleaning up

#### For containment

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.

#### For cleaning up

Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

Disposal: see section 13

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

#### Advice on safe handling

Wear suitable protective clothing. See section 8.

#### Advice on protection against fire and explosion

Usual measures for fire prevention.

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**Advice on general occupational hygiene**

Always close containers tightly after the removal of product. Do not eat, drink, smoke or sneeze at the workplace. Wash hands before breaks and after work.

**Further information on handling**

General protection and hygiene measures: See section 8.

**7.2. Conditions for safe storage, including any incompatibilities****Requirements for storage rooms and vessels**

Keep container tightly closed in a cool, well-ventilated place.

**Hints on joint storage**

Do not store together with: Explosives. Oxidizing solids. Oxidizing liquids. Radioactive substances. Infectious substances. Food and animal feedingstuff.

**Further information on storage conditions**

Keep the packing dry and well sealed to prevent contamination and absorption of humidity.

Recommended storage temperature: 20°C

Protect against: frost. UV-radiation/sunlight. heat. Humidity

**7.3. Specific end use(s)**

See section 1.

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****Additional advice on limit values**

To date, no national critical limit values exist.

**8.2. Exposure controls****Appropriate engineering controls**

Technical measures and the application of suitable work processes have priority over personal protection equipment.

Provide adequate ventilation.

**Individual protection measures, such as personal protective equipment****Eye/face protection**

Wear safety glasses; chemical goggles (if splashing is possible). BS/EN 166

**Hand protection**

Wear suitable gloves.

Suitable material:

FKM (fluororubber). - Thickness of glove material: 0,4 mm

Breakthrough time  $\geq$  8 h

Butyl rubber. - Thickness of glove material: 0,5 mm

Breakthrough time  $\geq$  8 h

CR (polychloroprenes, Chloroprene rubber). - Thickness of glove material: 0,5 mm

Breakthrough time  $\geq$  8 h

NBR (Nitrile rubber). - Thickness of glove material: 0,35 mm

Breakthrough time  $\geq$  8 h

PVC (Polyvinyl chloride). - Thickness of glove material: 0,5 mm

Breakthrough time  $\geq$  8 h

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

The selected protective gloves have to satisfy the specifications of EU Directive EC/2016/425 and the standard EN ISO 374 derived from it.

Check leak tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well.

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**Skin protection**

Suitable protective clothing: Lab apron.

Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500 (D).

**Respiratory protection**

With correct and proper use, and under normal conditions, breathing protection is not required.

Respiratory protection necessary at:

- Exceeding exposure limit values
- Insufficient ventilation and aerosol or mist formation

Suitable respiratory protective equipment: particulates filter device (DIN EN 143). Type: P1-3

The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used.

**Environmental exposure controls**

Do not allow uncontrolled discharge of product into the environment.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state:	liquid
Colour:	not determined
Odour:	characteristic

**Changes in the physical state**

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	not determined
Sublimation point:	not determined
Softening point:	not determined
Pour point:	not determined
Flash point:	not determined

**Explosive properties**

none

Lower explosion limits:	not determined
Upper explosion limits:	not determined
Auto-ignition temperature:	not determined

**Self-ignition temperature**

Gas:	not determined
Decomposition temperature:	not determined
pH-Value:	not determined
Viscosity / dynamic:	not determined
Viscosity / kinematic:	not determined
Flow time:	not determined
Water solubility:	not determined

**Solubility in other solvents**

not determined

Partition coefficient n-octanol/water:	SECTION 12: Ecological information
Vapour pressure:	not determined
Density:	not determined

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Relative vapour density: not determined

### 9.2. Other information

#### Information with regard to physical hazard classes

Sustaining combustion: Not sustaining combustion

Oxidizing properties  
none

#### Other safety characteristics

Solvent separation test: not determined

Solvent content: not determined

Solid content: not determined

Evaporation rate: not determined

#### Further Information

No information available.

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No information available.

### 10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

### 10.3. Possibility of hazardous reactions

Refer to chapter 10.5.

### 10.4. Conditions to avoid

Protect against: UV-radiation/sunlight. heat.

### 10.5. Incompatible materials

Materials to avoid: Oxidizing agents, strong. Reducing agents, strong.

### 10.6. Hazardous decomposition products

Does not decompose when used for intended uses.

Can be released in case of fire: Carbon monoxide. Carbon dioxide (CO<sub>2</sub>).

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in GB CLP Regulation

#### Toxicokinetics, metabolism and distribution

No data available.

#### Acute toxicity

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

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)				
	oral	LD50 53 mg/kg	Rat.	RTECS	
	dermal	LD50 87,12 mg/kg	Rabbit	RAC Opinion	
	inhalation vapour	ATE 0,5 mg/l			
	inhalation (4 h) dust/mist	LC50 0,169-0,33 mg/l	Rat.	RAC Opinion	

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### Irritation and corrosivity

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

### Sensitising effects

May cause an allergic skin reaction. (reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1))

### Carcinogenic/mutagenic/toxic effects for reproduction

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.

### Specific effects in experiment on an animal

No data available.

## 11.2. Information on other hazards

### Endocrine disrupting properties

No data available.

## SECTION 12: Ecological information

### 12.1. Toxicity

The product has not been tested.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)					
	Acute fish toxicity	LC50 mg/l	0,19	96 h	Oncorhynchus mykiss	RAC opinion US EPA FIFRA 72-1
	Acute algae toxicity	ErC50 mg/l	0,0052	48h	Skeletonema costatum	RAC opinion OECD 201
	Acute crustacea toxicity	EC50	0,1 mg/l	48 h	Daphnia magna	RAC opinion OECD 202
	Fish toxicity	NOEC mg/l	0,098	21 d	Oncorhynchus mykis-	RAC opinion OECD 215
	Algae toxicity	NOEC mg/l	0,00064	2 d	Skeletonema costatum	RAC opinion OECD 201
	Crustacea toxicity	NOEC mg/l	0.0036	21 d	Daphnia magna	RAC opinion OECD Guideline 202

### 12.2. Persistence and degradability

The product has not been tested.

### 12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

### Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	-0,71 - 0,75 (OECD107)

### BCF

CAS No	Chemical name	BCF	Species	Source
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	3,6	calc.	

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**12.4. Mobility in soil**

No data available.

**12.5. Results of PBT and vPvB assessment**

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

The aforementioned statement applies to substances contained in the product with a minimum content of 0.1 %.

**12.6. Endocrine disrupting properties**

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

The aforementioned statement applies to substances contained in the product with a minimum content of 0.1 %.

**12.7. Other adverse effects**

No data available.

**Further information**

Do not allow to enter into surface water or drains.

**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Disposal recommendations**

Observe in addition any national regulations! Consult the local waste disposal expert about waste disposal.

Non-contaminated packages may be recycled.

According to (EWC) European Waste Catalogue, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.

Control report for waste code/ waste marking according to (EWC) European Waste Catalogue:

**List of Wastes Code - residues/unused products**

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

**List of Wastes Code - used product**

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

**List of Wastes Code - contaminated packaging**

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

**Contaminated packaging**

Handle contaminated packages in the same way as the substance itself.

**SECTION 14: Transport information****Land transport (ADR/RID)****14.1. UN number or ID number:**

No dangerous good in sense of this transport regulation.

**14.2. UN proper shipping name:**

No dangerous good in sense of this transport regulation.

**14.3. Transport hazard class(es):**

No dangerous good in sense of this transport regulation.

**14.4. Packing group:**

No dangerous good in sense of this transport regulation.

**Inland waterways transport (ADN)****14.1. UN number or ID number:**

No dangerous good in sense of this transport regulation.

**14.2. UN proper shipping name:**

No dangerous good in sense of this transport regulation.



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**14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.

**14.4. Packing group:** No dangerous good in sense of this transport regulation.

#### Marine transport (IMDG)

**14.1. UN number or ID number:** No dangerous good in sense of this transport regulation.

**14.2. UN proper shipping name:** No dangerous good in sense of this transport regulation.

**14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.

**14.4. Packing group:** No dangerous good in sense of this transport regulation.

#### Air transport (ICAO-TI/IATA-DGR)

**14.1. UN number or ID number:** No dangerous good in sense of this transport regulation.

**14.2. UN proper shipping name:** No dangerous good in sense of this transport regulation.

**14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.

**14.4. Packing group:** No dangerous good in sense of this transport regulation.

#### 14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

#### 14.6. Special precautions for user

Refer to section 6-8

#### 14.7. Maritime transport in bulk according to IMO instruments

not relevant

## SECTION 15: Regulatory information

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

#### EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

2010/75/EU (VOC): No information available.

2004/42/EC (VOC): No information available.

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

#### Additional information

Safety Data Sheet according to UK-REACH Regulation

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

UK REACH Appendix XVII, No (mixture): 3

#### National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D): 2 - obviously hazardous to water

### 15.2. Chemical safety assessment

For the following substances of this mixture a chemical safety assessment has been carried out:

## SECTION 16: Other information

#### Changes

Rev. 1.0; Initial release: 04.03.2022

Rev. 1,1; Changes in chapter: 1

#### 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)

AGW: Arbeitsplatzgrenzwert

CAS: Chemical Abstracts Service

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CLP: Classification, Labelling and Packaging of substances and mixtures  
 DNEL: Derived No Effect Level  
 d: day(s)  
 EINECS: European INventory of Existing Commercial chemical Substances  
 ELINCS: European List of Notified Chemical Substances  
 ECHA: European Chemicals Agency  
 EWC: European Waste Catalogue  
 IARC: INTERNATIONAL AGENCY FOR RESEARCH ON CANCER  
 IMDG: International Maritime Code for Dangerous Goods  
 IATA: International Air Transport Association  
 IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)  
 ICAO: International Civil Aviation Organization  
 ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)  
 GHS: Globally Harmonized System of Classification and Labelling of Chemicals  
 GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)  
 h: hour  
 LOAEL: Lowest observed adverse effect level  
 LOAEC: Lowest observed adverse effect concentration  
 LC50: Lethal concentration, 50 percent  
 LD50: Lethal dose, 50 percent  
 NOAEL: No observed adverse effect level  
 NOAEC: No observed adverse effect concentration  
 NLP: No-Longer Polymers  
 N/A: not applicable  
 OECD: Organisation for Economic Co-operation and Development  
 PNEC: predicted no effect concentration  
 PBT: Persistent bioaccumulative toxic  
 RID: Regulation Concerning the International Transport of Dangerous Goods by Rail  
 REACH: Registration, Evaluation, Authorisation of Chemicals  
 SVHC: substance of very high concern  
 TRGS: Technische Regeln für Gefahrstoffe  
 UN: United Nations  
 VOC: Volatile Organic Compounds

### Classification for mixtures and used evaluation method according to GB CLP Regulation

Classification	Classification procedure
Skin Sens. 1; H317	Calculation method
Aquatic Chronic 3; H412	Calculation method

### Relevant H and EUH statements (number and full text)

H301 Toxic if swallowed.  
 H310 Fatal in contact with skin.  
 H314 Causes severe skin burns and eye damage.  
 H317 May cause an allergic skin reaction.  
 H318 Causes serious eye damage.  
 H330 Fatal if inhaled.  
 H400 Very toxic to aquatic life.  
 H410 Very toxic to aquatic life with long lasting effects.  
 H412 Harmful to aquatic life with long lasting effects.  
 EUH071 Corrosive to the respiratory tract.

### Further Information

Classification according to GHS [UK CLP] - Classification procedure:  
 Health hazards: Calculation method.  
 Environmental hazards: Calculation method.  
 Physical hazards: On basis of test data and / or calculated and / or estimated.

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The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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*(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*