Safety Data Sheet Frontispiece

1 Product identifier

Product form **Kit box**

Trade Name **Androstenedione saliva** ELISA

Dia.metra code **DKO027**

Kit component (Name and label reference):

Calibrators	**DCE002/27(06-10)-0**
Conjugate	**DCE002/2702-0**
Incubation Buffer	**DCE001-0**
Coated Microplate	**DCE002/2703-0**
TMB Substrate	**DCE004-0**
Stop Solution	**DCE005-0**
Conc. Wash Solution	**DCE006-0**
Control A	**DCE045/2703A-0**
Control B	**DCE045/2703B-0**

2 Changes from previous version

Changes from previous versions:

Rev. 6: updating to Regulation (CE) n. 1907/2006, Regulation (EC) n. 453/2010, and according to Regulation (EC) n. 1272/2008 (CLP).

Rev. 7: change in Headquarter address

Rev. 8: controls A e B added to the kit

Rev. 9: Updated SDS model according to REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878. introduced new software to produce SDS. Rectified proclin 300 concentration.

3 Details of the supplier of the safety data sheet

Dia.Metra s.r.l
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conjugate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 24.10.2023 Revision date: 20.10.2023 Supersedes version of: 18.01.2023

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

1.1. Product identifier

Product form : Mixture
Product name : conjugate
Product code : see SDS Frontispiece point 1

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

1.2.1. Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : IVD

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

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carlo.massini@idsplc.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital Msida MSD 2090 Msida	+356 2545 6508	
United Kingdom	NHS 111/NHS 24/NHS Direct		111 0845 4647	or call a doctor

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin sensitisation, Category 1	H317
Hazardous to the aquatic environment – Chronic Hazard, Category 3	H412

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

Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.

2.2. Label elements

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

Hazard pictograms (CLP) :

GHS07

Signal word (CLP) : Warning

Contains : A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6]

Hazard statements (CLP) : H317 - May cause an allergic skin reaction.
H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP) : P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
TRIS(HYDROXYMETHYL) AMINOMETHANE HYDROCHLORIDE SALT	CAS-No.: 1185-53-1 EC-No.: 214-684-5	≥ 1 – < 10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
CALCIUM CHLORIDE DIHYDRATE	CAS-No.: 10035-04-8 EC-No.: 600-075-5	< 1	Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319 Aquatic Chronic 1, H410
A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6]	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	< 1	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Acute Tox. 2 (Inhalation:dust,mist), H330 Skin Corr. 1A, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:		
Name	**Product identifier**	**Specific concentration limits (%)**
A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6]	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	(0,0015 ≤ C < 100) Skin Sens. 1, H317 (0,06 ≤ C ≤ 0,6) Skin Irrit. 2, H315 (0,06 ≤ C ≤ 0,6) Eye Irrit. 2, H319 (0,6 ≤ C < 100) Skin Corr. 1B, H314

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact : Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact : Rinse eyes with water as a precaution.
First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after skin contact : May cause an allergic skin reaction.

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 : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray. Wear personal protective equipment.

Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6] (55965-84-9)	
Austria - Occupational Exposure Limits	
Local name	5-Chlor-2-methyl-2,3-dihydroisothiazol-3-on und 2-Methyl-2,3-di-hydroisothiazol-3-on (Gemisch im Verhältnis 3:1)
MAK (OEL TWA)	0,05 mg/m³
Remark	Sh
Regulatory reference	BGBl. II Nr. 156/2021
Switzerland - Occupational Exposure Limits	
Local name	2,3-Dihydro-isothiazol-3-one de 5-chloro-2-méthyle et 2,3-dihydro-isothiazol-3-one de 2-méthyle [2,3-Dihydro-isothiazol-3-one de 5-chloro-2-méthyle, 2,3-Dihydro-isothiazol-3-one de 2-méthyle] / 5-Chlor-2-methyl-2,3-dihydro-isothiazol-3-on und 2-Methyl-2,3-dihydroisothiazol-3-on [2-Methyl-2,3-dihydroisothiazol-3-on, 5-Chlor-2-methyl-2,3-dihydroisothiazol-3-on]
MAK (OEL TWA) [1]	0,2 mg/m³ (i) / (e)
KZGW (OEL STEL)	0,4 mg/m³ (i) / (e)
Critical toxicity	VRS, Peau, Yeux / OAW, Haut, Auge
Notation	S, SS_C / S, SS_C
Regulatory reference	www.suva.ch, 01.01.2023

Exposure limit values for the other components

SODIUM HYDROXIDE (1310-73-2)		
Austria - Occupational Exposure Limits		
Local name	Natriumhydroxid (Ätznatron)	
MAK (OEL TWA)	2 mg/m³ (E)	

SODIUM HYDROXIDE (1310-73-2)		
MAK (OEL STEL)	4 mg/m³ (E, 8x 5(Mow) min)	
Regulatory reference	BGBl. II Nr. 156/2021	
Belgium - Occupational Exposure Limits		
Local name	Sodium (hydroxyde de) # Natriumhydroxide	
OEL TWA	2 mg/m³	
Remark	M: la mention “M” indique que lors d’une exposition supérieure à la valeur limite, des irritations apparaissent ou un danger d’intoxication aiguë existe. Le procédé de travail doit être conçu de telle façon que l’exposition ne dépasse jamais la valeur limite. Lors des mesurages, la période d’échantillonnage doit être aussi courte que possible afin de pouvoir effectuer des mesurages fiables. Le résultat des mesurages est calculé en fonction de la période d’échantillonnage. # M: de vermelding “M” duidt aan dat bij de blootstelling boven de grenswaarde irritatie optreedt of er gevaar bestaat voor acute vergiftiging. Het werkprocédé moet zo zijn ontworpen dat de blootstelling de grenswaarde nooit overschrijdt. Bij een controle geldt dat de bemonsterde periode zo kort mogelijk moet zijn om een betrouwbare meting te kunnen verrichten. Het meetresultaat wordt dan gerelateerd aan de beschouwde periode.	
Regulatory reference	Koninklijk besluit/Arrêté royal 11/05/2021	
Bulgaria - Occupational Exposure Limits		
Local name	Натриева основа	
OEL TWA	2 mg/m³ (алкални аерозоли)	
Remark	• (Химични агенти, за които са определени гранични стойности във въздуха на работната среда за Европейската общност)	
Regulatory reference	Наредба № 13 от 30.12.2003 г. за защита на работещите от рискове, свързани с експозиция на химични агенти при работа (изм. и доп. ДВ. бр. 47 от 2021 г., в сила от 04.06.2021 г.)	
Croatia - Occupational Exposure Limits		
Local name	Natrijev hidroksid; kaustična soda	
KGVI (OEL STEL)	2 mg/m³	
Regulatory reference	Pravilnik o zaštiti radnika od izloženosti opasnim kemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)	
Czech Republic - Occupational Exposure Limits		
Local name	Hydroxid sodný	

SODIUM HYDROXIDE (1310-73-2)		
PEL (OEL TWA)	1 mg/m³	
NPK-P (OEL C)	2 mg/m³	
Remark	I - dráždí sliznice (oči, dýchací cesty), respektive kůži.	
Regulatory reference	Nařízení vlády č. 361/2007 Sb. (Předpis 195/2021 Sb.)	
Denmark - Occupational Exposure Limits		
Local name	Natriumhydroxid	
OEL C	2 mg/m³	
Regulatory reference	BEK nr 202 af 21/02/2023	
Estonia - Occupational Exposure Limits		
Local name	Naatriumhüdroksiid	
OEL TWA	1 mg/m³	
OEL STEL	2 mg/m³ arvutatud 5-minutisele kokkupuuteajale	
Regulatory reference	Vabariigi Valitsuse 20. märtsi 2001. a määruse nr 105 (RT I, 21.12.2022, 3)	
Finland - Occupational Exposure Limits		
Local name	Natriumhydroksidi	
HTP (OEL C)	2 mg/m³	
Regulatory reference	HTP-ARVOT 2020 (Sosiaali- ja terveysministeriö)	
France - Occupational Exposure Limits		
Local name	Sodium (hydroxyde de)	
VME (OEL TWA)	2 mg/m³	
Remark	Valeurs recommandées/admises	
Regulatory reference	Circulaire du Ministère du travail (réf.: INRS ED 984, 2016)	
Greece - Occupational Exposure Limits		
Local name	Υδροξείδιο του νατρίου	
OEL TWA	2 mg/m³	
OEL STEL	2 mg/m³	
Regulatory reference	Π.Δ. 90/1999 - Προστασία της υγείας των εργαζομένων που εκτίθενται σε ορισμένους χημικούς παράγοντες κατά τη διάρκεια της εργασίας τους	
Hungary - Occupational Exposure Limits		
Local name	NÁTRIUM-HIDROXID	
AK (OEL TWA)	1 mg/m³	
CK (OEL STEL)	2 mg/m³	

SODIUM HYDROXIDE (1310-73-2)		
Remark	m (maró hatású anyag, amely felmarja a bőrt, nyálkahártyát, szemet vagy mindhármat); N (Irritáló anyagok, egyszerű fojtógázok, csekély egészségkárosító hatással bíró anyagok)	
Regulatory reference	5/2020. (II. 6.) ITM rendelet - A kémiai kóroki tényezők hatásának kitett munkavállalók egészségének és biztonságának védelméről	
Ireland - Occupational Exposure Limits		
Local name	Sodium hydroxide	
OEL STEL	2 mg/m³	
Regulatory reference	Chemical Agents Code of Practice 2021	
Latvia - Occupational Exposure Limits		
Local name	Nātrija hidroksīds (nātrija sārms, kaustiskā soda)	
OEL TWA	0,5 mg/m³	
Regulatory reference	Ministru kabineta 2007. gada 15. maija noteikumiem Nr. 325 (Grozījumi Ministru kabineta 2011. gada 1. februārī noteikumiem Nr. 92)	
Lithuania - Occupational Exposure Limits		
Local name	Natrio hidroksidas	
NRV (OEL C)	2 mg/m³	
Remark	Ū (ūmus poveikis)	
Regulatory reference	LIETUVOS HIGIENOS NORMA HN 23:2011 (Nr. V-695/A1-272, 2018-06-12)	
Poland - Occupational Exposure Limits		
Local name	Wodorotlenek sodu	
NDS (OEL TWA)	0,5 mg/m³	
NDSCh (OEL STEL)	1 mg/m³	
Regulatory reference	Dz. U. 2018 poz. 1286	
Portugal - Occupational Exposure Limits		
Local name	Hidróxido de sódio	
OEL C [ppm]	2 ppm	
Regulatory reference	Norma Portuguesa NP 1796:2014	
Slovakia - Occupational Exposure Limits		
Local name	Hydroxid sodný	
NPHV (OEL TWA) [1]	2 mg/m³	
Regulatory reference	Nariadenie vlády č. 355/2006 Z. z. (236/2020 Z. z.)	
Spain - Occupational Exposure Limits		
Local name	Hidróxido de sodio	

SODIUM HYDROXIDE (1310-73-2)		
VLA-EC (OEL STEL)	2 mg/m³	
Regulatory reference	Límites de Exposición Profesional para Agentes Químicos en España 2023. INSHT	
Sweden - Occupational Exposure Limits		
Local name	Natriumhydroxid	
NGV (OEL TWA)	1 mg/m³ inhalerbar fraktion	
KTV (OEL STEL)	2 mg/m³ inhalerbar fraktion	
Remark	3 (Med inhalerbar fraktion menas den mängd partiklar, av totalmängden partiklar i luften, som man inandas genom näsa och mun)	
Regulatory reference	Hygieniska gränsvärden (AFS 2018:1)	
United Kingdom - Occupational Exposure Limits		
Local name	Sodium hydroxide	
WEL STEL (OEL STEL)	2 mg/m³	
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE	
Iceland - Occupational Exposure Limits		
Local name	Natríumhýdroxíð (vítissóti)	
OEL STEL	2 mg/m³	
Regulatory reference	Reglugerð um mengunarmörk og aðgerðir til að draga úr mengun á vinnustöðum (Nr. 390/2009)	
Norway - Occupational Exposure Limits		
Local name	Natriumhydroksid	
Takverdi (OEL C) [1]	2 mg/m³	
Regulatory reference	FOR-2021-06-28-2248	
North Macedonia - Occupational Exposure Limits		
Local name	Натриум хидроксид	
OEL TWA	2 mg/m³ (I) инхалабилна фракција – дел на вкупно суспендирани материи, кои работникот ги вдишува	
KTV	1	
Short time value [mg/m³]	2 mg/m³	

SODIUM HYDROXIDE (1310-73-2)		
Remark	(KTV) краткотрајна вредност (КТВ) значи концентрација на опасни хемиски супстанци во воздухот на работното место внатре во зона на дишење, на која работникот без опасност по здравјето може да е изложен на покусо време. Изложеноста на краткотрајни вредности може да трае најмногу 15 минути и не смее да се повтори повеќе од четирипати во работната смена, при што меѓу две изложености на оваа концентрација мора да измине најмалку 60 минути. Краткотрајната вредност е изразена во mg/m3 или во ml/m3(ppm) а е дадена како многукратни дозволени пречекорувања на граничната вредност; (Y)	
Regulatory reference	Правилник за минималните барања за безбедност и здравје при работа на вработени од ризици поврзани со изложување на хемиски супстанци („Службен весник на Република Македонија" бр.46/10)	
Switzerland - Occupational Exposure Limits		
Local name	Soude caustique / Natriumhydroxid [Aetznatron]	
MAK (OEL TWA) [1]	2 mg/m³ (i) / (e)	
KZGW (OEL STEL)	2 mg/m³ (i) / (e)	
Critical toxicity	VRS, Peau, Yeux / OAW, Haut, Auge	
Notation	SS_C / SS_C	
Remark	NIOSH, OSHA	
Regulatory reference	www.suva.ch, 01.01.2023	

4-CHLORO-3-METHYLPHENOL (59-50-7)		
Estonia - Occupational Exposure Limits		
Local name	Klorokresool	
OEL TWA	3 mg/m³	
OEL STEL	6 mg/m³	
Regulatory reference	Vabariigi Valitsuse 20. märtsi 2001. a määruse nr 105 (RT I, 21.12.2022, 3)	
Poland - Occupational Exposure Limits		
Local name	4-Chloro-3-metylofenol	
NDS (OEL TWA)	5 mg/m³ frakcja wdychalna	
Remark	Frakcja wdychalna – frakcja aerozolu wnikająca przez nos i usta, która po zdeponowaniu w drogach oddechowych stwarza zagrożenie dla zdrowia.	
Regulatory reference	Dz. U. 2018 poz. 1286 wraz z późn. zm.	

4-CHLORO-3-METHYLPHENOL (59-50-7)		
Sweden - Occupational Exposure Limits		
Local name	Klorkresol	
NGV (OEL TWA)	3 mg/m³	
KTV (OEL STEL)	6 mg/m³	
Remark	S (Ämnet är sensibiliserande. Sensibiliserande ämnen kan ge allergi eller annan överkänslighet. Överkänslighetsbesvären drabbar främst huden eller andningsorganen. Överkänslighet innebär att man reagerar vid kontakt med ämnen som normalt inte ger besvär. Allergi är en undergrupp av överkänslighet som orsakas av reaktioner i kroppens immunsystem. Särskilt låga gränsvärden har fastställts för ämnen med mer uttalat luftvägssensibiliserande egenskaper. Några ämnen med starkt sensibiliserande egenskaper får endast hanteras efter tillstånd från Arbetsmiljöverket, se föreskrifterna om kemiska arbetsmiljörisker. Dessa ämnen har inga gränsvärden men i vissa fall riktvärden); V (Vägledande korttidsgränsvärde ska användas som ett rekommenderat högsta värde som inte bör överskridas)	
Regulatory reference	Hygieniska gränsvärden (AFS 2018:1)	

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

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

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):

8.2.2.1. Eye and face protection

Eye protection:
Safety glasses

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing

Hand protection:
Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:
In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	red.
Appearance	:	Liquid.
Odour	:	characteristic.
Odour threshold	:	Not available
Melting point	:	Not applicable
Freezing point	:	< 0 °C
Boiling point	:	> 100 °C
Flammability	:	Non flammable.
Lower explosion limit	:	Not available
Upper explosion limit	:	Not available
Flash point	:	Not available
Auto-ignition temperature	:	Not available
Decomposition temperature	:	Not available
pH	:	7,4
Viscosity, kinematic	:	Not available
Solubility	:	Not available
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20°C	:	Not available
Particle characteristics	:	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

conjugate	
LD50 oral	<

TRIS(HYDROXYMETHYL) AMINOMETHANE HYDROCHLORIDE SALT (1185-53-1)	
LD50 oral rat	> 5000 mg/kg
LD50 dermal rat	> 5000 mg/kg

CALCIUM CHLORIDE DIHYDRATE (10035-04-8)	
LD50 oral	1000 mg/kg bodyweight Animal: rabbit, Animal sex: male, Guideline: OECD Guideline 401 (Acute Oral Toxicity)
LD50 dermal rabbit	> 5000 mg/kg bodyweight Animal: rabbit

Skin corrosion/irritation : Not classified
pH: 7,4
Serious eye damage/irritation : Not classified
pH: 7,4
Respiratory or skin sensitisation : May cause an allergic skin reaction.
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : Not classified

TRIS(HYDROXYMETHYL) AMINOMETHANE HYDROCHLORIDE SALT (1185-53-1)	
STOT-single exposure	May cause respiratory irritation.

STOT-repeated exposure : Not classified
Aspiration hazard : Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Harmful to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short–term (acute) : Not classified
Hazardous to the aquatic environment, long–term (chronic) : Harmful to aquatic life with long lasting effects.
Not rapidly degradable

CALCIUM CHLORIDE DIHYDRATE (10035-04-8)	
LC50 - Fish [1]	4630 mg/l Test organisms (species): Pimephales promelas
LOEC (chronic)	240 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC (chronic)	481 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC chronic fish	230 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri) Duration: '25 d'

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not applicable	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not applicable	Not regulated	Not regulated	Not regulated	Not regulated

ADR	IMDG	IATA	ADN	RID
14.4. Packing group				
Not applicable	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not applicable	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport
Not applicable

Transport by sea
Not regulated

Air transport
Not regulated

Inland waterway transport
Not regulated

Rail transport
Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Employment restrictions	:	Observe restrictions according Act on the Protection of Working Mothers (MuSchG). Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).
Water hazard class (WGK)	:	WGK 2, Significantly hazardous to water (Classification according to AwSV, Annex 1).
Hazardous Incident Ordinance (12. BImSchV)	:	Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen	:	None of the components are listed
SZW-lijst van mutagene stoffen	:	None of the components are listed
SZW-lijst van reprotoxische stoffen – Borstvoeding	:	None of the components are listed
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid	:	None of the components are listed
SZW-lijst van reprotoxische stoffen – Ontwikkeling	:	None of the components are listed

Denmark

Danish National Regulations	:	Young people below the age of 18 years are not allowed to use the product Pregnant/breastfeeding women working with the product must not be in direct contact with the product

Switzerland

Storage class (LK)	:	LK 10/12 - Liquids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration

Abbreviations and acronyms:	
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Full text of H- and EUH-statements:	
Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.

Full text of H- and EUH-statements:	
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.
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Incubation Buffer

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 25.10.2023

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

1.1. Product identifier

Product form : Mixture
Product name : Incubation Buffer
Product code : see SDS Frontispiece point 1

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

1.2.1. Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : IVD

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Dia.Metra s.r.l
Via Pozzuolo , 14
P.O. Box 06038
Spello (PG) – Italia
T +39074224851 - F +390742316197
carlo.massini@idsplc.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital Msida MSD 2090 Msida	+356 2545 6508	
United Kingdom	NHS 111/NHS 24/NHS Direct		111 0845 4647	or call a doctor

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin sensitisation, Category 1 H317
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

2.2. Label elements

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

Hazard pictograms (CLP) :

GHS07

Signal word (CLP) : Warning

Contains : A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6]

Hazard statements (CLP) : H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) : P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6]	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	< 1	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Acute Tox. 2 (Inhalation:dust,mist), H330 Skin Corr. 1A, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

Name	Product identifier	Specific concentration limits (%)
A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6]	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	(0,0015 ≤ C < 100) Skin Sens. 1, H317 (0,06 ≤ C ≤ 0,6) Skin Irrit. 2, H315 (0,06 ≤ C ≤ 0,6) Eye Irrit. 2, H319 (0,6 ≤ C < 100) Skin Corr. 1B, H314

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.

First-aid measures after eye contact : Rinse eyes with water as a precaution.

First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after skin contact : May cause an allergic skin reaction.

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 : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray. Wear personal protective equipment.

Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6] (55965-84-9)	
Austria - Occupational Exposure Limits	
Local name	5-Chlor-2-methyl-2,3-dihydroisothiazol-3-on und 2-Methyl-2,3-di-hydroisothiazol-3-on (Gemisch im Verhältnis 3:1)
MAK (OEL TWA)	0,05 mg/m³
Remark	Sh
Regulatory reference	BGBl. II Nr. 156/2021
Switzerland - Occupational Exposure Limits	
Local name	2,3-Dihydro-isothiazol-3-one de 5-chloro-2-méthyle et 2,3-dihydro-isothiazol-3-one de 2-méthyle [2,3-Dihydro-isothiazol-3-one de 5-chloro-2-méthyle, 2,3-Dihydro-isothiazol-3-one de 2-méthyle] / 5-Chlor-2-methyl-2,3-dihydro-isothiazol-3-on und 2-Methyl-2,3-dihydroisothiazol-3-on [2-Methyl-2,3-dihydroisothiazol-3-on, 5-Chlor-2-methyl-2,3-dihydroisothiazol-3-on]
MAK (OEL TWA) [1]	0,2 mg/m³ (i) / (e)
KZGW (OEL STEL)	0,4 mg/m³ (i) / (e)
Critical toxicity	VRS, Peau, Yeux / OAW, Haut, Auge
Notation	S, SS_C / S, SS_C
Regulatory reference	www.suva.ch, 01.01.2023

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

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

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):

8.2.2.1. Eye and face protection

Eye protection:
Safety glasses

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing

Hand protection:
Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:
In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	Colourless.
Appearance	:	Liquid.
Odour	:	odourless.
Odour threshold	:	Not available
Melting point	:	Not applicable
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Non flammable.
Lower explosion limit	:	Not available
Upper explosion limit	:	Not available
Flash point	:	Not available
Auto-ignition temperature	:	Not available
Decomposition temperature	:	Not available
pH	:	Not available
Viscosity, kinematic	:	Not available
Solubility	:	Not available
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20°C	:	Not available
Particle characteristics	:	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	:	Not classified
Acute toxicity (dermal)	:	Not classified
Acute toxicity (inhalation)	:	Not classified
Skin corrosion/irritation	:	Not classified
Serious eye damage/irritation	:	Not classified
Respiratory or skin sensitisation	:	May cause an allergic skin reaction.
Germ cell mutagenicity	:	Not classified
Carcinogenicity	:	Not classified
Reproductive toxicity	:	Not classified
STOT-single exposure	:	Not classified
STOT-repeated exposure	:	Not classified
Aspiration hazard	:	Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	:	The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short–term (acute)	:	Not classified
Hazardous to the aquatic environment, long–term (chronic)	:	Not classified

Not rapidly degradable

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport
Not applicable

Transport by sea
Not applicable

Air transport
Not applicable

Inland waterway transport
Not applicable

Rail transport
Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Employment restrictions	:	Observe restrictions according Act on the Protection of Working Mothers (MuSchG). Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).
Water hazard class (WGK)	:	WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).
Hazardous Incident Ordinance (12. BImSchV)	:	Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen	:	None of the components are listed
SZW-lijst van mutagene stoffen	:	None of the components are listed
SZW-lijst van reprotoxische stoffen – Borstvoeding	:	None of the components are listed
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid	:	None of the components are listed
SZW-lijst van reprotoxische stoffen – Ontwikkeling	:	None of the components are listed

Denmark

Danish National Regulations	:	Young people below the age of 18 years are not allowed to use the product Pregnant/breastfeeding women working with the product must not be in direct contact with the product

Switzerland

Storage class (LK)	:	LK 10/12 - Liquids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Full text of H- and EUH-statements:	
Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H331	Toxic if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Stop solution

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 20.10.2023

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

1.1. Product identifier

Product form : Mixture
Product name : Stop solution
Product code : see SDS Frontispiece point 1

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

1.2.1. Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : IVD

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Dia.Metra s.r.l
Via Pozzuolo , 14
P.O. Box 06038
Spello (PG) – Italia
T +39074224851 - F +390742316197
carlo.massini@idsplc.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital Msida MSD 2090 Msida	+356 2545 6508	
United Kingdom	NHS 111/NHS 24/NHS Direct		111 0845 4647	or call a doctor

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact : Wash skin with plenty of water.
First-aid measures after eye contact : Rinse eyes with water as a precaution.
First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

No additional 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 : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

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

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):

8.2.2.1. Eye and face protection

Eye protection:
Safety glasses

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing

Hand protection:
Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:
In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	Not available
Odour	:	Not available
Odour threshold	:	Not available
Melting point	:	Not applicable
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Non flammable.
Lower explosion limit	:	Not available
Upper explosion limit	:	Not available
Flash point	:	Not available
Auto-ignition temperature	:	Not available
Decomposition temperature	:	Not available
pH	:	Not available
Viscosity, kinematic	:	Not available
Solubility	:	Not available
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20°C	:	Not available
Particle characteristics	:	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	:	Not classified
Acute toxicity (dermal)	:	Not classified
Acute toxicity (inhalation)	:	Not classified
Skin corrosion/irritation	:	Not classified
Serious eye damage/irritation	:	Not classified
Respiratory or skin sensitisation	:	Not classified
Germ cell mutagenicity	:	Not classified
Carcinogenicity	:	Not classified
Reproductive toxicity	:	Not classified
STOT-single exposure	:	Not classified
STOT-repeated exposure	:	Not classified
Aspiration hazard	:	Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	:	The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short–term (acute)	:	Not classified
Hazardous to the aquatic environment, long–term (chronic)	:	Not classified

Not rapidly degradable

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport
Not applicable

Transport by sea
Not applicable

Air transport
Not applicable

Inland waterway transport
Not applicable

Rail transport
Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)
Please see https://home-affairs.ec.europa.eu/policies/internal-security/counter-terrorism-and-radicalisation/protection/legislation-chemicals-used-home-made-explosives_en

Drug Precursors Regulation (273/2004)

Contains substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Employment restrictions	:	Observe restrictions according Act on the Protection of Working Mothers (MuSchG). Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).
Water hazard class (WGK)	:	WGK nwg, Non-hazardous to water (Classification according to AwSV, Annex 1).
Hazardous Incident Ordinance (12. BImSchV)	:	Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen	:	None of the components are listed
SZW-lijst van mutagene stoffen	:	None of the components are listed
SZW-lijst van reprotoxische stoffen – Borstvoeding	:	None of the components are listed
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid	:	None of the components are listed
SZW-lijst van reprotoxische stoffen – Ontwikkeling	:	None of the components are listed

Switzerland

Storage class (LK)	:	LK 10/12 - Liquids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road

Abbreviations and acronyms:	
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

TMB Substrate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 28.08.2023 Revision date: 19.10.2023 Supersedes version of: 28.08.2023

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

1.1. Product identifier

Product form : Mixture
Product name : TMB Substrate
Product code : see SDS Frontispiece point 1

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

1.2.1. Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : IVD

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer
Dia.Metra s.r.l
Via Pozzuolo , 14
P.O. Box 06038
Spello (PG) – Italia
T +39074224851 - F +390742316197
carlo.massini@idsplc.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital Msida MSD 2090 Msida	+356 2545 6508	
United Kingdom	NHS 111/NHS 24/NHS Direct		111 0845 4647	or call a doctor

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

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

EUH-statements : EUH208 - Contains A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6](55965-84-9). May produce an allergic reaction.
EUH210 - Safety data sheet available on request.

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6]	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	< 1	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Acute Tox. 2 (Inhalation:dust,mist), H330 Skin Corr. 1A, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:		
Name	**Product identifier**	**Specific concentration limits (%)**
A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6]	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	(0,0015 ≤ C < 100) Skin Sens. 1, H317 (0,06 ≤ C ≤ 0,6) Skin Irrit. 2, H315 (0,06 ≤ C ≤ 0,6) Eye Irrit. 2, H319 (0,6 ≤ C < 100) Skin Corr. 1B, H314

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact : Wash skin with plenty of water.
First-aid measures after eye contact : Rinse eyes with water as a precaution.
First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

No additional 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 : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

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

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):

8.2.2.1. Eye and face protection

Eye protection:
Safety glasses

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing

Hand protection:
Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:
In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	light yellow.
Appearance	:	Colorless to pale yellow liquid.
Odour	:	characteristic.
Odour threshold	:	Not available
Melting point	:	Not applicable
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Non flammable.
Lower explosion limit	:	Not available
Upper explosion limit	:	Not available
Flash point	:	Not available
Auto-ignition temperature	:	Not available
Decomposition temperature	:	Not available
pH	:	Not available
Viscosity, kinematic	:	Not available
Solubility	:	Not available
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available

Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20°C	:	Not available
Particle characteristics	:	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	:	Not classified
Acute toxicity (dermal)	:	Not classified
Acute toxicity (inhalation)	:	Not classified
Skin corrosion/irritation	:	Not classified
Serious eye damage/irritation	:	Not classified
Respiratory or skin sensitisation	:	Not classified
Germ cell mutagenicity	:	Not classified
Carcinogenicity	:	Not classified
Reproductive toxicity	:	Not classified
STOT-single exposure	:	Not classified
STOT-repeated exposure	:	Not classified
Aspiration hazard	:	Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.

Hazardous to the aquatic environment, short–term (acute) : Not classified

Hazardous to the aquatic environment, long–term (chronic) : Not classified

Not rapidly degradable

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport
Not applicable

Transport by sea
Not applicable

Air transport
Not applicable

Inland waterway transport
Not applicable

Rail transport
Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Employment restrictions	:	Observe restrictions according Act on the Protection of Working Mothers (MuSchG). Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).
Water hazard class (WGK)	:	WGK nwg, Non-hazardous to water (Classification according to AwSV, Annex 1).
Hazardous Incident Ordinance (12. BImSchV)	:	Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen	:	None of the components are listed
SZW-lijst van mutagene stoffen	:	None of the components are listed
SZW-lijst van reprotoxische stoffen – Borstvoeding	:	None of the components are listed

SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : None of the components are listed

SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product

Switzerland

Storage class (LK) : LK 10/12 - Liquids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant

Abbreviations and acronyms:	
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Full text of H- and EUH-statements:	
Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
EUH208	Contains A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6](55965-84-9). May produce an allergic reaction.
EUH210	Safety data sheet available on request.
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H331	Toxic if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Calibrators, Control

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 30.10.2023

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

1.1. Product identifier

Product form : Mixture
Product name : Calibrators, Control
Product code : see SDS Frontispiece point 1

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

1.2.1. Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : IVD

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Dia.Metra s.r.l
Via Pozzuolo , 14
P.O. Box 06038
Spello (PG) – Italia
T +39074224851 - F +390742316197
carlo.massini@idsplc.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital Msida MSD 2090 Msida	+356 2545 6508	
United Kingdom	NHS 111/NHS 24/NHS Direct		111 0845 4647	or call a doctor

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin sensitisation, Category 1 H317
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

2.2. Label elements

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

Hazard pictograms (CLP) :

GHS07

Signal word (CLP) : Warning

Contains : A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6]

Hazard statements (CLP) : H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) : P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6]	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	< 1	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Acute Tox. 2 (Inhalation:dust,mist), H330 Skin Corr. 1A, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

Name	Product identifier	Specific concentration limits (%)
A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6]	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	(0,0015 ≤ C < 100) Skin Sens. 1, H317 (0,06 ≤ C ≤ 0,6) Skin Irrit. 2, H315 (0,06 ≤ C ≤ 0,6) Eye Irrit. 2, H319 (0,6 ≤ C < 100) Skin Corr. 1B, H314

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.

First-aid measures after eye contact : Rinse eyes with water as a precaution.

First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after skin contact : May cause an allergic skin reaction.

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 : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray. Wear personal protective equipment.
Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6] (55965-84-9)	
Austria - Occupational Exposure Limits	
Local name	5-Chlor-2-methyl-2,3-dihydroisothiazol-3-on und 2-Methyl-2,3-di-hydroisothiazol-3-on (Gemisch im Verhältnis 3:1)
MAK (OEL TWA)	0,05 mg/m³
Remark	Sh
Regulatory reference	BGBl. II Nr. 156/2021
Switzerland - Occupational Exposure Limits	
Local name	2,3-Dihydro-isothiazol-3-one de 5-chloro-2-méthyle et 2,3-dihydro-isothiazol-3-one de 2-méthyle [2,3-Dihydro-isothiazol-3-one de 5-chloro-2-méthyle, 2,3-Dihydro-isothiazol-3-one de 2-méthyle] / 5-Chlor-2-methyl-2,3-dihydro-isothiazol-3-on und 2-Methyl-2,3-dihydroisothiazol-3-on [2-Methyl-2,3-dihydroisothiazol-3-on, 5-Chlor-2-methyl-2,3-dihydroisothiazol-3-on]
MAK (OEL TWA) [1]	0,2 mg/m³ (i) / (e)
KZGW (OEL STEL)	0,4 mg/m³ (i) / (e)
Critical toxicity	VRS, Peau, Yeux / OAW, Haut, Auge
Notation	S, SS_C / S, SS_C
Regulatory reference	www.suva.ch, 01.01.2023

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

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

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):

8.2.2.1. Eye and face protection

Eye protection:
Safety glasses

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing

Hand protection:
Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:
In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	Pale yellow.
Appearance	:	Liquid.
Odour	:	odourless.
Odour threshold	:	Not available
Melting point	:	Not applicable
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Non flammable.
Lower explosion limit	:	Not available
Upper explosion limit	:	Not available
Flash point	:	Not available
Auto-ignition temperature	:	Not available
Decomposition temperature	:	Not available
pH	:	Not available
Viscosity, kinematic	:	Not available
Solubility	:	Not available
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20°C	:	Not available
Particle characteristics	:	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6] (55965-84-9)	
ATE CLP (oral)	100 mg/kg bodyweight
ATE CLP (dermal)	300 mg/kg bodyweight
ATE CLP (gases)	700 ppmv/4h
ATE CLP (vapours)	3 mg/l/4h
ATE CLP (dust,mist)	0,05 mg/l/4h

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified
Respiratory or skin sensitisation : May cause an allergic skin reaction.
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified
Aspiration hazard : Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short–term (acute) : Not classified
Hazardous to the aquatic environment, long–term (chronic) : Not classified
Not rapidly degradable

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport
Not applicable

Transport by sea
Not applicable

Air transport
Not applicable

Inland waterway transport
Not applicable

Rail transport
Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)
Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)
Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)
Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)
Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)
Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)
Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)
Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)
Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Employment restrictions	:	Observe restrictions according Act on the Protection of Working Mothers (MuSchG). Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).
Water hazard class (WGK)	:	WGK nwg, Non-hazardous to water (Classification according to AwSV, Annex 1).
Hazardous Incident Ordinance (12. BImSchV)	:	Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen	:	None of the components are listed
SZW-lijst van mutagene stoffen	:	None of the components are listed
SZW-lijst van reprotoxische stoffen – Borstvoeding	:	None of the components are listed
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid	:	None of the components are listed
SZW-lijst van reprotoxische stoffen – Ontwikkeling	:	None of the components are listed

Denmark

Danish National Regulations	:	Young people below the age of 18 years are not allowed to use the product Pregnant/breastfeeding women working with the product must not be in direct contact with the product

Switzerland

Storage class (LK)	:	LK 10/12 - Liquids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Full text of H- and EUH-statements:	
Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H331	Toxic if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Conc wash solution

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 20.10.2023

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

1.1. Product identifier

Product form : Mixture
Product name : Conc wash solution
Product code : see SDS Frontispiece point 1

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

1.2.1. Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : IVD

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Dia.Metra s.r.l
Via Pozzuolo , 14
P.O. Box 06038
Spello (PG) – Italia
T +39074224851 - F +390742316197
carlo.massini@idsplc.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital Msida MSD 2090 Msida	+356 2545 6508	
United Kingdom	NHS 111/NHS 24/NHS Direct		111 0845 4647	or call a doctor

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin sensitisation, Category 1 H317
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

2.2. Label elements

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

Hazard pictograms (CLP) :

GHS07

Signal word (CLP) : Warning

Contains : A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6]

Hazard statements (CLP) : H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) : P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6]	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	< 1	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Acute Tox. 2 (Inhalation:dust,mist), H330 Skin Corr. 1A, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

Name	Product identifier	Specific concentration limits (%)
A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6]	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	(0,0015 ≤ C < 100) Skin Sens. 1, H317 (0,06 ≤ C ≤ 0,6) Skin Irrit. 2, H315 (0,06 ≤ C ≤ 0,6) Eye Irrit. 2, H319 (0,6 ≤ C < 100) Skin Corr. 1B, H314

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.

First-aid measures after eye contact : Rinse eyes with water as a precaution.

First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after skin contact : May cause an allergic skin reaction.

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 : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray. Wear personal protective equipment.

Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

A MIXTURE OF: 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 247-500-7] AND 2-METHYL-2H-ISOTHIAZOL-3-ONE [EC NO 220-239-6] (55965-84-9)	
Austria - Occupational Exposure Limits	
Local name	5-Chlor-2-methyl-2,3-dihydroisothiazol-3-on und 2-Methyl-2,3-di-hydroisothiazol-3-on (Gemisch im Verhältnis 3:1)
MAK (OEL TWA)	0,05 mg/m³
Remark	Sh
Regulatory reference	BGBl. II Nr. 156/2021
Switzerland - Occupational Exposure Limits	
Local name	2,3-Dihydro-isothiazol-3-one de 5-chloro-2-méthyle et 2,3-dihydro-isothiazol-3-one de 2-méthyle [2,3-Dihydro-isothiazol-3-one de 5-chloro-2-méthyle, 2,3-Dihydro-isothiazol-3-one de 2-méthyle] / 5-Chlor-2-methyl-2,3-dihydro-isothiazol-3-on und 2-Methyl-2,3-dihydroisothiazol-3-on [2-Methyl-2,3-dihydroisothiazol-3-on, 5-Chlor-2-methyl-2,3-dihydroisothiazol-3-on]
MAK (OEL TWA) [1]	0,2 mg/m³ (i) / (e)
KZGW (OEL STEL)	0,4 mg/m³ (i) / (e)
Critical toxicity	VRS, Peau, Yeux / OAW, Haut, Auge
Notation	S, SS_C / S, SS_C
Regulatory reference	www.suva.ch, 01.01.2023

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

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

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):

8.2.2.1. Eye and face protection

Eye protection:
Safety glasses

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing

Hand protection:
Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:
In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	Colourless.
Appearance	:	Colorless liquid.
Odour	:	Characteristic odour.
Odour threshold	:	Not available
Melting point	:	Not applicable
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Non flammable.
Lower explosion limit	:	Not available
Upper explosion limit	:	Not available
Flash point	:	Not available
Auto-ignition temperature	:	Not available
Decomposition temperature	:	Not available
pH	:	Not available
Viscosity, kinematic	:	Not available
Solubility	:	Not available
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20°C	:	Not available
Particle characteristics	:	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	:	Not classified
Acute toxicity (dermal)	:	Not classified
Acute toxicity (inhalation)	:	Not classified
Skin corrosion/irritation	:	Not classified
Serious eye damage/irritation	:	Not classified
Respiratory or skin sensitisation	:	May cause an allergic skin reaction.
Germ cell mutagenicity	:	Not classified
Carcinogenicity	:	Not classified
Reproductive toxicity	:	Not classified
STOT-single exposure	:	Not classified
STOT-repeated exposure	:	Not classified
Aspiration hazard	:	Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	:	The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short–term (acute)	:	Not classified
Hazardous to the aquatic environment, long–term (chronic)	:	Not classified

Not rapidly degradable

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport
Not applicable

Transport by sea
Not applicable

Air transport
Not applicable

Inland waterway transport
Not applicable

Rail transport
Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Employment restrictions	:	Observe restrictions according Act on the Protection of Working Mothers (MuSchG). Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).
Water hazard class (WGK)	:	WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).
Hazardous Incident Ordinance (12. BImSchV)	:	Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen	:	None of the components are listed
SZW-lijst van mutagene stoffen	:	None of the components are listed
SZW-lijst van reprotoxische stoffen – Borstvoeding	:	None of the components are listed
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid	:	None of the components are listed
SZW-lijst van reprotoxische stoffen – Ontwikkeling	:	None of the components are listed

Denmark

Danish National Regulations	:	Young people below the age of 18 years are not allowed to use the product Pregnant/breastfeeding women working with the product must not be in direct contact with the product

Switzerland

Storage class (LK)	:	LK 10/12 - Liquids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Full text of H- and EUH-statements:	
Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H331	Toxic if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.