

Kit RAL Stainer Gram-Nicolle, Slide counting

SIS (Safety Information Sheet) del Kit

Revision date: 15/04/2021Version: 1.0

SECTION 1: Kit identification

1.1 Kit identifier

: Kit RAL Stainer Gram-Nicolle, Slide counting Product name

Product code 360225

1.2 Details of the supplier of the Kit safety information sheet

RAL DIAGNOSTICS Site Montesquieu 33650 MARTILLAC - FRANCE T 33 05 57 96 04 04 - F 33 05 57 96 04 05

commercial@ral-diagnostics.fr - www.ral-diagnostics.com

SECTION 2: General information

Restrictions on use : For professional use only

In vitro diagnostic medical device.

General description : Staining for the differentiation of GRAM-positive and GRAM-negative bacteria.

This product is a Kit which consists of several independently packaged components One or more of these components include a substance or mixture that is subject to classification according to Regulation (EC) No. 1272/2008 [CLP] A SDS for each of these components is included. Please do not separate any component SDS from this cover page

SECTION 3: Kit contents

Name	General description	Weight or Volume	Quantity	Unit	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Differentiator			1	pcs (pieces)	Flam. Liq. 2, H225
Ziehl carbolic fuchsin 1/10			1	pcs (pieces)	Not classified
Lugol, PVP-stabilized solution			1	pcs (pieces)	Not classified
Carbolic gentian violet			1	pcs (pieces)	Not classified

SECTION 4: General advice

No data available

SECTION 5: Safe handling advice

General measures : Do not handle until all safety precautions have been read and understood.

Environmental precautions : Avoid release to the environment

This material and its container must be disposed of in a safe way, and as per local

legislation

Store in original container Storage conditions

> Keep container tightly closed Store in dry, well-ventilated area

SECTION 6: First aid measures

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

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First-aid measures after ingestion : If swallowed, seek medical advice immediately and show this container or label

Rinse mouth out with water

First-aid measures after skin contact : Rinse with plenty of water

First-aid measures general : If you feel unwell, seek medical advice (show the label where possible)

SECTION 7: Fire fighting measures

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection

Exercise caution when fighting any chemical fire

SECTION 8: Transport information

Refer to section 14 of kit products' SDS

SECTION 9: Other information

No data available

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Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Revision date: 3/1/2021 Supersedes version of: 4/18/2016 Version: 4.0

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

1.1. Product identifier

Product form : Mixture
Product name : Differentiator
Product code : 361515

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

1.2.1. Relevant identified uses

Main use category : For professional use only

Use of the substance/mixture : In vitro diagnostic medical device.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

RAL DIAGNOSTICS Site Montesquieu 33650 MARTILLAC FRANCE

T 33 05 57 96 04 04 - F 33 05 57 96 04 05

 $\underline{commercial@ral\text{-}diagnostics.fr} - \underline{www.ral\text{-}diagnostics.com}$

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 MSD Msida	+356 2545 6504	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Flammable liquids, Category 2 H225

Full text of H and EUH statements: see section 16

Adverse physicochemical, human health and environmental effects

Highly flammable liquid and vapour.

2.2. Label elements

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

Hazard pictograms (CLP)

GHS02

Signal word (CLP) : Danger

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

: H225 - Highly flammable liquid and vapour. Hazard statements (CLP)

Precautionary statements (CLP) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other

ignition sources. No smoking.

2.3. Other hazards

No additional information available

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]
Ethyl alcohol substance with national workplace exposure limit(s) (IE, GB)	CAS-No.: 64-17-5 EC-No.: 200-578-6 EC Index-No.: 603-002- 00-5 REACH-no: 01- 2119457610-43	env. 90 %	Flam. Liq. 2, H225

Full text of H and EUH statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

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

First-aid measures after skin contact : Rinse skin with water/shower. Take off immediately all contaminated clothing.

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

: Water spray. Dry powder. Foam. Carbon dioxide. Suitable extinguishing media

5.2. Special hazards arising from the substance or mixture

Fire hazard : Highly flammable liquid and vapour. 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

: Ventilate spillage area. No open flames, no sparks, and no smoking. Emergency procedures

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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. Notify authorities if product enters

sewers or public waters.

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. Keep away from heat, hot surfaces,

sparks, open flames and other ignition sources. No smoking. 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 container tightly closed.

Storage temperature : 15 – 25 °C

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

Ethyl alcohol (64-17-5)		
Ireland - Occupational Exposure Limits		
Local name	Ethanol [Ethyl alcohol]	
OEL STEL [ppm]	1000 ppm	
Regulatory reference Chemical Agents Code of Practice 2020		
United Kingdom - Occupational Exposure Limits		
Local name	Ethanol	
WEL TWA (OEL TWA) [1]	1920 mg/m³	
WEL TWA (OEL TWA) [2] 1000 ppm		
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE	

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

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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.
Odour : alcoholic.

Odour threshold : No data available pΗ : No data available : No data available Relative evaporation rate (butylacetate=1) Melting point : Not applicable Freezing point : No data available **Boiling point** : No data available : No data available Flash point Auto-ignition temperature : No data available Decomposition temperature : No data available Flammability (solid, gas) : Not applicable Vapour pressure : No data available Relative vapour density at 20 °C : No data available Relative density : 0.811 - 0.817

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Solubility : No data available

Partition coefficient n-octanol/water (Log

Pow)

: No data available

Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : No data available
Oxidising properties : No data available
Explosive limits : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable liquid and vapour.

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

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

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 toxicological effects

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

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Ethyl alcohol (64-17-5)	
LD50 oral rat	15010 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 401 (Acute Oral Toxicity), 95% CL: 14450 - 15560
LD50 oral	8300 mg/kg bodyweight Animal: mouse
LD50 dermal rat	> 2000 mg/kg
LC50 Inhalation - Rat	> 20 mg/l
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
Ethyl alcohol (64-17-5)	
IARC group	1 - Carcinogenic to humans
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified

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STOT-repeated exposure : Not classified

Ethyl alcohol (64-17-5)	
	< 9700 mg/kg bodyweight Animal: mouse, Animal sex: male, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)
NOAEL (subchronic, oral, animal/female, 90 days)	> 9400 mg/kg bodyweight Animal: mouse, Animal sex: female, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)

Aspiration hazard : Not classified

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

Ethyl alcohol (64-17-5)	
LC50 - Fish [1]	14.2 g/l Test organisms (species): Pimephales promelas
EC50 72h - Algae [1]	1900 – 1970 mg/l (marine water)
EC50 96h - Algae [1]	275 mg/l (freshwater)
ErC50 algae	275 mg/l Source: ECHA
NOEC (chronic)	9.6 mg/l Test organisms (species): Daphnia magna Duration: '9 d'
NOEC chronic fish	250 mg/l

12.2. Persistence and degradability

Ethyl alcohol (64-17-5)	
Persistence and degradability	Readily biodegradable.

12.3. Bioaccumulative potential

12.0. Bloaddamaiative potential	
Ethyl alcohol (64-17-5)	
Partition coefficient n-octanol/water (Log Pow)	-0.32 Source: ICSC
Bioaccumulative potential	No bioaccumulation.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other adverse effects : Not release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

instructions. Dispose in a safe manner in accordance with local/national

regulations.

Additional information : Flammable vapours may accumulate in the container.

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SECTION 14: Transport information

ln	accordance	with ADF	R / IMDG	/ IATA /	ADN / RID)
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ADR	IMDG	IATA	ADN	RID
14.1. UN number				
UN 1170	UN 1170	UN 1170	UN 1170	UN 1170
14.2. UN proper shippin	g name			
ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	Ethanol solution	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
Transport document descr	iption			
UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II, (D/E)	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II	UN 1170 Ethanol solution, 3, II	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II
14.3. Transport hazard o	class(es)			
3	3	3	3	3
3	3		3	3
14.4. Packing group				
II	II	II	II	II
14.5. Environmental haz	ards			
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No	Dangerous for the environment: No	Dangerous for the environment: No	Dangerous for the environment: No
No supplementary informa	ation available			

14.6. Special precautions for user

Overland transport

Classification code (ADR) : F1
Special provisions (ADR) : 144, 601
Limited quantities (ADR) : 11
Excepted quantities (ADR) : E2

Packing instructions (ADR) : P001, IBC02, R001

Mixed packing provisions (ADR) : MP19
Portable tank and bulk container instructions : T4
(ADR)

Portable tank and bulk container special

provisions (ADR)

: TP1

Tank code (ADR) : LGBF

Vehicle for tank carriage : FL

Transport category (ADR) : 2

Special provisions for carriage - Operation : S2, S20

(ADR)

Hazard identification number (Kemler No.) : 33

Orange plates :

33 1170

: D/E

Tunnel restriction code (ADR)

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EAC code : •2YE

Transport by sea

Special provisions (IMDG) : 144 Limited quantities (IMDG) : 1 L Excepted quantities (IMDG) : E2 Packing instructions (IMDG) : P001 IBC packing instructions (IMDG) : IBC02 Tank instructions (IMDG) : T4 Tank special provisions (IMDG) : TP1 EmS-No. (Fire) : F-E : S-D EmS-No. (Spillage) Stowage category (IMDG) : A

Properties and observations (IMDG) : Colourless, volatile liquids. Pure ETHANOL: flashpoint 13°C c.c. Explosive limits:

3.3% to 19% Miscible with water.

MFAG-No : 127

Air transport

PCA Excepted quantities (IATA) : E2 PCA Limited quantities (IATA) : Y341 PCA limited quantity max net quantity (IATA) : 1L PCA packing instructions (IATA) : 353 PCA max net quantity (IATA) : 5L CAO packing instructions (IATA) : 364 CAO max net quantity (IATA) : 60L

Special provisions (IATA) : A3, A58, A180

ERG code (IATA) : 3L

Inland waterway transport

Classification code (ADN) : F1 Special provisions (ADN) : 144, 601 Limited quantities (ADN) :1L Excepted quantities (ADN) : E2 Equipment required (ADN) : PP, EX, A

Ventilation (ADN) : VE01

Number of blue cones/lights (ADN) : 1

Rail transport

Classification code (RID) : F1 Special provisions (RID) : 144, 601 Limited quantities (RID) : 1L Excepted quantities (RID)

: P001, IBC02, R001 Packing instructions (RID)

Mixed packing provisions (RID) : MP19 Portable tank and bulk container instructions : T4

(RID)

Portable tank and bulk container special

provisions (RID)

: TP1

Tank codes for RID tanks (RID) : LGBF Transport category (RID) : 2 Colis express (express parcels) (RID) : CE7 Hazard identification number (RID) : 33

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14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

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

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes				
Section	Changed item	Change	Comments	
	Supersedes	Modified		
	Revision date	Modified		
2.2	Precautionary statements (CLP)	Modified		
7.2	Storage temperature	Added		
14.1	UN-No. (IATA)	Added		
14.1	UN-No. (IMDG)	Added		
14.1	UN-No. (ADN)	Added		
14.1	UN-No. (ADR)	Added		
16	Abbreviations and acronyms	Added		

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	
BLV	Biological limit value	
CAS-No.	Chemical Abstract Service number	
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008	
DMEL	Derived Minimal Effect level	
DNEL	Derived-No Effect Level	
EC50	Median effective concentration	
EC-No.	European Community number	
EN	European Standard	
IATA	International Air Transport Association	

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Abbreviations ar	Abbreviations and acronyms:		
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		
OEL	Occupational Exposure Limit		
PBT	Persistent Bioaccumulative Toxic		
PNEC	Predicted No-Effect Concentration		
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006		
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail		
SDS	Safety Data Sheet		
vPvB	Very Persistent and Very Bioaccumulative		
WGK	Water Hazard Class		

Full text of H- and EUH-statements:		
Flam. Liq. 2	Flammable liquids, Category 2	
H225	Highly flammable liquid and vapour.	

The classification complies with : ATP 12

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.



Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Issue date: 4/17/2021 Revision date: 2/15/2021 Supersedes version of: 8/10/2017 Version: 1.0

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

1.1. Product identifier

Product form : Mixture

Product name : Carbolic gentian violet

Product code : 320965

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

1.2.1. Relevant identified uses

Main use category : For professional use only

Use of the substance/mixture : In vitro diagnostic medical device.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

RAL DIAGNOSTICS Site Montesquieu 33650 MARTILLAC FRANCE

T 33 05 57 96 04 04 - F 33 05 57 96 04 05

commercial@ral-diagnostics.fr - www.ral-diagnostics.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 MSD Msida	+356 2545 6504	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	

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

No additional information available

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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]
Ethyl alcohol substance with national workplace exposure limit(s) (IE, GB)	CAS-No.: 64-17-5 EC-No.: 200-578-6 EC Index-No.: 603-002- 00-5 REACH-no: 01- 2119457610-43	1 - 5	Flam. Liq. 2, H225
Phenol	CAS-No.: 108-95-2 EC-No.: 203-632-7 EC Index-No.: 604-001- 00-2	< = 1	Muta. 2, H341 Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Oral), H301 STOT RE 2, H373 Skin Corr. 1B, H314
C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride substance listed as REACH Candidate ([4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)])	CAS-No.: 548-62-9 EC-No.: 208-953-6 EC Index-No.: 612-204- 00-2 REACH-no: 02- 2119824931-38	<= 0,2	Carc. 2, H351 Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:		
Name	Product identifier	Specific concentration limits
Phenol	CAS-No.: 108-95-2 EC-No.: 203-632-7 EC Index-No.: 604-001- 00-2	(1 ≤C < 3) Eye Irrit. 2, H319 (1 ≤C < 3) Skin Irrit. 2, H315 (3 ≤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

<u>5.1. Extinguishing media</u> Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case

: Toxic fumes may be released.

of fire

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.

Storage temperature : 15 - 25 °C

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

Phenol (108-95-2)		
EU - Indicative Occupational Exposure Limit (IOEL)		
Local name	Phenol	
IOEL TWA	8 mg/m³	
IOEL STEL	16 mg/m ³	
IOEL STEL [ppm]	4 ppm	
Remark	skin	
Regulatory reference	COMMISSION DIRECTIVE 2009/161/EU	

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Phenol (108-95-2)		
EU - Biological Limit Value (BLV)		
Local name	Phenol	
BLV	120 mg/g creatinine Parameter: phenol - Medium: urine	
Regulatory reference	SCOEL List of recommended health-based BLVs and BGVs	
Ireland - Occupational Exposure Limits		
Local name	Phenol	
OEL TWA [1]	8 mg/m³	
OEL TWA [2]	2 ppm	
OEL STEL	16 mg/m³	
OEL STEL [ppm]	4 ppm	
Regulatory reference	Chemical Agents Code of Practice 2020	
Malta - Occupational Exposure Limits		
Local name	Phenol	
OEL TWA	8 mg/m³	
OEL TWA [ppm]	2 ppm	
OEL STEL	16 mg/m³	
OEL STEL [ppm]	4 ppm	
Remark	Skin # Ġilda	
Regulatory reference	S.L.424.24 - Chemical Agents at Work Regulations (L.N.57 of 2018)	
United Kingdom - Occupational Exposure Limits		
Local name	Phenol	
WEL TWA (OEL TWA) [1]	7.8 mg/m³	
WEL TWA (OEL TWA) [2]	2 ppm	
WEL STEL (OEL STEL)	16 mg/m³	
WEL STEL (OEL STEL) [ppm]	4 ppm	
Remark	Sk (Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity)	
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE	
Ethyl alcohol (64-17-5)		
Ireland - Occupational Exposure Limits		
Local name	Ethanol [Ethyl alcohol]	
OEL STEL [ppm]	1000 ppm	
Regulatory reference	Chemical Agents Code of Practice 2020	
United Kingdom - Occupational Exposure Limits		
Local name	Ethanol	
WEL TWA (OEL TWA) [1]	1920 mg/m³	
WEL TWA (OEL TWA) [2]	1000 ppm	
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE	

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

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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: LiquidAppearance: clear.Colour: Violet.Odour: Phenolic.

Odour threshold : No data available

pH : 4 – 6

Relative evaporation rate (butylacetate=1) : No data available

Melting point : Not applicable

Freezing point : No data available

Boiling point : No data available

Flash point : $> 60 \, ^{\circ}\text{C}$

Auto-ignition temperature : No data available Decomposition temperature : No data available

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Flammability (solid, gas) : Not applicable Vapour pressure : No data available Relative vapour density at 20 °C : No data available

Relative density : 4 – 6

Solubility : No data available Partition coefficient n-octanol/water (Log : No data available

Pow)

Viscosity, kinematic : No data available Viscosity, dynamic : No data available Explosive properties : No data available : No data available Oxidising properties **Explosive limits** : No data available

9.2. Other information

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 toxicological effects

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

Phenol (108-95-2)	
LD50 oral rat	650 mg/kg Source: ECHA
LD50 dermal rat	625 mg/kg Source: ECHA
LC50 Inhalation - Rat	900 mg/m³ 8 Hours
LC50 Inhalation - Rat (Dust/Mist)	1.27 mg/l Source: ECHA

C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (548-62-9)

LD50 oral	711 mg/kg
LD50 dermal rat	> 6869 mg/kg

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Ethyl alcohol (64-17-5)	
LD50 oral rat	15010 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 401 (Acute Oral Toxicity), 95% CL: 14450 - 15560
LD50 oral	8300 mg/kg bodyweight Animal: mouse
LD50 dermal rat	> 2000 mg/kg
LC50 Inhalation - Rat	> 20 mg/l
Skin corrosion/irritation	: Not classified
	pH: 4 – 6
Serious eye damage/irritation	: Not classified
	pH: 4 – 6
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Phenol (108-95-2)	
IARC group	3 - Not classifiable
Ethyl alcohol (64-17-5)	
IARC group	1 - Carcinogenic to humans
C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino (548-62-9)	o) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloric
NOAEL (chronic, oral, animal/male, 2 years)	250 mg/kg bodyweight mouse
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Phenol (108-95-2)	
LOAEL (dermal, rat/rabbit, 90 days)	260 mg/kg bodyweight Animal: rabbit
NOAEL (dermal, rat/rabbit, 90 days)	130 mg/kg bodyweight Animal: rabbit
STOT-repeated exposure	May cause damage to organs through prolonged or repeated exposure.
Ethyl alcohol (64-17-5)	
NOAEL (subchronic, oral, animal/male, 90 days	 < 9700 mg/kg bodyweight Animal: mouse, Animal sex: male, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)
NOAEL (subchronic, oral, animal/female, 90 days)	> 9400 mg/kg bodyweight Animal: mouse, Animal sex: female, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)
Aspiration hazard	: Not classified

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

Phenol (108-95-2)	
LC50 - Fish [1]	21.93 mg/l Source: ECHA
EC50 - Crustacea [1]	3.1 mg/l Source: ECHA

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Phenol (108-95-2)				
EC50 72h - Algae [1]	180 mg/l Test organisms (species): Dunaliella tertiolecta			
EC50 72h - Algae [2]	217.6 mg/l Test organisms (species): Dunaliella tertiolecta			
EC50 96h - Algae [1]	61.1 mg/l Source: ECHA			
NOEC (chronic)	0.16 mg/l Test organisms (species): Daphnia magna Duration: '16 d'			
NOEC chronic fish	0.077 mg/l Test organisms (species): other:Cirrhina mrigala Duration: '60 d'			
NOEC chronic crustacea	0.46 mg/l			
C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) (548-62-9)	benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride			
LC50 - Fish [1]	82 µg/l			
EC50 - Crustacea [1]	350 μg/l			
EC50 72h - Algae [1]	0.21 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)			
Ethyl alcohol (64-17-5)				
LC50 - Fish [1]	14.2 g/l Test organisms (species): Pimephales promelas			
EC50 72h - Algae [1]	1900 – 1970 mg/l (marine water)			
EC50 96h - Algae [1]	275 mg/l (freshwater)			
ErC50 algae	275 mg/l Source: ECHA			
NOEC (chronic)	9.6 mg/l Test organisms (species): Daphnia magna Duration: '9 d'			
NOEC chronic fish	250 mg/l			

12.2. Persistence and degradability

Phenol (108-95-2)			
Persistence and degradability Readily biodegradable.			
C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (548-62-9)			
Persistence and degradability Not readily biodegradable.			
BOD (% of ThOD) 0.12 % ThOD			
Biodegradation 10 %			
Ethyl alcohol (64-17-5)			
Persistence and degradability	Readily biodegradable.		

12.3. Bioaccumulative potential

Phenol (108-95-2)		
BCF - Fish [1]	2 mg/l (Danio rerio) - 5h	
Bioconcentration factor (BCF REACH)	17.5	
Partition coefficient n-octanol/water (Log Pow)	1.46 Source: HSDB	
Ethyl alcohol (64-17-5)		
Partition coefficient n-octanol/water (Log Pow) -0.32 Source: ICSC		
Bioaccumulative potential	No bioaccumulation.	

12.4. Mobility in soil

Phenol (108-95-2)		
Mobility in soil	14 – 73 Source: ECHA	

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12.5. Results of PBT and vPvB assessment

Component		
C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (548-62-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6. Other adverse effects

Other adverse effects : Not release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods

: Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

ADR	IMDG	IATA	ADN	RID
14.1. UN number			,	
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shippin	g name			
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard o	class(es)			
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental haz	ards			
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary inform	ation available			

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

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SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains a substance on the REACH candidate list in concentration ≥ 0.1% or with a lower specific limit: [4-[4,4'-bis(dimethylamino)

benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) [with \geq 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] (EC 208-953-6, CAS 548-62-9)

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes					
Section Changed item Change Comments					
	Supersedes	Modified			
	Revision date	Modified			

Abbreviations a	nd 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

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Abbreviations and acronyms:		
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 EUI	H-statements:
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
Carc. 2	Carcinogenicity, Category 2
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
H225	Highly flammable liquid and vapour.
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.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H341	Suspected of causing genetic defects.
H351	Suspected of causing cancer.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.

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Full text of H- and EUH-statements:		
H410 Very toxic to aquatic life with long lasting effects.		
Muta. 2	Germ cell mutagenicity, Category 2	
Skin Corr. 1B	Sorr. 1B Skin corrosion/irritation, Category 1, Sub-Category 1B	
Skin Irrit. 2	Skin Irrit. 2 Skin corrosion/irritation, Category 2	
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2	

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.



Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Revision date: 1/12/2021 Supersedes version of: 4/26/2016 Version: 9.0

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

1.1. Product identifier

Product form : Mixture

Product name : Lugol, PVP-stabilized solution

Product code : 367400

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

1.2.1. Relevant identified uses

Main use category : For professional use only

Use of the substance/mixture : In vitro diagnostic medical device.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

RAL DIAGNOSTICS Site Montesquieu 33650 MARTILLAC FRANCE

T 33 05 57 96 04 04 - F 33 05 57 96 04 05

<u>commercial@ral-diagnostics.fr</u> - <u>www.ral-diagnostics.com</u>

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 MSD Msida	+356 2545 6504	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	

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

No additional information available

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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]
loda substance with national workplace exposure limit(s) (IE, GB)	CAS-No.: 7553-56-2 EC-No.: 231-442-4 EC Index-No.: 053-001- 00-3 REACH-no: 01- 2119485285-30	≤ 1	Acute Tox. 4 (Inhalation), H332 Acute Tox. 4 (Dermal), H312 Aquatic Acute 1, H400

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

: Toxic fumes may be released.

of fire

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.

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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.

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

loda (7553-56-2)	
Ireland - Occupational Exposure Limits	
Local name	lodine
OEL TWA [2]	0.01 ppm IFV (Inhlable Fraction and Vapour)
OEL STEL [ppm]	0.1 ppm
Regulatory reference	Chemical Agents Code of Practice 2020
United Kingdom - Occupational Exposure Limits	
Local name	lodine
WEL STEL (OEL STEL)	1.1 mg/m³
WEL STEL (OEL STEL) [ppm]	0.1 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

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.

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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
Appearance : clear.
Colour : brown.

Odour : No data available Odour threshold : No data available : No data available Relative evaporation rate (butylacetate=1) : No data available Melting point : Not applicable Freezing point : No data available **Boiling point** : No data available Flash point : No data available Auto-ignition temperature : No data available Decomposition temperature : No data available Flammability (solid, gas) : Not applicable Vapour pressure : No data available Relative vapour density at 20 °C : No data available

Relative density : 1.035

Solubility : No data available Partition coefficient n-octanol/water (Log : No data available

Pow)

Viscosity, kinematic : No data available Viscosity, dynamic : No data available Explosive properties : No data available

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Oxidising properties : No data available Explosive limits : No data available

9.2. Other information

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

	<u> 11.1 </u>	<u>Information</u>	on toxico	logical effects
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Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Acute toxicity (inhalation)	: Not classified
loda (7553-56-2)	
LD50 oral rat	315 mg/kg Source: ECHA
LD50 dermal rabbit	1425 mg/kg Source: ECHA
LC50 Inhalation - Rat	> 4.588 mg/l air Animal: rat, Guideline: OECD Guideline 403 (Acute Inhalation Toxicity)
LC50 Inhalation - Rat (Dust/Mist)	> 4.588 mg/l Source: ECHA
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
loda (7553-56-2)	
NOAEL (chronic, oral, animal/male, 2 years)	10 mg/kg bodyweight
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
loda (7553-56-2)	
NOAEL (oral, rat, 90 days)	10 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)
Aspiration hazard	: Not classified

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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

loda (7553-56-2)	
LC50 - Fish [1]	1.67 mg/l Source: ECHA
EC50 - Crustacea [1]	0.55 mg/l Daphnia magna
EC50 72h - Algae [1]	0.13 mg/l Source: ECHA

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

loda (7553-56-2)	
Partition coefficient n-octanol/water (Log Pow)	2.49 Source: ECHA

12.4. Mobility in soil

loda (7553-56-2)	
Mobility in soil	1.64 at 20 °C

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other adverse effects : Not release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods

: Dispose of contents/container in accordance with licensed collector's sorting instructions. Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shippin	ng 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

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

ADR	IMDG	IATA	ADN	RID
14.5. Environmental haz	ards			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary inform	ation 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. Transport in bulk according to Annex II of Marpol and the IBC Code

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

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes	ndication of changes		
Section Changed item		Change	Comments
	Supersedes	Modified	
	Revision date	Modified	

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

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Abbreviations and acronyms:		
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road	
ATE	Acute Toxicity Estimate	
BLV	Biological limit value	
CAS-No.	Chemical Abstract Service number	
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008	
DMEL	Derived Minimal Effect level	
DNEL	Derived-No Effect Level	
EC50	Median effective concentration	
EC-No.	European Community number	
EN	European Standard	
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	
OEL	Occupational Exposure Limit	
PBT	Persistent Bioaccumulative Toxic	
PNEC	Predicted No-Effect Concentration	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006	
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail	
SDS	Safety Data Sheet	
vPvB	Very Persistent and Very Bioaccumulative	
WGK	Water Hazard Class	

Full text of H- and EUH-statements:		
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4	
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4	
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1	
H312	Harmful in contact with skin.	
H332	Harmful if inhaled.	
H400	Very toxic to aquatic life.	

The classification complies with

: ATP 12

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.



Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Revision date: 2/15/2021 Supersedes version of: 4/25/2016 Version: 8.0

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

1.1. Product identifier

Product form : Mixture

Product name : Ziehl carbolic fuchsin 1/10

Product code : 364540

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

1.2.1. Relevant identified uses

Main use category : For professional use only

Use of the substance/mixture : In vitro diagnostic medical device.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

RAL DIAGNOSTICS Site Montesquieu 33650 MARTILLAC FRANCE

T 33 05 57 96 04 04 - F 33 05 57 96 04 05

commercial@ral-diagnostics.fr - www.ral-diagnostics.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 MSD Msida	+356 2545 6504	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	

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

No additional information available

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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]
Ethyl alcohol substance with national workplace exposure limit(s) (IE, GB)	CAS-No.: 64-17-5 EC-No.: 200-578-6 EC Index-No.: 603-002- 00-5 REACH-no: 01- 2119457610-43	1 - 5	Flam. Liq. 2, H225

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

: Toxic fumes may be released.

of fire

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.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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.

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

Ethyl alcohol (64-17-5)		
Ireland - Occupational Exposure Limits		
Local name	Ethanol [Ethyl alcohol]	
OEL STEL [ppm]	1000 ppm	
Regulatory reference Chemical Agents Code of Practice 2020		
United Kingdom - Occupational Exposure Limits		
Local name Ethanol		
WEL TWA (OEL TWA) [1] 1920 mg/m³		
WEL TWA (OEL TWA) [2] 1000 ppm		
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE	

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.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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
Appearance : clear.
Colour : red.

Odour : No data available
Odour threshold : No data available
pH : No data available
Relative evaporation rate (butylacetate=1) : No data available
Melting point : Not applicable
Freezing point : No data available
Boiling point : No data available

Flash point : $> 60 \, ^{\circ}\text{C}$

Auto-ignition temperature : No data available Decomposition temperature : No data available Flammability (solid, gas) : Not applicable Vapour pressure : No data available Relative vapour density at 20 °C : No data available : No data available Relative density Solubility : No data available Partition coefficient n-octanol/water (Log : No data available

Pow)

Viscosity, kinematic : No data available Viscosity, dynamic : No data available Explosive properties : No data available

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Oxidising properties : No data available Explosive limits : No data available

9.2. Other information

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

|--|

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

Acute toxicity (inhalation) :	Not classified	
Ethyl alcohol (64-17-5)		
LD50 oral rat	15010 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 401 (Acute Oral Toxicity), 95% CL: 14450 - 15560	
LD50 oral	8300 mg/kg bodyweight Animal: mouse	
LD50 dermal rat	> 2000 mg/kg	
LC50 Inhalation - Rat	> 20 mg/l	
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	
Ethyl alcohol (64-17-5)		
IARC group	1 - Carcinogenic to humans	
Reproductive toxicity :	Not classified	
STOT-single exposure :	Not classified	
STOT-repeated exposure :	Not classified	

Ethyl alcohol (64-17-5)	
	< 9700 mg/kg bodyweight Animal: mouse, Animal sex: male, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Ethyl alcohol (64-17-5)		
NOAEL (subchronic, oral, animal/female, 90 days)	> 9400 mg/kg bodyweight Animal: mouse, Animal sex: female, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)	
Aspiration hazard	: Not classified	

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

Ethyl alcohol (64-17-5)	
LC50 - Fish [1]	14.2 g/l Test organisms (species): Pimephales promelas
EC50 72h - Algae [1]	1900 – 1970 mg/l (marine water)
EC50 96h - Algae [1]	275 mg/l (freshwater)
ErC50 algae	275 mg/l Source: ECHA
NOEC (chronic)	9.6 mg/l Test organisms (species): Daphnia magna Duration: '9 d'
NOEC chronic fish	250 mg/l

12.2. Persistence and degradability

Ethyl alcohol (64-17-5)		
Persistence and degradability	Readily biodegradable.	

12.3. Bioaccumulative potential

2101 Bloaddannalativo potential		
Ethyl alcohol (64-17-5)		
Partition coefficient n-octanol/water (Log Pow)	-0.32 Source: ICSC	
Bioaccumulative potential	No bioaccumulation.	

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other adverse effects : Not release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods

 Dispose of contents/container in accordance with licensed collector's sorting instructions. Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

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

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

ADR	IMDG	IATA	ADN	RID		
14.1. UN number						
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable		
14.2. UN proper shippin	ng 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 inform	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. Transport in bulk according to Annex II of Marpol and the IBC Code

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

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	Revision date	Modified	
16	Abbreviations and acronyms	Added	

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	
BLV	Biological limit value	
CAS-No.	Chemical Abstract Service number	
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008	
DMEL	Derived Minimal Effect level	
DNEL	Derived-No Effect Level	
EC50	Median effective concentration	
EC-No.	European Community number	
EN	European Standard	
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	
OEL	Occupational Exposure Limit	
PBT	Persistent Bioaccumulative Toxic	
PNEC	Predicted No-Effect Concentration	
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006	
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail	
SDS	Safety Data Sheet	
vPvB	Very Persistent and Very Bioaccumulative	
WGK	Water Hazard Class	

Full text of H- and EUH-statements:		
Flam. Liq. 2	Flammable liquids, Category 2	
H225	Highly flammable liquid and vapour.	

The classification complies with

: ATP 12

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.