

Kit Fluo-RAL

SIS (Safety Information Sheet) del Kit

Revision date: 15/04/2021Version: 1.0

SECTION 1: Kit identification

1.1 Kit identifier

Product name : Kit Fluo-RAL
Product code : 359000

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 : Auramine staining kit for mycobacteria detection.

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]
Absolute ethanol			1	pcs (pieces)	Flam. Liq. 2, H225
Fixative Fluo-RAL			1	pcs (pieces)	Skin Corr. 1, H314 Aquatic Chronic 3, H412
Discolouring Solution Fluo- RAL			1	pcs (pieces)	Flam. Liq. 2, H225 Skin Corr. 1, H314
Carbolic Solution for Auramine Fluo-RAL / Solution for Auramine			1	pcs (pieces)	Acute Tox. 4 (Oral), H302 Skin Corr. 1B, H314 Muta. 2, H341
Auramine Fluo-RAL			1	pcs (pieces)	Flam. Liq. 3, H226
Thiazine Red Fluo-RAL			1	pcs (pieces)	Not classified
Carbolic Solution for Thiazine red Fluo-RAL / Solution for Thiazine Red			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.

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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

Storage conditions : Store in original container

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

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



Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Revision date: 4/13/2021 Supersedes version of: 4/26/2016 Version: 8.0

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

1.1. Product identifier

Product form : Mixture

Product name : Carbolic Solution for Thiazine red Fluo-RAL / Solution for Thiazine Red

Product code : 362610

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

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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]
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

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

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.

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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	
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	

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Phenol (108-95-2)		
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/m ³	
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	

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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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: Colourless.

Odour Codour : No data available Codour 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 : No data available

Flash point : > 100 $^{\circ}$ 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

Relative density : 1 - 1.002

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

Pow)

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

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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

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

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : 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
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
Phenol (108-95-2)	
IARC group	3 - Not classifiable
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

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Phenol (108-95-2)		
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.	

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-

: Not classified

term (chronic)

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

12.2. Persistence and degradability

Phenol (108-95-2)	
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	

12.4. Mobility in soil

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

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.

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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

pplicable	Not applicable		
plicable	Not applicable		
	i voi applicable	Not applicable	Not applicable
plicable	Not applicable	Not applicable	Not applicable
plicable	Not applicable	plicable Not applicable Not ap	
plicable	Not applicable	Not applicable	Not applicable
plicable	Not applicable	Not applicable	Not applicable
,	•		plicable Not applicable Not applicable

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

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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			
Revision date		Added	
	Supersedes	Modified	
7.2	Storage conditions	Added	
16	Abbreviations and acronyms	Added	

Abbreviations a	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

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

Abbreviations and acronyms:		
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 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
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.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H341	Suspected of causing genetic defects.
H373	May cause damage to organs through prolonged or repeated exposure.
Muta. 2	Germ cell mutagenicity, Category 2
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2

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: 7/27/2021 Supersedes version of: 4/16/2021 Version: 11.0

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

1.1. Product identifier

Product form : Mixture

Product name : Auramine Fluo-RAL

Product code : 362325

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]

Flammable liquids, Category 3 H226

Full text of H and EUH statements: see section 16

Adverse physicochemical, human health and environmental effects

Flammable liquid and vapour.

2.2. Label elements

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

Hazard pictograms (CLP)

GHS02

VA/ :

Signal word (CLP) : Warning

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

Hazard statements (CLP) : H226 - Flammable liquid and vapour.

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

ignition sources. No smoking.

Labelling according to: exemption for packages of a capacity of 125ml or less

Hazard pictograms (CLP)

GHS02

Signal word (CLP) : Warning

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	5 - 10	Flam. Liq. 2, H225
Phenol substance with national workplace exposure limit(s) (IE, MT, GB); substance with a Community workplace exposure limit	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
Auramine O	CAS-No.: 2465-27-2 EC-No.: 219-567-2 EC Index-No.: 612-097- 00-2	< 1	Acute Tox. 3 (Dermal), H311 Acute Tox. 4 (Oral), H302 Carc. 2, H351

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 : 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.

Safety Data Sheet

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

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.

5.2. Special hazards arising from the substance or mixture

Fire hazard : 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

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

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

7/27/2021 (Revision date) EN (English) 15/73

Safety Data Sheet

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

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 (IOEI	L)	
Local name	Phenol	
IOEL TWA	8 mg/m³	
IOEL STEL	16 mg/m³	
IOEL STEL [ppm]	4 ppm	
Remark	skin	
Regulatory reference	COMMISSION DIRECTIVE 2009/161/EU	
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]	

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Ethyl alcohol (64-17-5)			
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.

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.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Cloudy.
Colour : Yellow.

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 : $> 80 \, ^{\circ}\text{C}$ Flash point : $53.1 \, ^{\circ}\text{C}$

: No data available Auto-ignition temperature 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 : 0.98 - 0.99Solubility : 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
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

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

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according to Regulation (ECHNO.	1907/2000 (REACH) Willi its amenument	Redulation (EU) 2015/650	

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

reate toxicity (definal)	Not diaddined
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
Auramine O (2465-27-2)	
LD50 oral rat	1000 mg/kg
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
Phenol (108-95-2)	
IARC group	3 - Not classifiable
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
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)
	in the second se

SECTION 12: Ecological information

Aspiration hazard

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

: Not classified

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Hazardous to the aquatic environment, long-: Not classified

term (chronic)

Phenol (108-95-2)	
LC50 - Fish [1]	21.93 mg/l Source: ECHA
EC50 - Crustacea [1]	3.1 mg/l Source: ECHA
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
Auramine O (2465-27-2)	
LC50 - Fish [1]	3.2 mg/l Oryzias latipes, 48h
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	Persistence and degradability Readily biodegradable.		
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		
Auramine O (2465-27-2)		
Partition coefficient n-octanol/water (Log Pow) 2.98 (calculated value)		
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

12.5. Results of PBT and vPvB assessment No additional information available

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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.

SECTION 14: Transport information

In accordance with ADR / IME	OG / IATA / ADN / RID				
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, III, (D/E)	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III	UN 1170 Ethanol solution, 3, III	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III	
14.3. Transport hazard	class(es)				
3	3	3	3	3	
	3			3	
14.4. Packing group					
III	III	III	III	III	
14.5. Environmental hazards					
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 inform	ation available				

14.6. Special precautions for user

Overland transport

Classification code (ADR) : F1
Special provisions (ADR) : 144, 601
Limited quantities (ADR) : 5I

Excepted quantities (ADR) : E

Packing instructions (ADR) : P001, IBC03, LP01, R001

Mixed packing provisions (ADR) : MP19
Portable tank and bulk container instructions : T2

(ADR)

Portable tank and bulk container special

provisions (ADR)

: TP1

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Tank code (ADR) : LGBF
Vehicle for tank carriage : FL
Transport category (ADR) : 3
Special provisions for carriage - Packages : V12

(ADR)

Special provisions for carriage - Operation

(ADR)

Hazard identification number (Kemler No.) : 30

Orange plates

30 1170

: S2

Tunnel restriction code (ADR) : D/E EAC code : •2YE

Transport by sea

Special provisions (IMDG) : 144, 223 Limited quantities (IMDG) : 5 L Excepted quantities (IMDG) : E1

Packing instructions (IMDG) : P001, LP01
IBC packing instructions (IMDG) : IBC03
Tank instructions (IMDG) : T2
Tank special provisions (IMDG) : TP1
EmS-No. (Fire) : F-E
EmS-No. (Spillage) : S-D
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 : 128

Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y344
PCA limited quantity max net quantity (IATA) : 10L
PCA packing instructions (IATA) : 355
PCA max net quantity (IATA) : 60L
CAO packing instructions (IATA) : 366
CAO max net quantity (IATA) : 220L

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) : 5 L

Excepted quantities (ADN) : E1

Equipment required (ADN) : PP, EX, A

Ventilation (ADN) : VE01

Number of blue cones/lights (ADN) : 0

Rail transport

Classification code (RID) : F1
Special provisions (RID) : 144, 601

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Limited quantities (RID) : 5L Excepted quantities (RID) : E1

Packing instructions (RID) : P001, IBC03, LP01, R001

Mixed packing provisions (RID) : MP19
Portable tank and bulk container instructions : T2

(RID)

Portable tank and bulk container special : TP1

provisions (RID)

Tank codes for RID tanks (RID) : LGBF
Transport category (RID) : 3
Special provisions for carriage – Packages : W12

(RID)

Colis express (express parcels) (RID) : CE4
Hazard identification number (RID) : 30

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	
14.1	UN-No. (IATA)	Added	
14.1	UN-No. (IMDG)	Added	
14.1	UN-No. (ADN)	Added	
14.1	UN-No. (ADR)	Added	

Abbreviations and acr	obreviations 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	ATE Acute Toxicity Estimate	

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Abbreviations a	nd acronyms:
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. 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	
Carc. 2	Carcinogenicity, Category 2	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
Flam. Liq. 2	Flammable liquids, Category 2	
H225	Highly flammable liquid and vapour.	
H226	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.	

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Full text of H- and EUH-statements:		
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.	
Muta. 2	Germ cell mutagenicity, Category 2	
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2	

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.



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

1.1. Product identifier

Product form : Mixture

Product name : Thiazine Red Fluo-RAL

Product code : 362780

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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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]
Sodium hydroxyde solution 30%	CAS-No.: 1310-73-2 EC-No.: 215-185-5 EC Index-No.: 011-002- 00-6	< = 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318

Specific concentration limits:			
Name	Product identifier	Specific concentration limits	
Sodium hydroxyde solution 30%	CAS-No.: 1310-73-2 EC-No.: 215-185-5 EC Index-No.: 011-002- 00-6	(0.5 ≤C < 2) Skin Irrit. 2, H315 (0.5 ≤C < 2) Eye Irrit. 2, H319 (2 ≤C < 5) Skin Corr. 1B, H314 (5 ≤C < 100) Skin Corr. 1A, 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 : 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.

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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.

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

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):



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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 : 11 – 11.4

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

Flash point : > 100 °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

Relative density : 1

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

9.2. Other information

No additional information available

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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
---------------------	---------------	---------

Acute toxicity (oral) : Not classified Acute toxicity (dermal) : Not classified Acute toxicity (inhalation) : Not classified Skin corrosion/irritation : Not classified pH: 11 - 11.4 Serious eye damage/irritation

: Not classified

pH: 11 - 11.4 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 : Not classified Aspiration hazard

SECTION 12: Ecological information

12.1. Toxicity

: The product is not considered harmful to aquatic organisms nor to cause long-Ecology - general

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

Sodium hydroxyde solution 30% (1310-73-2)

EC50 - Crustacea [1] 40.4 mg/l Test organisms (species): Ceriodaphnia sp.

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

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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

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shippin	g name			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard o	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 haz	ards			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

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

Safety Data Sheet

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

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
	Revision date	Modified	
7.2	Storage conditions	Added	
9.1	pH	Added	
15.2	Chemical safety assessment	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
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

Safety Data Sheet

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

Abbreviations and acronyms:		
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:		
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
H290	May be corrosive to metals.	
H314	Causes severe skin burns and eye damage.	
H315	Causes skin irritation.	
H318	Causes serious eye damage.	
H319	Causes serious eye irritation.	
Met. Corr. 1	Corrosive to metals, Category 1	
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	

The classification complies with

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.

: ATP 12



Carbolic Solution for Auramine Fluo-RAL / Solution for Auramine

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Revision date: 3/24/2021 Supersedes version of: 4/26/2016 Version: 7.0

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

1.1. Product identifier

Product form : Mixture

Product name : Carbolic Solution for Auramine Fluo-RAL / Solution for Auramine

Product code : 362530

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]

Acute toxicity (oral), Category 4 H302
Skin corrosion/irritation, Category 1, Sub-Category 1B H314
Germ cell mutagenicity, Category 2 H341

Full text of H and EUH statements: see section 16

Adverse physicochemical, human health and environmental effects

Suspected of causing genetic defects. Causes severe skin burns and eye damage.

Carbolic Solution for Auramine Fluo-RAL / Solution for Auramine

Safety Data Sheet

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

2.2. Label elements

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

Hazard pictograms (CLP)



Signal word (CLP) : Danger Contains : Phenol

Hazard statements (CLP) : H302 - Harmful if swallowed.

> H314 - Causes severe skin burns and eye damage. H341 - Suspected of causing genetic defects.

Precautionary statements (CLP) : P201 - Obtain special instructions before use. P264 - Wash hands thoroughly after handling.

P280 - Wear protective gloves, protective clothing, eye protection, face

P301+P330+P331+P310 - IF SWALLOWED: rinse mouth. Do NOT induce

vomiting. Immediately call a POISON CENTER or doctor.

P303+P361+P353+P310 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.. Immediately call a

POISON CENTER or doctor.

P305+P351+P338+P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER or doctor.

Labelling according to: exemption for packages of a capacity of 125ml or less

Hazard pictograms (CLP)





GHS05

GHS07

GHS08

Signal word (CLP) : Danger Hazardous ingredients : Phenol

Hazard statements (CLP) : H314 - Causes severe skin burns and eye damage.

H341 - Suspected of causing genetic defects.

: P201 - Obtain special instructions before use. Precautionary statements (CLP) P264 - Wash hands thoroughly after handling.

P280 - Wear protective gloves, protective clothing, eye protection, face

protection.

P301+P330+P331+P310 - IF SWALLOWED: rinse mouth. Do NOT induce

vomiting. Immediately call a POISON CENTER or doctor.

P303+P361+P353+P310 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.. Immediately call a

POISON CENTER or doctor.

P305+P351+P338+P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER or doctor.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

Carbolic Solution for Auramine Fluo-RAL / Solution for Auramine

Safety Data Sheet

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

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Phenol substance with national workplace exposure limit(s) (IE, MT, GB); substance with a Community workplace exposure limit	CAS-No.: 108-95-2 EC-No.: 203-632-7 EC Index-No.: 604-001- 00-2	5 - 10	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

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 general : Call a physician immediately.

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

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

Call a physician immediately.

: Rinse cautiously with water for several minutes. Remove contact lenses, if First-aid measures after eye contact

present and easy to do. Continue rinsing. Call a physician immediately.

First-aid measures after ingestion : Rinse mouth. Do not induce vomiting. Call a physician immediately.

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

Symptoms/effects after skin contact : Burns.

Symptoms/effects after eye contact : Serious damage to eyes.

Symptoms/effects after ingestion : Burns.

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.

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.

Safety Data Sheet

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

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. Do not breathe

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. 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. Obtain special instructions before

use. Do not handle until all safety precautions have been read and understood.

Avoid contact with skin and eyes. Do not breathe

dust/fume/gas/mist/vapours/spray. Wear personal protective equipment.

Hygiene measures : 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

: Store locked up. Store in a well-ventilated place. Storage conditions

: 15 - 25 °C Storage temperature

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		
OEL STEL 16 mg/m³		
IOEL STEL [ppm] 4 ppm		
Remark skin		
Regulatory reference COMMISSION DIRECTIVE 2009/161/EU		
EU - Biological Limit Value (BLV)		
Local name Phenol		

Safety Data Sheet

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

Phenol (108-95-2)			
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		

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 inadequate ventilation] wear respiratory protection.

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 : Colourless. 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 : > 100 °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

Relative density : 1 - 1.01

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

11.1 Information on toxicological effects

: Harmful if swallowed. Acute toxicity (oral) : Not classified Acute toxicity (dermal)

Acute toxicity (inhalation) : Not classified

Carbolic Solution for Auramine Fluo-RAL / Solution for Auramine			
ATE CLP (oral)	1531.394 mg/kg bodyweight		
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		
Skin corrosion/irritation : Causes severe skin burns.			
Serious eye damage/irritation	: Assumed to cause serious eye damage		
Respiratory or skin sensitisation	: Not classified		

Germ cell mutagenicity : Suspected of causing genetic defects.

: Not classified Carcinogenicity

Phenol (108-95-2)		
IARC group 3 - Not classifiable		
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	

Safety Data Sheet

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

Phenol (108-95-2)	
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.
Assiration hazard	· Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Before neutralisation, the product may represent a danger to aquatic organisms.

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		
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		

12.2. Persistence and degradability

Phenol (108-95-2)	
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		

12.4. Mobility in soil

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

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.

Safety Data Sheet

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

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 shipping	g name			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard c	lass(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 haz	ards			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

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

Safety Data Sheet

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

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
	Revision date		
2.2	Precautionary statements (CLP)	Modified	
2.2	Hazard statements (CLP)	Modified	
15.2	Chemical safety assessment	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	
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 EUF	H-statements:
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3

Safety Data Sheet

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

Full text of H- and EUH-statements:		
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3	
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3	
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.	
H319	Causes serious eye irritation.	
H331	Toxic if inhaled.	
H341	Suspected of causing genetic defects.	
H373	May cause damage to organs through prolonged or repeated exposure.	
Muta. 2	Germ cell mutagenicity, Category 2	
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2	

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: 3/24/2021 Supersedes version of: 7/18/2019 Version: 9.0

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

1.1. Product identifier

Product form : Mixture

Product name : Discolouring Solution Fluo-RAL

Product code : 362210

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]

Flammable liquids, Category 2 H225 Skin corrosion/irritation, Category 1 H314

Full text of H and EUH statements: see section 16

Adverse physicochemical, human health and environmental effects

Highly flammable liquid and vapour. Causes severe skin burns and eye damage.

2.2. Label elements

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

Hazard pictograms (CLP)



GHS02 GH

GHS05

Safety Data Sheet

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

Signal word (CLP) : Danger

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

H314 - Causes severe skin burns and eye damage.

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

ignition sources. No smoking.

P280 - Wear protective gloves, protective clothing, eye protection.

P301+P330+P331+P310 - IF SWALLOWED: rinse mouth. Do NOT induce

vomiting. Immediately call a POISON CENTER or doctor.

P303+P361+P353+P310 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.. Immediately call a

POISON CENTER or doctor.

P305+P351+P338+P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER or doctor.

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	≥ 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

First-aid measures general : Call a physician immediately.

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

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

Call a physician immediately.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing. Call a physician immediately.

First-aid measures after ingestion : Rinse mouth. Do not induce vomiting. Call a physician immediately.

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

Symptoms/effects after skin contact : Burns.

Symptoms/effects after eye contact : Serious damage to eyes.

Symptoms/effects after ingestion : Burns.

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.

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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

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

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

contact with skin and eyes. Do not breathe 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. 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 : Keep away from heat, hot surfaces, sparks, open flames and other ignition

sources. No smoking. Wear personal protective equipment. Avoid contact with skin and eyes. Do not breathe dust/fume/gas/mist/vapours/spray. Ensure good

ventilation of the work station.

Hygiene measures : 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 container tightly closed. Store locked up.

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

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Ethyl alcohol (64-17-5)		
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.

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.

Safety Data Sheet

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : clear.
Colour : Colourless.
Odour : alcoholic.

Odour threshold : No data available

pH : < 2

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

Melting point : Not applicable

Freezing point : No data available

Boiling point : $80 \, ^{\circ}\text{C}$ Flash point : $17.5 \, ^{\circ}\text{C}$

: No data available Auto-ignition temperature : No data available Decomposition temperature Flammability (solid, gas) : Not applicable Vapour pressure : No data available Relative vapour density at 20 °C : No data available Relative density : 0.825 - 0.835Solubility : 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
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

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

Acute toxicity (dermal) : 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 : Causes severe skin burns.

pH: < 2

Serious eye damage/irritation : Assumed to cause serious eye damage

pH: < 2

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)	
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 : Before neutralisation, the product may represent a danger to aquatic organisms.

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.

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

12.3. Bioaccumulative 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 in a safe manner in accordance with local/national regulations. Dispose

of contents/container in accordance with licensed collector's sorting instructions.

Additional information : Flammable vapours may accumulate in the container.

SECTION 14: Transport information

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

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	·			

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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): LGBFVehicle for tank carriage: FLTransport category (ADR): 2

Special provisions for carriage - Operation

(ADR)

: S2, S20

Hazard identification number (Kemler No.) : 33

Orange plates

33 1170

Tunnel restriction code (ADR) : D/E EAC code : •2YE

Transport by sea

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

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

Safety Data Sheet

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

Special provisions (ADN) : 144, 601

Limited quantities (ADN) : 1 L

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) : E2

Packing instructions (RID) : P001, IBC02, R001

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

(RID)

Portable tank and bulk container special

provisions (RID)

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

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

: TP1

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		
2.2	Hazard pictograms (CLP)	Modified		
2.2	Hazard statements (CLP)	Modified		

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Indication of changes				
Section	Changed item	Change	Comments	
7.2	Storage temperature	Added		
9.1	Boiling point	Added		
15.2	Chemical safety assessment	Added		
16	Abbreviations and acronyms	Added		

Abbreviations a	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

Safety Data Sheet

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

Abbreviations and acr	onyms:
ED	Endocrine disrupting properties

Full text of H- and EUH-statements:		
Flam. Liq. 2	Flammable liquids, Category 2	
H225	Highly flammable liquid and vapour.	
H314 Causes severe skin burns and eye damage.		

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: 4/8/2021 Supersedes version of: 4/25/2016 Version: 7.0

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

1.1. Product identifier

Product form : Mixture

Product name : Fixative Fluo-RAL

Product code : 362115

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]

Skin corrosion/irritation, Category 1 H314
Hazardous to the aquatic environment — Chronic Hazard, H412

Category 3

Full text of H and EUH statements: see section 16

Adverse physicochemical, human health and environmental effects

Causes severe skin burns and eye damage. Harmful to aquatic life with long lasting effects.

2.2. Label elements

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

Hazard pictograms (CLP)



Safety Data Sheet

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

GHS05

Signal word (CLP) : Danger

Hazard statements (CLP) : H314 - Causes severe skin burns and eye damage.

H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP) : P280 - Wear protective clothing, protective gloves, eye protection.

P301+P330+P331+P310 - IF SWALLOWED: rinse mouth. Do NOT induce

vomiting. Immediately call a POISON CENTER or doctor.

P303+P361+P353+P310 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.. Immediately call a

POISON CENTER or doctor.

P305+P351+P338+P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER or doctor.

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]
trichloroacetic acid substance with national workplace exposure limit(s) (IE)	CAS-No.: 76-03-9 EC-No.: 200-927-2 EC Index-No.: 607-004- 00-7	< 1	Skin Corr. 1A, H314 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:			
Name	Product identifier	Specific concentration limits	
trichloroacetic acid	CAS-No.: 76-03-9 EC-No.: 200-927-2 EC Index-No.: 607-004- 00-7	(1 ≤C < 100) STOT SE 3, H335	

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 general : Call a physician immediately.

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

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

Call a physician immediately.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing. Call a physician immediately.

First-aid measures after ingestion : Rinse mouth. Do not induce vomiting. Call a physician immediately.

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

Symptoms/effects after skin contact : Burns.

Symptoms/effects after eye contact : Serious damage to eyes.

Symptoms/effects after ingestion : Burns.

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

Treat symptomatically.

Safety Data Sheet

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

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. Avoid contact with skin and eyes. Do not breathe

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. Do

not breathe dust/fume/gas/mist/vapours/spray. Wear personal protective

equipment.

Hygiene measures : 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 locked up. Store in a well-ventilated place.

Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

No additional information available

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Safety Data Sheet

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

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

trichloroacetic acid (76-03-9)				
EU - Indicative Occupational Exposure Limit (IOEL)				
Local name	Trichloroacetic acid			
Remark SCOEL Recommendations (2004)				
Ireland - Occupational Exposure Limits	Ireland - Occupational Exposure Limits			
Local name	Trichloroacetic acid			
OEL TWA [2]	0.5 ppm			
OEL STEL [ppm] 1.5 ppm				
Regulatory reference Chemical Agents Code of Practice 2020				

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

Safety Data Sheet

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

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 : Colourless.
Odour : No data available
Odour threshold : 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

: < 2

Flash point : > 60 °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

Relative density : 1 - 1.005

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
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.

Safety Data Sheet

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

SECTION 11: Toxicological information

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

trichloroacetic acid (76-03-9)	
LD50 oral rat	3320 mg/kg
LD50 dermal rat	≥ 2000 µl/kg

Skin corrosion/irritation : Causes severe skin burns.

pH: < 2

Serious eye damage/irritation : Assumed to cause serious eye damage

pH: < 2

Respiratory or skin sensitisation : Not classified Germ cell mutagenicity : Not classified : Not classified Carcinogenicity

trichloroacetic acid (76-03-9)	
IARC group	2B - Possibly carcinogenic to humans
Reproductive toxicity	: Not classified

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

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.

trichloroacetic acid (76-03-9)		
LC50 - Fish [1]	> 277 mg/l	
EC50 - Crustacea [1]	110 mg/l Daphnia magna	
EC50 72h - Algae [1]	0.27 mg/l	

12.2. Persistence and degradabilityNo additional information available

12.3. Bioaccumulative potential

trichloroacetic acid (76-03-9)		
BCF - Other aquatic organisms [1]	0.14 – 1.7 Cyprinus carpio	
Partition coefficient n-octanol/water (Log Pow)	1.44	

12.4. Mobility in soil

trichloroacetic acid (76-03-9)		
Mobility in soil	2.738 Source: ECHA	
Ecology - soil	Soluble in water. Very mobile.	

Safety Data Sheet

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

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

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

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	g name			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard o	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 haz	ards			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

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

Safety Data Sheet

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

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
	Flammability (solid, gas)	Added	
2.2	Precautionary statements (CLP)	Modified	
2.2	Signal word (CLP)	Modified	
2.2	Hazard statements	Modified	
15.2	Chemical safety assessment	Added	
16	Abbreviations and acronyms	Added	

Abbreviations and a	cronyms:
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

Safety Data Sheet

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

Abbreviations and acronyms:		
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:		
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1	
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1	
H314	Causes severe skin burns and eye damage.	
H335	May cause respiratory irritation.	
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	
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation	

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.

4/8/2021 (Revision date) EN (English) 64/73



Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Revision date: 6/18/2020 Supersedes version of: 2/12/2013 Version: 6.0

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

1.1. Product identifier

Product form : Substance

Trade name : Ethyl alcohol 96

Chemical name : ethanol; ethyl alcohol

 IUPAC name
 : ethanol

 EC Index-No.
 : 603-002-00-5

 EC-No.
 : 200-578-6

 CAS-No.
 : 64-17-5

REACH registration No : 01-2119457610-43

Product code : 300180 Formula : C2H6O

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

1.2.1. Relevant identified uses

No additional information available

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]

Flammable liquids, Category 2 H225

Full text of H and EUH statements: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

Safety Data Sheet

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

2.2. Label elements

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

Hazard pictograms (CLP)



GHS02

Signal word (CLP) : Danger

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

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

Substance type : Mono-constituent
Name : Absolute ethanol

CAS-No. : 64-17-5 EC-No. : 200-578-6 EC Index-No. : 603-002-00-5

Name	Product identifier		Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethyl alcohol	CAS-No.: 64-17-5 EC-No.: 200-578-6 EC Index-No.: 603-002- 00-5	96	Flam. Liq. 2, H225

Full text of H and EUH statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

No additional information available

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

No additional information available

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

No additional information available

Safety Data Sheet

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

No additional information available

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

No additional information available

7.2. Conditions for safe storage, including any incompatibilities

No additional information available

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 96 (64-17-5)		
Ireland - Occupational Exposure Limits		
Local name	Ethanol [Ethyl alcohol]	
OEL STEL [ppm]	1000 ppm	
United Kingdom - Occupational Exposure Limits		
Local name	Ethanol	
WEL TWA (OEL TWA) [1]	1920 mg/m³	
WEL TWA (OEL TWA) [2]	1000 ppm	

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

Ethyl alcohol 96 (64-17-5)	
DNEL/DMEL (Workers)	
Acute - local effects, inhalation	1900 mg/m³
Long-term - systemic effects, dermal	343 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	950 mg/m³

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Ethyl alcohol 96 (64-17-5)		
DNEL/DMEL (General population)		
Acute - local effects, inhalation	950 mg/m³	
Long-term - systemic effects,oral	87 mg/kg bodyweight/day	
Long-term - systemic effects, inhalation	114 mg/m³	
Long-term - systemic effects, dermal	206 mg/kg bodyweight/day	
PNEC (Water)		
PNEC aqua (freshwater)	0.96 mg/l	
PNEC aqua (marine water)	0.79 mg/l	
PNEC aqua (intermittent, freshwater)	2.75 mg/l	
PNEC (Sediment)		
PNEC sediment (freshwater)	3.6 mg/kg dwt	
PNEC sediment (marine water)	2.9 mg/kg dwt	
PNEC (Soil)		
PNEC soil	0.63 mg/kg dwt	
PNEC (Oral)		
PNEC oral (secondary poisoning)	0.72 g/kg food	
PNEC (STP)		
PNEC sewage treatment plant	580 mg/l	

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No additional information available

8.2.2. Personal protection equipment

No additional information available

8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Molecular mass : 46.0684 g/mol Source: HSDB

Colour : Colourless.
Odour : alcoholic.

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

Melting point : -114.1 °C Source: HSDB

Freezing point : No data available

Boiling point : 78.29001 °C Atm. press.: 1013,25 hPa Decomposition: 'no'

Flash point : 13 °C Atm. press.: 1 atm
Auto-ignition temperature : 400 °C Source: ICSC
Decomposition temperature : No data available
Flammability (solid, gas) : No data available

Safety Data Sheet

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

Vapour pressure : 5.8 kPa 20 °C Source: ICSC

Relative vapour density at 20 °C : 1.6 Source: ICSC Relative density : 0.79 Source: ICSC

Solubility : Water: 789000 mg/l 20 °C Source: ECHA Registered substances

Partition coefficient n-octanol/water (Log : -0.32 Source: ICSC

Pow)

: No data available

Viscosity, dynamic : 1.17 mPa·s Temp.: '20°C' Parameter: 'dynamic viscosity (in mPa s)'

Explosive properties : No data available
Oxidising properties : No data available
Explosive limits : 0 (3.5 – 15) vol %

Upper explosive limit (UEL) : 3.1 – 27.7 % Source: ICSC

9.2. Other information

Viscosity, kinematic

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

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

Ethyl alcohol 96 (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
Ethyl alcohol (64-17-5)	
LD50 oral	> 8300 mg/kg bodyweight Animal: mouse
Ckin correction/irritation	· Not algorified

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified
Respiratory or skin sensitisation : Not classified

Safety Data Sheet

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

Germ cell mutagenicity : Not classified : Not classified Carcinogenicity

Ethyl alcohol 96 (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 96 (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)
Ethyl alcohol (64-17-5)	

NOAEL (subchronic, oral, animal/female, 90

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

OPPTS 870.3100 (90-Day Oral Toxicity in Rodents) days) Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-

term (acute)

: Not classified

Hazardous to the aquatic environment, long-

term (chronic)

: Not classified

Ethyl alcohol 96 (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	
Ethyl alcohol (64-17-5)		
LC50 - Fish [1]	11.2 – 14.2 Test organisms (species): Pimephales promelas	
EC50 72h - Algae [1]	1900 – 1970 mg/l (marine water)	
EC50 96h - Algae [1]	275 mg/l (freshwater)	
NOEC (chronic)	9.6 mg/l Test organisms (species): Daphnia magna Duration: '9 d'	
NOEC chronic fish	250 mg/l (freshwater)	

12.2. Persistence and degradability

Ethyl alcohol 96 (64-17-5)	
Persistence and degradability	Readily biodegradable.

12.3. Bioaccumulative potential

Ethyl alcohol 96 (64-17-5)	
Partition coefficient n-octanol/water (Log Pow)	-0.32 Source: ICSC

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

Ethyl alcohol 96 (64-17-5)	
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

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transpor	rt information			
In accordance with ADR / IMD	OG / IATA / ADN / RID			
ADR	IMDG	IATA	ADN	RID
14.1. UN number				
UN 1170	UN 1170	UN 1170	UN 1170	UN 1170
14.2. UN proper shipping	g name			
ETHANOL (ETHYL ALCOHOL) / 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 (ETHYL ALCOHOL) / ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II, (D/E)	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III	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	3
14.4. Packing group				
II	III	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

14.6. Special precautions for user

No supplementary information available

Overland transport

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

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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 : TP1

provisions (ADR)

Tank code (ADR) : LGBF : FL Vehicle for tank carriage Transport category (ADR) : 2 Special provisions for carriage - Operation : S2, S20

(ADR)

Hazard identification number (Kemler No.) : 33

Orange plates

33 1170

Tunnel restriction code (ADR) : D/E

Transport by sea

Special provisions (IMDG) : 144, 223 Limited quantities (IMDG) : 5 L Excepted quantities (IMDG) : E1

Packing instructions (IMDG) : P001, LP01 : IBC03 IBC packing instructions (IMDG) Tank instructions (IMDG) : T2 Tank special provisions (IMDG) : TP1 : F-E EmS-No. (Fire) : 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.

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

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

: VE01 Ventilation (ADN) Number of blue cones/lights (ADN) : 1

Safety Data Sheet

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

Rail transport

Classification code (RID) : F1

Special provisions (RID) : 144, 601

Limited quantities (RID) : 1L Excepted quantities (RID) : E2

Packing instructions (RID) : P001, IBC02, R001

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

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

No REACH Annex XVII restrictions

Ethyl alcohol 96 is not on the REACH Candidate List

Ethyl alcohol 96 is not on the REACH Annex XIV List

Ethyl alcohol 96 is not 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.

Ethyl alcohol 96 is not 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 additional information available

SECTION 16: Other information

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 8

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.

6/18/2020 (Revision date) EN (English) 73/73