

SECTION 1: Kit identification

1.1 Kit identifier

Product name : Kit RAL Stainer Fluo-RAL
 Product code : 360230

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 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]
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
Carbolic Solution for Thiazine red Fluo-RAL / Solution for Thiazine Red			1	pcs (pieces)	Not classified
Thiazine Red Fluo-RAL			1	pcs (pieces)	Not classified

SECTION 4: General advice

No data available

SECTION 5: Safe handling advice

General measures : Do not handle until all safety precautions have been read and understood.
 Environmental precautions : Avoid release to the environment
 This material and its container must be disposed of in a safe way, and as per local legislation

Kit RAL Stainer Fluo-RAL

SIS (Safety Information Sheet) del Kit

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

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
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

Thiazine Red Fluo-RAL

Safety Data Sheet

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

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
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 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.

Thiazine Red Fluo-RAL

Safety Data Sheet

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

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):



Thiazine Red Fluo-RAL

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

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

9.2. Other information

No additional information available

Thiazine Red Fluo-RAL

Safety Data Sheet

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

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
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

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

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

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

No additional information available

12.3. Bioaccumulative potential

No additional information available

Thiazine Red Fluo-RAL

Safety Data Sheet

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

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 shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

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

Not applicable

Thiazine Red Fluo-RAL

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

Thiazine Red Fluo-RAL

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 : 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.

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

Carbolic Solution for Thiazine red Fluo-RAL / Solution for Thiazine Red

Safety Data Sheet

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

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
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 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.

Carbolic Solution for Thiazine red Fluo-RAL / Solution for Thiazine Red

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.

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/m ³
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

Carbolic Solution for Thiazine red Fluo-RAL / Solution for Thiazine Red

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

Phenol (108-95-2)	
Ireland - Occupational Exposure Limits	
Local name	Phenol
OEL TWA [1]	8 mg/m ³
OEL TWA [2]	2 ppm
OEL STEL	16 mg/m ³
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/m ³
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/m ³
WEL TWA (OEL TWA) [2]	2 ppm
WEL STEL (OEL STEL)	16 mg/m ³
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.

Carbolic Solution for Thiazine red Fluo-RAL / Solution for Thiazine Red

Safety Data Sheet

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

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: clear.
Colour	: Colourless.
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: > 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 – 1.002
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available

Carbolic Solution for Thiazine red Fluo-RAL / Solution for Thiazine Red

Safety Data Sheet

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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

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/m ³ 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

Carbolic Solution for Thiazine red Fluo-RAL / Solution for Thiazine Red

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.

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

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

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

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

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

Carbolic Solution for Thiazine red Fluo-RAL / Solution for Thiazine Red

Safety Data Sheet

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

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 shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. 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 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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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 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
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.

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
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 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

Signal word (CLP)

: Warning

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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.

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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

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

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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/m ³
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
Ireland - Occupational Exposure Limits	
Local name	Phenol
OEL TWA [1]	8 mg/m ³
OEL TWA [2]	2 ppm
OEL STEL	16 mg/m ³
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/m ³
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/m ³
WEL TWA (OEL TWA) [2]	2 ppm
WEL STEL (OEL STEL)	16 mg/m ³
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/m ³
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 °C
Flash point	: 53.1 °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	: 0.98 – 0.99
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

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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Acute toxicity (dermal) : Not classified

Acute toxicity (inhalation) : Not classified

Phenol (108-95-2)	
LD50 oral rat	650 mg/kg Source: ECHA
LD50 dermal rat	625 mg/kg Source: ECHA
LC50 Inhalation - Rat	900 mg/m ³ 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)

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

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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): <i>Dunaliella tertiolecta</i>
EC50 72h - Algae [2]	217.6 mg/l Test organisms (species): <i>Dunaliella tertiolecta</i>
EC50 96h - Algae [1]	61.1 mg/l Source: ECHA
NOEC (chronic)	0.16 mg/l Test organisms (species): <i>Daphnia magna</i> Duration: '16 d'
NOEC chronic fish	0.077 mg/l Test organisms (species): other: <i>Cirrhina mrigala</i> Duration: '60 d'
NOEC chronic crustacea	0.46 mg/l

Auramine O (2465-27-2)	
LC50 - Fish [1]	3.2 mg/l <i>Oryzias latipes</i> , 48h

Ethyl alcohol (64-17-5)	
LC50 - Fish [1]	14.2 g/l Test organisms (species): <i>Pimephales promelas</i>
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): <i>Daphnia magna</i> Duration: '9 d'
NOEC chronic fish	250 mg/l

12.2. Persistence and degradability

Phenol (108-95-2)	
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 (<i>Danio rerio</i>) - 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 / 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 shipping 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 description				
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
				
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 information available				

14.6. Special precautions for user

Overland transport

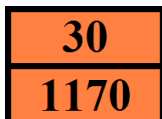
Classification code (ADR) : F1
Special provisions (ADR) : 144, 601
Limited quantities (ADR) : 5I
Excepted quantities (ADR) : E1
Packing instructions (ADR) : P001, IBC03, LP01, R001
Mixed packing provisions (ADR) : MP19
Portable tank and bulk container instructions (ADR) : T2
Portable tank and bulk container 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 (ADR) : V12
Special provisions for carriage - Operation (ADR) : S2
Hazard identification number (Kemler No.) : 30
Orange plates :



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

Auramine Fluo-RAL

Safety Data Sheet

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

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 (RID)	: T2
Portable tank and bulk container special provisions (RID)	: TP1
Tank codes for RID tanks (RID)	: LGBF
Transport category (RID)	: 3
Special provisions for carriage – Packages (RID)	: W12
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 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

Auramine Fluo-RAL

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

Abbreviations and 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.

Auramine Fluo-RAL

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

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.

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 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.

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

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Hazardous ingredients

: Phenol

Hazard statements (CLP)

: 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 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.
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.

5.2. Special hazards arising from the substance or mixture

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

5.3. Advice for firefighters

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

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

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

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

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/m ³
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

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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/m ³
OEL TWA [2]	2 ppm
OEL STEL	16 mg/m ³
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/m ³
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/m ³
WEL TWA (OEL TWA) [2]	2 ppm
WEL STEL (OEL STEL)	16 mg/m ³
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.

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

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
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: > 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 Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available

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

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) : Harmful if swallowed.

Acute toxicity (dermal) : Not classified

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/m ³ 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.
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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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.
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.

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

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 name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. 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

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

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 EUH-statements:	
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3

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

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.

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

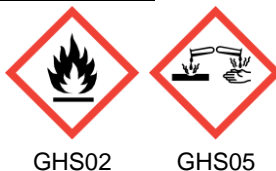
Adverse physicochemical, human health and environmental effects

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) :



Discolouring Solution Fluo-RAL

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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Safety Data Sheet

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/m ³
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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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 °C
Flash point	: 17.5 °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	: 0.825 – 0.835
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable liquid and vapour.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

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

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

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

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity (oral) : Not classified

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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 shipping 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 description				
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 class(es)				
3	3	3	3	3
				
14.4. Packing group				
II	II	II	II	II
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 information available				

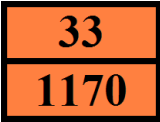
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14.6. Special precautions for user

Overland transport

Classification code (ADR)	: F1
Special provisions (ADR)	: 144, 601
Limited quantities (ADR)	: 1I
Excepted quantities (ADR)	: E2
Packing instructions (ADR)	: P001, IBC02, R001
Mixed packing provisions (ADR)	: MP19
Portable tank and bulk container instructions (ADR)	: T4
Portable tank and bulk container special provisions (ADR)	: TP1
Tank code (ADR)	: LGBF
Vehicle for tank carriage	: FL
Transport category (ADR)	: 2
Special provisions for carriage - Operation (ADR)	: S2, S20
Hazard identification number (Kemler No.)	: 33
Orange plates	: 
Tunnel restriction code (ADR)	: D/E
EAC code	: •2YE

Transport by sea

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

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

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 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

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Abbreviations and acronyms:	
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.

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
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]

Skin corrosion/irritation, Category 1 H314
Hazardous to the aquatic environment — Chronic Hazard, Category 3 H412

Full text of H and EUH statements: see section 16

Adverse physicochemical, human health and environmental effects

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) :



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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.

Fixative Fluo-RAL

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 of fire : Toxic fumes may be released.

5.3. Advice for firefighters

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes. 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

Fixative Fluo-RAL

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	
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

Fixative Fluo-RAL

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
pH	: < 2
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: > 60 °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 Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

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.

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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

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

Carcinogenicity : Not classified

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 degradability

No 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.

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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 shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. 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

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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 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

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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.