

SECTION 1: Kit identification

1.1 Kit identifier

Product name : Kit Copro-Duo 2x24
Product code : 362350

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 : Kit for the parasitic examination of stools using two concentration techniques.

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]
Aceto-acetic buffer pH=5.0 according to Bailenger			1	pcs (pieces)	Not classified
Merthiolate-Formalin (M.F. solution)			1	pcs (pieces)	Flam. Liq. 3, H226 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 Muta. 2, H341 Carc. 1B, H350 STOT SE 3, H335
Organic Phase Ethyl Acetate Based			1	pcs (pieces)	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Coprology Lugol			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 Copro-Duo 2x24

SIS (Safety Information Sheet) del Kit

Kit SIS Ref.: 362350

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 : Organic Phase Ethyl Acetate Based
 Product code : 335350

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

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 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
 Serious eye damage/eye irritation, Category 2 H319
 Specific target organ toxicity — Single exposure, Category 3,
 Narcosis H336

Full text of H and EUH statements: see section 16

Adverse physicochemical, human health and environmental effects

Highly flammable liquid and vapour. May cause drowsiness or dizziness. Causes serious eye irritation.

Organic Phase Ethyl Acetate Based

Safety Data Sheet

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

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS02

GHS07

Signal word (CLP) :

Danger

Contains :

ethyl acetate

Hazard statements (CLP) :

H225 - Highly flammable liquid and vapour.
H319 - Causes serious eye irritation.
H336 - May cause drowsiness or dizziness.

Precautionary statements (CLP) :

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 - Wear protective gloves, protective clothing, eye protection.
P312 - Call a POISON CENTRE or doctor if you feel unwell.
P337+P313 - If eye irritation persists: Get medical advice/attention.

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

Hazard pictograms (CLP) :



GHS02

GHS07

Signal word (CLP) :

Danger

Hazardous ingredients :

ethyl acetate

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 acetate substance with a Community workplace exposure limit	CAS-No.: 141-78-6 EC-No.: 205-500-4 EC Index-No.: 607-022-00-5 REACH-no: 01-2119475103-46	> 95	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Diethyl ether substance with national workplace exposure limit(s) (IE, MT, GB); substance with a Community workplace exposure limit	CAS-No.: 60-29-7 EC-No.: 200-467-2 EC Index-No.: 603-022-00-4 REACH-no: 01-2119535785-29	< 0.1	Flam. Liq. 1, H224 Acute Tox. 4 (Oral), H302 STOT SE 3, H336

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 poison center or a doctor if you feel unwell.

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Safety Data Sheet

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

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 cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects	: May cause drowsiness or dizziness.
Symptoms/effects after skin contact	: Repeated exposure may cause skin dryness or cracking.
Symptoms/effects after eye contact	: Eye irritation.

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	: 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 breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes.

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. Use only outdoors or in a well-ventilated area. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes.

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Safety Data Sheet

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

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. 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 acetate (141-78-6)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Ethyl Acetate
IOEL TWA	734 mg/m ³
IOEL STEL	1468 mg/m ³
IOEL STEL [ppm]	400 ppm
Remark	SCOEL Recommendations (2008)
Regulatory reference	COMMISSION DIRECTIVE (EU) 2017/164
Diethyl ether (60-29-7)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Diethylether
IOEL TWA	308 mg/m ³
IOEL STEL	616 mg/m ³
IOEL STEL [ppm]	200 ppm
Regulatory reference	COMMISSION DIRECTIVE 2000/39/EC
Ireland - Occupational Exposure Limits	
Local name	Ether [Diethyl ether, Ethyl ether]
OEL TWA [1]	308 mg/m ³
OEL TWA [2]	100 ppm
OEL STEL	616 mg/m ³
OEL STEL [ppm]	200 ppm
Regulatory reference	Chemical Agents Code of Practice 2020
Malta - Occupational Exposure Limits	
Local name	Diethylether
OEL TWA	308 mg/m ³
OEL TWA [ppm]	100 ppm
OEL STEL	616 mg/m ³
OEL STEL [ppm]	200 ppm
Regulatory reference	S.L.424.24 - Chemical Agents at Work Regulations (L.N.57 of 2018)
United Kingdom - Occupational Exposure Limits	
Local name	Diethyl ether

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

Diethyl ether (60-29-7)	
WEL TWA (OEL TWA) [1]	310 mg/m ³
WEL TWA (OEL TWA) [2]	100 ppm
WEL STEL (OEL STEL)	620 mg/m ³
WEL STEL (OEL STEL) [ppm]	200 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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

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

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	: ≈ -84 °C
Freezing point	: No data available
Boiling point	: 77 °C
Flash point	: < 0 °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	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable liquid and vapour.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

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

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

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

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

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ethyl acetate (141-78-6)	
LD50 oral rat	5620 mg/kg
LD50 oral	4934 mg/kg bodyweight Animal: rabbit, Guideline: OECD Guideline 401 (Acute Oral Toxicity)
LD50 dermal rabbit	> 2000 mg/kg
LC50 Inhalation - Rat	> 22.5 mg/l 6 Hours
LC50 Inhalation - Rat [ppm]	> 6000 ppm

Diethyl ether (60-29-7)	
LD50 oral rat	1200 mg/kg Source: ECHA
LD50 dermal rabbit	> 20000 mg/kg Source: ECHA

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Causes serious eye irritation.
Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : May cause drowsiness or dizziness.

ethyl acetate (141-78-6)	
NOAEL (acute, oral, animal/male)	26400 mg/kg bodyweight (OECD 416 method)
STOT-single exposure	May cause drowsiness or dizziness.

Diethyl ether (60-29-7)	
STOT-single exposure	May cause drowsiness or dizziness.

STOT-repeated exposure : Not classified

ethyl acetate (141-78-6)	
LOAEL (oral, rat, 90 days)	3600 mg/kg bodyweight Animal: rat, Guideline: EPA OTS 795.2600 (Subchronic Oral Toxicity Test)
NOAEL (oral, rat, 90 days)	900 mg/kg bodyweight (OECD 416 method)
NOAEC (inhalation, rat, gas, 90 days)	1.28 mg/l EPA OTS 798. 2450

Diethyl ether (60-29-7)	
LOAEL (oral, rat, 90 days)	2000 mg/kg bodyweight Animal: rat, Animal sex: male, Guideline: other:no information available
NOAEL (oral, rat, 90 days)	500 mg/kg bodyweight Animal: rat, Guideline: other:no information available

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

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

ethyl acetate (141-78-6)	
LC50 - Fish [1]	230 ml/l Pimephales promelas
EC50 - Crustacea [1]	165 mg/l Daphnia magna

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

ethyl acetate (141-78-6)	
NOEC (chronic)	2.4 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC chronic fish	> 9.65 ml/l Pimephales promelas
Diethyl ether (60-29-7)	
LC50 - Fish [1]	2560 mg/l Source: ECHA
EC50 72h - Algae [1]	> 100 mg/l Source: ECHA
LOEC (chronic)	> 100 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC (chronic)	100 mg/l Test organisms (species): Daphnia magna Duration: '21 d'

12.2. Persistence and degradability

ethyl acetate (141-78-6)	
Chemical oxygen demand (COD)	1.82 g O ₂ /g substance
Biodegradation	70 % Readily biodegradable

12.3. Bioaccumulative potential

ethyl acetate (141-78-6)	
Partition coefficient n-octanol/water (Log Pow)	0.75 at 20 °C
Bioaccumulative potential	Not bioaccumulate.
Diethyl ether (60-29-7)	
Partition coefficient n-octanol/water (Log Pow)	0.89 Source: HSDB

12.4. Mobility in soil

Diethyl ether (60-29-7)	
Mobility in soil	26 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.

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 1173	UN 1173	UN 1173	UN 1173	UN 1173
14.2. UN proper shipping name				
ETHYL ACETATE	ETHYL ACETATE	Ethyl acetate	ETHYL ACETATE	ETHYL ACETATE

Organic Phase Ethyl Acetate Based


Safety Data Sheet

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

ADR	IMDG	IATA	ADN	RID
Transport document description				
UN 1173 ETHYL ACETATE, 3, II, (D/E)	UN 1173 ETHYL ACETATE, 3, II (-4°C c.c.)	UN 1173 Ethyl acetate, 3, II	UN 1173 ETHYL ACETATE, 3, II	UN 1173 ETHYL ACETATE, 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				

14.6. Special precautions for user

Overland transport

Classification code (ADR)	: F1
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	: •3YE

Transport by sea

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

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

EmS-No. (Spillage)	: S-D
Stowage category (IMDG)	: B
Flash point (IMDG)	: -4°C c.c.
Properties and observations (IMDG)	: Colourless liquid with a fragrant odour. Flashpoint: -4°C c.c. Explosive limits: 2.18% to 11.5% Immiscible with water.
MFAG-No	: 129

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
ERG code (IATA)	: 3L

Inland waterway transport

Classification code (ADN)	: F1
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
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

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

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	
3	Composition/information on ingredients	Modified	
7.2	Storage temperature	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

Organic Phase Ethyl Acetate Based

Safety Data Sheet

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

Abbreviations and acronyms:	
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 1	Flammable liquids, Category 1
Flam. Liq. 2	Flammable liquids, Category 2
H224	Extremely flammable liquid and vapour.
H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Narcosis

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 : Merthiolate-Formalin (M.F. solution)
 Product code : 365020

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
 Skin corrosion/irritation, Category 2 H315
 Serious eye damage/eye irritation, Category 2 H319
 Skin sensitisation, Category 1 H317
 Germ cell mutagenicity, Category 2 H341
 Carcinogenicity, Category 1B H350
 Specific target organ toxicity — Single exposure, Category 3,
 Respiratory tract irritation H335

Full text of H and EUH statements: see section 16

Adverse physicochemical, human health and environmental effects

Flammable liquid and vapour. May cause cancer. Suspected of causing genetic defects. May cause respiratory irritation. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation.

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2.2. Label elements

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

Hazard pictograms (CLP) :



GHS02

GHS07

GHS08

Signal word (CLP) :

Danger

Contains :

Formol 24%

Hazard statements (CLP) :

H226 - Flammable liquid and vapour.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H341 - Suspected of causing genetic defects.
H350 - May cause cancer.

Precautionary statements (CLP) :

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P264 - Wash hands thoroughly after handling.
P280 - Wear protective gloves, protective clothing, eye protection, face protection.
P308+P313 - IF exposed or concerned: Get medical advice/attention.

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

Hazard pictograms (CLP) :



GHS02

GHS07

GHS08

Signal word (CLP) :

Danger

Hazardous ingredients :

Formol 24%

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.
H341 - Suspected of causing genetic defects.
H350 - May cause cancer.

Precautionary statements (CLP) :

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 - Wear protective gloves, protective clothing, eye protection, face protection.
P308+P313 - IF exposed or concerned: Get medical advice/attention.

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	10 - 20	Flam. Liq. 2, H225

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Formol 24% substance with national workplace exposure limit(s) (IE, GB); substance with a Community workplace exposure limit	CAS-No.: 50-00-0 EC-No.: 200-001-8 EC Index-No.: 605-001-00-5	5-10	Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 Muta. 2, H341 Carc. 1B, H350 STOT SE 3, H335
Acetone substance with a Community workplace exposure limit	CAS-No.: 67-64-1 EC-No.: 200-662-2 EC Index-No.: 606-001-00-8 REACH-no: 01-2119471330-49	≤ 2	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Ethanolamine substance with national workplace exposure limit(s) (IE, MT, GB); substance with a Community workplace exposure limit	CAS-No.: 141-43-5 EC-No.: 205-483-3 EC Index-No.: 603-030-00-8 REACH-no: 01-2119486455-28	< 0.1	Acute Tox. 4 (Inhalation), H332 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Oral), H302 Skin Corr. 1B, H314

Specific concentration limits:		
Name	Product identifier	Specific concentration limits
Formol 24%	CAS-No.: 50-00-0 EC-No.: 200-001-8 EC Index-No.: 605-001-00-5	(0.2 ≤C < 100) Skin Sens. 1, H317 (5 ≤C < 100) STOT SE 3, H335 (5 ≤C < 25) Eye Irrit. 2, H319 (5 ≤C < 25) Skin Irrit. 2, H315 (25 ≤C < 100) Skin Corr. 1B, H314
Ethanolamine	CAS-No.: 141-43-5 EC-No.: 205-483-3 EC Index-No.: 603-030-00-8 REACH-no: 01-2119486455-28	(5 ≤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	: IF exposed or concerned: Get medical advice/attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a poison center or a doctor if you feel unwell.
First-aid measures after skin contact	: Rinse skin with water/shower. Take off immediately all contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: Irritation. May cause an allergic skin reaction.
Symptoms/effects after eye contact	: Eye irritation.

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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 : No open flames, no sparks, and no smoking. Only qualified personnel equipped with suitable protective equipment may intervene. Avoid breathing dust/fume/gas/mist/vapours/spray.

6.1.2. For emergency responders

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

6.2. Environmental precautions

Avoid release to the environment. Notify authorities if product enters sewers or public waters.

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. Wear personal protective equipment. Do not handle until all safety precautions have been read and understood. Limit quantities of product at the minimum necessary for handling and limit the number of exposed workers. Provide local exhaust or general room ventilation. Floors, walls and other surfaces in the hazard area must be cleaned regularly. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes.

Hygiene measures : Separate working clothes from town clothes. Launder separately. Wash contaminated clothing before reuse. Contaminated work clothing should not be allowed out of the workplace. 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

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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

Ethanolamine (141-43-5)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	2-Aminoethanol
IOEL TWA	2.5 mg/m ³
IOEL TWA [ppm]	1 ppm
IOEL STEL	7.6 mg/m ³
IOEL STEL [ppm]	3 ppm
Remark	skin
Regulatory reference	COMMISSION DIRECTIVE 2006/15/EC
Ireland - Occupational Exposure Limits	
Local name	2-Aminoethanol [Ethanolamine]
OEL TWA [1]	2.5 mg/m ³
OEL TWA [2]	1 ppm
OEL STEL	7.6 mg/m ³
OEL STEL [ppm]	3 ppm
Regulatory reference	Chemical Agents Code of Practice 2020
Malta - Occupational Exposure Limits	
Local name	2-Aminoethanol
OEL TWA	2.5 mg/m ³
OEL TWA [ppm]	1 ppm
OEL STEL	7.6 mg/m ³
OEL STEL [ppm]	3 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	2-Aminoethanol
WEL TWA (OEL TWA) [1]	2.5 mg/m ³
WEL TWA (OEL TWA) [2]	1 ppm
WEL STEL (OEL STEL)	7.6 mg/m ³
WEL STEL (OEL STEL) [ppm]	3 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
Acetone (67-64-1)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Acetone
IOEL TWA	1210 mg/m ³

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Acetone (67-64-1)	
Regulatory reference	COMMISSION DIRECTIVE 2000/39/EC
Formol 24% (50-00-0)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Formaldehyde
IOEL TWA	0.37 mg/m ³ (BOEL) 0.62 mg/m ³ (Limit value for the health care, funeral and embalming sectors until 11 July 2024)
IOEL STEL	0.74 mg/m ³ (BOEL)
IOEL STEL [ppm]	0.4 ppm
Remark	skin sensitiser. SCOEL Recommendations (2008/Ongoing)
Regulatory reference	DIRECTIVE (EU) 2019/983 (amending Directive 2004/37/EC)
Ireland - Occupational Exposure Limits	
Local name	Formaldehyde
OEL TWA [1]	0.37 mg/m ³ 0.62 mg/m ³ for the healthcare, funeral and embalming sectors until 11 July 2024
OEL TWA [2]	0.3 ppm 0.5 ppm for the healthcare, funeral and embalming sectors until 11 July 2024
OEL STEL	0.738 mg/m ³
OEL STEL [ppm]	0.6 ppm
Regulatory reference	Chemical Agents Code of Practice 2020
United Kingdom - Occupational Exposure Limits	
Local name	Formaldehyde
WEL TWA (OEL TWA) [1]	2.5 mg/m ³
WEL TWA (OEL TWA) [2]	2 ppm
WEL STEL (OEL STEL)	2.5 mg/m ³
WEL STEL (OEL STEL) [ppm]	2 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE
Ethyl alcohol (64-17-5)	
Ireland - Occupational Exposure Limits	
Local name	Ethanol [Ethyl alcohol]
OEL STEL [ppm]	1000 ppm
Regulatory reference	Chemical Agents Code of Practice 2020
United Kingdom - Occupational Exposure Limits	
Local name	Ethanol
WEL TWA (OEL TWA) [1]	1920 mg/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

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8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

[In case of 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
Colour	: orange. red.
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: 32.9 °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	: 0.985 – 1

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Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Flammable liquid and vapour.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

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

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

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

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

Ethanolamine (141-43-5)	
LD50 oral rat	1089 mg/kg Source: OECD SIDS
LD50 dermal rabbit	2504 mg/kg Source: OECD SIDS
LC50 Inhalation - Rat (Vapours)	> 1487 mg/l Source: ECHA
Acetone (67-64-1)	
LD50 oral rat	5800 mg/kg
LD50 dermal rabbit	≥ 15800 mg/kg
LC50 Inhalation - Rat	76 mg/l/4h
Formol 24% (50-00-0)	
LD50 oral rat	460 mg/kg Source: ECHA
LD50 dermal rabbit	292 mg/kg Source: GESTIS
LC50 Inhalation - Rat	0.588 mg/l/4h

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Ethyl alcohol (64-17-5)	
LD50 oral rat	15010 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 401 (Acute Oral Toxicity), 95% CL: 14450 - 15560
LD50 oral	8300 mg/kg bodyweight Animal: mouse
LD50 dermal rat	> 2000 mg/kg
LC50 Inhalation - Rat	> 20 mg/l
Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Suspected of causing genetic defects.
Carcinogenicity	: May cause cancer.
Formol 24% (50-00-0)	
IARC group	1 - Carcinogenic to humans
Ethyl alcohol (64-17-5)	
IARC group	1 - Carcinogenic to humans
Reproductive toxicity	: Not classified
Acetone (67-64-1)	
LOAEL (animal/female, F0/P)	11298 mg/kg bodyweight Animal: mouse, Animal sex: female
NOAEL (animal/male, F0/P)	900 mg/kg bodyweight Animal: rat, Animal sex: male, Remarks on results: other:Generation not specified (migrated information)
STOT-single exposure	: May cause respiratory irritation.
Acetone (67-64-1)	
STOT-single exposure	May cause drowsiness or dizziness.
Formol 24% (50-00-0)	
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Ethanolamine (141-43-5)	
NOAEL (oral, rat, 90 days)	300 mg/kg bodyweight Animal: rat, Guideline: other:OECD Guideline 416 (Two-generation reproduction toxicity study)
Ethyl alcohol (64-17-5)	
NOAEL (subchronic, oral, animal/male, 90 days)	< 9700 mg/kg bodyweight Animal: mouse, Animal sex: male, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)
NOAEL (subchronic, oral, animal/female, 90 days)	> 9400 mg/kg bodyweight Animal: mouse, Animal sex: female, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

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

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Ethanolamine (141-43-5)	
LC50 - Fish [1]	349 mg/l Test organisms (species): <i>Cyprinus carpio</i>
LC50 - Fish [2]	> 200 mg/l <i>Leuciscus idus</i> , 48h
EC50 - Crustacea [1]	65 mg/l Test organisms (species): <i>Daphnia magna</i>
EC50 72h - Algae [1]	2.8 mg/l Test organisms (species): <i>Pseudokirchneriella subcapitata</i> (previous names: <i>Raphidocelis subcapitata</i> , <i>Selenastrum capricornutum</i>)
EC50 72h - Algae [2]	2.1 mg/l Test organisms (species): <i>Pseudokirchneriella subcapitata</i> (previous names: <i>Raphidocelis subcapitata</i> , <i>Selenastrum capricornutum</i>)
ErC50 algae	2.8 mg/l Source: OECD SIDS
NOEC (chronic)	0.85 mg/l Test organisms (species): <i>Daphnia magna</i> Duration: '21 d'
NOEC chronic fish	1.24 mg/l Test organisms (species): <i>Oryzias latipes</i> Duration: '41 d'
Acetone (67-64-1)	
LC50 - Fish [1]	13000 mg/l
EC50 - Crustacea [1]	12600 – 12700 mg/l <i>Daphnia magna</i>
EC50 96h - Algae [1]	7000 mg/l
LOEC (chronic)	> 79 mg/l Test organisms (species): <i>Daphnia magna</i> Duration: '21 d'
NOEC (chronic)	≥ 79 mg/l Test organisms (species): <i>Daphnia magna</i> Duration: '21 d'
Formol 24% (50-00-0)	
LC50 - Fish [1]	31.8 mg/l Source: ECHA
EC50 - Crustacea [1]	5.8 mg/l Test organisms (species): <i>Daphnia pulex</i>
EC50 72h - Algae [1]	3.48 mg/l Source: ECHA
EC50 72h - Algae [2]	4.89 mg/l Test organisms (species): <i>Desmodesmus subspicatus</i> (previous name: <i>Scenedesmus subspicatus</i>)
NOEC chronic fish	≥ 48 mg/l Test organisms (species): <i>Oryzias latipes</i> Duration: '28 d'
Additional information	Avoid discarding in the environment.
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

Ethanolamine (141-43-5)	
Persistence and degradability	Readily biodegradable. In water, material soluble.
Acetone (67-64-1)	
Persistence and degradability	Readily biodegradable.
Ethyl alcohol (64-17-5)	
Persistence and degradability	Readily biodegradable.

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12.3. Bioaccumulative potential

Ethanolamine (141-43-5)	
Partition coefficient n-octanol/water (Log Pow)	-1.31 Source: ICSC
Bioaccumulative potential	Bioaccumulation unlikely.
Acetone (67-64-1)	
Bioaccumulative potential	Not bioaccumulate.
Formol 24% (50-00-0)	
Partition coefficient n-octanol/water (Log Pow)	0.35 Source: ECHA
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

Ethanolamine (141-43-5)	
Mobility in soil	1.167 Source: ECHA
Ecology - soil	Very mobile.

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other adverse effects : Avoid discarding in 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 1993	UN 1993	UN 1993	UN 1993	UN 1993
14.2. UN proper shipping name				
FLAMMABLE LIQUID, N.O.S.	FLAMMABLE LIQUID, N.O.S.	Flammable liquid, n.o.s.	FLAMMABLE LIQUID, N.O.S.	FLAMMABLE LIQUID, N.O.S.
Transport document description				
UN 1993 FLAMMABLE LIQUID, N.O.S., 3, III, (D/E)	UN 1993 FLAMMABLE LIQUID, N.O.S., 3, III	UN 1993 Flammable liquid, n.o.s., 3, III	UN 1993 FLAMMABLE LIQUID, N.O.S., 3, III	UN 1993 FLAMMABLE LIQUID, N.O.S., 3, III
14.3. Transport hazard class(es)				
3	3	3	3	3
				

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ADR	IMDG	IATA	ADN	RID
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)	: 274, 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)	: T4
Portable tank and bulk container special provisions (ADR)	: TP1, TP29
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	: •3YE

Transport by sea

Special provisions (IMDG)	: 223, 274, 955
Limited quantities (IMDG)	: 5 L
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: LP01, P001
IBC packing instructions (IMDG)	: IBC03
Tank instructions (IMDG)	: T4
Tank special provisions (IMDG)	: TP1, TP29
EmS-No. (Fire)	: F-E
EmS-No. (Spillage)	: S-E
Stowage category (IMDG)	: A
MFAG-No	: 128

Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y344

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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
ERG code (IATA)	: 3L

Inland waterway transport

Classification code (ADN)	: F1
Special provisions (ADN)	: 274, 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)	: 274, 601
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)	: T4
Portable tank and bulk container special provisions (RID)	: TP1, TP29
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

Merthiolate-Formalin (M.F. solution)

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
	Supersedes	Modified	
	Revision date	Modified	
2.2	Precautionary statements (CLP)	Modified	
3	Composition/information on ingredients	Modified	
7.2	Storage conditions	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

Merthiolate-Formalin (M.F. solution)

Safety Data Sheet

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

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

Full text of H- and EUH-statements:	
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Carc. 1B	Carcinogenicity, Category 1B
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.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H341	Suspected of causing genetic defects.
H350	May cause cancer.
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
Skin Sens. 1	Skin sensitisation, Category 1
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.

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

1.1. Product identifier

Product form : Mixture
Product name : Coprology Lugol
Product code : 367240

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

Coprology Lugol

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

Full text of H and EUH statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

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

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

No additional information available

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

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

5.3. Advice for firefighters

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

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

6.2. Environmental precautions

Avoid release to the environment.

Coprolgy Lugol

Safety Data Sheet

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

6.3. Methods and material for containment and cleaning up

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

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place.
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

Ioda (7553-56-2)	
Ireland - Occupational Exposure Limits	
Local name	Iodine
OEL TWA [2]	0.01 ppm IFV (Inhable Fraction and Vapour)
OEL STEL [ppm]	0.1 ppm
Regulatory reference	Chemical Agents Code of Practice 2020
United Kingdom - Occupational Exposure Limits	
Local name	Iodine
WEL STEL (OEL STEL)	1.1 mg/m ³
WEL STEL (OEL STEL) [ppm]	0.1 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Coprology Lugol

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
Colour	: dark brown.
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: > 60 °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	: No data available
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

Coprology Lugol

Safety Data Sheet

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

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

Ioda (7553-56-2)	
LD50 oral rat	315 mg/kg Source: ECHA
LD50 dermal rabbit	1425 mg/kg Source: ECHA
LC50 Inhalation - Rat	> 4.588 mg/l air Animal: rat, Guideline: OECD Guideline 403 (Acute Inhalation Toxicity)
LC50 Inhalation - Rat (Dust/Mist)	> 4.588 mg/l Source: ECHA

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Ioda (7553-56-2)	
NOAEL (chronic, oral, animal/male, 2 years)	10 mg/kg bodyweight
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified

Ioda (7553-56-2)	
NOAEL (oral, rat, 90 days)	10 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)

Aspiration hazard : Not classified

Coprology Lugol

Safety Data Sheet

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

SECTION 12: Ecological information

12.1. Toxicity

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

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

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

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

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

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

12.4. Mobility in soil

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

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other adverse effects : Not release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

SECTION 14: Transport information

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

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

Coprology Lugol

Safety Data Sheet

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

ADR	IMDG	IATA	ADN	RID
14.5. Environmental 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

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	
3	Composition/information on ingredients	Modified	
9.1	Flash point	Added	
16	Abbreviations and acronyms	Added	

Coprology Lugol

Safety Data Sheet

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

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. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
H312	Harmful in contact with skin.
H332	Harmful if inhaled.
H400	Very toxic to aquatic life.

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

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

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

1.1. Product identifier

Product form : Mixture
Product name : Aceto-acetic buffer pH=5.0 according to Bailenger
Product code : 366220

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

Aceto-acetic buffer pH=5.0 according to Bailenger

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

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

SECTION 4: First aid measures

4.1. Description of first aid measures

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

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

No additional information available

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

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

5.3. Advice for firefighters

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

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

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

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

6.4. Reference to other sections

For further information refer to section 13.

Aceto-acetic buffer pH=5.0 according to Bailenger

Safety Data Sheet

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Exposure limit values for the other components

Acetic acid 90% (64-19-7)		
EU - Indicative Occupational Exposure Limit (IOEL)		
Local name	Acetic acid	
IOEL TWA	25 mg/m ³	
IOEL STEL	50 mg/m ³	
IOEL STEL [ppm]	20 ppm	
Remark	SCOEL Recommendations (2012)	
Regulatory reference	COMMISSION DIRECTIVE (EU) 2017/164	
Ireland - Occupational Exposure Limits		
Local name	Acetic acid	
OEL TWA [1]	25 mg/m ³	
OEL TWA [2]	10 ppm	
OEL STEL	50 mg/m ³	
OEL STEL [ppm]	20 ppm	
Regulatory reference	Chemical Agents Code of Practice 2020	
Malta - Occupational Exposure Limits		
Local name	Acetic acid	
OEL TWA	25 mg/m ³	
OEL TWA [ppm]	10 ppm	
OEL STEL	50 mg/m ³	
OEL STEL [ppm]	20 ppm	
Regulatory reference	S.L.424.24 - Chemical Agents at Work Regulations (L.N.57 of 2018)	
United Kingdom - Occupational Exposure Limits		
Local name	Acetic acid	
WEL TWA (OEL TWA) [1]	25 mg/m ³	
WEL TWA (OEL TWA) [2]	10 ppm	

Aceto-acetic buffer pH=5.0 according to Bailenger

Safety Data Sheet

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

Acetic acid 90% (64-19-7)		
WEL STEL (OEL STEL)	50 mg/m ³	
WEL STEL (OEL STEL) [ppm]	20 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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colourless.
Odour	: No data available

Aceto-acetic buffer pH=5.0 according to Bailenger

Safety Data Sheet

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

Odour threshold	: No data available
pH	: 4.95 – 5.05
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	: No data available
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.

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: 4.95 – 5.05
Serious eye damage/irritation	: Not classified
	pH: 4.95 – 5.05

Aceto-acetic buffer pH=5.0 according to Bailenger

Safety Data Sheet

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

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

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. 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

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ADR	IMDG	IATA	ADN	RID
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

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	
9.1	Flash point	Added	
16	Abbreviations and acronyms	Added	

Aceto-acetic buffer pH=5.0 according to Bailenger

Safety Data Sheet

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

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

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.