

SECTION 1: Kit identification

1.1 Kit identifier

Product name : Kit Gram-Hücker R,fast action
Product code : 361520

1.2 Details of the supplier of the Kit safety information sheet

RAL DIAGNOSTICS
Site Montesquieu
33650 MARTILLAC - FRANCE
T 33 05 57 96 04 04 - F 33 05 57 96 04 05
commercial@ral-diagnostics.fr - www.ral-diagnostics.com

SECTION 2: General information

Restrictions on use : For professional use only
In vitro diagnostic medical device.

General description : Staining kit for the differentiation of GRAM-positive from GRAM-negative.

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] |
|---|---------------------|------------------|----------|--------------|--|
| Crystal violet oxalate | | | 1 | pcs (pieces) | Flam. Liq. 3, H226 Eye Irrit. 2, H319 Carc. 2, H351 Aquatic Chronic 3, H412 |
| Safranin | | | 1 | pcs (pieces) | Flam. Liq. 3, H226 |
| Fast differentiator (alcohol / acetone) | | | 1 | pcs (pieces) | Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336 |
| Lugol, PVP-stabilized solution | | | 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
Storage conditions : Store in original container
Keep container tightly closed
Store in dry, well-ventilated area

Kit Gram-Hücker R,fast action

SIS (Safety Information Sheet) del Kit

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 : Fast differentiator (alcohol / acetone)
 Product code : 361510

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
 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.

Fast differentiator (alcohol / acetone)

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 :

Acetone, Butanone, Isopropyl alcohol

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.

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] |
|---|---|---------|---|
| 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 | 40 - 50 | Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336 |
| Butanone substance with national workplace exposure limit(s) (IE, MT, GB); substance with a Community workplace exposure limit | CAS-No.: 78-93-3 EC-No.: 201-159-0 EC Index-No.: 606-002-00-3 REACH-no: 01-2119457290-43 | 0 - 1 | Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336 |
| Isopropyl alcohol substance with national workplace exposure limit(s) (IE, GB) | CAS-No.: 67-63-0 EC-No.: 200-661-7 EC Index-No.: 603-117-00-0 REACH-no: 01-2119457558-25 | 0 - 1 | Flam. Liq. 2, H225 Eye Irrit. 2, H319 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.

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.

Fast differentiator (alcohol / acetone)

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

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 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.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

Fast differentiator (alcohol / acetone)

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

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

| Acetone (67-64-1) | |
|---|---------------------------------------|
| EU - Indicative Occupational Exposure Limit (IOEL) | |
| Local name | Acetone |
| IOEL TWA | 1210 mg/m ³ |
| Regulatory reference | COMMISSION DIRECTIVE 2000/39/EC |
| Isopropyl alcohol (67-63-0) | |
| Ireland - Occupational Exposure Limits | |
| Local name | Isopropyl alcohol [Propan-2-ol] |
| OEL TWA [2] | 200 ppm |
| OEL STEL [ppm] | 400 ppm |
| Regulatory reference | Chemical Agents Code of Practice 2020 |
| United Kingdom - Occupational Exposure Limits | |
| Local name | Propan-2-ol |
| WEL TWA (OEL TWA) [1] | 999 mg/m ³ |
| WEL TWA (OEL TWA) [2] | 400 ppm |
| WEL STEL (OEL STEL) | 1250 mg/m ³ |
| WEL STEL (OEL STEL) [ppm] | 500 ppm |
| Regulatory reference | EH40/2005 (Fourth edition, 2020). HSE |
| Butanone (78-93-3) | |
| EU - Indicative Occupational Exposure Limit (IOEL) | |
| Local name | Butanone |
| IOEL TWA | 600 mg/m ³ |
| IOEL STEL | 900 mg/m ³ |
| IOEL STEL [ppm] | 300 ppm |
| Regulatory reference | COMMISSION DIRECTIVE 2000/39/EC |
| Ireland - Occupational Exposure Limits | |
| Local name | Methyl ethyl ketone (MEK) |
| OEL TWA [1] | 600 mg/m ³ |
| OEL TWA [2] | 200 ppm |
| OEL STEL | 900 mg/m ³ |
| OEL STEL [ppm] | 300 ppm |
| Regulatory reference | Chemical Agents Code of Practice 2020 |

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| Butanone (78-93-3) | |
|--|---|
| Malta - Occupational Exposure Limits | |
| Local name | Butanone |
| OEL TWA | 600 mg/m ³ |
| OEL TWA [ppm] | 200 ppm |
| OEL STEL | 900 mg/m ³ |
| OEL STEL [ppm] | 300 ppm |
| Regulatory reference | S.L.424.24 - Chemical Agents at Work Regulations (L.N.57 of 2018) |
| United Kingdom - Occupational Exposure Limits | |
| Local name | Butan-2-one (methyl ethyl ketone) |
| WEL TWA (OEL TWA) [1] | 600 mg/m ³ |
| WEL TWA (OEL TWA) [2] | 200 ppm |
| WEL STEL (OEL STEL) | 899 mg/m ³ |
| WEL STEL (OEL STEL) [ppm] | 300 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 |
| United Kingdom - Biological limit values | |
| Local name | Butan-2-one (methyl ethyl ketone) |
| BMGV | 70 µmol/l Parameter: butan-2-one - Medium: urine - Sampling time: Post shift |
| 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

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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 | : characteristic. |
| 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 | : > 35 °C |
| Flash point | : -19 °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 | : 0.798 |
| 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.

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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

| Acetone (67-64-1) | |
|--------------------------|---------------|
| LD50 oral rat | 5800 mg/kg |
| LD50 dermal rabbit | ≥ 15800 mg/kg |
| LC50 Inhalation - Rat | 76 mg/l/4h |

| Isopropyl alcohol (67-63-0) | |
|------------------------------------|--|
| LD50 oral rat | 5840 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 401 (Acute Oral Toxicity) |
| LD50 dermal rabbit | 16400 mg/kg Source: ECHA |
| LC50 Inhalation - Rat | 25 mg/l 6 Hours |

| Butanone (78-93-3) | |
|---------------------------------|-------------------------|
| LD50 oral rat | 2193 mg/kg Source: ECHA |
| LD50 dermal rabbit | > 8 g/kg |
| LC50 Inhalation - Rat | 34500 mg/l/4h |
| LC50 Inhalation - Rat (Vapours) | 32 mg/l Source: RTECS |

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

| Isopropyl alcohol (67-63-0) | |
|------------------------------------|----------------------|
| IARC group | 3 - Not classifiable |
| 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 drowsiness or dizziness.

| Acetone (67-64-1) | |
|--------------------------|------------------------------------|
| STOT-single exposure | May cause drowsiness or dizziness. |

Fast differentiator (alcohol / acetone)

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| | |
|------------------------------------|------------------------------------|
| Isopropyl alcohol (67-63-0) | |
| STOT-single exposure | May cause drowsiness or dizziness. |
| Butanone (78-93-3) | |
| STOT-single exposure | May cause drowsiness or dizziness. |
| 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 |

| | |
|------------------------------------|---|
| Acetone (67-64-1) | |
| LC50 - Fish [1] | 13000 mg/l |
| EC50 - Crustacea [1] | 12600 – 12700 mg/l Daphnia magna |
| EC50 96h - Algae [1] | 7000 mg/l |
| LOEC (chronic) | > 79 mg/l Test organisms (species): Daphnia magna Duration: '21 d' |
| NOEC (chronic) | ≥ 79 mg/l Test organisms (species): Daphnia magna Duration: '21 d' |
| Isopropyl alcohol (67-63-0) | |
| LC50 - Fish [1] | 10000 mg/l Test organisms (species): Pimephales promelas |
| LC50 - Fish [2] | 9640 mg/l Test organisms (species): Pimephales promelas |
| EC50 - Crustacea [1] | ≥ 100 mg/l |
| EC50 72h - Algae [1] | > 1000 mg/l |
| Butanone (78-93-3) | |
| LC50 - Fish [1] | 2993 mg/l Source: ECHA |
| EC50 - Crustacea [1] | 308 mg/l Source: ECHA |
| EC50 72h - Algae [1] | 1972 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) |
| EC50 96h - Algae [1] | 2029 mg/l Source: ECHA |

12.2. Persistence and degradability

| | |
|------------------------------------|------------------------|
| Acetone (67-64-1) | |
| Persistence and degradability | Readily biodegradable. |
| Isopropyl alcohol (67-63-0) | |
| Persistence and degradability | Readily biodegradable. |
| Biodegradation | 100 % (96h) |

12.3. Bioaccumulative potential

| | |
|---------------------------|--------------------|
| Acetone (67-64-1) | |
| Bioaccumulative potential | Not bioaccumulate. |

Fast differentiator (alcohol / acetone)

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| | |
|---|--------------------|
| Isopropyl alcohol (67-63-0) | |
| Partition coefficient n-octanol/water (Log Pow) | 0.05 Source: ICSC |
| Bioaccumulative potential | Not bioaccumulate. |
| Butanone (78-93-3) | |
| Partition coefficient n-octanol/water (Log Pow) | 0.29 Source: ICSC |

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 1993 | UN 1993 | UN 1993 | UN 1993 | UN 1993 |
| 14.2. UN proper shipping name | | | | |
| FLAMMABLE LIQUID, N.O.S. (Ethyl alcohol ; Acetone) | FLAMMABLE LIQUID, N.O.S. (Ethyl alcohol ; Acetone) | Flammable liquid, n.o.s. (Ethyl alcohol ; Acetone) | FLAMMABLE LIQUID, N.O.S. (Ethyl alcohol ; Acetone) | FLAMMABLE LIQUID, N.O.S. (Ethyl alcohol ; Acetone) |
| Transport document description | | | | |
| UN 1993 FLAMMABLE LIQUID, N.O.S. (Ethyl alcohol ; Acetone), 3, II, (D/E) | UN 1993 FLAMMABLE LIQUID, N.O.S. (Ethyl alcohol ; Acetone), 3, II | UN 1993 Flammable liquid, n.o.s. (Ethyl alcohol ; Acetone), 3, II | UN 1993 FLAMMABLE LIQUID, N.O.S. (Ethyl alcohol ; Acetone), 3, II | UN 1993 FLAMMABLE LIQUID, N.O.S. (Ethyl alcohol ; Acetone), 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 | | | | |



Fast differentiator (alcohol / acetone)

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14.6. Special precautions for user

Overland transport

| | |
|---|--|
| Classification code (ADR) | : F1 |
| Special provisions (ADR) | : 274, 601, 640D |
| 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) | : T7 |
| Portable tank and bulk container special provisions (ADR) | : TP1, TP8, TP28 |
| 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

| | |
|---------------------------------|------------------|
| Special provisions (IMDG) | : 274 |
| Limited quantities (IMDG) | : 1 L |
| Excepted quantities (IMDG) | : E2 |
| Packing instructions (IMDG) | : P001 |
| IBC packing instructions (IMDG) | : IBC02 |
| Tank instructions (IMDG) | : T7 |
| Tank special provisions (IMDG) | : TP1, TP28, TP8 |
| EmS-No. (Fire) | : F-E |
| EmS-No. (Spillage) | : S-E |
| Stowage category (IMDG) | : B |

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 |
| ERG code (IATA) | : 3H |

Inland waterway transport

| | |
|---------------------------|------------------|
| Classification code (ADN) | : F1 |
| Special provisions (ADN) | : 274, 601, 640C |
| Limited quantities (ADN) | : 1 L |
| Excepted quantities (ADN) | : E2 |

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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) : 274, 601, 640C
Limited quantities (RID) : 1L
Excepted quantities (RID) : E2
Packing instructions (RID) : P001
Mixed packing provisions (RID) : MP19
Portable tank and bulk container instructions (RID) : T7
Portable tank and bulk container special provisions (RID) : TP1, TP8, TP28
Tank codes for RID tanks (RID) : L1.5BN
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 | Added | |
| | Revision date | Modified | |
| 2.2 | Precautionary statements (CLP) | Modified | |
| 2.2 | Hazard statements (CLP) | Modified | |
| 7.2 | Storage conditions | Modified | |
| 13.1 | Waste treatment methods | Modified | |
| 14.1 | Proper Shipping Name (ADN) | Modified | |

Fast differentiator (alcohol / acetone)

Safety Data Sheet

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

| Indication of changes | | | |
|-----------------------|-----------------------------|----------|----------|
| Section | Changed item | Change | Comments |
| 14.1 | Proper Shipping Name (ADR) | Modified | |
| 14.1 | Proper Shipping Name (IATA) | Modified | |
| 14.1 | Proper Shipping Name (IMDG) | Modified | |
| 14.1 | Proper Shipping Name (RID) | Modified | |
| 16 | Other information | Modified | |

| 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 |

Fast differentiator (alcohol / acetone)

Safety Data Sheet

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

| Abbreviations and acronyms: | |
|-----------------------------|--|
| vPvB | Very Persistent and Very Bioaccumulative |
| ED | Endocrine disrupting properties |

| Full text of H- and EUH-statements: | |
|-------------------------------------|--|
| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2 |
| Flam. Liq. 2 | Flammable liquids, Category 2 |
| H225 | Highly flammable liquid and vapour. |
| H319 | Causes serious eye irritation. |
| H336 | May cause drowsiness or dizziness. |
| STOT SE 3 | Specific target organ toxicity — Single exposure, Category 3, Narcosis |

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 : Safranin
Product code : 361500

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

Safranin

Safety Data Sheet

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

Hazard statements (CLP) : H226 - Flammable liquid and vapour.
Precautionary statements (CLP) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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 |

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.

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.

Safranin

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. 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.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed.

Storage temperature : 15 – 25 °C

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

| Safranin | |
|--|---------------------------------------|
| 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 |
| 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 |

Safranin

Safety Data Sheet

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

| | |
|--------------------------------|---------------------------------------|
| Ethyl alcohol (64-17-5) | |
| 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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|----------------|----------|
| Physical state | : Liquid |
| Appearance | : clear. |
| Colour | : red. |

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Safety Data Sheet

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

| | |
|---|---------------------|
| 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 | : 51.23 °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 |
| 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 |

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

Safranin

Safety Data Sheet

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

| Ethyl alcohol (64-17-5) | |
|--------------------------------|-------------------------------------|
| LD50 oral | 8300 mg/kg bodyweight Animal: mouse |
| LD50 dermal rat | > 2000 mg/kg |
| LC50 Inhalation - Rat | > 20 mg/l |

| | |
|-----------------------------------|------------------|
| Skin corrosion/irritation | : Not classified |
| Serious eye damage/irritation | : Not classified |
| Respiratory or skin sensitisation | : Not classified |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |

| Ethyl alcohol (64-17-5) | |
|--------------------------------|----------------------------|
| IARC group | 1 - Carcinogenic to humans |
| Reproductive toxicity | : Not classified |
| STOT-single exposure | : Not classified |
| STOT-repeated exposure | : Not classified |

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

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

12.2. Persistence and degradability

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

12.3. Bioaccumulative potential

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

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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other adverse effects : Not release to the environment.

SECTION 13: Disposal considerations






13.1. Waste treatment methods

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

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

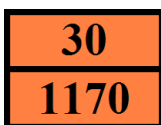
Classification code (ADR) : F1
Special provisions (ADR) : 144, 601
Limited quantities (ADR) : 5I
Excepted quantities (ADR) : E1
Packing instructions (ADR) : P001, IBC03, LP01, R001

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Mixed packing provisions (ADR) : MP19
Portable tank and bulk container instructions (ADR) : T2
Portable tank and bulk container special provisions (ADR) : TP1
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.

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

Safranin

Safety Data Sheet

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

Rail transport

| | |
|---|---------------------------|
| Classification code (RID) | : F1 |
| Special provisions (RID) | : 144, 601 |
| Limited quantities (RID) | : 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 |
| | Revision date | Modified | |
| | Supersedes | 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 |
|-----|---|

Safranin

Safety Data Sheet

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

| Abbreviations and acronyms: | |
|------------------------------------|---|
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ATE | Acute Toxicity Estimate |
| BLV | Biological limit value |
| CAS-No. | Chemical Abstract Service number |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |
| DMEL | Derived Minimal Effect level |
| DNEL | Derived-No Effect Level |
| EC50 | Median effective concentration |
| EC-No. | European Community number |
| EN | European Standard |
| IATA | International Air Transport Association |
| IMDG | International Maritime Dangerous Goods |
| LC50 | Median lethal concentration |
| LD50 | Median lethal dose |
| LOAEL | Lowest Observed Adverse Effect Level |
| NOAEC | No-Observed Adverse Effect Concentration |
| NOAEL | No-Observed Adverse Effect Level |
| NOEC | No-Observed Effect Concentration |
| OEL | Occupational Exposure Limit |
| PBT | Persistent Bioaccumulative Toxic |
| PNEC | Predicted No-Effect Concentration |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| SDS | Safety Data Sheet |
| vPvB | Very Persistent and Very Bioaccumulative |
| WGK | Water Hazard Class |

| Full text of H- and EUH-statements: | |
|--|-------------------------------------|
| Flam. Liq. 2 | Flammable liquids, Category 2 |
| H225 | Highly flammable liquid and vapour. |
| H226 | Flammable liquid and vapour. |

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

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

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

1.1. Product identifier

Product form : Mixture
Product name : Crystal violet oxalate
Product code : 361490

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
Serious eye damage/eye irritation, Category 2 H319
Carcinogenicity, Category 2 H351
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

Flammable liquid and vapour. Suspected of causing cancer. Causes serious eye irritation. Harmful to aquatic life with long lasting effects.

Crystal violet oxalate

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

GHS08

Signal word (CLP) :

Warning

Contains :

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

Hazard statements (CLP) :

H226 - Flammable liquid and vapour.
H319 - Causes serious eye irritation.
H351 - Suspected of causing cancer.
H412 - Harmful to aquatic life with long lasting effects.

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, face protection.
P308+P313 - IF exposed or concerned: Get medical advice/attention.
P337+P313 - If eye irritation persists: 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 |
| C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride substance listed as REACH Candidate ([4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) [with $\geq 0.1\%$ of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]) | CAS-No.: 548-62-9 EC-No.: 208-953-6 EC Index-No.: 612-204-00-2 REACH-no: 02-2119824931-38 | ≤ 5 | Carc. 2, H351 Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 |

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.

First-aid measures after skin contact

: Rinse skin with water/shower. Take off immediately all contaminated clothing.

Crystal violet oxalate

Safety Data Sheet

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

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 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 : 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.

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. Do not handle until all safety precautions have been read and understood. Avoid contact with skin and eyes.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

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

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 |
| 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

Crystal violet oxalate

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

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 | : Violet. Dark. |
| 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 | : 39.57 °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 |
| 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.

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

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

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

| | |
|-----------|-----------|
| LD50 oral | 711 mg/kg |
|-----------|-----------|

| | |
|-----------------|--------------|
| LD50 dermal rat | > 6869 mg/kg |
|-----------------|--------------|

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 : Causes serious eye irritation.

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Suspected of causing cancer.

Ethyl alcohol (64-17-5)

| | |
|------------|----------------------------|
| IARC group | 1 - Carcinogenic to humans |
|------------|----------------------------|

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

| | |
|---|----------------------------|
| NOAEL (chronic, oral, animal/male, 2 years) | 250 mg/kg bodyweight mouse |
|---|----------------------------|

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

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 : Harmful to aquatic life with long lasting effects.

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

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.

| C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (548-62-9) | |
|--|---|
| LC50 - Fish [1] | 82 µg/l |
| EC50 - Crustacea [1] | 350 µg/l |
| EC50 72h - Algae [1] | 0.21 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) |

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

12.2. Persistence and degradability

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

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

12.3. Bioaccumulative potential

| 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

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

12.6. Other adverse effects

Other adverse effects

: Avoid discarding in the environment. Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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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.

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, MARINE POLLUTANT | 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: Yes | 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

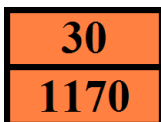
| | |
|---|---------------------------|
| Classification code (ADR) | : F1 |
| Special provisions (ADR) | : 144, 601 |
| Limited quantities (ADR) | : 5I |
| Excepted quantities (ADR) | : E1 |
| Packing instructions (ADR) | : P001, IBC03, LP01, R001 |
| Mixed packing provisions (ADR) | : MP19 |
| Portable tank and bulk container instructions (ADR) | : T2 |
| Portable tank and bulk container special provisions (ADR) | : TP1 |
| Tank code (ADR) | : LGBF |
| Vehicle for tank carriage | : FL |

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

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| | |
|---|---------------------------|
| 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 a substance on the REACH candidate list in concentration $\geq 0.1\%$ or with a lower specific limit: [4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) [with $\geq 0.1\%$ of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] (EC 208-953-6, CAS 548-62-9)

Contains no REACH Annex XIV substances

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

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

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

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

| Indication of changes | | | |
|-----------------------|---|----------|----------|
| Section | Changed item | Change | Comments |
| | Properties and observations (IMDG) | Added | |
| | UN-No. (RID) | Modified | |
| | Issue date | Added | |
| | Supersedes | Modified | |
| | Revision date | Modified | |
| | Proper Shipping Name (RID) | Modified | |
| | Portable tank and bulk container special provisions (RID) | Modified | |
| | Portable tank and bulk container instructions (RID) | Modified | |
| | Special provisions (RID) | Modified | |
| | Special provisions (IATA) | Modified | |

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| Indication of changes | | | |
|-----------------------|---|----------|----------|
| Section | Changed item | Change | Comments |
| | Proper Shipping Name (IATA) | Modified | |
| | Proper Shipping Name (IMDG) | Modified | |
| | EmS-No. (Spillage) | Modified | |
| | Tank special provisions (IMDG) | Modified | |
| | Tank instructions (IMDG) | Modified | |
| | Special provisions (IMDG) | Modified | |
| | Portable tank and bulk container special provisions (ADR) | Modified | |
| | Portable tank and bulk container instructions (ADR) | Modified | |
| 5.3 | EAC code | Modified | |
| 14.1 | UN-No. (IMDG) | Modified | |
| 14.1 | UN-No. (IATA) | Modified | |
| 14.1 | UN-No. (ADR) | Modified | |
| 14.1 | UN-No. (ADN) | Modified | |
| 14.2 | Proper Shipping Name (ADN) | Modified | |
| 14.2 | Proper Shipping Name (ADR) | Modified | |
| 14.6 | Special provisions (ADN) | Modified | |
| 14.6 | Packing instructions (IMDG) | Modified | |
| 14.6 | Special provisions (ADR) | Modified | |

| 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 |

Crystal violet oxalate

Safety Data Sheet

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

| Abbreviations and acronyms: | |
|-----------------------------|---|
| 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 (Oral) | Acute toxicity (oral), Category 4 |
| Aquatic Acute 1 | Hazardous to the aquatic environment — Acute Hazard, Category 1 |
| Aquatic Chronic 1 | Hazardous to the aquatic environment — Chronic Hazard, Category 1 |
| Carc. 2 | Carcinogenicity, Category 2 |
| Eye Dam. 1 | Serious eye damage/eye irritation, Category 1 |
| Flam. Liq. 2 | Flammable liquids, Category 2 |
| H225 | Highly flammable liquid and vapour. |
| H226 | Flammable liquid and vapour. |
| H302 | Harmful if swallowed. |
| H318 | Causes serious eye damage. |
| H319 | Causes serious eye irritation. |
| H351 | Suspected of causing cancer. |
| 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. |

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 : Lugol, PVP-stabilized solution
Product code : 367400

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

1.2.1. Relevant identified uses

Main use category : For professional use only
Use of the substance/mixture : In vitro diagnostic medical device.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

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

Lugol, PVP-stabilized solution

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 | ≤ 1 | Acute Tox. 4 (Inhalation), H332 Acute Tox. 4 (Dermal), H312 Aquatic Acute 1, H400 |

Full text of H and EUH statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

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

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

No additional information available

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case 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.

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6.3. Methods and material for containment and cleaning up

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

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

| 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.

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8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|---------------------|
| Physical state | : Liquid |
| Appearance | : clear. |
| Colour | : 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 | : No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Flammability (solid, gas) | : Not applicable |
| Vapour pressure | : No data available |
| Relative vapour density at 20 °C | : No data available |
| Relative density | : 1.035 |
| Solubility | : No data available |
| Partition coefficient n-octanol/water (Log Pow) | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosive properties | : No data available |

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Oxidising properties : No data available

Explosive limits : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

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

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

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

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

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

SECTION 11: Toxicological information

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

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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 |

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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 |
| | Supersedes | Modified | |
| | Revision date | Modified | |

Abbreviations and acronyms:

| | |
|-----|---|
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
|-----|---|

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| Abbreviations and acronyms: | |
|------------------------------------|---|
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ATE | Acute Toxicity Estimate |
| BLV | Biological limit value |
| CAS-No. | Chemical Abstract Service number |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |
| DMEL | Derived Minimal Effect level |
| DNEL | Derived-No Effect Level |
| EC50 | Median effective concentration |
| EC-No. | European Community number |
| EN | European Standard |
| IATA | International Air Transport Association |
| IMDG | International Maritime Dangerous Goods |
| LC50 | Median lethal concentration |
| LD50 | Median lethal dose |
| LOAEL | Lowest Observed Adverse Effect Level |
| NOAEC | No-Observed Adverse Effect Concentration |
| NOAEL | No-Observed Adverse Effect Level |
| NOEC | No-Observed Effect Concentration |
| OEL | Occupational Exposure Limit |
| PBT | Persistent Bioaccumulative Toxic |
| PNEC | Predicted No-Effect Concentration |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| SDS | Safety Data Sheet |
| vPvB | Very Persistent and Very Bioaccumulative |
| WGK | Water Hazard Class |

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

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

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