



# SAFETY DATA SHEET

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Revision nr : 8

Date : 26 / 4 / 2016

Supersedes : 26 / 5 / 2014

## Lugol, PVP-stabilized solution

**367400**

### SECTION 1. Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Trade name : Lugol, PVP-stabilized solution

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

Use : In vitro diagnostic medical device.  
For professional use only.

#### 1.3. Details of the supplier of the safety data sheet

Company identification : RAL DIAGNOSTICS  
Site Montesquieu  
33650 MARTILLAC FRANCE  
Tel : +33 (0) 5 57 96 04 04 Fax : +33 (0) 5 57 96 04 05  
www.ral-diagnostics.com  
Email: commercial@ral-diagnostics.fr

#### 1.4. Emergency telephone number

Emergency phone nr : ORFILA : +33 (0) 1 45 42 59 59

### SECTION 2 Hazards identification

#### 2.1. Classification of the substance or mixture

##### Hazard Class and Category Code(s), Regulation (EC) No 1272/2008 (CLP)

Not regulated.

#### 2.2. Label elements

##### Labelling Regulation EC 1272/2008 (CLP)

- Hazard pictograms : None.
- Signal words : None.
- Hazard statements : None.
- Precautionary statements : None.

#### 2.3. Other hazards

Other hazards : None under normal conditions.

### SECTION 3 Composition/information on ingredients

Substance / Preparation : Preparation.

This product is not considered to be hazardous but contains hazardous components.

| Substance name              | Value(s)  | CAS nr    | EINECS nr | EC index     | REACH | Classification   |
|-----------------------------|-----------|-----------|-----------|--------------|-------|--|
| Iodize potassium            | : ca 2 %  | 7681-11-0 | 231-659-4 | -----        | ----  | Acute Tox. 4 (Oral);H302<br>Eye Irrit. 2;H319<br>Skin Irrit. 2;H315                  |
| Iodine                      | : ca 1 %  | 7553-56-2 | 231-442-4 | 053-001-00-3 | ----  | Acute Tox. 4 (Dermal);H312<br>Acute Tox. 4 (Inhalation);H332<br>Aquatic Acute 1;H400 |
| PolyvinylPyrrolidone K29-32 | : ca 10 % | 9003-39-8 | 201-800-4 | -----        | ----  | Not classified. (GHS)  |

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### SECTION 4. First aid measures

#### 4.1. Description of first aid measures

##### First aid

- **Inhalation** : Take victim to fresh air. Obtain medical attention if breathing difficulty persists.
- **Skin contact** : Seek medical attention if ill effect or irritation develops.
- **Eye contact** : Rinse with water. Seek medical attention if irritation develops.
- **Ingestion** : Rinse mouth. Seek medical attention if ill effect develops.

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

- **Inhalation** : Not expected to present a significant inhalation hazard under anticipated conditions of normal use.
- **Skin contact** : Not expected to present a significant skin hazard under anticipated conditions of normal use.
- **Eye contact** : Not expected to present a significant eye contact hazard under anticipated conditions of normal use.
- **Ingestion** : Must not come into contact with food or be consumed. No significant signs or symptoms indicative of any adverse health hazard are expected to occur as a result of ingestion.

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

No data available.

### SECTION 5. Fire-fighting measures

#### 5.1. Extinguishing media

**Extinguishing media** : Powder. Carbon dioxide. Use extinguishing media appropriate for surrounding fire.

#### 5.2. Special hazards arising from the substance or mixture

No significant hazards.

#### 5.3. Advice for fire-fighters

- Flammable class** : Not flammable.
- Protection against fire** : Do not enter fire area without proper protective equipment, including respiratory protection.

### SECTION 6. Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** : Equip cleanup crew with proper protection.

#### 6.2. Environmental precautions

**Environmental precautions** : Prevent entry to sewers and public waters.

#### 6.3. Methods and material for containment and cleaning up

**After spillage and/or leakage** : Clean up any spills as soon as possible, using an absorbent material to collect it. Dispose in a safe manner in accordance with local/national regulations.

#### 6.4. Reference to other sections

See Heading 8.



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### SECTION 7. Handling and storage

#### 7.1. Precautions for safe handling

**Handling** : Handle in accordance with appropriate industrial hygiene and safety procedures. Keep away from food, drink and animal feeding stuffs. Wash hands and other exposed areas with mild soap and water before eat, drink or smoke and when leaving work.

#### 7.2. Conditions for safe storage, including any incompatibilities

**Storage** : Keep container closed when not in use.

#### 7.3. Specific end use(s)

Not applicable.

### SECTION 8. Exposure controls/personal protection

#### 8.1. Control parameters

##### Occupational Exposure Limits

**On ingredients** : Iodine : VLE - France [ppm] : indicative 0.1  
Iodine : VLE - France [mg/m<sup>3</sup>] : indicative 1  
Iodine : VLE - Unated States [ppm] : indicative 0.1

#### 8.2. Exposure controls

##### Personal protection



- **Respiratory protection** : Not required.
- **Hand protection** : Gloves. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.  
In full:  
Material: nitrile rubber.  
Minimum thickness: 0.10 mm.  
Break through time: Not tested.  
Proposed equipment : Touch N Tuff® (Ansell 92-500 ou 92-670).  
In the event of splashes:  
Material: nitrile rubber.  
Minimum thickness: 0.10 mm.  
Break through time: Not tested.  
Proposed equipment : Touch N Tuff® (Ansell 92-500 ou 92-670).  
Source of data: Ansell Healthcare Europe N.V., Riverside Business Park, Block J, Boulevard International 55, B-1070 Brussels, Belgium, Tel. +32 (0)2 528 74 00, e-mail : info@ansell.eu.
- **Skin protection** : Wear suitable protective clothing. Choose body protection in relation to the dangerousness of the product, its concentration and the amounts used depending on the workstation.
- **Eye protection** : Safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
- **Ingestion** : When using, do not eat, drink or smoke.
- Industrial hygiene** : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.



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## SECTION 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### 9.1.a. Appearance

Physical state : Liquid.

Colour : Brown.

#### 9.1.b. Odour

No data available.

#### 9.1.c. Odour threshold

No data available.

#### 9.1.d. pH

No data available.

#### 9.1.e. Melting point / Freezing point

No data available.

#### 9.1.f. Initial boiling point - boiling range

No data available.

#### 9.1.g. Flash point

No data available.

#### 9.1.h. Evaporation rate

No data available.

#### 9.1.i. Flammability

No data available.

#### 9.1.j. Explosion limits (lower - upper)

No data available.

#### 9.1.k. Vapour pressure

No data available.

#### 9.1.l. Vapour density

No data available.

#### 9.1.m. Relative density

Density : 1.035

#### 9.1.n. Solubility

No data available.

#### 9.1.o. Partition coefficient : n-octanol / water

No data available.

#### 9.1.p. Auto-ignition temperature

No data available.

#### 9.1.q. Thermal decomposition

No data available.

#### 9.1.r. Viscosity

No data available.

#### 9.1.s. Explosive Properties

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### SECTION 9. Physical and chemical properties (continued)

No data available.

#### 9.1.t. Oxidising properties

No data available.

#### 9.2. Other information

No data available.

### SECTION 10. Stability and reactivity

#### 10.1. Reactivity

No data available.

#### 10.2. Chemical stability

**Physico-chemical stability** : Stable in normal temperature and pressure conditions.

#### 10.3. Possibility of hazardous reactions

No data available.

#### 10.4. Conditions to avoid

No data available.

#### 10.5. Incompatible materials

No data available.

#### 10.6. Hazardous decomposition products

No data available.

### SECTION 11. Toxicological information

#### 11.1. Information on toxicological effects

##### • Acute toxicity

##### On ingredients

**Iodize potassium** : Rat oral LD50 [mg/kg] : 2100**PolyvinylPyrrolidone K29-32** : Rat oral LD50 [mg/kg] : > 5000

: Rat inhalation LC50 [mg/l/4h] : &gt; 5.2

• **Skin corrosion/irritation** : No data available.• **Serious eye damage/irritation** : No data available.• **Respiratory or skin sensitisation** : No data available.• **Germ cell mutagenicity** : No data available.• **Carcinogenicity** : No data available.• **Reproductive toxicity** : No data available.• **STOT-single exposure** : No data available.• **STOT-repeated exposure** : No data available.• **Aspiration hazard** : No data available.• **Potential effects on health** : Not expected to present a significant hazard under anticipated conditions of normal use.• **Signs and symptoms of exposure** : To our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.



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### SECTION 12. Ecological information

#### 12.1. Toxicity

##### On ingredients

- Iodize potassium : LC50-96 Hour - fish [mg/l] : (Rainbow trout) 8960  
PolyvinylPyrrolidone K29-32 : LC50-96 Hour - fish [mg/l] : > 1000 (Juvenile Turbot).  
: 72 H-CE50 - Algae [mg/l] : > 1000

#### 12.2. Persistence - degradability

No data available.

#### 12.3. Bioaccumulative potential

No data available.

#### 12.4. Mobility in soil

No data available.

#### 12.5. Results of PBT and vPvB assessment

No data available.

#### 12.6. Other adverse effects

Not release to the environment.

### SECTION 13. Disposal considerations

#### 13.1. Waste treatment methods

- Disposal : Dispose in a safe manner in accordance with local/national regulations.

### SECTION 14. Transport information

#### 14.1. UN number

- UN No. : Unregulated.

#### 14.2. UN proper shipping name

- Proper shipping name : Unregulated.

#### 14.3. Transport hazard class(es)

- Hazard Label(s) : Unregulated.  
• Class : Unregulated.  
- H.I. nr : Unregulated.  
• Classification code : Unregulated.

#### 14.4. Packing group

- ADR Packing group : Unregulated.  
• IMO Packing group : Unregulated.  
• IATA Packing group : Unregulated.

#### 14.5. Environmental hazards

- IMDG-Marine pollution : Unregulated.

#### 14.6. Special precautions for user

Emergency action in case of accident

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• IMO-IMDG code : FS : Unregulated.

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable.

**SECTION 15. Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Ensure all national/local regulations are observed.

**15.2. Chemical Safety Assessment**

Not applicable.

**SECTION 16. Other information**

**H Substances ' sentences' text** : H302 - Harmful if swallowed  
H312 - Harmful in contact with skin.  
H315 - Causes skin irritation.  
H319 - Causes serious eye irritation.  
H332 - Harmful if inhaled.  
H400 - Very toxic to aquatic life.

**Revision** : 8**Print date** : 26 / 4 / 2016**Further information** : Product intended for professional use only.

The contents and format of this SDS are in accordance with REGULATION (EC) No 453/2010 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.

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