

**I.C.F. Srl**

Revision nr. 3

Dated 29/4/2014

**OTODINE**

Printed on 29/04/2014

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## Safety data sheet

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

**1.1. Product identifier**

Product name

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

Intended use

**Ear wax softening detergent for cats and dogs****1.3. Details of the supplier of the safety data sheet**

Name

**I.C.F. Srl**

Full address

**Via G.B. Benzoni, 50**

District and Country

**26020 Palazzo Pignano (CR)****ITALIA****Tel. 0373/982024****Fax 0373/982025**

e-mail address of the competent person

responsible for the Safety Data Sheet

**info@icfsrl.com****1.4. Emergency telephone number**

For urgent inquiries refer to

**Bergamo - Ospedali Riuniti di Bergamo - Tel. +39 035 269111****Firenze - Azienda Ospedaliero-Universitaria - Tel. +39 055 7947 819****Milano- Ospedale Niguarda Tel. +39 02 66101029****Pavia - IRCC - Tel. +39 0382 24444****Roma- Università - Tel. +39 06 3054343, +39 06 49978000**

### SECTION 2. Hazards identification.

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

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to EC Regulation 1907/2006 and subsequent amendments.

**2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments.**

Hazard classification and indication:

**2.2. Label elements.**

This product is not subject to hazard labeling pursuant to Directives 67/548/EEC and 1999/45/EC and subsequent amendments and supplements.

Warning symbols: None.

Hazard sentences (R): None.

**S 2****KEEP OUT OF THE REACH OF CHILDREN.**

External use only

For veterinary use

**2.3. Other hazards.**

Information not available.

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### SECTION 3. Composition/information on ingredients.

#### 3.1. Substances.

Information not relevant.

#### 3.2. Mixtures.

Contains:

Identification.	Conc. %.	Classification 67/548/EEC.	Classification 1272/2008 (CLP).
<b>Chlorhexidine digluconate</b>			
CAS. 18472-51-0	0,1 - 0,5	Xi R41, N R50	Eye Irrit. 2 H319, Aquatic Acute 1 H400 M=10
EC. 242-354-0			
INDEX. -			

Note: Upper limit is not included into the range.

The full wording of the Risk (R) and hazard (H) phrases is given in section 16 of the sheet.

T+ = Very Toxic(T+), T = Toxic(T), Xn = Harmful(Xn), C = Corrosive(C), Xi = Irritant(Xi), O = Oxidizing(O), E = Explosive(E), F+ = Extremely Flammable(F+), F = Highly Flammable(F), N = Dangerous for the Environment(N)

### SECTION 4. First aid measures.

#### 4.1. Description of first aid measures.

Not specifically necessary. Observance of good industrial hygiene is recommended.

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

No episodes of damage to health ascribable to the product have been reported.

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

Information not available.

### SECTION 5. Firefighting measures.

#### 5.1. Extinguishing media.

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

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

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products.

#### 5.3. Advice for firefighters.

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**GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

**SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS**

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

**SECTION 6. Accidental release measures.****6.1. Personal precautions, protective equipment and emergency procedures.**

Use breathing equipment if fumes or powders are released into the air. These indications apply for both processing staff and those involved in emergency procedures.

**6.2. Environmental precautions.**

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

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

Confine using earth or inert material. Collect as much material as possible and eliminate the rest using jets of water. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

**6.4. Reference to other sections.**

Any information on personal protection and disposal is given in sections 8 and 13.

**SECTION 7. Handling and storage.****7.1. Precautions for safe handling.**

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

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

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

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

For veterinary use.

**SECTION 8. Exposure controls/personal protection.****8.1. Control parameters.**

Information not available.

**8.2. Exposure controls.**

Observance of safety measures used in handling chemical substances

**HAND PROTECTION**



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None required

**SKIN PROTECTION**

None required

**RESPIRATORY PROTECTION**

None required

**EYE PROTECTION**

None required

## SECTION 9. Physical and chemical properties.

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

Appearance	Clear liquid
Colour	colourless
Odour	characteristic
Odour threshold.	Not available.
pH. (20°C)	7,6 - 8,4
Melting point / freezing point.	Not available.
Initial boiling point.	Not available.
Boiling range.	Not available.
Flash point.	Not available.
Evaporation Rate	Not available.
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Relative density.	950 - 1050 g/l
Solubility	Not available.
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.

### 9.2. Other information.

Information not available.

## SECTION 10. Stability and reactivity.

### 10.1. Reactivity.

There are no particular risks of reaction with other substances in normal conditions of use.

### 10.2. Chemical stability.

The product is stable in normal conditions of use and storage.

### 10.3. Possibility of hazardous reactions.

No hazardous reactions are foreseeable in normal conditions of use and storage.



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#### 10.4. Conditions to avoid.

None in particular. However the usual precautions used for chemical products should be respected.

#### 10.5. Incompatible materials.

Information not available.

#### 10.6. Hazardous decomposition products.

Information not available.

### SECTION 11. Toxicological information.

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled carefully according to good industrial practices. This product may have slight health effects on sensitive people, by inhalation and/or cutaneous absorption and/or contact with eyes and/or ingestion.

#### 11.1. Information on toxicological effects.

Chlorhexidine digluconate: LD50 (Oral). 2000 mg/kg Rat

### SECTION 12. Ecological information.

No specific data are available for this product. Handle it according to good working practices. Avoid littering. Do not contaminate soil, sewers and waterways. Inform the competent authorities, should the product reach waterways or sewers or contaminate soil or vegetation. Please take all the proper measures to reduce harmful effects on aquifers.

#### 12.1. Toxicity.

Chlorhexidine digluconate:  
LC50: 2,08 mg/l Fish  
EC50: 0,087 mg/l Daphnia magna  
EC50: 0,081 mg/l Alghe

#### 12.2. Persistence and degradability.

Information not available.

#### 12.3. Bioaccumulative potential.

Information not available.

#### 12.4. Mobility in soil.

Information not available.

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

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

#### 12.6. Other adverse effects.

Information not available.



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## SECTION 13. Disposal considerations.

### 13.1. Waste treatment methods.

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

Avoid littering. Do not contaminate soil, sewers and waterways.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

## SECTION 14. Transport information.

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

## SECTION 15. Regulatory information.

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.

Seveso category.

None.

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

None.

Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None.

Substances subject to the Rotterdam Convention:

None.

Substances subject to the Stockholm Convention:

None.

Healthcare controls.

Information not available.

### 15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

## SECTION 16. Other information.

**H319** Causes serious eye irritation.

**H400** Very toxic to aquatic life.

Text of risk (R) phrases mentioned in section 2-3 of the sheet:

**R41** RISK OF SERIOUS DAMAGE TO EYES.

**R50** VERY TOXIC TO AQUATIC ORGANISMS.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road

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- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

**GENERAL BIBLIOGRAPHY**

1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and adjustments
3. Regulation (EC) 1907/2006 (REACH) of the European Parliament
4. Regulation (EC) 1272/2008 (CLP) of the European Parliament
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EC) 453/2010 of the European Parliament
7. Regulation (EC) 286/2011 (II Atp. CLP) of the European Parliament
8. Regulation (EC) 618/2012 (III Atp. CLP) of the European Parliament
9. The Merck Index. - 10th Edition
10. Handling Chemical Safety
11. Niosh - Registry of Toxic Effects of Chemical Substances
12. INRS - Fiche Toxicologique (toxicological sheet)
13. Patty - Industrial Hygiene and Toxicology
14. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
15. ECHA website

**Note for users:**

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:

The following sections were modified:

01 // 16.