

## SAFETY DATA SHEET – DENTAL FILM “ECO 30 – ERGONOM X ERGONOM X E-SPEED”

Under current regulations ( V. Next item 15) the product in question is not subject to the issuing of the SDS , as an "article " and as such does not enter within the rule field of application, in this respect, the rule only disciplines the dangerous preparations , or articles that would release particularly dangerous substances.

It is however considered appropriate to provide the below information , designed to allow proper use of the medical device , using the scheme in sixteen points set out in Reg . EC 453/2010 , while leaving blank sections that are clearly not applicable to the products in question.

### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

**Manufacturer : Dentalfilm s.r.l.**  
**V. Verga n° 30**  
**10036 Settimo Torinese (TO)**

#### **1.1 Product identifier**

Self developing instant x-ray film

#### **1.2 Recommended use**

Professional use – dental studios

#### **1.4 Emergency phone numbers**

Dentalfilm s.r.l.: +39 011 8000090  
+39 011 8000398

Poison Control Centre Niguarda Hospital : +39 02 66101029 (Available H24)

### SECTION 2. HAZARD IDENTIFICATION

#### **2.1 Hazard classification**

The product consists in a radiographic instant x-ray film, containing a monobath solution required for the developing and fixing of the image impressed on the film after exposure to the x-ray.

The article is not dangerous if properly used in accordance with the instructions of the manufacturer.

#### **2.2 Label elements**

Not Applicable

#### **2.3 Other hazards**

Professional use . Follow the instructions of the technical manual included into each box.

## SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

### 3.1 Substances

The monobath liquid contained in the pouch is used for the developing of the film. In each individual device there is in an amount of about 3 ml of monobath solution and is packed in a special pouch that during developing, allows the realization of radiography and its fixing . All the packagings are made of inert plastic material (polypropylene , PET , PVC without plasticizers SVHC)

Hazardous components contained in the monobath solution :

| Substance                 | CAS        | Concentration | Signal words<br>*                                    | Symbol                                                                                |
|---------------------------|------------|---------------|------------------------------------------------------|---------------------------------------------------------------------------------------|
| Metil Idrochinone         | 95-71-6    | < 1%          | H302 - H315<br>H319 - H335                           |    |
| Idrochinone               | 123-31-9   | <1%           | H302 - H317<br>H318 - H341<br>H351 - H410            |   |
| Potassio Idrossido        | 1310-58-3  | 2 – 5%        | H290 - H302<br>H314                                  |  |
| Potassio metabisolfito    | 10117-38-1 | 3 – 7%        | Non pericoloso<br>Secondo Reg.<br>CE N.<br>1272/2008 | /                                                                                     |
| Coformulanti e attivatori |            | 2 – 6%        | H302 - H315<br>H335 - H318                           |  |

\*For a complete list of Signal Words please see next section 16

## SECTION 4. FIRST AID MEASURES

**Inhalation** : Very unlikely given the nature of the product and the conditions of use . Not provided  
**Accidental contact of the liquid with skin** : Wash with plenty of water . In case of allergic skin reaction seek medical advice.

See Section 8 DPI

## SECTION 5. FIRE –FIGHTING MEASURES

The article does not presents flammable components , but is combustible .  
During combustion can develop dangerous gases ( NO<sub>x</sub> , SO<sub>x</sub> , CO ) .

## SECTION 6. ACCIDENTAL RELEASE MEASURES

In case of accidental release of the liquid , contain and absorb liquid with inert materials ( sand , absorbent specific products , etc . ) Collect leaking liquid, waste collection and disposal them properly.

Wash contaminated area with detergent .

In case of high capacity containers storage, prepare a containment tank

## SECTION 7. HANDLING AND STORAGE

Store away from light , at temperatures between +10 ° C and +24 ° C in cool dry place , away from heat and / or fire sources .

If possible, store in anti-spilling containers to prevent leakage .

## SECTION 8. EXPOSURE CONTROL / PERSONAL PROTECTION

Avoid contact with skin and eyes .

DPI Recommended : latex or nitrile gloves, safety glasses .

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

The article is composed of solid parts ( external envelop, internal pouch , film , etc . ) And liquid ( monobath solution) .

Color : Green

Smell : N.A.

liquid pH : 10-12

Solubility in water : Miscible ( liquid )

Liquid density : 1.08 ± 0.05 kg / l

Boiling point : 100 ° C ( liquid )

Explosion limits: N.A.

Auto-ignition temperature : N.A.

## SECTION 10. STABILITY AND REACTIVITY

All products constituting the article are stable under normal conditions of storage and use.

The monobath solution is composed of an alkaline reducing solution. Avoid contact or mix with strong acids and energetic oxidizing.

## SECTION 11. TOXICOLOGICAL INFORMATION

Toxicological information on hazardous constituents known in point 3.1 ( literature ) :

### **Potassium hydroxide CAS 1310-58-3:**

**Acute toxicity** : LD50 (rat test): 333 mg/kg

**Corrosion / skin irritation**: skin – rabbit test : serious skin irritation - 24 h

**Serious eye damage / serious eye irritation**: Eyes – Rabbit test. Result : Eyes corrosive

**Respiratory or skin sensitization** : No data available

### **Idrochinone CAS 123-31-9**

**Acute toxicity** : LD50 (rat test): 367,3 mg/kg

LD 50 Skin – rabbit test - > 2.000 mg/kg

**Corrosion / skin irritation**: No data available

**Serious eye damage / serious eye irritation** : Classified Regolamento (EU) 1272/2008, Allegato VI (Tabelle 3.1/3.2)

**Respiratory or skin sensitization** : rat test. Result : May cause sensitization by skin contact . May cause allergic skin reaction .

**Germ cell mutagenicity** : Laboratory tests has shown mutagenic effects . The essays in vitro have shown mutagenic effects .

**Carcinogenicity** : Limited highlighted carcinogenicity in animal studies .

IARC: 3 - Gruppo 3: Not classifiable as regards its carcinogenicity to humans

### **Metil Idrochinone CAS 95-71-6**

**Acute toxicity** : LD50 (rat test): > 400 mg/kg. Inhalation : no data available

## SECTION 12. ECOLOGICAL INFORMATION

The solid parts of the article, composed of plastic materials , can be recycled.

For the monobath solution, refer to the Signal Words to Sec . 3.1 and reported to the Sec . 16 (Hydroquinone , toxic to aquatic organisms ) .

## SECTION 13. DISPOSAL CONSIDERATION

Suggested CER: 18 01 03\* Signal Word HP 9.

## SECTION 14. TRANSPORT INFORMATION

This article is not subject to regulations on the transport of dangerous goods ( RID , ADR , IATA )

## SECTION 15. REGULATORY INFORMATION

### Regulations :

Reg. CE 1272/2008 e s.m.i (CLP, GHS)

Reg. CE 1907/ 2006 e s.m.i. (REACH)

D. Lgs 81/08 e s.m.i. (TU Sicurezza nei luoghi di lavoro)

ACGIH, Ed. 2010

Letteratura Sigma – Aldrich

## SECTION 16. OTHER INFORMATION

List of Signal Words H as described in previous sections :

H290 May be corrosive to metals.

H302 Harmful if swallowed .

H314 Causes severe skin burns and eye damage .

H315 Causes skin irritation .

H317 May cause an allergic skin reaction .

H318 Causes serious eye damage .

H319 Causes serious eye irritation .

H335 May cause respiratory irritation .

H341 Suspected of causing genetic defects .

H351 Suspected of causing cancer .

H410 Very toxic to aquatic life with long lasting effects .