

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifiers: **Evicrol**

1.2 Relevant identified uses of the substance or mixture and uses advised against:
A standard powder/liquid composite material for the fillings of class III, IV and V cavities;
splint fixation; root restoration. It's intended for professional use only.

1.3 Details of the supplier of the safety data sheet:

Business Name: **SpofaDental a.s.**
Company Headquarters: **Markova 238, 506 46 Jičín, The Czech Republic**
Company Identification Nr.: **63999447**
Telephone: +420 - 493 583 111
Fax: +420 - 493 583 333
E-mail: info@spofadental.com

1.4 Telephone number for urgent situations: +420 - 224 919 293
(National Toxicological Centre, Na bojišti 1, 120 00 Praha 2, CR)

2. INFORMATION REGARDING THE DANGERS OF THE SUBSTANCE OR PRODUCT

2.1 Classification of the substance or mixture (accord. to Council Directive 67/548/EHS):

a) **Evicrol plv. :**



Xn - Harmful

R48/20: Harmful: danger of serious damage to health by prolonged exposure through inhalation.



Xi - Irritant

R34: Irritating to eyes

R43: May cause sensitisation by skin contact.

b) **Evicrol liq. :**



Xi - Irritant

R 36/37/38: Irritating to eyes, respiratory system and skin.

R 43: May cause sensitisation by skin contact.



N - Dangerous for the environment

R 51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

c) **Evicrol etching gel:**



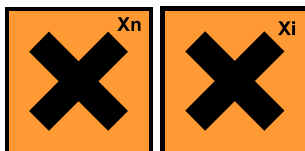
C - Corrosive

R 34: Causes burns.

2.2 Label elements:

a) Evicrol plv. :

Hazard symbols:



Hazard statements:

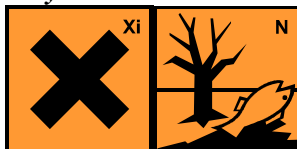
R48/20: Harmful: danger of serious damage to health by prolonged exposure through inhalation.

R34: Irritating to eyes.

R43: May cause sensitisation by skin contact.

b) Evicrol liq. :

Hazard symbols:



Hazard statements:

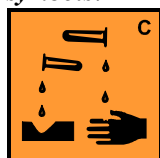
R 36/37/38: Irritating to eyes, respiratory system and skin.

R 43: May cause sensitisation by skin contact.

R 51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

c) Evicrol etching gel :

Hazard symbols:



Hazard statements:

R 34: Causes burns.

Safety phrases:

S 28: After contact with skin, wash immediately with plenty of water.

S 37/39: Wear suitable gloves and eye/face protection.

S 61: Avoid release to the environment.

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(as per 1907/2006/ES)

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3. COMPOSITION/INFORMATION ON INGREDIENTS

a) Evicrol plv. contains the following dangerous substances:

Chemical name	Contents (%)	INECS	CAS	DSD-classific.	CLP-classific.
silica	< 99	215-322-5	13□4-13-2	Xn R48/20	STOT RE1, H372
dibenzoyl-peroxid	1,5-2	202-327-6	94-36-0	E, Xi, N R 2-7-36-43-50	Org. Perox. C, H242 Eye Irrit. 2, H319 Skin. Sens. 1, H317 Aquatic Acute 1 H400

b) Evicrol liq. contains the following dangerous substances:

Chemical name	Contents (%)	INECS	CAS	DSD-classific.	CLP-classific.
mixture of synthetic resins based on acrylate monomers	90-100	-	-	Xi, N R 36/37/38-43-51/53	

c) Evicrol etching gel contains the following dangerous substances:

Chemical name	Contents (%)	INECS	CAS	DSD-classific.	CLP-classific.
Orthophosphoric acid	30-55	231-633-2	7664-38-2	C R 34	Skin Corr. 1B, H314

For R-phrases, see sect. 2 or 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures:

Ensure the safety of all persons present. Provide mental rest and calm to anyone affected. Avoid further exposure. Provide a sufficient supply of fresh air. With apparent health problems, seek medical assistance. Wash with water and soap, use regenerating ointment afterwards. If the skin is affected to a greater extent, seek medical assistance. Wash out with plenty of lukewarm water, seek medical assistance. Wash the mouth out thoroughly. With apparent health problems, seek medical assistance. Do not induce vomiting.

4.2 Most important acute and delayed symptoms and effects: See safety phrases.

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

In case of damage to the skin seek medical assistance.

5. FIREFIGHTING MEASURES

- 5.1 *Extinguishing media:* powder, heavy or medium foam, CO₂
Unsuitable extinguishing agents: direct stream of water
- 5.2 *Special hazards arising from the substance or mixture:* not
- 5.3 *Advice for firefighters:* use of fire protective clothing, respiratory protection

6. ACCIDENTAL RELEASE MEASURES

- 6.1 *Personal precautions, protective equipment and emergency procedures:*
Provide a sufficient supply of fresh air, avoid direct contact with the product.
Use rubber gloves and, depending on the extent of leak, also a rubber apron.
- 6.2 *Environmental precautions:*
Avoid leakage to the aquatic system, soil or vegetation.
- 6.3 *Methods and materials for containment and cleaning up:*
The liquid must be thoroughly removed using an absorbent, which is positioned in a fixed container. The powder must be put into a replacement container.

7. HANDLING AND STORAGE

- 7.1 *Precautions for safe handling:*
The product must be stored in a tightly-sealed container in a well-ventilated place.
When handling, suitable protective garments and gloves must be used; direct contact with the skin must be avoided. Personal sanitary measures must be adopted.
After work, the hands must be thoroughly washed in lukewarm water and soap.
- 7.2 *Conditions for safe storage, including any incompatibilities:*
To be stored in a well sealed container.
- 7.3 *Specific end uses:*
See 1.2 herein. The product is classified as a medical device as per directive 93/42/EHS (in the Czech Republic: Government Decree 336/2004 Coll.) and is intended for professional use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 *Control parameters:* No information is available for the product.

Silicon dioxide:

Permissible exposure limit PEL (mg/m³): 0.1

Dibenzoyl peroxide:

Permissible exposure limit PEL (mg/m³): 5

Maximum permissible concentration NPK-P (mg/m³): 10

Note: The content of the powder is low - see sect. 3.1.

The substance has a sensitising effect.

Orthophosphoric acid:

Permissible exposure limit PEL_c (mg/m³): 2

Maximum permissible concentration NPK-P (mg/m³): 4

8.2 *Exposure controls:* The product must be handled in a well-ventilated area.

Eye protection: Goggles or shield

Hand protection: Rubber gloves

Skin protection: Working garment

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

State: (at 20°C): solid and liquid

Colour: powder: white; liquid: yellow

9.2 Other informations: not available

10. STABILITY AND REACTIVITY

10.1 Reactivity:

The powder contains an activator, which causes the polymerization of the liquid, and can operate in the same way to other similar substances. The result is solid.

Etching solution covers metals passivation layer.

10.2 Chemical stability:

Stable under normal conditions. When stored in a cool area, there is no significant reduction in activity throughout the intended life.

10.3 Possibility of hazardous reactions:

Etching solution is moderately strong acid and therefore reacts with metal oxides and hydroxides for the evolution of heat.

10.4 Conditions to avoid:

Do not store near heat sources or areas exposed to direct solar radiation.

10.5 Incompatible materials:

For liquid are strongly oxidising agents, particularly peroxides.

10.6 Dangerous decomposition products:

During a fire, may produce hazardous fumes.

11. TOXICOLOGICAL INFORMATION

No information is available for the product.

Orthophosphoric acid:

Acute toxicity

<i>LD₅₀ per os, rabbit:</i>	1530 mg/kg
<i>LC₅₀, inhaled, brown rat, 4 hrs:</i>	25.5 mg/m ³

12. ECOLOGICAL INFORMATION - No information available for the product.

Orthophosphoric acid:

LC₅₀, 1 hr, fishes: 100-1000 mg/litre

13. DISPOSAL CONSIDERATIONS

13.1, Waste treatment methods:

Unusable waste and contaminated packages must be burnt in an incineration plant or handled by a company authorised for dangerous waste disposal.

14. TRANSPORT INFORMATION

Note: Packaged in quantities below the threshold and therefore is considered safe for transportation.

15. REGULATORY INFORMATION

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

European Parliament and Council Directive (ES) 1907/2006
Act 350/2012 Coll. (applicable in the Czech Republic)
Act No. 201/2012 Coll., On air protection
Act No. 258/2000 Coll., On protection of public health, as amended

15.2 Chemical Safety Assessment:

Not available

16. OTHER INFORMATION

R-phrases used:

R 2: Risk of explosion caused by shock, friction, fire or other source of ignition.
R 7: May cause fire.

H-phrases used:

H242: Heating may cause a fire.
H314: Causes severe skin burns and eye damage.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.

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H372: Causes damage to organs through prolonged or repeated exposure.

H400: Very toxic to aquatic life.

Updates in the safety data sheet: most passages have been changes made by COMMISSION REGULATION (EU) Nr. 453/2010 (REACH).

The above information applies to customer packages unless stated otherwise, and fully expresses our current knowledge and experience. The product is assumed for use at worksites corresponding to its designation, and the instructions on the enclosed instruction sheet as well as the standard labour safety regulations for the handling of chemical products are assumed to be adhered to.