

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

1.1 Product identifiers: **Adhesor**
 Adhesor Fine

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

Adhesor:

Liners under amalgam or composite fillings; temporary fillings; fixation of crowns and bridges; filling of root canals with gutta-percha points.

Adhesor Fine:

Cementing of onlays, inlays, fixed dentures, bridges; temporary tooth fillings.

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 Product classification (according to CLP):

- a) Adhesor plv.:
Aquatic Acute 1/Aquatic Chronic 1
H410: Very toxic to aquatic life with long lasting effects.
- b) Adhesor liq,
Skin Corr. 1B H314: Causes severe skin burns and eye damage.

2.2 Label elements

Hazard pictograms:

Adhesor plv.: WARNING



Hazard statements: H410
Very toxic to aquatic life,
with long lasting effects.

Adhesor liq.: DANGER



H314
Causes severe skin burns and eye damage.

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Precautionary statements: P273

Avoid release to the environment.

P302+352, P280:

AFTER CONTACT WITH SKIN,
wash immediately with plenty of water.
Wear protective gloves / protective
clothing / protective goggles / face shield.

2.3 Other hazards: Not known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

a) The powder contains the following dangerous substances:

Chemical name	Contents (%)	INECS	CAS	DSD-classific.	CLP-classific.
Zinc oxide	60-95	215-222-5	1314-13-2	N R: 50/53	Aquatic Acute 1, Aquatic Chronic 1 H410

b) The liquid contains the following dangerous substances:

Chemical name	Contents (%)	INECS	CAS	DSD-classific.	CLP-classific.
Orthophosphoric acid	50-75	231-633-2	7664-38-2	C R-34	Skin Corr. 1B H314

For H-phrases, see sect. 2. For R-phrases, see sect. 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. If breathing is difficult, 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: -

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 Safety regulations for the protection of persons:

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 Safety regulations for the protection of the environment:

Avoid leakage to the aquatic system, soil or vegetation.

6.3 Recommended cleaning and disposal methods:

Spilled liquid must be left to soak in an absorbent and removed.
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.

Zinc oxide:

Permissible exposure limit PEL (mg/m^3): 2

Maximum permissible concentration NPK-P (mg/m^3): 5

Magnesium oxide:

Permissible exposure limit PEL (mg/m^3): 5

Maximum permissible concentration NPK-P (mg/m^3): 10

Orthophosphoric acid:

Permissible exposure limit PEL (mg/m^3): 2

Maximum permissible concentration NPK-P (mg/m^3): 4

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

Air passage protection: Sufficient aeration

Eye protection: Goggles or shield

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<i>Hand protection:</i>	Gloves
<i>Skin protection:</i>	Working garment

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

Liquid:

Appearance

State: (at 20°C):

liquid

Colour:

clear

Powder:

Appearance

State: (at 20°C):

solid

Colour:

yellowish

9.2 Other informations:

not available

10. STABILITY AND REACTIVITY

10.1 Reactivity:

Etching solution covers metals passivation layer.

10.2 Chemical stability:

Stable under normal conditions.

10.3 Possibility of hazardous reactions:

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

10.4 Conditions to avoid:

Adhesor liq. not store with alcalic.

10.5 Incompatible materials:

For Adhesor liq. are metals.

10.6 Dangerous decomposition products:

During a fire, may produce hazardous fumes - phosphoric oxide.

11. TOXICOLOGICAL INFORMATION

No information is available for the product.

Zinc oxide:

Acute toxicity

LD₅₀ per os, brown rat:

7950 mg/kg

LD₅₀ inhaled, brown rat, 4 hrs:

2500 mg/m³

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Orthophosphoric acid:

Acute toxicity

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

12. ECOLOGICAL INFORMATION

No information available for the product.

Zinc oxide:

Acute toxicity to aquatic organisms:

<i>EC₅₀, 72 hrs:</i>	170 µg/l
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Orthophosphoric acid:

<i>LC₅₀, 1 hr, fishes:</i>	100-1000 mg/l
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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

The product is not classified as dangerous for transport - less than limit amount.

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 34: Causes burns.
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Updates in the safety data sheet: Sections 2 and 16 were revised - change to CLP labelling.

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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.