

SAFETY DATA SHEET

as per 1907/2006/ES

**Product Name: Stomaflex Liquid Catalyst
Gel Catalyst**

Revision: 2

Date of Issue: 18/01/2011

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1. IDENTIFICATION REGARDING THE SUBSTANCE OR PRODUCT AND THE MANUFACTURER

1.1 Trading name of the product: **Stomaflex Liquid Catalyst
Gel catalyst**

1.2 Product application: Catalysts for Stomaflex silicone materials.

1.3 Manufacturer Identification:

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 Emergency Telephone Number: +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

T - Toxic R 23
Xi - Irritable R 37/38-41
N - Dangerous to the environment R 50/53

2.2 Most serious adverse effects

The product contains toxic and irritating components; in low concentration contains highly toxic component which can damage the eyes and adversely affect human health upon ingestion, inhalation or absorption through the skin. It is dangerous for the aquatic environment and toxic for aquatic organisms.

3. INFORMATION REGARDING THE COMPOSITION OF THE SUBSTANCE OR PRODUCT

Stomaflex Liquid Catalyst contains the following dangerous substances:

CAS	INECS (ES)	Name	Risk	Contents
-	-	alkyloxysilan mixture	T+, flammable R: 10-26-37/38-41	< 7 %
-	-	catalyst (organic compounds of tin)	T,N R 60-61-22-48-38-68-50/53	< 15 %
127087-87-0	247-555-7	Tergitol	Xn, N, R: 22-37-41-50	< 45%

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Gel Catalyst contains the following dangerous substances:

CAS	INECS (ES)	Name	Risk	Contents
-	-	alkyloxysilan mixture	T+, flammable R: 10-26-37/38-41	< 7 %
-	-	catalyst (organic compounds of tin)	T,N R 60-61-22-48-38-68-50/53	< 12 %
127087-87-0	247-555-7	Tergitol	Xn, N, R: 22-37-41-50	< 40%

For R-phrases, see sect. 16.

4. FIRST AID INSTRUCTIONS

- 4.1 General instructions:** Ensure the safety of all persons present. Avoid panic. Provide mental rest and calm to anyone affected. Avoid further exposure.
- 4.2 Upon inhaling:** Provide a sufficient supply of fresh air. Begin intense aeration or take the affected persons to fresh air. With apparent health problems, seek medical assistance.
- 4.3 Upon contact with skin:** Wash with water and soap, use regenerating ointment afterwards.
- 4.4 Upon contact with eyes:** Wash out with plenty of lukewarm water, seek medical assistance.
- 4.5 Upon ingestion:** Wash the mouth out thoroughly. Seek immediate medical assistance.

5. MEASURES FOR FIRE EXTINCTION

The product is inflammable. Surrounding materials must be taken into consideration.

6. MEASURES TO BE TAKEN IN CASE OF RANDOM LEAK

- 6.1 Safety regulations for the protection of persons:**
Provide a sufficient supply of fresh air.
- 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:**
The product must be thoroughly removed into replacement containers using

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7. INSTRUCTIONS FOR HANDLING AND STORAGE

7.1 Instructions for handling:

The product must be stored in a tightly-sealed container in a well-ventilated place. When handling, smoking and naked flame is prohibited. Suitable protective garments must be used; direct contact with eyes must be avoided. Personal sanitary measures must be adopted. After work, hands must be thoroughly washed in lukewarm water and soap.

7.2 Instructions for storage: To be stored in a dry and well ventilated place.

7.3 Specific use:

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.).

8. EXPOSURE CHECK AND PROTECTION OF PERSONS

8.1 Exposure limits: No information is available for the product.

8.2 Technical measures: The product must be handled in a well-ventilated area.

8.3 Personal protective aids:

<i>Air passage protection:</i>	Sufficient aeration
<i>Eye protection:</i>	Goggles or shield
<i>Hand protection:</i>	Rubber gloves
<i>Skin protection:</i>	Working garment

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Stomaflex Liquid Catalyst:

State: (at 20°C): liquid

Colour: clear

Gel Catalyst:

State: (at 20°C): solid (gel)

Colour: red

No other information is available.

10. STABILITY AND REACTIVE POWER

10.1 Conditions that should be avoided: Moisture.

10.2 Substances and materials with which the product may not come into contact: N/D

10.3 Dangerous decomposition products: The product is stable.

11. TOXICOLOGICAL INFORMATION

No information is available for the product.

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Dibutyltin dilaurate:

Acute toxicity

LC₅₀, brown rat: 2 071 mg/kg

Tetramethoxysilane:

Acute toxicity

LC₅₀, brown rat: 0.4 mg/kg

LD₅₀, brown rat: 100 mg/kg

12. ENVIRONMENTAL INFORMATION

No information is available for the product.

Dibutyltin dilaurate:

Acute toxicity for aquatic organisms:

LC₅₀, 96 hrs, daphnia: > 3 mg/litre

LC₅₀, 72 hrs, algae: > 3 mg/litre

13. DISPOSAL

13.1, 13.2 Unusable waste and contaminated packages must be handled by a company authorised for dangerous waste disposal.

13.3 The relevant national legislation must be adhered to when disposing of the substance (in the Czech Republic, this is Act 185/2001 Coll., the Waste Act).

14. TRANSPORT INFORMATION

Not subject to ADR; the amount is less than limit.

15. INFORMATION CONCERNING LEGAL REGULATIONS

15.1 According to the law, the product is classified as a medical device, therefore no risk symbols and no phrases are used on the container.

15.2 Relevant legislation

European Parliament and Council Directive (ES) 1907/2006

Act 356/2003 Coll. (applicable in the Czech Republic)

16. OTHER INFORMATION

R-phrases used:

R 10 - Flammable

R 22 - Harmful if swallowed

R 26 - Very Toxic by inhalation

R 38 - Irritating to the skin

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- R 41 - Risk of serious damage to eyes
- R 60 - May impair fertility
- R 61 - May cause harm to the unborn child
- R 68 - Possible risk of irreversible effects
- R 37/38 - Irritating to respiratory system and skin
- R 48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed
- R 50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Updates in the safety data sheet:

The safety data sheet was updated to comply with Annex 2 of Directive 1907/2006/ES

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.