

**FORMEROL<sup>®</sup> F.10**

Material Safety Data Sheet Revision: 21 December 2012

**SECTION 1: Identification of the substance/mixture and company/undertaking**

1.1 Product identifier	Formulation F.10
1.2 Relevant identified uses of the substance or mixture and uses advised against	Mouldable self-adhesive silicone Uses advised against: not available.
1.3 Details of the supplier of the safety data sheet	FormFormForm Ltd. Unit 2, 47-49 Tudor Road @cbXcbž9- +GB UK
1.4 Emergency telephone number	Supplier emergency number: +44 (0) 20 7998 0022.  Danish national emergency number: 82 12 12 12 (Giftlinjen, Bispebjerg Hospital). Dutch national emergency number: 030 274 88 88 (Nationaal Vergiftigingen Informatie Centrum). Finnish national emergency number: (09) 4711 (Poison Information Centre, Hospital District of Helsinki and Uusimaa). French national emergency number: + 33 (0)1 45 42 59 59 (numéro ORFILA; INRS). Norwegian national emergency number: 22 59 13 00 (Helsedirektoratet, Norwegian Directorate of Health). Swedish national emergency number: 112 (Giftinformationscentralen; Swedish Poison Information Centre).

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FORMEROL<sup>®</sup> technology is protected by the following international patent applications:  
US Patent Application 10/517,057 and related filings in Europe, China and India.  
US Patent Application 11/921,006 and related filings in Europe, Japan, China and India.  
US Patent Application 11/921,005 and related filings in Europe, Japan, China and India.

**SECTION 2: Hazards identification**

2.1 Classification of the substance or mixture	Does not meet the criteria for classification according to 99/45/EC. For the classification according to 1272/2008, see Section 16
2.2 Label elements	
Symbol	None
Risk phrases	None
Safety phrases	None
Special Labeling	None
2.3 Other Hazards	Contains 3-aminopropyltriethoxysilane. May produce an allergic reaction. Contains ingredients whose properties have not been well investigated, so handle and dispose of with care.

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**SECTION 3: Composition / information on ingredients**

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**3.2 Mixtures <sup>a</sup>**

Declarable components	Conc. (wt%)	EC No.	CAS No.	Reg. No.	Classification	
					67/548/EEC	1272/2008
None						
Other components						
Talc	25-50	238-877-9	14807-96-6			
Barium sulfate	15-25	231-784-4	7727-43-7			
Silicon dioxide	5-10	231-545-4	7631-86-9			
3-Aminopropyl-triethoxysilane	<1	213-048-4	919-30-2			
Sodium silicate	<1	215-687-4	1344-09-8			

<sup>a</sup> See Section 16 'Other information' for the full text of the R- and H-phrases, if applicable.

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**SECTION 4: First aid measures**

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**4.1 Description of first aid measures**

Inhalation	If inhalation is suspected, remove exposed person to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms, call a poison centre or doctor.
Skin	Wash affected area with soap and water. Call a doctor if irritation, rash, or other symptoms occur. Wash contaminated clothing before re-use.
Eye	In case of contact with eyes, irrigate with room-temperature water for several minutes, occasionally lifting eyelids. Remove any contact lenses if easy to do. Continue rinsing. Get prompt medical attention if irritation occurs.
Ingestion	If swallowed, rinse mouth thoroughly and give water to drink. Get medical attention. Do not induce vomiting, unless instructed by medical personnel.

**4.2 Most important symptoms and effects, both acute and delayed.** May cause allergy in some individuals.

**4.3 Indication of any immediate medical attention and special treatment needed.** Treat symptoms as they occur.

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**SECTION 5: Firefighting measures**

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**5.1 Extinguishing media**

Suitable	Water spray, carbon dioxide, dry chemical powder and alcohol resistant foam are recommended.
Unsuitable	Not available.

**5.2 Special hazards arising from the substance or mixture.** The product is not classified as flammable. However, if involved in a fire product will produce hazardous smoke, vapours and gasses.

**5.3 Advice for firefighters** Remove containers from fire or cool them with water spray. Firefighters should wear self-contained breathing apparatus and full protective clothing.

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**SECTION 6: Accidental release measures**

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6.1 Personal precautions, protective equipment and emergency procedures.	For large spills, wear personal protection. Follow prescribed procedures for responding to large spills and reporting to authorities.
6.2 Environmental precautions.	Prevent product from entering water courses or drainage system.
6.3 Methods and material for containment and cleaning up.	Clean up spill as soon as possible. For small quantities, pick up pieces or wipe off with cloth or paper, and wash affected area with water and detergent. For large quantities, carefully sweep up or collect using vacuum cleaner. Wash contaminated surfaces with water and detergent, and collect washings for safe disposal. Place waste in a suitable container for disposal.
6.4 Reference to other sections.	For recommended personal protective equipment, see Section 8. For disposal considerations, see Section 13.

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**SECTION 7: Handling and storage**

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7.1 Precautions for safe handling	For industrial use, avoid contact with skin and eyes. Wear protective clothing as in Section 8. Good general ventilation is recommended. Wash hands after handling.
7.2 Conditions for safe storage, including any incompatibilities	Keep containers in a cool, dry place away from direct sunlight. Product is supplied in sealed containers. Opening the container and exposing the product to air will cause the product to self-react to form a cured polymer.
7.3 Specific end uses(s)	Not available.

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**SECTION 8: Exposure controls / personal protection**

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8.1 Control parameters	
EU limit values	None.
UK limit values	Silica, amorphous: WEL: 8 h TWA, 6 mg/m <sup>3</sup> (inhalable), 2.4 mg/m <sup>3</sup> (respirable). Talc, respirable dust: WEL: 8 h TWA, 1 mg/m <sup>3</sup> . Barium sulphate: WEL: 8 h TWA, 10 mg/m <sup>3</sup> (inhalable), 4 mg/m <sup>3</sup> (respirable).
German limit values	Silica, amorphous: MAK: 8 h TWA, 4 mg/m <sup>3</sup> (inhalable). Barium sulphate: MAK: 8 h TWA, 4 mg/m <sup>3</sup> (inhalable), 1.5 mg/m <sup>3</sup> (respirable).
French limit values	None.
Dutch limit values	Talc, respirable dust: 8 h TWA, 0.25 mg/m <sup>3</sup> .
Swedish limit values	Talc: 8 h TWA, 2 mg/m <sup>3</sup> (inhalable), 1 mg/m <sup>3</sup> (respirable).
Norwegian limit values	None.
Danish limit values	Silica, amorphous: 8 h TWA, 2 mg/m <sup>3</sup> (inhalable); STEL 4 mg/m <sup>3</sup> (inhalable).
Finnish limit values	Talc: 8 h TWA, 5 mg/m <sup>3</sup> (granular), 0.5 fibres/cm <sup>3</sup> (fibrous).
Other: human health (DNELs, DMELs)	Barium sulphate: worker, long-term exposure, systemic effects, inhalation, 10 mg/m <sup>3</sup> ; worker, long-term exposure, local effects, inhalation, 10 mg/m <sup>3</sup> . General population, long-term exposure, systemic effects, inhalation, 10 mg/m <sup>3</sup> ; long-term exposure, systemic effects, oral, 13 000 mg/kg/day. 3-Aminopropyltriethoxysilane: DNELs: workers, short-term exposure, systemic effects, dermal, 8.3 mg/kg bw/day; workers, short-term exposure, systemic effects, inhalation, 59 mg/m <sup>3</sup> ; workers, long-term exposure, systemic effects, dermal, 8.3 mg/kg bw/day; workers, long-term exposure, systemic effects, inhalation, 59 mg/m <sup>3</sup> . General population, short-term exposure, systemic effects, dermal, 5 mg/kg bw/day; general population, short-term exposure, systemic effects, inhalation, 17.4 mg/m <sup>3</sup> ; general population, long-term exposure, systemic effects, dermal, 5 mg/kg bw/day; general

population, long-term exposure, systemic effects, inhalation, 17.4 mg/m<sup>3</sup>.  
 Sodium silicate: workers, long-term exposure, systemic effects, dermal, 1.59 mg/kg bw/day; workers, long-term exposure, systemic effects, inhalation, 5.61 mg/m<sup>3</sup>. General population, long-term exposure, systemic effects, dermal, 0.8 mg/kg bw/day; general population, long-term exposure, systemic effects, inhalation, 1.38 mg/m<sup>3</sup>; general population, long-term exposure, systemic effects, oral, 0.8 mg/kg/day.

Other environmental (PNEC) Barium sulphate: PNECs: PNECs: freshwater, 227.8 mg/L; intermittent release, 21 mg/L; sewage treatment plant, 50.1 mg/L; freshwater sediment, 792.7 mg/kg dry sediment; soil, 207.7 mg/kg dry soil.  
 3-Aminopropyltriethoxysilane: PNECs: freshwater, 0.33 mg/L; intermittent release, 3.3 mg/L; sewage treatment plant, 13 mg/L; freshwater sediment, 1.2 mg/kg dry sediment; soil, 0.05 mg/kg dry soil.  
 Sodium silicate: PNECs: freshwater, 7.5 mg/L; intermittent release, 7.5 mg/L; sewage treatment plant, 348 mg/L.

## 8.2 Exposure controls

Engineering controls	Good general ventilation is recommended.
Personal protective equipment.	For professional use, the need for personal protective equipment should be based on a workplace risk assessment for the particular use. Avoid skin and eye contact by wearing chemical resistant gloves (eg nitrile, neoprene, PVC) and safety goggles. Where more extensive contact may occur, wear protective clothing (eg overalls, boots). Wear respiratory protective equipment if exposure to mists or vapours is possible. PPE should be to European (EN) standards. Consult manufacturers concerning breakthrough times.
Environmental exposure controls.	Not available.

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## SECTION 9: Physical and chemical properties

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### 9.1 Information on basic physical and chemical properties

Appearance	Highly coloured paste.
Odour	Characteristic.
Odour threshold	Not available.
pH	Not available.
Melting / freezing point	Not available.
Initial boiling point / range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Flamm. or expl. limits	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubilities	Insoluble in water.
Partition coeff. (Kow)	Not available.
Auto-ignition temp.	Not available.
Decomposition temp.	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.

9.2 Other information Not available.

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## SECTION 10: Stability and reactivity

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10.1 Reactivity Not available.

10.2 Chemical Stability The product will polymerise on exposure to air. The polymerisation reaction is not hazardous.

10.3 Possibility of hazardous reactions	Not available.
10.4 Conditions to avoid	Product is supplied in sealed containers. Opening the container and exposing the product to air will cause the product to self-react to form a cured polymer. Avoid prolonged storage at high temperature or exposure to sunlight.
10.5 Incompatible materials	Acids, alkalis, and oxidizing agents.
10.6 Hazardous decompositions products	Not available.

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## SECTION 11: Toxicological information

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### 11.1 Information on toxicological effects

Acute	The following refers to uncured product. The cured product is not expected to have toxicological effects. The product is not expected to meet the criteria for classification.
Skin corrosion	The product is not expected to meet the criteria for classification as a skin irritant.
Serious eye damage / irritation	The product is not expected to meet the criteria for classification as an eye irritant.
Respiratory or skin sensitisation	One ingredient, present at less than 1%, has been identified as being a skin sensitiser.
Germ cell mutagenicity	Based on available information, the product is not expected to meet the criteria for classification for this effect.
Carcinogenicity	Based on available information, the product is not expected to meet the criteria for classification for this effect.
Reproductive toxicity	Based on available information, the product is not expected to meet the criteria for classification for this effect.
STOT-single exposure	The product is not expected to meet the criteria for classification.
STOT-repeated exposure	Not classified due to lack of data.
Aspiration hazard	Not classified due to lack of data.

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## SECTION 12: Ecological information

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12.1 Toxicity	The cured product is not expected to have toxicological effects.
12.2 Persistence and degradability	The cured product is not expected to have toxicological effects.
12.3 Bioaccumulative potential	Not available.
12.4 Mobility in soil	Not available.
12.5 Results of PBT and vPvB assessment	Not available.
12.6 Other adverse effects	Not available.

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## SECTION 13: Disposal considerations

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13.1 Waste treatment methods	The product is not classified as hazardous and may be suitable for landfill or incineration. Disposal must be in accordance with current national and local regulations. Chemical residues generally count as special waste, and their disposal may be regulated in
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the EC member countries through corresponding laws and regulations. General EU requirements are given in the Waste Framework Directive (75/442/EEC) and the Hazardous Waste Directive (91/689/EEC).

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#### SECTION 14: Transport information

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14.1 UN Number	Not classified as dangerous goods for transport.
14.2 UN proper shipping	Not applicable.
14.3 Transport hazard class(es)	Not applicable.
14.4 Packing group	Not applicable.
14.5 Environmental hazards	Not marine pollutant / environmentally hazardous.
14.6 Special precautions for user	Product is supplied in sealed containers. Opening the container and exposing the product to air will cause the product to self-react to form a cured polymer.
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

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#### SECTION 15: Regulatory information

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15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	<p>UK: Control of Substances Hazardous to Health Regulations 2002 (COSHH). Workplace Exposure Limits EH40/2005, with 2007 supplement, Health and Safety Executive.</p> <p>Germany: WGK (Wassergefährdungsklassen) Regulation: Verwaltungsvorschrift wassergefährdende Stoffe (VwVwS), designating water hazard classes. Product WGK, 1 (self-classification).</p> <p>Occupational exposure limits: List of MAK and BAT Values 2006, Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Report No. 42, Wiley-VCH.</p> <p>France: Valeurs limites d'exposition professionnelle aux agents chimiques en France (professional exposure limit values to chemical agents in France); Institut National de Recherche et de Sécurité, Document ED 984.</p> <p>Netherlands: Occupational exposure limits: Appendix XIII of the Working Conditions Regulations; Government Gazette (Staatscourant) of 28 December 2006, no. 252.</p> <p>Sweden: Occupational Exposure Limit Values and Measures Against Air Contaminants; AFS 2005:17; Statute Book of the Swedish Work Environment Authority.</p> <p>Norway: Occupational Exposure Limits: Veiledning om Administrative normer for forurensning i arbeidsatmosfæren, 2010; Arbeidstilsynet; best. nr. 361.</p> <p>Denmark: Limit Values for Substances and Materials; WEA-Guide C.0.1; Arbejdstilsynet; October 2002.</p> <p>Finland: Occupational exposure limit values: Sosiaali- ja terveystieteiden tutkimuskeskus julkaisu 2007:4, HTP-arvot 2007.</p>
15.2 Chemical safety assessment	Not available.

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#### SECTION 16: Other information

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Revisions	This SDS is the first version in EU format.
Abbreviations	DNEL, derived no-effect level; DMEL, derived minimum effect level; LD, lethal dose; STOT RE, specific organ toxicity repeated exposure; STOT SE, specific target organ toxicity single exposure.
References	Annex VI of Regulation 1272/2008 on Harmonised Classification and Labelling for Certain Hazardous Substances. Information on Registered Substances; Chemical Substance Search; European Chemicals Agency (ECHA), available at the ECHA website: <a href="http://echa.europa.eu">http://echa.europa.eu</a> .

Basis of classification	The mixture is self-classified on the basis of available information on the ingredients.
List of R-phrases	None.
Classification according to 1272/2008	Not classified.
List of hazard statements	None.