

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

### 1.1. Product identifier

Product form : Mixture, Liquid  
Product name : TransFix  
Product code : CAL001

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

#### 1.2.1. Relevant identified uses

Main use category : Professional use  
Use of the substance/mixture : Health Care

#### 1.2.2. Uses advised against

No additional information available

### 1.3. Details of the supplier of the safety data sheet

Caltag Medsystems Ltd  
Whiteleaf Business Centre  
11 Little Balmer  
Buckingham, MK18 1TF - United Kingdom  
T +44 1280 827460  
[support@caltag.co.uk](mailto:support@caltag.co.uk)

### 1.4. Emergency telephone number

Emergency number : +44 (0)1280 827460

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin sensitisation, Category 1 H317  
Carcinogenicity, Category 1B H350

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Suspected of causing cancer. When heated may give off formaldehyde gas.

### 2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to displayExtra classification(s) to display

Hazard pictograms (CLP) :



GHS07

GHS08

Signal word (CLP) : Danger  
Hazardous ingredients : formaldehyde  
Hazard statements (CLP) : H317 - May cause an allergic skin reaction.  
H350 - May cause cancer.  
Precautionary statements (CLP) : P261 - Avoid breathing fume, mist, spray, vapours.  
P280 - Wear protective gloves, protective clothing, eye protection.  
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.  
P308+P313 - IF exposed or concerned: Get medical advice/attention.  
P362+P364 - Take off contaminated clothing and wash it before reuse.

### 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
formaldehyde (Note B)(Note D)	(CAS-No.) 50-00-0 (EC-No.) 200-001-8 (EC Index-No.) 605-001-00-5 (REACH-no) 01-2119488953-20	< 1	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Muta. 2, H341 Carc. 1B, H350

#### Specific concentration limits:

Name	Product identifier	Specific concentration limits
formaldehyde	(CAS-No.) 50-00-0 (EC-No.) 200-001-8 (EC Index-No.) 605-001-00-5 (REACH-no) 01-2119488953-20	( 0.2 =<C < 100) Skin Sens. 1, H317 ( 5 =<C < 100) STOT SE 3, H335 ( 5 =<C < 25) Eye Irrit. 2, H319 ( 5 =<C < 25) Skin Irrit. 2, H315 ( 25 =<C < 100) Skin Corr. 1B, H314

Note B : Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

Note D : Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier must state on the label the name of the substance followed by the words 'non-stabilised'.

Full text of H-statements: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: If experiencing respiratory symptoms: Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest.
First-aid measures after skin contact	: If skin irritation or rash occurs: Gently wash with plenty of soap and water. Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Get medical advice/attention. Wash contaminated clothing before reuse.
First-aid measures after eye contact	: Rinse immediately with plenty of water. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: If you feel unwell, seek medical advice. Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects	: May cause cancer.
Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: May cause an allergic skin reaction.
Symptoms/effects after eye contact	: May cause eye irritation.
Symptoms/effects after ingestion	: Ingestion may cause nausea, vomiting and diarrhea.

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: Do not use a heavy water stream.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard	: The product is not flammable.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Toxic fumes may be released. Carbon monoxide. Unidentified organic compounds. When heated may give off formaldehyde gas.

### 5.3. Advice for firefighters

Precautionary measures fire	: Exercise caution when fighting any chemical fire.
Firefighting instructions	: Prevent fire fighting water from entering the environment. Use water spray or fog for cooling exposed containers.

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Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Ensure adequate ventilation. Avoid breathing vapour or mist. Avoid contact with skin and eyes.

##### 6.1.1. For non-emergency personnel

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

Emergency procedures : Evacuate unnecessary personnel.

##### 6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection. For further information refer to section 8: "Exposure controls/personal protection".

Emergency procedures : Ventilate area.

#### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

#### 6.3. Methods and material for containment and cleaning up

For containment : Absorb spillage.

Methods for cleaning up : Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

#### 6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of solid materials or residues refer to section 13 : "Disposal considerations".

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin and eyes. Always wash hands after handling the product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing fume, mist, spray, vapours. Do not handle until all safety precautions have been read and understood.

Hygiene measures : Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

#### 7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Does not require any specific or particular technical measures.

Storage conditions : Keep only in the original container in a cool, well ventilated place away from : Direct sunlight. Keep container closed when not in use.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

#### 7.3. Specific end use(s)

No additional information available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

formaldehyde (50-00-0)		
United Kingdom	Local name	Formaldehyde
United Kingdom	WEL TWA (mg/m <sup>3</sup> )	2.5 mg/m <sup>3</sup>
United Kingdom	WEL TWA (ppm)	2 ppm
United Kingdom	WEL STEL (mg/m <sup>3</sup> )	2.5 mg/m <sup>3</sup>
United Kingdom	WEL STEL (ppm)	2 ppm

#### 8.2. Exposure controls

##### Appropriate engineering controls:

Ensure adequate ventilation.

##### Personal protective equipment:

Avoid all unnecessary exposure.

##### Hand protection:

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Wear chemically resistant protective gloves. Standard EN 374 - Protective gloves against chemicals.

### Eye protection:

Chemical goggles or safety glasses. Standard EN 166 - Personal eye-protection - specifications

### Skin and body protection:

Wear suitable protective clothing

### Respiratory protection:

Wear respiratory protection when concentrations are above exposure limits.

### Other information:

Do not eat, drink or smoke during use.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Green.
Odour	: odourless.
Odour threshold	: No data available
pH	: 5.8 - 7.4
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: > 70 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable.
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

None under normal use.

### 10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

### 10.5. Incompatible materials

Strong acids. Strong bases.

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

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### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

Acute toxicity : Not classified

formaldehyde (50-00-0)	
LD50 oral	100 mg/kg bodyweight
LD50 dermal	270 mg/kg bodyweight
LC50 inhalation rat (Dust/Mist - mg/l/4h)	497 mg/l

Skin corrosion/irritation : Not classified  
pH: 5.8 - 7.4

Additional information : Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified  
pH: 5.8 - 7.4

Additional information : Based on available data, the classification criteria are not met

Respiratory or skin sensitisation : May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified  
Based on available data, the classification criteria are not met

Carcinogenicity : May cause cancer.

Reproductive toxicity : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-single exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Additional information : Based on available data, the classification criteria are not met

### SECTION 12: Ecological information

#### 12.1. Toxicity

formaldehyde (50-00-0)	
LC50 fish 1	6.7 mg/l
EC50 other aquatic organisms 1	5.8 mg/l waterflea
EC50 other aquatic organisms 2	3.48 mg/l

#### 12.2. Persistence and degradability

TransFix	
Persistence and degradability	Not established.

#### 12.3. Bioaccumulative potential

TransFix	
Bioaccumulative potential	Not established.

formaldehyde (50-00-0)	
Log Pow	0.779

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Results of PBT and vPvB assessment

No additional information available

#### 12.6. Other adverse effects

Additional information : Avoid release to the environment.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

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Ecology - waste materials : Avoid release to the environment.

### SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

#### 14.6. Special precautions for user

- Overland transport

Not applicable

- Transport by sea

Not applicable

- Air transport

Not applicable

- Inland waterway transport

Not applicable

- Rail transport

Not applicable

#### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

### SECTION 15: Regulatory information

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

##### 15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

##### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H- and EUH-statements:

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Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Carc. 1B	Carcinogenicity, Category 1B
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Muta. 2	Germ cell mutagenicity, Category 2
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H350	May cause cancer.

SDS EU (REACH Annex II) - Llewellyn

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*