

SAFETY DATA SHEET

In accordance with REACH Regulation EC No.1907/2006

Product: TransFix CAL001

Version: 6

Section 1. Identification of the substance or the mixture and of the supplier

1.1 Product Identifier

Product identifier: TransFix CAL001(Contains:Paraformaldehyde)

Other identifiers: None

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

Product uses: Health care

1.3 Details of the supplier of the safety data sheet

Company name: Caltag Medsystems Ltd

Company address: Whiteleaf Business Centre
11, Little Balmer
Buckingham
MK18 1TF
UK

Contact: Daniel Harrison

E-Mail address:

Company phone: 44 (0)1280 827460

1.4 Emergency telephone number

Emergency phone: 44 (0)1280 827460

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Classification under Regulation (EC) No 1272/2008

Class and category of danger: Eye Damage / Irritation Category 2
Sensitization - Skin Category 1
Germ Cell Mutagenicity Category 2
Carcinogenicity Category 1B
H317, May cause an allergic skin reaction.
H319, Causes serious eye irritation.
H341, Suspected of causing genetic defects (exposure route).
H350, May cause cancer (exposure route).

2.2 Label elements

Signal word: Danger

Hazard statements: H317, May cause an allergic skin reaction.
H319, Causes serious eye irritation.
H341, Suspected of causing genetic defects (exposure route).

SAFETY DATA SHEET

In accordance with REACH Regulation EC No.1907/2006

Product: TransFix CAL001

Version: 6

H350, May cause cancer (exposure route).

Supplemental Information: None

Precautionary statements:

- P202, Do not handle until all safety precautions have been read and understood.
- P261, Avoid breathing vapour or dust.
- P264, Wash hands and other contacted skin thoroughly after handling.
- P272, Contaminated work clothing should not be allowed out of the workplace.
- P280, Wear protective gloves/eye protection/face protection.
- P302/352, IF ON SKIN: Wash with plenty of soap and water.
- P305/351/338, IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P308/313, IF exposed or concerned: Get medical advice/attention.
- P333/313, If skin irritation or rash occurs: Get medical advice/attention.
- P337/313, If eye irritation persists: Get medical advice/attention.
- P363, Wash contaminated clothing before reuse.
- P405, Store locked up.
- P501, Dispose of contents/container to approved disposal site, in accordance with local regulations.

Pictograms:



Other hazards: None

Section 3. Composition / information on ingredients

3.2 Mixtures

Contains:

Name	CAS	EC	REACH Registration No.	%	Classification for (CLP) 1272/2008
Paraformaldehyde	30525-89-4			1-<5%	FS 1-FS 2-ATD 4-SCI 2-EDI 1-SS 1B-MUT 2-CAR 1B-STO-SE 3 (NE);H228-H312-H315-H317-H318-H336-H341-H350,-

Substances with Community workplace exposure limits:

Not Applicable

SAFETY DATA SHEET

In accordance with REACH Regulation EC No.1907/2006

Product: TransFix CAL001

Version: 6

Substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, greater than 0.1%:

Not Applicable

Section 4. First-aid measures

4.1 Description of first aid measures

IF ON SKIN: Wash with plenty of soap and water.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

IF exposed or concerned: Get medical advice/attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause an allergic skin reaction.

Causes serious eye irritation.

Suspected of causing genetic defects (exposure route).

May cause cancer (exposure route).

4.3 Indication of any immediate medical attention and special treatment needed

None expected, see Section 4.1 for further information.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable media: Carbon dioxide, Dry chemical, Foam.

5.2 Special hazards arising from the substance or mixture

In case of fire, may be liberated: Carbon monoxide, Unidentified organic compounds.

5.3 Advice for fire fighters:

In case of insufficient ventilation, wear suitable respiratory equipment.

Section 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Avoid inhalation. Avoid contact with skin and eyes. See protective measures under Section 7 and 8.

6.2 Environmental precautions:

Keep away from drains, surface and ground water, and soil.

SAFETY DATA SHEET

In accordance with REACH Regulation EC No.1907/2006

Product: TransFix CAL001

Version: 6

6.3 Methods and material for containment and cleaning up:

Remove ignition sources. Provide adequate ventilation. Avoid excessive inhalation of vapours. Contain spillage immediately by use of sand or inert powder. Dispose of according to local regulations.

6.4 Reference to other sections:

Also refer to sections 8 and 13.

Section 7. Handling and storage

7.1 Precautions for safe handling:

Keep away from heat, sparks, open flames and hot surfaces. - No smoking. Use personal protective equipment as required. Use in accordance with good manufacturing and industrial hygiene practices. Use in areas with adequate ventilation. Do not eat, drink or smoke when using this product.

7.2 Conditions for safe storage, including any incompatibilities:

Store in a well-ventilated place. Keep container tightly closed. Keep cool. Ground/bond container and receiving equipment. Use explosion-proof electrical, ventilating and lighting equipment. Use only non-sparking tools. Take precautionary measures against static discharge.

7.3 Specific end use(s):

Health care: Use in accordance with good manufacturing and industrial hygiene practices.

Section 8. Exposure controls/personal protection

8.1 Control parameters

Workplace exposure limits: Not Applicable

8.2 Exposure Controls

Eye / Skin Protection

Wear protective gloves/eye protection/face protection

Respiratory Protection

Under normal conditions of use and where adequate ventilation is available to prevent build up of excessive vapour, this material should not require special engineering controls. However, in conditions of high or prolonged use, or high temperature or other conditions which increase exposure, the following engineering controls can be used to minimise exposure to personnel: a) Increase ventilation of the area with local exhaust ventilation. b) Personnel can use an approved, appropriately fitted respirator with organic vapour cartridge or canisters and particulate filters. c) Use closed systems for transferring and processing this material.

Also refer to Sections 2 and 7.

Section 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: Not determined

Odour: Not determined

SAFETY DATA SHEET

In accordance with REACH Regulation EC No.1907/2006

Product: TransFix CAL001

Version: 6

Odour threshold:	Not determined
pH:	Not determined
Melting point / freezing point:	Not determined
Initial boiling point / range:	Not determined
Flash point:	> 70 °C
Evaporation rate:	Not determined
Flammability (solid, gas):	Not determined
Upper/lower flammability or explosive limits:	Product does not present an explosion hazard
Vapour pressure:	Not determined
Vapour density:	Not determined
Relative density:	Not determined
Solubility(ies):	Not determined
Partition coefficient: n-octanol/water:	Not determined
Auto-ignition temperature:	Not determined
Decomposition temperature:	Not determined
Viscosity:	Not determined
Explosive properties:	Not expected
Oxidising properties:	Not expected

9.2 Other information: None available

Section 10. Stability and reactivity

10.1 Reactivity:

Presents no significant reactivity hazard, by itself or in contact with water.

10.2 Chemical stability:

Good stability under normal storage conditions.

10.3 Possibility of hazardous reactions:

Not expected under normal conditions of use.

10.4 Conditions to avoid:

Avoid extreme heat.

10.5 Incompatible materials:

Avoid contact with strong acids, alkalis or oxidising agents.

10.6 Hazardous decomposition products:

Not expected.

SAFETY DATA SHEET

In accordance with REACH Regulation EC No.1907/2006

Product: TransFix CAL001

Version: 6

Section 11. Toxicological information

11.1 Information on toxicological effects

This mixture has not been tested as a whole for health effects. The health effects have been calculated using the methods outlined in Regulation (EC) No 1272/2008 (CLP).

Acute Toxicity:	Based on available data the classification criteria are not met.
Acute Toxicity Oral	>5000
Acute Toxicity Dermal	Not Applicable
Acute Toxicity Inhalation	Not Available
Skin corrosion/irritation:	Based on available data the classification criteria are not met.
Serious eye damage/irritation:	Eye Damage / Irritation Category 2
Respiratory or skin sensitisation:	Sensitization - Skin Category 1
Germ cell mutagenicity:	Germ Cell Mutagenicity Category 2
Carcinogenicity:	Carcinogenicity Category 1B
Reproductive toxicity:	Based on available data the classification criteria are not met.
STOT-single exposure:	Based on available data the classification criteria are not met.
STOT-repeated exposure:	Based on available data the classification criteria are not met.
Aspiration hazard:	Based on available data the classification criteria are not met.

Information about hazardous ingredients in the mixture

Ingredient	CAS	EC	LD50/ATE Oral	LD50/ATE Dermal	LC50/ATE Inhalation	LC50 Route
Paraformaldehyde	30525-89-4		592	10000	1.07	Not available

Refer to Sections 2 and 3 for additional information.

Section 12. Ecological information

12.1 Toxicity:	Not available
12.2 Persistence and degradability:	Not available
12.3 Bioaccumulative potential:	Not available
12.4 Mobility in soil:	Not available
12.5 Results of PBT and vPvB assessment:	
This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.	
12.6 Other adverse effects:	Not available

SAFETY DATA SHEET

In accordance with REACH Regulation EC No.1907/2006

Product: TransFix CAL001

Version: 6

Section 13. Disposal considerations

13.1 Waste treatment methods:

Dispose of in accordance with local regulations. Avoid disposing into drainage systems and into the environment. Empty containers should be taken to an approved waste handling site for recycling or disposal.

Section 14. Transport information

14.1 UN number: Not classified
14.2 UN Proper Shipping Name: -
14.3 Transport hazard class(es): Not classified
Sub Risk: Not classified
14.4. Packing Group: Not classified
14.5 Environmental hazards: Not environmentally hazardous for transport
14.6 Special precautions for user: None additional
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:
Not classified

Section 15. Regulatory information

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

None additional

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out for this product.

Section 16. Other information

Concentration % Limits: EDI 2=100.00% SS 1=100.00% MUT 2=100.00% CAR 1B=10.00%

Total Fractional Values: EDI 2=1.00 SS 1=1.00 MUT 2=1.00 CAR 1B=10.00

Key to revisions:

Classification under Regulation (EC) No 1272/2008

Concentration % Limits

SECTION 3: Composition/information on ingredients

Total Fractional Values

Key to abbreviations:

Abbreviation	Meaning
ATD 4	Acute Toxicity - Dermal Category 4
CAR 1B	Carcinogenicity Category 1B
EDI 1	Eye Damage / Irritation Category 1
FS 1	Flammable Solid, Hazard Category 1

SAFETY DATA SHEET

In accordance with REACH Regulation EC No.1907/2006

Product: TransFix CAL001**Version:** 6

FS 2	Flammable Solid, Hazard Category 2
H228	Flammable solid.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H336	May cause drowsiness or dizziness.
H341	Suspected of causing genetic defects (exposure route).
H350	May cause cancer (exposure route).
MUT 2	Germ Cell Mutagenicity Category 2
P202	Do not handle until all safety precautions have been read and understood.
P210	Keep away from heat, sparks, open flames and hot surfaces. - No smoking.
P261	Avoid breathing vapour or dust.
P264	Wash hands and other contacted skin thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/eye protection/face protection.
P302/352	IF ON SKIN: Wash with plenty of soap and water.
P304/340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305/351/338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308/313	IF exposed or concerned: Get medical advice/attention.
P310	Immediately call a POISON CENTER or doctor/physician.
P333/313	If skin irritation or rash occurs: Get medical advice/attention.
P362	Take off contaminated clothing and wash before reuse.
P403/233/235	Store in a well-ventilated place. Keep container tightly closed. Keep cool.
P405	Store locked up.
P501	Dispose of contents/container to approved disposal site, in accordance with local regulations.
SCI 2	Skin Corrosion / Irritation Category 2
SS 1B	Sensitization - Skin Category 1B
STO-SE 3(NE)	Specific Target Organ Toxicity (Single Exposure) Category 3

The information in this safety data sheet is to the best of our knowledge true and accurate but all data, instructions, recommendations and/or suggestions are made without guarantee.