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: 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).
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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:

<table>
<thead>
<tr>
<th>Name</th>
<th>CAS</th>
<th>EC</th>
<th>REACH Registration No.</th>
<th>%</th>
<th>Classification for (CLP) 1272/2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraformaldehyde</td>
<td>30525-89-4</td>
<td></td>
<td></td>
<td>1-5%</td>
<td>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</td>
</tr>
</tbody>
</table>

Substances with Community workplace exposure limits:
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.
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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:

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
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.
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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS</th>
<th>EC</th>
<th>LD50/ATE Oral</th>
<th>LD50/ATE Dermal</th>
<th>LC50/ATE Inhalation</th>
<th>LC50 Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraformaldehyde</td>
<td>30525-89-4</td>
<td>592</td>
<td>10000</td>
<td>1.07</td>
<td>Not available</td>
<td></td>
</tr>
</tbody>
</table>

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
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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):
   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:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATD 4</td>
<td>Acute Toxicity - Dermal Category 4</td>
</tr>
<tr>
<td>CAR 1B</td>
<td>Carcinogenicity Category 1B</td>
</tr>
<tr>
<td>EDI 1</td>
<td>Eye Damage / Irritation Category 1</td>
</tr>
<tr>
<td>FS 1</td>
<td>Flammable Solid, Hazard Category 1</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>FS 2</td>
<td>Flammable Solid, Hazard Category 2</td>
</tr>
<tr>
<td>H228</td>
<td>Flammable solid.</td>
</tr>
<tr>
<td>H312</td>
<td>Harmful in contact with skin.</td>
</tr>
<tr>
<td>H315</td>
<td>Causes skin irritation.</td>
</tr>
<tr>
<td>H317</td>
<td>May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>H318</td>
<td>Causes serious eye damage.</td>
</tr>
<tr>
<td>H336</td>
<td>May cause drowsiness or dizziness.</td>
</tr>
<tr>
<td>H341</td>
<td>Suspected of causing genetic defects (exposure route).</td>
</tr>
<tr>
<td>H350</td>
<td>May cause cancer (exposure route).</td>
</tr>
<tr>
<td>MUT 2</td>
<td>Germ Cell Mutagenicity Category 2</td>
</tr>
<tr>
<td>P202</td>
<td>Do not handle until all safety precautions have been read and understood.</td>
</tr>
<tr>
<td>P210</td>
<td>Keep away from heat, sparks, open flames and hot surfaces. - No smoking.</td>
</tr>
<tr>
<td>P261</td>
<td>Avoid breathing vapour or dust.</td>
</tr>
<tr>
<td>P264</td>
<td>Wash hands and other contacted skin thoroughly after handling.</td>
</tr>
<tr>
<td>P271</td>
<td>Use only outdoors or in a well-ventilated area.</td>
</tr>
<tr>
<td>P272</td>
<td>Contaminated work clothing should not be allowed out of the workplace.</td>
</tr>
<tr>
<td>P280</td>
<td>Wear protective gloves/eye protection/face protection.</td>
</tr>
<tr>
<td>P302/352</td>
<td>IF ON SKIN: Wash with plenty of soap and water.</td>
</tr>
<tr>
<td>P304/340</td>
<td>IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.</td>
</tr>
<tr>
<td>P305/351/338</td>
<td>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</td>
</tr>
<tr>
<td>P308/313</td>
<td>IF exposed or concerned: Get medical advice/attention.</td>
</tr>
<tr>
<td>P310</td>
<td>Immediately call a POISON CENTER or doctor/physician.</td>
</tr>
<tr>
<td>P333/313</td>
<td>If skin irritation or rash occurs: Get medical advice/attention.</td>
</tr>
<tr>
<td>P362</td>
<td>Take off contaminated clothing and wash before reuse.</td>
</tr>
<tr>
<td>P405</td>
<td>Store locked up.</td>
</tr>
<tr>
<td>P501</td>
<td>Dispose of contents/container to approved disposal site, in accordance with local regulations.</td>
</tr>
<tr>
<td>SCI 2</td>
<td>Skin Corrosion / Irritation Category 2</td>
</tr>
<tr>
<td>SS 1B</td>
<td>Sensitization - Skin Category 1B</td>
</tr>
<tr>
<td>STO-SE 3(NE)</td>
<td>Specific Target Organ Toxicity (Single Exposure) Category 3</td>
</tr>
</tbody>
</table>

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.