

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Date of issue: 10/01/2024 Version: Rev10 2024-01

SECTION 1: Identification of the subs	stance/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 substa	ance 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 da	ata sheet
Cytomark, a division of Caltag Medsystems Whiteleaf Business Centre 11 Little Balmer Buckingham, MK18 1TF - United Kingdom T +44 1280 827460 <u>Support@cytomark.co.uk</u>	
1.4. Emergency telephone number	
Emergency number	: +44 (0)1280 827460
SECTION 2: Hazards identification	
2.1. Classification of the substance or mix	xture
Classification according to Regulation (EC) No Skin sensitisation, Category 1 H317 Carcinogenicity, Category 1B H350	n. 1272/2008 [CLP]
Full text of H statements : see section 16	
Adverse physicochemical, human health and e Suspected of causing cancer. When heated may g	
2.2. Label elements	
Labelling according to Regulation (EC) No. 127 Hazard pictograms (CLP)	
Signal word (CLP)	GHS07 GHS08 : Danger
Hazardous ingredients	: formaldehyde
Hazard statements (CLP)	: H317 - May cause an allergic skin reaction.
Precautionary statements (CLP)	 H350 - May cause cancer. 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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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		

Name	Product identifier	Specific concentration limits
formaldehyde	(CAS-No.) 50-00-0 (EC-No.) 200-001-8 (EC Index-No.) 605-001-00-5	(0.2 = <c 1,="" 100)="" <="" h317<br="" sens.="" skin="">(5 =<c 100)="" 3,="" <="" h335<br="" se="" stot="">(5 =<c 2,="" 25)="" <="" eye="" h319<="" irrit.="" th=""></c></c></c>
	(REACH-no) 01-2119488953-20	(5 = <c 2,="" 25)="" <="" h315<br="" irrit.="" skin="">(25 =<c 100)="" 1b,="" <="" corr.="" h314<="" skin="" th=""></c></c>

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 sub-	stance 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.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.
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SECTION 6: Accidental release 	neasures
6.1. Personal precautions, protection	ve 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 conta	ainment 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 stora	ge
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, in	cluding 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 ³)	2.5 mg/m ³
United Kingdom	WEL TWA (ppm)	2 ppm
United Kingdom	WEL STEL (mg/m ³)	2.5 mg/m ³
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:

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

Eye protection:

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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.

1. Information on basic physical and	chemical properties	
Physical state	: Liquid	
Colour	: Green.	
Odour	: odourless.	
Odour threshold	: No data available	
pН	: 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	

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.		
SECTION 11: Toxicological information		

11.1.	Information	on	toxicological	effects

Acute toxicity

: Not classified

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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,

Ecology - waste materials

regional, national and/or international regulation. : Avoid release to the environment.

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SECTION 14: Transpo	rt information			
In accordance with ADR / RID) / IMDG / IATA / ADN			
ADR	IMDG	ΙΑΤΑ	ADN	RID
14.1. UN number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipp	ing name			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard	l class(es)			
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental h	azards			
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

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

Not applicable

SECTION 15: Regulatory information

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

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 cher	mical 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:	
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

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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.