



MATERIAL SAFETY DATASHEET

1/ Product Identification:

1.1 Product name:	Neutral Buffered Formalin
1.2 Identified Use:	Fixative for Histology Laboratories
1.3 Supplier:	Genta Medical Unit 17D Marston Business Park Tockwith North Yorkshire YO26 7QF.
Tel:	01423 358 128
Fax:	01423 358 126
email:	info@genta-medical.co.uk
1.4 Emergency telephone	01423 358 128 (office hours)

2/ Hazard identification (CLP)

2.1 Product Identification: Formaldehyde and Methanol aqueous blend with pH buffer.

2.1.1 Classification of the substance or mixture according to Regulation (EC) No1272/2008

Acute Toxicity	Category 4 – H332
Skin Sensitizer	Category 1 - H317
Mutagen	Category 2 – H341
Carcinogen	Category 1B - H350

2.2 Label elements



SIGNAL WORD - DANGER

H332 – Harmful if inhaled

H317 - May cause an allergic reaction

H341 - Suspected of causing genetic defects

H350 – May cause cancer

P201 Obtain special instructions before use

P270 - Do not eat, drink or smoke when using this product

P271 - Use only outdoors or in a well ventilated area

P280 - Wear protective gloves/protective clothing/face protection

P305+P351+P338 - 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.

P280 – Wear protective gloves/protective clothing/eye protection/face protection.

P303+P361+P353 – IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

P308+P313 – IF exposed or concerned: Get medical advice/attention.

Special packaging requirements: Child resistant fastenings and tactile warnings not required as the product is not for sale to the general public.

2.3 Other hazards: Does not fulfil the criteria for classification as PBT or vPvB.

3/ Composition

3.1 Composition of mixture: Formaldehyde in water with methanol as stabiliser plus phosphate buffer salts.

Ingredient	Conc.	CLP Classification
Formaldehyde 01-2119488953-20-xxxx CAS 50-00-0 EC 200-001-8 (Substance)	<5%	Acute Toxicity Cat 3 - H H301, H311, H331 Skin Corrosive Cat 1B - H314 Skin Sensitizer Cat 1A - H317 Carcinogen Cat 1B - H350 Mutagen Cat 2 – H341
Methanol 01-2119433307-44-xxxx CAS 67-56-1 EC 200-659-6 (Substance)	<2%	Acute Toxicity Cat 3 – H301, H311, H331 Flammable Liquid Cat 2 – H225 STOT SE Cat 1 – H370
Monosodium Phosphate	<1%	None
Disodium Phosphate	<1%	None

Occupational exposure limits - see section 8.

4/ First Aid Measures

4.1 Description of first aid measures.

First Aiders: Trained first aiders only. Do not take any action if it involves personal risk, especially risk from contamination with the chemical through air, contact or artificial respiration.

Inhalation: Remove patient to fresh air, allow to rest and keep warm. If not breathing, give artificial respiration and seek medical attention.

Skin contact: Wash immediately with plenty of water. Remove any contaminated clothing and launder before reuse. If irritation persists or develops, seek medical attention.

Eye contact: Flush immediately with plenty of water for at least 15 minutes, keeping eyelids open and avoiding contamination of unaffected eye. Seek medical attention.

Ingestion: DO NOT induce vomiting! Rinse mouth out with water, but do not give anything to drink. Seek medical attention.

Personal precautions: Ensure that those giving first aid treatment do not get contaminated by product spills, etc. Wear suitable protective clothing, gloves and eye protection. See also Section 8 for details.

4.2 Most important symptoms

Potential Health Effects:

Contact dermatitis, skin / eye burns with permanent damage. Category 1B carcinogen based mainly on animal inhalation tests.

4.3 Indication of immediate medical attention / special treatment

Obtain medical attention if inhaled, ingested or in case of skin or eye contact.

5/ Fire hazards and fire fighting procedures.

5.1/ Extinguishing Media

Water spray/fog, foam, dry chemical or CO2. Do not use water jets. Cool containers with water spray.

5.2/ Special hazards

Will burn if involved in a fire. Risk of container burst / explosion. Vapours are heavy and can pool or travel long distances to ignition source. In fire may generate formaldehyde gas and carbon oxides.

5.3/ Advice for fire-fighters

Special fire-fighting procedures: Fire fighters should use self contained breathing apparatus and protective clothing. Use water to keep exposed containers cool and disperse vapours. Vapours may form explosive mixtures. Keep water run-off out of sewers and water sources. Dike for water control. Cool containers exposed to flames with water from the side until well after the flames are extinguished. Move container from the fire area if it is safe to do so without risk.

6/ Accidental release measures (Spillage).

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Shut off all ignition sources. No flares, smoking or flames in hazardous area. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders: if specialised clothing is required to deal with the spillage, take note of any information in section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

Avoid dispersal of spilt material and run off and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and material for containment and cleaning up

Small spill: Stop leak without risk. Move containers from spill area. Absorb with an inert dry material or formaldehyde neutralising granules and place in an appropriate waste disposal container. Use spark-proof tools and explosion-proof equipment. Dispose of via a licensed waste disposal contractor. Note: sale pack of this item is no more than 25 litres.

6.4 Reference to other sections

See section 1 for emergency contact information.

See Section 8 for information on appropriate personal protective equipment.

See section 13 for additional waste treatment information.

7/ Storage and handling.

7.1/ Precautions for safe handling

Usage precautions: Avoid contact with the skin, eyes or clothing. Ventilate well, avoid breathing vapours. Use approved respirator if air contamination is above accepted level. Read and follow manufacturer's recommendations. Wear full protective clothing for prolonged exposure and high concentrations. Do not eat drink or smoke in the same room as this material.

7.2/ Storage

Storage precautions: Keep away from oxidisers, heat & flames. Store with good ventilation. Keep containers tightly closed. Eliminate all sources of ignition and take precautions against static discharge.

Ventilation: Use local or general exhaust mechanical ventilation to control vapours. Note that vapours are heavier than air and can pool.

7.3/ Specific end uses: Histological fixative.

8/ Exposure control

8.1 Control Parameters

EH40 OCCUPATIONAL EXPOSURE LIMITS (Formaldehyde):

2.00ppm / 2.50mg/m³ 15 minute STEL

2.00ppm / 2.50mg/m³ 8hr TWA

This product has an occupational exposure limit. Monitoring should be undertaken to ensure limits are not breached.

EH40 OCCUPATIONAL EXPOSURE LIMITS (methanol):

250ppm / 333 mg/m³ 15 minute STEL Sk

200ppm / 266mg/m³ 8hr TWA Sk

This product has an occupational exposure limit. Monitoring should be undertaken to ensure limits are not breached.

Sk = can be absorbed via the skin.

8.2 Exposure controls: Use good ventilation to keep contaminants below exposure limits.

Respirators: in the absence of adequate mechanical ventilation, use a full face mask with organic filters.

Protective gloves: Use Nitrile gloves.

Eye protection: Use splash proof eye goggles.

Other: Provide eyewash stations or shower, protective clothing.

Hygiene measures: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before re-using. Ensure that eye wash stations and safety showers are close to the workstation location.

Eye protection: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. Recommended: Tightly-fitting goggles.

Hand protection: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. > 8 hours (breakthrough time): Rubber gloves - nitrile

Body Protection Use suitable protective equipment

Other Skin protection Suitable protective footwear

Respiratory protection If operating conditions cause high vapour concentrations or the TLV is exceeded, use full face respirator conforming to EN141, Type A or self-contained breathing apparatus

Environmental exposure controls Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

9/ Physical / Chemical properties

9.1 Basic physical & chemical properties

Appearance	Colourless liquid
Odour	Irritating, pungent
Odour Threshold Value	Not determined
pH (concentrated product)	Not applicable
Melting point (°C)	0C approx
Boiling point/ range (°C)	96 - 101C
Flash point (°C)	n/a
Evaporation rate	Not determined
Flammability	Not classified flammable
Lower explosion limit in air	6%
Upper explosion limit in air	73%
Vapour pressure (mmHg @ 35°C)	Not determined
Vapour density	Not determined
Density at 20°C (kg/m ³)	1020
Water solubility % by weight)	Miscible in all proportions
Solubility in solvents	Soluble in ethanol, acetone.
Partition coefficient (log Kow) (Octanol/water)	= 0.35
Auto-ignition temperature (°C)	300
Decomposition temperature (°C)	400
Viscosity (mPa.s at 25°C)	1.0
Oxidising properties	None

10/ Stability and reactivity

10.1 Reactivity : Product is stable under normal conditions of use. May polymerise in cold conditions or above 60C.

10.2 Chemical stability Product is stable under normal conditions of use.

10.3 Hazardous reactions: Reacts with strong oxidising agents. Can react with hydrochloric acid to form bis-chloromethyl ether (a potent human carcinogen).

10.4 Conditions to avoid: Keep away from heat and flames.

10.5 Incompatible materials Strong oxidising agents, metals.

10.6 Hazardous decomposition products: Formaldehyde gas and carbon oxides can be evolved when heating or burning.

11/ Toxicological information.

11.1 Information on toxicological effects

Formaldehyde

Acute Toxicity

LD50 (oral, rat): 100 mg/kg

LD50 (dermal, rabbit): 270 mg/kg.

LC50 (inhalation, rat): 203mg/m³.

Toxic if swallowed, in contact with skin or if inhaled. Can cause burns to throat, nose and gastrointestinal tract and severe irritation of the respiratory tract.

Methanol

Acute Toxicity

LD50 (oral, rat): > 1187 – 2769 mg/kg, LDLo (oral, human): 143 mg/kg. Readily absorbed by the gastrointestinal tract.

LD50 (dermal, rabbit): approx 17100 mg/kg. Readily absorbed through the skin.

LC50 (inhalation, rat): 128.2 mg/l/4 hour. TCLo (inhalation, human): 300 ppm. Readily absorbed by inhalation.

Corrosion/Irritation

Skin / Eye: Can cause skin irritation. Can cause severe eye irritation with permanent damage.

Sensitisation - Product may cause allergic contact dermatitis by skin contact (type IV immune reaction, acute and chronic skin sensitisation). Persons sensitised to formaldehyde should not handle this product.

Mutagenicity – Product is classified as a Category 2 mutagen under CLP in the EU.

Carcinogenicity

Product classified as a Category 1B carcinogen under CLP in the EU, mainly on grounds of inhalation experiments in animals that led to nasal cancer. However this is not proven in humans and there appears to be no definitive excess of lung cancer. Based on epidemiological evidence, no chronic adverse effects will be produced when working at below the UK WEL, although irritant effects may be experienced

Reproductive toxicity - Reason for no classification: conclusive evidence but not sufficient for classification

Specific target organ toxicity (single exposure) (STOT)

May cause respiratory irritation. Causes damage to organs. Can cause blindness.

Specific target organ toxicity (repeated exposure)

Reason for no classification: conclusive evidence but not sufficient for classification.

Aspiration hazard

Reason for no classification: conclusive evidence but not sufficient for classification.

Likely routes of exposure

Contact with skin and eyes or by inhalation of vapour.

Symptoms related to the physical, chemical and toxicological characteristics

May cause allergic contact dermatitis reaction by skin contact. Can cause skin burns, severe irritation with permanent damage, burns to throat, nose and gastrointestinal tract and severe irritation of the respiratory tract. Methanol can cause very serious irreversible effects by inhalation at > 05. mg/l/4 hour, or in contact with skin at >3.5 g/70 kg man, or by swallowing at > 1.75 g/70 kg man.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Classified as a Category 1B carcinogen under CLP in the EU, mainly on grounds of inhalation in animals

Classified as a Category 2 mutagen under CLP in the EU.

12/ Ecological information.

12.1 Toxicity

Data for active ingredient Formaldehyde

LC 50 Pimephales promelas, 96h 24 mg/l

LC50 Brachydanio rerio 96h 41 mg/l

EC50 Daphnia magna 48h approx. 2 mg/l

Bacterial toxicity: EC50 Photobacterium phosphoreum 30 min 8.5 mg/l

Activated sludge: EC20 Pseudomonas putida 5h >1995 mg/l

Formaldehyde exhibits a toxic effect on aquatic organisms, but is not officially classified as such. Not acutely toxic to vertebrate animals, but exerts activity against invertebrates, e.g. bacteria. Sludge decomposition can be impaired, but the inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations

12.2 Persistence and degradability - readily biodegradable.

12.3 Bio accumulative potential - Not accumulative.

12.4 Mobility in soil : Not available

12.5 Results of PBT and vPvB assessment : Does not fulfil the criteria for classification as PBT or vPvB

12.6 Other adverse effects No known significant effects or critical hazards.

13/ Disposal considerations.

13.1 Waste treatment methods:

Disposal of product

Users should acquaint themselves with local regulations. 4% Formaldehyde comes under European Waste Codes H5 and H7 therefore, waste is considered Hazardous Waste; European Waste Catalogue Index

No. 07 01 99, if not mixed with other waste. Disposal is usually carried out by incineration by a licensed waste material processor; stack gases may need to be scrubbed (See Section 5 above).

Disposal of packaging

Contaminated packing should be disposed of as Hazardous Waste, as above, according to local authority guidelines.

14/ Transport information

Not classified as hazardous for transport.

15/ Regulatory information

15.1 Applicable regulations:

- EC No. 1907/2006 REACH
- EC No. 1272/2008 CLP
- Highly flammable liquid regulations 1972
- Health & Safety at Work Act 1974
- Carriage of dangerous goods by road & rail (classification and labelling) Regulations 1994.

15.2 Chemical safety assessment has not been carried out for this substance.

16/ Other information

H-Statements used in Sections 2 and 3

H225: Highly flammable liquid and vapour

H332 – Harmful if inhaled

H317 - May cause an allergic reaction

H351 - Suspected of causing cancer

Based on EU Regulation 1907/2006 as amended by Regulation 453/2010

Disclaimer:

This information relates only to the specific material designated and as such may not be valid for such material used in a combination with other materials or processes. The information is believed to be accurate but is without warranty. Genta Medical is not liable for any injury or loss which may result from inappropriate use of the product.

This datasheet replaces version 4.2. The change is: Addition of Mutagen information.