

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 15.02.2019

Version 2.1

SECTION 1. Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Catalogue No.	R04650
Product name	S A F Fixative For Histology Harleco®
REACH Registration Number	This product is a mixture. REACH Registration Number see section 3.

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

Identified uses	Reagent for analysis For additional information on uses please refer to the Merck Chemicals portal (www.merckgroup.com).
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1.3 Details of the supplier of the safety data sheet

Responsible Department	LS-QHC * e-mail: prodsafe@merckgroup.com
Regional representation	Merck Chemicals Ltd * The Old Brickyard * New Road * Gillingham * Dorset * SP8 4XT * Tel. +44(0)1747 833000 * information@merckchem.co.uk .

1.4 Emergency telephone number +49 (0) 6151 722440**SECTION 2. Hazards identification****2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)**

Skin irritation, Category 2, H315
Eye irritation, Category 2, H319
Skin sensitisation, Category 1, H317
Germ cell mutagenicity, Category 2, H341
Carcinogenicity, Category 1B, H350

For the full text of the H-Statements mentioned in this Section, see Section 16.

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2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word

Danger

Hazard statements

H350 May cause cancer.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H341 Suspected of causing genetic defects.

Precautionary statements

Prevention

P201 Obtain special instructions before use.
P280 Wear protective gloves.

Response

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Restricted to professional users.

Reduced labelling (≤125 ml)

Hazard pictograms



Signal word

Danger

Hazard statements

H350 May cause cancer.
H317 May cause an allergic skin reaction.
H341 Suspected of causing genetic defects.

Precautionary statements

P201 Obtain special instructions before use.
P280 Wear protective gloves.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Contains: formaldehyde

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2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

3.1 Substance

Not applicable

3.2 Mixture

Hazardous components (REGULATION (EC) No 1272/2008)

Chemical name (Concentration)

CAS-No.	Registration number	Classification
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formaldehyde ($\geq 3\%$ - $< 5\%$)

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

50-00-0	01-2119488953-20-XXXX	Acute toxicity, Category 3, H301 Acute toxicity, Category 3, H331 Acute toxicity, Category 3, H311 Skin corrosion, Category 1B, H314 Skin sensitisation, Category 1, H317 Germ cell mutagenicity, Category 2, H341 Carcinogenicity, Category 1B, H350
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acetic acid ($\geq 1\%$ - $< 5\%$)

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

64-19-7	01-2119475328-30-XXXX	Flammable liquid, Category 3, H226 Skin corrosion, Category 1A, H314
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For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4. First aid measures

4.1 Description of first aid measures

After inhalation: fresh air. Call in physician.

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower. Consult a physician.

After eye contact: rinse out with plenty of water. Call in ophthalmologist.

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

irritant effects, Allergic reactions

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4.3 Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water, Foam, Carbon dioxide (CO₂), Dry powder

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Combustible.

Development of hazardous combustion gases or vapours possible in the event of fire.

5.3 Advice for firefighters

Special protective equipment for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Further information

Suppress (knock down) gases/vapours/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for emergency responders:

Protective equipment see section 8.

Advice for non-emergency personnel: Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up carefully with liquid-absorbent material (e.g. Chemizorb®). Dispose of properly. Clean up affected area.

Render harmless: Treatment with excess sodium hydrogen sulfite solution.

6.4 Reference to other sections

Indications about waste treatment see section 13.

SECTION 7. Handling and storage

7.1 Precautions for safe handling

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Advice on safe handling

Observe label precautions.

Work under hood. Do not inhale substance/mixture. Avoid generation of vapours/aerosols.

Hygiene measures

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Tightly closed. Keep in a well-ventilated place. Keep locked up or in an area accessible only to qualified or authorised persons.

Recommended storage temperature see product label.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

Components with workplace control parameters

Components

Basis	Value	Threshold limits	Remarks
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formaldehyde (50-00-0)

EH40 WEL	Short Term Exposure Limit (STEL):	2 ppm 2.5 mg/m ³	
	Time Weighted Average (TWA):	2 ppm 2.5 mg/m ³	

acetic acid (64-19-7)

EU ELV	Time Weighted Average (TWA):	10 ppm 25 mg/m ³	
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Derived No Effect Level (DNEL)

formaldehyde (50-00-0)

Worker DNEL, longterm	Systemic effects	inhalation	9 mg/m ³
Worker DNEL, longterm	Local effects	inhalation	0.5 mg/m ³
Worker DNEL, acute	Local effects	inhalation	1 mg/m ³
Worker DNEL, longterm	Systemic effects	dermal	240 mg/kg Body weight
Worker DNEL, longterm	Local effects	dermal	0.037 mg/cm ²
Consumer DNEL, longterm	Systemic effects	inhalation	3.2 mg/m ³
Consumer DNEL, longterm	Local effects	inhalation	0.1 mg/m ³

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Consumer DNEL, longterm	Systemic effects	dermal	120 mg/kg Body weight
Consumer DNEL, longterm	Local effects	dermal	0.012 mg/cm ²
Consumer DNEL, longterm	Systemic effects	oral	4.1 mg/kg Body weight
<i>acetic acid (64-19-7)</i>			
Worker DNEL, acute	Local effects	inhalation	25 mg/m ³
Worker DNEL, longterm	Local effects	inhalation	25 mg/m ³
Consumer DNEL, acute	Local effects	inhalation	25 mg/m ³
Consumer DNEL, longterm	Local effects	inhalation	25 mg/m ³

Recommended monitoring procedures

Methods for measurement of the workplace atmosphere have to correspond to the requirements of norms DIN EN 482 and DIN EN 689.

Predicted No Effect Concentration (PNEC)

formaldehyde (50-00-0)

PNEC Fresh water	0.47 mg/l
PNEC Marine water	0.47 mg/l
PNEC Aquatic intermittent release	4.7 mg/l
PNEC Fresh water sediment	2.44 mg/kg
PNEC Marine sediment	2.44 mg/kg
PNEC Soil	0.21 mg/kg
PNEC Sewage treatment plant	0.19 mg/l

acetic acid (64-19-7)

PNEC Fresh water	3.058 mg/l
PNEC Fresh water sediment	11.36 mg/kg
PNEC Marine water	0.3058 mg/l
PNEC Marine sediment	1.136 mg/kg
PNEC Aquatic intermittent release	30.58 mg/l
PNEC Sewage treatment plant	85 mg/l

8.2 Exposure controls

Engineering measures

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See section 7.1.

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Individual protection measures

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

Eye/face protection

Safety glasses

Hand protection

full contact:

Glove material:	Nitrile rubber
Glove thickness:	0.11 mm
Break through time:	> 480 min

splash contact:

Glove material:	Nitrile rubber
Glove thickness:	0.11 mm
Break through time:	> 480 min

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374, for example KCL 741 Dermatril® L (full contact), KCL 741 Dermatril® L (splash contact).

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Other protective equipment

protective clothing

Respiratory protection

required when vapours/aerosols are generated.

Recommended Filter type: filter ABEK

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer.

These measures have to be properly documented.

Environmental exposure controls

Do not let product enter drains.

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	liquid
Colour	colourless
Odour	No strong odour known.
Odour Threshold	No information available.

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pH	No information available.
Melting point	No information available.
Boiling point	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.
Upper explosion limit	No information available.
Vapour pressure	No information available.
Relative vapour density	No information available.
Density	No information available.
Relative density	No information available.
Water solubility	No information available.
Partition coefficient: n-octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

9.2 Other data

none

SECTION 10. Stability and reactivity

10.1 Reactivity

See section 10.3

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

10.3 Possibility of hazardous reactions

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The generally known reaction partners of water.

Risk of ignition or formation of inflammable gases or vapours with:

Metals

Violent reactions possible with:

10.4 Conditions to avoid

Heating.

no information available

10.5 Incompatible materials

various metals

10.6 Hazardous decomposition products

in the event of fire: See section 5.

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Mixture

Acute oral toxicity

Acute toxicity estimate: > 2,000 mg/kg

Calculation method

Acute inhalation toxicity

Acute toxicity estimate: > 20 mg/l; 4 h ; vapour

Calculation method

Symptoms: Possible damages: , mucosal irritations

Acute dermal toxicity

Acute toxicity estimate : > 2,000 mg/kg

Calculation method

Skin irritation

Mixture causes skin irritation.

Eye irritation

Mixture causes serious eye irritation.

Sensitisation

Mixture may cause an allergic skin reaction.

Germ cell mutagenicity

This information is not available.

Carcinogenicity

This information is not available.

Reproductive toxicity

This information is not available.

Teratogenicity

This information is not available.

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CMR effects

Carcinogenicity:

Possible carcinogen.

Mutagenicity:

Evidence of genetic defects.

Specific target organ toxicity - single exposure

This information is not available.

Specific target organ toxicity - repeated exposure

This information is not available.

Aspiration hazard

This information is not available.

11.2 Further information

Other dangerous properties can not be excluded.

Handle in accordance with good industrial hygiene and safety practice.

Components

formaldehyde

Acute oral toxicity

LD50 Rat: 100 mg/kg
(Lit.)

Acute inhalation toxicity

Acute toxicity estimate: 3.1 mg/l; vapour
Expert judgement

Acute dermal toxicity

Acute toxicity estimate : 300.1 mg/kg
Expert judgement

acetic acid

Acute oral toxicity

LD50 Rat: 3,310 mg/kg
(RTECS)

Acute inhalation toxicity

LCLO Rat: 39.95 mg/l; 4 h
(RTECS)

Skin irritation

Rabbit
Result: Causes burns.

(IUCLID)

Eye irritation

Rabbit
Result: Causes burns.

(IUCLID)

Germ cell mutagenicity

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Genotoxicity in vitro
Ames test
Salmonella typhimurium
Result: negative
Method: OECD Test Guideline 471

Mutagenicity (mammal cell test): chromosome aberration.
Result: negative
Method: OECD Test Guideline 473

Teratogenicity
Did not show teratogenic effects in animal experiments. (IUCLID)

SECTION 12. Ecological information

Mixture

12.1 Toxicity

No information available.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

Substance(s) in the mixture do(es) not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII, or a PBT/vPvB assessment was not conducted.

12.6 Other adverse effects

Discharge into the environment must be avoided.

Components

formaldehyde

Partition coefficient: n-octanol/water
log Pow: 0.021
(Lit.) Bioaccumulation is not expected.

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

acetic acid

Toxicity to fish
semi-static test LC50 *Oncorhynchus mykiss* (rainbow trout): > 300.8 mg/l; 96 h
OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates
EC50 *E.sulcatum*: 78 mg/l; 72 h
neutral (maximum permissible toxic concentration) (Lit.)

EC50 *Daphnia magna* (Water flea): 47 mg/l; 24 h
(Lit.)

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Toxicity to algae

IC50 *Scenedesmus quadricauda* (Green algae): 4,000 mg/l; 16 h
(maximum permissible toxic concentration) (Lit.)

Toxicity to bacteria

EC50 *Pseudomonas putida*: 2,850 mg/l; 16 h
neutral (maximum permissible toxic concentration) (Lit.)

microtox test EC50 *Photobacterium phosphoreum*: 11 mg/l; 15 min
(IUCLID)

Biodegradability

99 %; 30 d
OECD Test Guideline 301D
(HSDB)
Readily biodegradable

95 %; 5 d
OECD Test Guideline 302B
Readily eliminated from water

Biochemical Oxygen Demand (BOD)

880 mg/g (5 d)
(Lit.)

Ratio BOD/ThBOD

BOD5 76 %
(IUCLID)

Partition coefficient: n-octanol/water

log Pow: -0.17 (25 °C)
(experimental)
(ECHA) Bioaccumulation is not expected.

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

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SECTION 13. Disposal considerations

Waste treatment methods

Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

Notice Directive on waste 2008/98/EC.

See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

Notice Directive on waste 2008/98/EC.

SECTION 14. Transport information

Land transport (ADR/RID)

14.1 - 14.6 Not classified as dangerous in the meaning of transport regulations.

Inland waterway transport (ADN)

Not relevant

Air transport (IATA)

14.1 - 14.6 Not classified as dangerous in the meaning of transport regulations.

Sea transport (IMDG)

14.1 - 14.6 Not classified as dangerous in the meaning of transport regulations.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant

SECTION 15. Regulatory information

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

EU regulations

Major Accident Hazard SEVESO III
Legislation Not applicable

Occupational restrictions Take note of Dir 94/33/EC on the protection of young people at work. Observe work restrictions regarding maternity protection in accordance to Dir 92/85/EEC or stricter national regulations where applicable.

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Regulation (EC) No 1005/2009 on substances not regulated
that deplete the ozone layer

Regulation (EC) No 850/2004 of the not regulated
European Parliament and of the Council of 29
April 2004 on persistent organic pollutants
and amending Directive 79/117/EEC

Substances of very high concern (SVHC) This product does not contain
substances of very high concern
according to Regulation (EC) No
1907/2006 (REACH), Article 57
above the respective regulatory
concentration limit of $\geq 0.1\%$
(w/w).

National legislation

Storage class 6.1 D

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

SECTION 16. Other information

Full text of H-Statements referred to under sections 2 and 3.

H226	Flammable liquid and vapour.
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.
H341	Suspected of causing genetic defects.
H350	May cause cancer.

Training advice

Provide adequate information, instruction and training for operators.

Labelling

Hazard pictograms



Signal word

Danger

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Hazard statements

H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H341 Suspected of causing genetic defects.
H350 May cause cancer.

Precautionary statements

Prevention

P201 Obtain special instructions before use.
P280 Wear protective gloves.

Response

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Further information

Restricted to professional users.

Contains: formaldehyde

Key or legend to abbreviations and acronyms used in the safety data sheet

Used abbreviations and acronyms can be looked up at www.wikipedia.org.

The information contained herein is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.

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