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Safety data sheet according to 1907/2006/EC, Article 31

Printing date 24.01.2018 Version number 2 Revision: 15.09.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: Formamide Hybridization Buffer

Article number: 5960-0023, 50-86-09, 50-86-11, 50-86-12

Registration number

This product is a mixture (see chapter 3). Registration number(s) is/are not available for this substance/these substances as the substance(s) or its/their use are exempted from registration according to Article 2 REACH Regulation (EC) No. 1907/2006, the annual tonnage does not require registration or the registration is envisaged for a later registration deadline.

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

Relevant identified uses: RUO (Research Use Only). Uses advised against:

Not for in vitro diagnosis.

Sector of Use SU24 Scientific research and development

Product category PC21 Laboratory chemicals

Process category PROC15 Use as laboratory reagent

Application of the substance / the mixture Immunochemical reagent for detection / auxiliary reagent

1.3 Details of the supplier of the safety data sheet

Manufacturer/Distributor:

Manufacturer:

SeraCare Life Sciences (KPL)

910 Clopper Road

Gaithersburgh, Maryland 20878, USA

Distributor:

medac GmbH

Theaterstrasse 6

22880 Wedel, Germany

Informing department:

Product Safety

productsafety@medac.de

1.4 Emergency telephone number:

Giftinformationszentrum-Nord, Phone: ++49 551 19 240 (service in German and English, 24 hours permanently accessible).

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

According to Regulation (EC) No. 1272/2008 the mixture is classified as hazardous.

Repr. 1B H360D May damage the unborn child.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is labelled according to Regulation (EC) No. 1272/2008 (GHS/CLP).

Hazard pictograms



GHS08

Signal word Danger

Hazard-determining components of labelling:

formamide

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phone: +49 4103 8006-0



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Hazard statements

H360D May damage the unborn child.

Precautionary statements

P201 Obtain special instructions before use.

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

P405 Store locked up.

Additional information:

Restricted to professional users.

Reduced labelling (<125 ml):

Labelling of packages where the contents do not exceed 125 ml Hazard pictograms



CHCUS

Signal word Danger

Hazard-determining components of labelling:

formamide

Hazard statements

H360D May damage the unborn child.

Precautionary statements

P201 Obtain special instructions before use.

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

P405 Store locked up.

2.3 Other hazards

Results of PBT and vPvB assessment

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

SECTION 3: Composition/information on ingredients

3.1. Chemical characterisation: substances Not applicable. Product is a mixture.

3.2 Chemical characterisation: Mixtures

Description: Immunochemical reagent / auxiliary reagent

Dangerous components: CAS: 75-12-7

EINECS: 200-842-0 Index number: 616-052-00-8 RTECS: LQ 0525000

formamide

🗞 Repr. 1B, H360D

<50%

SVHC

75-12-7 formamide

Additional information For the wording of the listed H- and R-phrases please refer to Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information First aider: Take care of self-protection.

After inhalation

Supply fresh air.

In case of symptoms call a physician.

After skin contact

Instantly remove contaminated clothes.

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Wash with copious amounts of water.

Call in physician.

After eye contact

Rinse eyes cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.

Instantly consult ophthalmologist.

After swallowing

Let rinse out mouth and then drink plenty of water.

Call doctor.

4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

Information for doctor

Show Safety Data Sheet.

Treatment according to symptoms.

Danger Danger of skin resorption.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents

CO₂, foam or extinguishing powder.

Product itself does not burn. Use fire fighting measures that suit the environment.

For safety reasons unsuitable extinguishing agents For this mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

In the event of fire may develop:

Carbon monoxide (CO)

Carbon dioxide (CO₂)

Nitrogen oxides (NOx)

5.3 Advice for firefighters

Protective equipment:

Stay in the danger area only with self-contained breathing apparatus.

Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Additional information

Collect contaminated fire fighting water separately. It must not enter drains.

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel:

Avoid reagent contact with eyes and skin.

Provide fresh air in closed rooms.

Advice for emergency responders: Protective equipment: see Section 8.

6.2 Environmental precautions: Do not empty into drains.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Afterwards clean with water and cleansing agent.

Collect the material and dispose of properly.

Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

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See Section 13 for information on disposal.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Observe label precautions.

Open and handle container with care.

Information about protection against explosions and fires: The product is not flammable

7.2 Conditions for safe storage, including any incompatibilities No further relevant information available.

Requirements to be met by storerooms and containers: Store at +2 °C to +8 °C.

Information about storage in one common storage facility: Store separately from stong oxidants and halogens.

Further information about storage conditions:

Store in a locked cabinet or with access restricted to technical experts or their assistants.

Storage class Please see the respective national guidelines.

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

Additional information about design of technical systems: No further data; see Section 7.

8.1 Control parameters

Components with critical values that require monitoring at the workplace:

75-12-7 formamide

WEL Short-term value: 56 mg/m³, 30 ppm Long-term value: 37 mg/m³, 20 ppm

DNELs No further relevant information available.

PNECs No further relevant information available.

CAS No. Designation of material % Type Value Unit

Additional Occupational Exposure Limit Values for possible hazards during processing: Not applicable.

Additional information: The official lists that were valid during the compilation were used as basis.

8.2 Exposure controls

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

See Section 7.

Personal protective equipment

General protective and hygienic measures

The usual precautionary measures should be adhered to in handling the chemicals.

Avoid contact with the eyes and skin.

Remove contaminated clothing immediately.

Do not eat or drink while working.

Keep away from food and beverages.

Wash hands during breaks and at the end of the work.

Breathing equipment:

Essential if vapours/aerosols develop.

Filter A (according to standard EN 3181) for vapours of organic compounds...

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.

Protection of hands:

Protective gloves (AQL 1.5).

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation. The breakthrough times stated below base on laboratory test methods which cannot fully simulate working conditions. It is the responsibility of the enduser to choose the appropriate gloves for his application. If working with substances or mixtures harmful in contact with skin, check the gloves beforehand for holes and fissures.

Material of gloves

Nitrile rubber, NBR

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Natural rubber, NR Material thickness: 0.4 mm.

Product quality must comply with standard EN 374.

Penetration time of glove material Penetration time > 120 min.

For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:

Product has not been designed for permanent contact.

For the permanent contact gloves made of the following materials are suitable:

Product has not been designed for permanent contact.

For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Product has not been designed for permanent contact.

As protection from splashes gloves made of the following materials are suitable:

Nitrile rubber, NBR Natural rubber, NR Layer thickness: 0,4 mm. Penetration time > 120 min.

Eye protection: Safety glasses (standard EN 166). **Body protection:** Protective work clothing.

Limitation and supervision of exposure into the environment Do not empty into drains.

Risk management measures Void.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form: liquid
Colour: Gold coloured
Smell: slightly amine-like
Odour threshold: No information available.

Important information on protection of health and

environment, and on safety.No further relevant information available.

pH-value: No information available.

Change in condition Not applicable.

Melting point/freezing point: No information available.

Flash point: Not applicable. Inflammability (solid, gaseous) Not applicable.

Ignition temperature:No information available.Decomposition temperature:No information available.Self-inflammability:Not self-inflammable.Explosive properties:Not explosive.

Critical values for explosion:

Lower: No relevant information available.
Upper: No relevant information available.

Oxidising properties No information available.

Steam pressure at 20 °C: 23 hPa

DensityNo information available.Relative densityNo information available.Vapour densityNo information available.Evaporation rateNo information available.

Solubility in / Miscibility with

Water: Miscible Partition coefficient: n-octanol/water: Not determined.

Viscosity:

dynamic:kinematic:
No information available.
No information available.

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Solvent content:	
Organic solvents:	≤50 %
Water:	≥49 %
Solids content:	<1 %

9.2 Other informationNo further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity For this mixture no relevant information available.

10.2 Chemical stability The product is chemically stable under the indicated storage conditions.

Thernak decomposition / conditions to be avoided:

Conditions to be avoided:

Heating.

Light.

10.3 Possibility of hazardous reactions For these concentrations no relevant information available.

10.4 Conditions to avoid: No further relevant information available.

10.5 Incompatible materials:

Strong oxidising agents

Acids.

Rases

10.6 Hazardous decomposition products: In case of burning of larger amounts: See Section 5.

Additional information: No further relevant information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity Based on available data, the classification criteria are not met.

LD/LC50 values that are relevant for classification:

75-12-7 formamide

		5800 mg/kg (rat)
Dermal	LD50	17000 mg/kg (rab)

Specific symptoms in biological assay: No further relevant information available.

Primary irritant effect:

Skin corrosion/irritation Irritations possible.

Serious eye damage/irritation Strong irritant effects.

after swallowing: Mucosal irritations in mouth, pharynx and oesophagus possible.

after inhalation: Irritations possible.

Respiratory or skin sensitisation Based on available data, the classification criteria are not met. **Other information (about experimental toxicology):** No further relevant information available.

Subacute to chronic toxicity: Danger of cutaneous absorption.

Additional toxicological information: No further relevant information available. **Toxicokinetics, metabolism and distribution** No relevant information available.

Acute effects (acute toxicity, irritation and corrosivity) No acute toxicity information available for this product.

Sensitisation No sensitising effect known.

Repeated dose toxicity No further relevant information available.

CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Carcinogenicity Based on available data, the classification criteria are not met.

Reproductive toxicity

May damage the unborn child.

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.

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Aspiration hazard Based on available data, the classification criteria are not met.

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SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability Readily biodegradable (OECD Test Guideline 301D).

Other information: No further relevant information available.

Behaviour in environmental systems:

Components: No relevant information available.

12.3 Bioaccumulative potential No relevant information available.

12.4 Mobility in soil No relevant information available.

Ecotoxical effects:

Remark:

Fischtoxizität:

LC₅₀: Lepomis macrochirus: 6300 mg/l / 96h. LC₅₀: Onchorhynchus mykiss: 9800 mg/l / 96h. LC₅₀: Plimephales promelas: 10600 mg/l / 96h.

Daphnientoxizität:

LC₅₀: Daphnia magna: 15700 mg/l / 48h.

Algentoxizität:

 LC_{50} : Desmodesmus subspicatus IC50 > 500 mg/l / 96h.

Additional ecological information:

General notes: Void.

12.5 Results of PBT and vPvB assessment

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

12.6 Other adverse effects No relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product residues have to disposed of according to the Waste Framework Directive as well as national and regional regulations in each the latest versions.

Uncleaned packagings:

Recommendation: Uncleaned packagings have to be disposed of in the same manner as the product residues.

SECTION 14: Transport information	n	
14.1 UN-Number ADR, ADN, IMDG, IATA	-	
14.2 UN proper shipping name ADR, ADN, IMDG, IATA	-	
14.3 Transport hazard class(es)		
ADR, ADN, IMDG, IATA Class	-	
14.4 Packing group ADR, IMDG, IATA	-	
14.5 Environmental hazards: Marine pollutant:	No	
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14.6 Special precautions for user	Not applicable. (Contd. of page	
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable.		
Transport/Additional information:	Not classified as dangerous in the meaning of transport regulations as issued in the latest version. The transport regulations are cited according to internationa regulations and in the form applicable in Germany (GGVSE) Possible national deviations in other countries are not considered.	
UN "Model Regulation":	-	

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms See Section 2.

Signal word See Section 2.

Hazard-determining components of labelling: See Section 2.

Hazard statements See Section 2.

Precautionary statements See Section 2.

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

National regulations

Information about limitation of use:

Take note of the directive on the protection of young people at work in the latest version.

Take note of the directive on the safety and health at work for pregnant and breast feeding mothers and workers of childbearing age in the latest version.

Class	Share in %
NK	50.0

Water hazard class: Void.

Other regulations, limitations and prohibitive regulations Void.

Substances of very high concern (SVHC) according to REACH, Article 57

75-12-7 formamide

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out.

SECTION 16: Other information

All information and recommodations are believed to be correct as of the date of this Safety Data Sheet but shall not be taken to be all inclusive and shall be used only as a guide. All chemicals and preparations may present unknown hazards and should be used with caution. medac shall not be held liable for any damage resulting from handling or from contact with the above product.

This Safety Data Sheet is valid for the separately available Formamide Hybridization Buffer (article number 50-86-10), the Formamide Hybridization Buffer (article number 50-86-09) of the Detector HRP Chemiluminescent Blotting Kit (article number 54-30-00) and the Formamide Hybridization Buffer (article numbers 50-86-11 and 54-86-12, respectively) of the Detector AP Chemiluminescent Blotting Kit (article numbers 54-30-01 and 54-30-02, respectively).

Relevant phrases

H360D May damage the unborn child.

Department issuing data specification sheet: Product Safety

Contact: productsafety@medac.de Replaces version from: 18.07.2014

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Reason for alteration:

Change of manufacturer's address and of artice number(s).

General editorial revision.

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic SVHC: Substances of Very High Concern vPvB: very Persistent and very Bioaccumulative Repr. 1B: Reproductive toxicity - Category 1B