

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006
(amended by Regulation (EU) 2020/878)

Hybridization Buffer Enhancer - 30 µL

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

1.1. Product identifier

Product name	Hybridization Buffer Enhancer - 30 µL
CAS-No.	75-12-7
EC-No.	200-842-0
Product code	10011937

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

Use of the Substance/Mixture	Buffer solution for diagnostic device
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1.3. Details of the supplier of the safety data sheet

Company/Undertaking Identification	SOPHiA GENETICS SA La Pièce 12 CH-1180 Rolle Switzerland +41 21 694 10 60 http://www.sophiagenetics.com
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1.4. Emergency telephone number	local: 145 (Tox Info Suisse) international: +41 44 251 51 51
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Version	GHS 2
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008

Reproductive toxicity, Cat. 1B (D), H360D

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

Additional information

For the full text of the phrases mentioned in this Section, see Section 16.

2.2. Label elements



Signal Word

Danger

Hazard Statements

H360D: May damage the unborn child.

Precautionary statements

P201: Obtain special instructions before use.
P202: Do not handle until all safety precautions have been read and understood.
P260: Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P280: Wear protective gloves, protective clothing and eye protection.
P308+P313: IF exposed or concerned: Get medical advice/ attention.
P501: Dispose of contents/ container to an approved waste disposal plant.

Supplemental information

None.

Product identifier

formamide, CAS-No. 75-12-7, EC-No. 200-842-0

2.3. Other hazards

Slightly hazardous to water. Harmless in aqueous solution, but capable of detonation in crystallized state. This mixture does not contain any substances classified as PBT, vPvB or endocrine disruptors at a concentration above 0.1%.
Reproductive toxicity.

SECTION 3: Composition/information on ingredients

3.1. Substances

Liquid mixture.

Components	Weight %	Product identifier
formamide	100%	CAS-No.: 75-12-7 EC-No.: 200-842-0 Index-No: 616-052-00-8

For the full text of the phrases mentioned in this Section, see Section 16.

Hazardous impurities

None known.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	If coughing, shortness of breath, or other breathing difficulties occur, remove person to fresh air. If symptoms persist, seek medical attention. If necessary, restore normal breathing by administering first aid measures.
Skin contact	Wash off immediately with plenty of water.
Eye contact	Rinse thoroughly with plenty of water, also under the eyelids. If eye irritation persists, consult a specialist.
Ingestion	Clean mouth with water and drink afterwards plenty of water. Consult a physician for severe cases.

4.2. Most important symptoms and effects, both acute and delayed	The product contains no substances known to be hazardous to health in concentrations which need to be taken into account.
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4.3. Indication of any immediate medical attention and special treatment needed	None known.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	Use water spray, alcohol-resistant foam, dry extinguishing agent or carbon dioxide.
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Unsuitable extinguishing media	High volume water jet.
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5.2. Special hazards arising from the substance or mixture	Burning produces irritant fumes. Vapours are heavier than air and may spread along floors.
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5.3. Advice for firefighters

Special protective equipment for firefighters	Standard procedure for chemical fires. In the event of fire, wear self-contained breathing apparatus.
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Specific methods	Prevent fire extinguishing water from contaminating surface water or the ground water system.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Material can create slippery conditions. Sweep up to prevent slipping hazard.
For emergency responders	Use personal protective equipment. Evacuate personnel to safe areas.

6.2. Environmental precautions Do not flush into surface water or sanitary sewer system.

6.3. Methods and material for containment and cleaning up Small quantities: Wipe up with adsorbent material (e.g. cloth, fleece). Large quantities: Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). After cleaning, flush away traces with water.

6.4. Reference to other sections See chapter 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	When using, do not eat, drink or smoke. Protect from contamination. Suspect reproductive hazard - contains material which may injure unborn child.
7.2. Conditions for safe storage, including any incompatibilities	Store at room temperature in the original container. Do not store together with food.
7.3. Specific end use(s)	No information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limit(s) No data is available on the product itself.

formamide (CAS 75-12-7)	
Switzerland - Occupational Exposure Limits - Reproductive Toxins	Category 1B reproductive toxin
Switzerland - Occupational Exposure Limits - Skin Notation	skin notation
Switzerland - Occupational Exposure Limits - TWAs - (MAKs)	10 ppm TWA [MAK] 18 mg/m3 TWA [MAK]

8.2. Exposure controls

Appropriate engineering controls General industrial hygiene practice. Keep away from food, drink and animal feedingstuffs.

Personal protection equipment

<i>Respiratory protection</i>	No special protective equipment required.
<i>Hand protection</i>	Gloves made of Nitril. Break through time: > 4 h. The selected protective gloves have to satisfy the specifications of Regulation (EU) No. 2016/425 and the standard EN 374 derived from it. Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).
<i>Eye protection</i>	Safety glasses with side-shields.
<i>Skin and body protection</i>	Long sleeved clothing.
<i>Thermal hazards</i>	No special measures required.
Environmental exposure controls	Prevent product from entering surface water or sewage.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid.
Colour	Colourless to slightly yellowish.
Odour	Faintly of ammonia.
Melting point/ freezing point:	> 0°C
Boiling point or initial boiling point / range:	> 100°C
Flammability:	non-flammable
Lower and upper explosion limit:	Not determined.
Flash point:	175°C (open cup)
Auto-ignition temperature:	Not determined.
Decomposition temperature:	Not determined.
pH:	Not applicable.
Kinematic viscosity:	Not determined.
Solubility:	completely soluble (Water)
Partition coefficient n-octanol/water (log value):	Not determined.
Vapour pressure:	Not determined.
Density and/or relative density:	Not determined.
Relative vapour density:	Not determined.
Particle characteristics:	Not applicable.

9.2. Other information

9.2.1 Information with regard to physical hazard classes	No information available.
9.2.2 Other safety characteristics	No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	No information available.
10.2. Chemical stability	No decomposition if used as directed.
10.3. Possibility of hazardous reactions	No information available.
10.4. Conditions to avoid	Do not allow to dry. Heating in air.
10.5. Incompatible materials	Incompatible with oxidizing agents. Contact with strong bases liberates ammonia.
10.6. Hazardous decomposition products	None under normal use. In case of fire hazardous decomposition products may be produced such as: Ammonia. Hydrogen cyanide (hydrocyanic acid). In case of incomplete combustion an increased formation of oxides of nitrogen (NOx) is to be expected.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	No data is available on the product itself. formamide (CAS 75-12-7) Dermal LD50 Rabbit = 6 g/kg (NLM_HSDB) Inhalation LC50 Rat > 21 mg/L 4 h(ECHA) Oral LD50 Rat = 5577 mg/kg (NLM_CIP)
Skin corrosion/irritation	May irritate skin.
Serious eye damage/eye irritation	May cause eye irritation with susceptible persons.
Respiratory or skin sensitisation	None.
Carcinogenicity	Carcinogenicity classification not possible from current data.
Germ cell mutagenicity	Fertility classification not possible from current data.
Reproductive toxicity	May damage the unborn child.
Specific target organ toxicity - Single exposure	No data available.
Specific target organ toxicity - Repeated exposure	No data available.
Aspiration hazard	No data available.
Human experience	No data available.

11.2. Information on other hazards

Endocrine disrupting properties Contains no endocrine disrupting chemicals.

Other information No data available.

SECTION 12: Ecological information

12.1. Toxicity Ecological injuries are not known or expected under normal use.

formamide (CAS 75-12-7)

Ecotoxicity - Freshwater Algae -

Acute Toxicity Data

Ecotoxicity - Freshwater Fish -

Acute Toxicity Data

Ecotoxicity - Water Flea - Acute

Toxicity Data

EC50 72 h *Desmodesmus subspicatus* >500 mg/L (IUCLID)

EC50 96 h *Desmodesmus subspicatus* >500 mg/L (IUCLID)

LC50 96 h *Brachydanio rerio* 9135 mg/L [static] (IUCLID)

EC50 48 h *Daphnia magna* >500 mg/L (IUCLID)

12.2. Persistence and degradability

Expected to be ultimately biodegradable.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Endocrine disrupting properties

Contains no endocrine disrupting chemicals.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues / unused products

Where possible recycling is preferred to disposal or incineration. Hand over the product, including the partially emptied packaging, to an authorized disposal company or a hazardous waste collection point. Dispose of emptied containers/empty packaging in municipal waste collection without being cleaned. European Waste catalogue code (EWC-code): 07 07 01* .

Contaminated packaging

Offer rinsed packaging material to local recycling facilities.

SECTION 14: Transport information

14.1. UN number or ID number Not applicable.

14.2. UN proper shipping name	Not applicable.
14.3. Transport hazard class(es)	Not applicable.
14.4. Packing group	Not applicable.
14.5. Environmental hazards	Not applicable.
14.6. Special precautions for user	Not applicable.
14.7. Maritime transport in bulk according to IMO instruments	Not applicable.
UN Model Regulations	
ADR/RID	Not regulated.
IMDG	Not regulated.
IATA	Not regulated.
Further Information	Not classified as dangerous in the meaning of transport regulations.

SECTION 15: Regulatory information

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

Regulatory Information	Take note of Dir 94/33/EC on the protection of young people at work. Take note of Dir 92/85/EEC on the safety and health at work of pregnant workers. Water contaminating class (WGK Germany) = 1. Storage class 6.1D.
formamide (CAS 75-12-7)	
Switzerland - Candidate List	Toxic for reproduction (200-842-0)
Switzerland - Water Protection Ordinance - Water Polluting Liquids Classification	A
EU - Cosmetics (1223/2009) - Annex II - Prohibited Substances	Prohibited
EU - European Pollutant Release and Transfer Register (E-PRTR) (166/2006) - Threshold Quantities	"100000 kg/yr TQ (air)" As Non-methane volatile organic compounds (NMVOCs) [RR-14069-2]
EU - REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	Use restricted. See entry 30. Use restricted. See entry 75.
EU - REACH (1907/2006) - Appendix 6 - Entry 30 - Reproductive Toxicants: Category 1B	Present
EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very High Concern (SVHC) for Authorisation	Reason for inclusion Toxic for reproduction, Article 57c (200-842-0)
EU - REACH (1907/2006) - List of	Present ([200-842-0])

Registered Intermediates	
EU - REACH (1907/2006) - List of Registered Substances	Present
UNECE - Kiev Protocol on Pollutant Release and Transfer Registers (PRTR) - Annex II - Column 1a - Releases to Air	"100000 kg/yr" As Non-methane volatile organic compounds [RR-14069-2]
UNECE - Kiev Protocol on Pollutant Release and Transfer Registers (PRTR) - Annex II - Column 3	"100000 kg/yr" As Non-methane volatile compounds (NMVOC) [RR-14069-2]
15.2. Chemical safety assessment	Not required.

SECTION 16: Other information

Key or legend to abbreviations and acronyms	CLP: Classification according to Regulation (EC) No. 1272/2008 (GHS) EWC: European Waste catalogue code Reproductive toxicity (REACH 57c)
Key literature references and sources for data	Sources of key data used to compile the Safety Data Sheet: REACH, ECHA.
Classification procedure	Classification according to Regulation (EC) No. 1272/2008.
Full text of phrases referred to under sections 2 and 3	H360D: May damage the unborn child.
Instructions for use	Restricted to professional users.
Disclaimer	The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Document Approvals

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