

**SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY****1.1 Product identifier**

Trade name: ColoNode®  
Article number: CN 20201604  
Registration number (REACH): not relevant (mixture)

**1.2 Uses**

Relevant identified use: The intended use is for detection of tumor cells in lymph nodes (LNs) of colorectal cancer (CRC) patients and determination of CRC tumor aggressiveness to aid when decisions are to be made about adjuvant chemotherapy and follow-up.

Uses advised against: The product should only be used according to the relevant identified uses specified above. If the product is used for any other purposes, it is recommended to contact HiloProbe AB.

**1.3 Details of the supplier of the safety data sheet**

Supplier: HILOPROBE AB  
Address: Tvistevägen 48C, SE-90736 Umeå, Sweden  
Telephone No: +46 (0)76-8216770  
E-mail: info@hiloprobe.se

**1.4 Emergency telephone number**

Emergencies (24 hours): 112 (the European emergency number)

**SECTION 2: HAZARDS IDENTIFICATION****2.1 Classification of the substance****2.1.1 CLASSIFICATION ACCORDING TO CLP [REGULATION (EC) NO 1272/2008]**

Classification: The product is not a hazardous mixture according to regulations on classification and labeling.

**2.2 Label elements**

Labelling according to Regulation (EC) No 1272/2008 (CLP) not required.

**2.3 Other hazards**

PBT substance: None  
vPvB substance: None  
Physical hazards: No other known hazards.  
Health hazards: No other known hazards.  
Environmental hazards: No other known hazards

## 2.4 Authorization (substance)

See section 15.1.2 Authorizations and restrictions according to Reach sections VII and VIII.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Composition/information on ingredients

Substance identity				
Ethylenediaminetetraacetic acid disodium salt Solution	CAS No	EC No	REACH Reg. No	Conc (w/w)
	6381-92-6	205-358-3	01-2119486775-20-xxxx	< 1 %
Classification according to GHS	Acute Tox. 4; H332: Harmful if inhaled			
	STOT Rep. Exp. 2; H373: May cause damage to organs			
Pictograms	GHS08: health hazard, GHS07: exclamation mark			

Other included ingredients are not classified.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

Inhalation	Provide fresh air
Skin contact	Rinse skin with water. Immediate medical attention is not required
Eye contact	Remove contact lenses. Rinse with tempered, soft or low pressure water or eye wash.
In case of ingestion:	Drink a couple of glasses of water.
Notes for the doctor:	Exposure does generally not possess any hazard to the health.

### 4.2 Most important symptoms and effects, both acute and delayed

Not applicable

### 4.3 Indication of immediate medical attention and special treatment needed

None

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media:	The product is not flammable. Extinguishing media should be chosen according to fire and surroundings.
Unsuitable extinguishing media:	No information available.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards: Not known

### 5.3 Advice for fire-fighters

General safety measures: Apply general fire safety precautions.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

## 6.1 Personal precautions, protective equipment and emergency procedures

General safety measures:	Avoid inhalation of vapors and exposure to eyes and skin. Use personal protection equipment. See section 8 for more information
Personal protective equipment:	Always wear gloves when handling chemical substances.
Protection for emergency responders:	See section 8.2.2 Personal protection.

## 6.2 Environmental precautions

General safety measures:	None.
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## 6.3 Methods and material for containment and cleaning up

Containment techniques:	Specific containment is normally not necessary.
Methods for cleaning up:	Wipe up with inert absorbent material.

## 6.4 Reference to other sections

Sections 8 and 13:	Information regarding personal protective equipment, see section 8.2 Exposure controls, and regarding waste disposal, see section 13 Disposal considerations.
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## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

General requirements:	Use personal protective equipment as required. Standard industry hygiene applies. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.
Measures to prevent fire:	The product is not flammable or combustible.
Measures to protect the environment:	See section 6.2 Environmental precautions

### 7.2 Conditions for safe storage, including any incompatibilities

General conditions for safe storage:	Keep dark and frozen in a properly labelled container. The storage place should be kept clean.
Specific storage requirements:	-15 to -25°C for box 1 and -70 to -90°C for box 2.
Packaging compatibilities:	None.
Specific designs for storage rooms or vessels:	None.

### 7.3 Specific end use(s)

End use only according to section 1.2. For In-Vitro Diagnostics.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

#### 8.1.1 NATIONAL OCCUPATIONAL EXPOSURE LIMITS OR COMMUNITY OCCUPATIONAL EXPOSURE LIMITS

National limit values:  YES, see table below.  NO  
 Community limit values:  YES, see table below.  NO

Substance name	CAS No	Value	Occupational exposure limits	
			Control parameters	Basis
Glycerol mist	56-81-5	TWA	10 mg/m <sup>3</sup>	UK.
			200 mg/m <sup>3</sup>	Germany

### 8.2 Exposure controls

#### 8.2.1 APPROPRIATE ENGINEERING CONTROLS

Precautionary measures: No respiratory protection is ordinarily required under normal conditions of use and when adequate ventilation is ensured.

#### 8.2.2 PERSONAL PROTECTION

Requirements for protection equipment: Personal protective clothing should meet recommended standards.

Eye/face protection: With risk of exposure to the eyes, always wear protective glasses [EN 166 (Personal eye-protection - Specifications)].

Skin protection: Always wear gloves when handling the chemical substance [EN 374 (Protective gloves against chemicals and micro-organisms)]. For advice about suitable gloves for the type of work, period and frequency of exposure, contact the glove supplier:

Body protection: Standard protective clothing.

Respiratory protection: Not applicable

Thermal hazards: None.

#### 8.2.3 ENVIRONMENTAL EXPOSURE CONTROLS

General risk management measures: No specific measures.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

ColoNode® Master mixes:

Property	Value
Physical state :	liquid
Colour:	clear
Odour:	None
Odour Threshold:	Not applicable
Melting point/range:	No data available
Boiling point/boiling range:	No data available
Flammability:	The product is not flammable.

Upper /lower flammability or explosive limits:	Nonexplosive
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH:	No data available
Viscosity, dynamic:	No data available
Viscosity, kinematic:	No data available
Water solubility:	completely miscible
Solubility in other solvents:	No data available
Partition coefficient: noctanol/water:	No data available
Vapour pressure:	No data available
Relative density:	No data available
Relative vapour density:	No data available
Particle Size Distribution:	Not applicable

Manganese acetate, 25 mM:

Property	Value
Physical state :	liquid
Colour:	colourless
Odour:	none
Odour Threshold:	No data available
Melting point/range:	No data available
Boiling point/boiling range:	No data available
Flammability:	The product is not flammable
Upper explosion limit / Upper flammability limit:	No data available
Lower explosion limit / Lower flammability limit:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH:	No data available
Viscosity, dynamic:	No data available
Viscosity, kinematic:	No data available
Water solubility:	completely miscible
Solubility in other solvents:	No data available
Partition coefficient: noctanol/water:	No data available
Vapour pressure:	No data available
Relative density:	No data available
Relative vapour density:	No data available
Particle Size Distribution:	Not applicable

Standard A-F

Property	Value
Physical state :	liquid
Colour: colourless,	clear
Odour:	odourless

Odour Threshold:	No data available
Melting point/freezing point:	0,0 °C
Boiling point/boiling range:	100°C
Upper explosion limit / Upper flammability limit:	No data available
Lower explosion limit / Lower flammability limit:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH:	7,0
Viscosity, dynamic:	1,0016 mPa.s (20 °C) 0,282 mPa.s (100 °C)
Viscosity, kinematic:	No data available
Water solubility:	completely miscible
Solubility in other solvents:	No data available
Partition coefficient: noctanol/water:	No data available
Vapour pressure	: 0,61 kPa (0 °C) 101.3 kPa (100 °C)
Relative density:	No data available
Density:	1,000 g/cm <sup>3</sup> (20 °C)
Relative vapour density:	No data available
Particle Size Distribution:	Not applicable

Negative control:

Property	Value
Physical state :	liquid
Colour: colourless,	clear
Odour:	odourless
Odour Threshold:	No data available
Melting point/freezing point:	0,0 °C
Boiling point/boiling range:	100°C
Upper explosion limit / Upper flammability limit:	No data available
Lower explosion limit / Lower flammability limit:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH:	7,0
Viscosity, dynamic:	1,0016 mPa.s (20 °C) 0,282 mPa.s (100 °C)
Viscosity, kinematic:	No data available
Water solubility:	completely miscible
Solubility in other solvents:	No data available
Partition coefficient: noctanol/water:	No data available
Vapour pressure	: 0,61 kPa (0 °C) 101.3 kPa (100 °C)
Relative density:	No data available
Density:	1,000 g/cm <sup>3</sup> (20 °C)
Relative vapour density:	No data available
Particle Size Distribution:	Not applicable

## 9.2 Other safety information

Not applicable

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Reactivity hazards: The substance is not reactive.

### 10.2 Chemical stability

Stability under normal handling and storage: Stable substance under normal and intended handling conditions and storage, e.g. temperature. See section 7.2 Conditions for safe storage, including any incompatibilities.

### 10.3 Possibility of hazardous reactions

Hazardous reactions: Not expected to cause any hazardous reactions.

### 10.4 Conditions to avoid

Hazardous conditions: No data available  
 Risk management measures: See section 7 Handling and storage.

### 10.5 Incompatible materials

Specific materials: No data available

### 10.6 Hazardous decomposition products

Decomposition products: No known hazardous decomposition products.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### 11.1.1 MIXTURE - INFORMATION ON RELEVANT HAZARD CLASSES

ColoNode® Master mixes:

Acute toxicity:	Not classified based on available information. Components: Glycerol: LD50 Oral - Rat - 27,200 mg/kg (ECHA) LD50 Dermal - Rabbit - > 10,000 mg/kg
Skin corrosion/irritation:	Based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization:	Based on available data, the classification criteria are not met.
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:	Based on available data, the classification criteria are not met.
Specific target organ toxicity – single exposure:	Based on available data, the classification criteria are not met.

Specific target organ toxicity – repeated exposure:	Based on available data, the classification criteria are not met
Aspiration hazard:	Based on available data, the classification criteria are not met
Manganese acetate, 25 mM:	
Acute toxicity:	Not classified based on available information. Components: Bis(acetic acid) tetrahydrate manganese salt dihydride LD50 Oral - Rat - male - 3.730 mg/kg (OECD Test Guideline 401)
Inhalation:	No data available
Dermal:	No data available
Skin corrosion/irritation:	Based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization:	Based on available data, the classification criteria are not met.
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:	Based on available data, the classification criteria are not met.
Specific target organ toxicity – single exposure:	Based on available data, the classification criteria are not met.
Specific target organ toxicity – repeated exposure:	Based on available data, the classification criteria are not met.
Aspiration hazard:	Based on available data, the classification criteria are not met.
Standard A-F:	
Acute toxicity:	Not classified based on available information.
Inhalation:	No data available
Dermal:	No data available
Skin corrosion/irritation:	Based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization:	Based on available data, the classification criteria are not met.
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:	Based on available data, the classification criteria are not met.
Specific target organ toxicity – single exposure:	Based on available data, the classification criteria are not met.
Specific target organ toxicity – repeated exposure:	Based on available data, the classification criteria are not met.
Aspiration hazard:	Based on available data, the classification criteria are not met.
Negative control:	
Acute toxicity:	Not classified based on available information.
Inhalation:	No data available
Dermal:	No data available
Skin corrosion/irritation:	Based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization:	Based on available data, the classification criteria are not met.
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:	Based on available data, the classification criteria are not met.
Specific target organ toxicity – single exposure:	Based on available data, the classification criteria are not met.
Specific target organ toxicity – repeated exposure:	Based on available data, the classification criteria are not met.
Aspiration hazard:	Based on available data, the classification criteria are not met.

## 11.2 Brief summaries of the information derived from the application of Annexes VII to XI

Summary:	Information is given to each hazard class in section 11.1.1 Substance - Information on relevant hazard classes
CMR properties cat. 1A and 1B:	Based on available data, the classification criteria are not met

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity – mixture

#### 12.1.1 TOXICITY

ColoNode Master Mixes:

The mixture is not expected to be dangerous for the aquatic or terrestrial environment.

EDTA:

Acute and chronic aquatic toxicity for fish, crustaceans, algae and other aquatic plants: No data available

Glycerol:

Toxicity to fish: Static test LC50 *Oncorhynchus mykiss* (rainbow trout) 54,000 mg/l exposure time 96 h (ECHA)

Toxicity to daphnia and other aquatic invertebrates: No data available

Toxicity to algae: No data available

Manganese acetate, 25mM:

Toxicity to fish, daphnia and other aquatic invertebrates or algae: No data available

Standard A-F

Toxicity to fish, daphnia and other aquatic invertebrates or algae: No data available

Negative control:

Toxicity to fish, daphnia and other aquatic invertebrates or algae: No data available

**12.2 Persistence and degradability**

ColoNode Master Mix:

Glycerol:

Biodegradability aerobic - Exposure time 2 d

Result: 90 % - Readily biodegradable.

(ECHA)Biotic degradability:

**12.3 Bio accumulative potential**

No data available

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment**

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**12.6 Other adverse effects**

No known adverse effects.

**SECTION 13: DISPOSAL CONSIDERATIONS****13.1 Disposal considerations****13.1.1 CLASSIFICATION OF WASTE**

Hazardous waste: No

**13.1.2 HANDLING OF WASTE**

General information: The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in accordance with approved disposal technique. Disposal of this product, its solutions or of any by-products, shall comply with the requirements of all applicable local, regional or national/federal regulations.

Handling of waste product: Handled as nonhazardous waste.

Handling of packaging: Clean packages can be recycled.

**SECTION 14: TRANSPORT INFORMATION****14.1 General information**

Dangerous goods: No

IATA / ADR / DOT-US / IMDG Not regulated in the meaning of transport regulations

UN number or ID number Not Applicable

UN proper shipping name Not Applicable

Transport hazard class Not Applicable

Packing group Not Applicable

Environmental hazards Not Applicable

Special precautions for user	Not Applicable
Maritime transport in bulk according to IMO instruments	Not Applicable

## SECTION 15: REGULATORY INFORMATION

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

#### 15.1.1 REGULATIONS/LEGISLATION REGARDING SAFETY, HEALTH AND ENVIRONMENT

Safety Data Sheet according to Regulation (EC) No 1907/2006

National legislation

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances: Not applicable

Take note of Directive 94/33/EC on the protection of young people at work

Take note of Dir 92/85/EC on the protection of pregnant and breastfeeding women at work

#### 15.1.2 AUTHORIZATIONS AND RESTRICTIONS ACCORDING TO REACH SECTIONS VII AND VIII

Authorization (substance): No

Restriction (substance/mixture): No

### 15.2 Chemical Safety Assessment (CSR)

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

## SECTION 16: OTHER INFORMATION

### 16.1 Indication of changes

Information to the user: Version history will be described in this section for future revisions.

### 16.2 Abbreviations and acronyms

CAS No:	Chemical Abstracts Service number.
Cat:	Category. Subdivision of a hazard class, used in classification.
CLP:	Classification, Labelling and Packaging of chemical substances and mixtures. Short for: 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.
CMR properties:	Carcinogenic, Mutagenic or toxic for Reproduction
CSR:	Chemical Safety Report.
DSD:	Dangerous Substances Directive. Council Directive 67/548/EEC.
EC No:	The EC number, i.e. EINECS, ELINCS or NLP, is the official number of the substance within the European Union.
Einecs:	European Inventory of Existing Commercial Chemical Substances.
Elincs:	The European List of Notified Chemical Substances.
EN 140:	Respiratory protective devices - Half masks and quarter masks - Requirements, testing, marking.

EN 143:	Respiratory protective devices - Particle filters - Requirements, testing marking.
EN 149:	Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking.
EN 166:	Personal eye-protection – Specifications.
EN 374:	Protective gloves against chemicals and micro-organisms - Part 3: Determination of resistance to permeation by chemicals.
EN 388:	Protective gloves against mechanical risks.
ES:	Exposure scenario.
EWC:	The European Waste Catalogue. The EWC is a hierarchical list of waste descriptions established by Commission Decision 2000/532/EC.
Index No:	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008.
LOAEL:	Lowest Observable Adverse Effect Level. The lowest dose tested which gives a specific adverse effect.
LC50:	Lethal Concentration. In ecotoxicology, the LC50 is the concentration which kills 50 % of a population of one species, within a specified period of time.
LD50:	Lethal Dose. The LD50 is the dose of a substance which kills 50 % of a population of one species and is expressed as weight (mg, g) or as weight per weight of test animal (mg/kg).
NLP:	No-Longer Polymers List.
OECD:	Organization for Economic Co-operation and Development. The OECD Guidelines for the Testing of Chemicals are a collection of internationally agreed test methods. They cover tests for the physical-chemical properties, human health effects and environmental effects.
PBT substance:	Persistent, bio accumulative and toxic substance.
Reach:	Registration, Evaluation, Authorization and Restriction of Chemicals. REACH is the European Community Regulation on chemicals and their safe use.
vPvB substance:	Very persistent and very bio accumulative substance.
WEL:	Workplace Exposure Limits.

### 16.3 Key literature references and sources for data

#### References:

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing

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Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

**16.4 Information on the classification****16.4.1 CLASSIFICATION ACCORDING TO CLP REGULATION (EC) NO 1272/2008**

Classification: The product is not classified as a dangerous substance under the current legislation for classification and labelling of dangerous chemical substances and mixtures

This Safety Data Sheet contains information that to our knowledge is correct at the date of publication. The information given is designed only for safe handling of the product.