

Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 1 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

## SECTION 1: Identification

- 1.1 Product Name:** Covid DnaCartridge™  
**Cat Number:** 3822 00 0000
- 1.2. Recommended use:** For use as point-of-care Covid-19 test, only in conjunction with NudgeBox™ as per Instructions For Use.

### 1.3 Details of the supplier of the safety data sheet:

**Supplier:**

<b>Name</b>	DnaNudge Ltd
<b>Address</b>	Level 11, The Translation and Innovation Hub, Imperial College, White City Campus, London. W12 0BZ
<b>Information contact</b>	+44(0)20 8103 9278
<b>E-Mail</b>	covid@dnanudge.com

- 1.4 EMERGENCY TELEPHONE NUMBER:** +44(0)20 8103 9278
-

Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 2 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture:

Hazardous chemicals in limited use. Small quantities in sealed unit that are not released in normal use.

Acute oral toxicity	Cat 4 (H301)
Acute Inhalation Toxicity- Dusts and Mists	Cat 4 (H304)
Skin Corrosion/ Irritation	Cat 2 (H315)
Serious Eye Damage/ Eye Irritation	Cat 2 (H319)
Specific target organ toxicity- Central Nervous System	Cat 3 (H373)
Combustible Dust	Yes, if punctured
Flammable Liquids	Cat 2 (H225)

#### Additional information:

0.45ml of Guanadine Hydrochloride per cartridge- considered hazardous by 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Based on available data, there are no classifiable hazards to environment.

### 2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP/GHS]

#### Hazard pictograms



#### Signal word:

**Danger**

#### Precautionary Statements

##### Prevention

Reagents are sealed in cartridge and there should be no contact of chemicals with Operator.  
Keep product away from heat source and excess temperatures.

In case of accidental contact with chemicals due to pierced cartridge:  
Wash face, hands and any exposed skin thoroughly after handling  
Avoid breathing dust/fume/gas/mist/vapours/spray

##### Inhalation

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing  
Call a POISON CENTER or doctor/physician if you feel unwell

##### Skin

IF ON SKIN: Wash with plenty of soap and water

Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 3 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

If skin irritation occurs: Get medical advice/attention  
Take off contaminated clothing and wash before reuse

**Eyes**

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

If eye irritation persists: Get medical advice/attention

**Ingestion**

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

Rinse mouth

**Storage**

Store away from heat sources, ideally 5-25°C.

**Disposal**

Dispose of contents/container to an approved waste disposal plant

**Hazards not otherwise classified (HNOC)**

None identified

---

Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 4 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

**SECTION 3. Composition/information on ingredients****3.1 Substances**

<b>Product Description:</b>	<b>Triton® X-100</b>
<b>Cat No. :</b>	<b>215680000; 215680010; 215680050; 215682500; 215680100; 215680025</b>
<b>Synonyms</b>	Polyoxyethylene(10) octylphenyl ether
<b>CAS-No</b>	9002-93-1
<b>Molecular Formula</b>	C34 H62 O11

&lt;1% of weight, 1.05ml

<b>Product Description:</b>	<b><u>Ethanol 96%, technical, duty free</u></b>
<b>Cat No. :</b>	<b>444190000; 444190050</b>
<b>Synonyms</b>	Ethyl alcohol
<b>CAS-No</b>	64-17-5
<b>EC-No.</b>	200-578-6
<b>Molecular Formula</b>	C2 H6 O

&lt;1% of weight, 0.45ml. UN1170, packaging group 3.

<b>Product Name</b>	<b>Guanidine hydrochloride</b>
<b>Cat No. :</b>	<b>FSHO2983-500</b>
<b>CAS-No</b>	50-01-1
<b>Synonyms</b>	Aminoformamidine hydrochloride; Guanidine monohydrochloride; Guanidinium chloride

<1% of weight, 0.45ml

---

Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 5 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General information

Reagents are sealed in cartridge and there should be no contact of chemicals with Operator.

In case of damage to cartridge and reagent spillage, following guidance.

#### Inhalation

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing  
Call a POISON CENTER or doctor/physician if you feel unwell

#### Skin

IF ON SKIN: Wash with plenty of soap and water  
If skin irritation occurs: Get medical advice/attention  
Take off contaminated clothing and wash before reuse

#### Eyes

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
If eye irritation persists: Get medical advice/attention

#### Ingestion

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell  
Rinse mouth. Do not induce vomiting.

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

Symptoms. None reasonably foreseeable.

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

Notes for the doctor Treat symptomatically

---

Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 6 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

#### Suitable extinguishing media

Water Spray, Carbon Dioxide (CO<sub>2</sub>), Dry Chemical. Cool exposed containers exposed to fire with water spray.

#### Unsuitable extinguishing media

No information available

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

Flammable. Risk of ignition. Vapours may form explosive mixtures with air. Vapours may travel to source of ignition and flash back. Containers may explode when heated. Thermal decomposition can lead to release of irritating gasses and vapours. Keep product away from heat and sources of ignition. Vapours may form explosive mixtures with air.

#### Hazardous combustion products

Carbon Monoxide (CO), Carbon Dioxide (CO<sub>2</sub>), Hydrogen Chloride gas, Nitrogen Oxides (NO<sub>x</sub>), Aldehydes, Ketones

### 5.3 Advice for fire-fighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

---

Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 7 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

**SECTION 6: Accidental release measures**

**6.1 Personal precautions, protective equipment, and emergency procedures**

In case of accidental release, use personal protective equipment. Ensure adequate ventilation. Remove all sources of ignition.

**6.2 Environmental precautions**

Do not flush into surface water or sanitary sewer system.

**6.3 Methods and material for containment and cleaning up**

Remove all sources of ignition. Soak up with inert absorbent material. Keep in suitable, closed containers for disposal. Do not let chemical enter the environment.

**6.4 Reference to other sections**

Refer to protective measures listed in sections 8 and 13.

---

Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 8 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

**SECTION 7: Handling and storage**

**7.1 Precautions for safe handling**

The cartridge is in a sealed unit and can be handled without PPE.

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

Keep in a dry, cool, and well-ventilated place. Avoid prolonged temperatures outside 5°C-25°C. Avoid direct heat sources.

---



Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 9 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

**SECTION 8: Exposure controls/personal protection**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region-specific regulatory bodies.

All components are under EU limits for TWA, WEL and STEL

All components are under OSHA PEL limits

All components are under NIOSH IDLH limits

**Respiratory Protection** not required under intended use

**Ventilation** not required under intended use

**Protective Gloves** not required under intended use

**Eye Protection** not required under intended use

**Other Protection** not required under intended use

---

Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 10 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

**SECTION 9. Physical and chemical properties**

Reagents are sealed in cartridge and there should be no contact of chemicals with Operator. Three active chemicals are included in the sealed cartridge.

## Triton X-100

**Appearance** Clear**Physical State** Liquid**Odour** Characteristic**Odour Threshold** No data available**pH** 6-8 5% aq.sol**Melting Point/Range** 6 °C / 42.8 °F**Softening Point** No data available**Boiling Point/Range** 270 °C / 518 °F @ 760 mmHg**Flash Point** 274 °C / 525.2 °F **Method** - No information available**Evaporation Rate** No data available**Flammability (solid, gas)** Not applicable Liquid**Explosion Limits** No data available**Vapor Pressure** No data available**Vapor Density** No data available (Air = 1.0)**Specific Gravity / Density** 1.067**Bulk Density** Not applicable Liquid**Water Solubility** soluble**Solubility in other solvents** No information available**Partition Coefficient (n-octanol/water)**

Component	log Pow
Poly(oxy-1,2-ethanediyl).alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy	-2.7

**Molecular Formula** C34 H62 O11**Molecular Weight** 646.85

## Ethanol

**Appearance** Clear, Colourless**Physical State** Liquid**Odour** sweet, Characteristic**Odour Threshold** No data available**pH** No information available**Melting Point/Range** -114 °C / -173.2 °F**Softening Point** No data available**Boiling Point/Range** 78 °C / 172.4 °F**Flash Point** 13 - 17 °C / 55.4 - 62.6 °F **Method** - No information available**Evaporation Rate** No data available**Flammability (solid, gas)** Not applicable Liquid**Explosion Limits Lower** 3.3 vol %**Upper** 19 vol %**Vapor Pressure** No data available**Vapor Density** No data available (Air = 1.0)**Specific Gravity / Density** 0.80

Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 11 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

**Bulk Density** Not applicable Liquid**Water Solubility** soluble**Solubility in other solvents** No information available**Partition Coefficient (n-octanol/water)**

Component	log Pow
Ethyl Alcohol	-0.32

**Autoignition Temperature** No data available**Decomposition Temperature** No data available**Viscosity** No data available**Explosive Properties** No information available**Oxidizing Properties** No information available**Molecular Formula** C34 H62 O11**Molecular Weight** 646.85

Guanadine Hydrochloride

**Physical State** Powder Solid**Appearance** Off-white**Odour** Odourless**Odour Threshold** No information available**pH** 4.8 250 g/l aq.sol**Melting Point/Range** 179 - 186 °C / 354.2 - 366.8 °F**Boiling Point/Range** No information available**Flash Point** No information available**Evaporation Rate** Not applicable**Flammability (solid, gas)** No information available**Flammability or explosive limits****Upper** No data available**Lower** No data available**Vapor Pressure** No information available**Vapor Density** Not applicable**Specific Gravity** 1.340**Solubility** No information available**Partition coefficient (n-octanol/water)** No data available**Autoignition Temperature** Not applicable**Decomposition Temperature** 310 °C**Viscosity** Not applicable**Molecular Formula** C H5 N3 . H Cl**Molecular Weight** 95.53

Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 12 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

## **SECTION 10: Stability and reactivity**

### **10.1 Reactivity**

None known, based on information available

### **10.2 Chemical stability**

Stable under normal conditions

### **10.3 Possibility of hazardous reactions**

Hazardous polymerisation does not occur. No hazardous reactions under normal processing.

### **10.4 Conditions to avoid:**

Incompatible products. Excess heat.

### **10.5 Incompatible materials:**

Strong oxidizing agents. Strong acids. Strong reducing agents.

### **10.6 Hazardous decomposition products:**

None in normal processing.

---

Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 13 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Toxicity risk is minimal in normal use. All reagents are sealed and do not come into contact with operator in normal conditions.

Active Reagents as follows:

Triton X-100

#### Product Information

##### (a) acute toxicity;

**Oral** Category 4

**Dermal** No data available

**Inhalation** No data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]- .omega.-hydroxy-	1800 mg/kg ( Rat )		

**(b) skin corrosion/irritation;** No data available

**(c) serious eye damage/irritation;** Category 1

**(d) respiratory or skin sensitization;** No data available

**(e) germ cell mutagenicity;** No data available

**(f) carcinogenicity;** There are no known carcinogenic chemicals in this product

**(g) reproductive toxicity;** No data available

**(h) STOT-single exposure;** No data available

**(i) STOT-repeated exposure;** No data available

**(j) aspiration hazard;** No data available

**Symptoms / effects, both acute and delayed;** No information available

Ethanol

#### Product Information

##### (a) acute toxicity;

**Oral** Based on available data, the classification criteria are not met

**Dermal** Based on available data, the classification criteria are not met

**Inhalation** Based on available data, the classification criteria are not met

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Ethyl alcohol	3450 mg/kg ( Mouse )		20000 ppm/10H ( Rat )

**(b) skin corrosion/irritation;** Based on available data, the classification criteria are not met

**(c) serious eye damage/irritation;** Category 2

**(d) respiratory or skin sensitization;**

**Respiratory** Based on available data, the classification criteria are not met

**Skin** Based on available data, the classification criteria are not met

**(e) germ cell mutagenicity;** Based on available data, the classification criteria are not met

Mutagenic effects have occurred in humans

**(f) carcinogenicity;** Based on available data, the classification criteria are not met

The table below indicates whether each agency has listed any ingredient as a carcinogen

Component	EU	UK	Germany	IARC
Ethyl alcohol				Group 1

**(g) reproductive toxicity;** Based on available data, the classification criteria are not met

**Developmental Effects** Substances known to cause developmental toxicity in humans.

Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 14 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

**Teratogenicity** Teratogenic effects have occurred in humans.

**(h) STOT-single exposure;** Based on available data, the classification criteria are not met

**(i) STOT-repeated exposure;** Based on available data, the classification criteria are not met

**Target Organs** None known.

**(j) aspiration hazard;** Based on available data, the classification criteria are not met

**Other Adverse Effects** Tumorigenic effects have been reported in experimental animals.

**Symptoms / effects, both acute and delayed;** Inhalation of high vapor concentrations

Guanidine Hydrochloride

**Product Information**

**(a) acute toxicity;**

**Oral** Category 4

**Dermal** No data available

**Inhalation** No data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Guanidine hydrochloride	475 mg/kg (Rat)	>2000 mg/kg (Rabbit)	3.2 mg/L/4h (Rat)
Silica, amorphous	>5000 mg/kg (Rat)	>2000 mg/kg (Rabbit)	>2.2 mg/L (Rat) 4 h

**(b) skin corrosion/irritation;** Irritating to skin and eyes

**(c) serious eye damage/irritation;** Category 2

**(d) respiratory or skin sensitization;** No data available

**(e) germ cell mutagenicity;** No data available

**(f) carcinogenicity;** Based on available data, the classification criteria are not met

The table below indicates whether each agency has listed any ingredient as a carcinogen

Component	CAS-No	IARC	NTP	ACGIH	OSHA	Mexico
Guanidine hydrochloride	50-01-1	Not listed	Not listed	Not listed	Not listed	Not listed
Silica, amorphous	7631-86-9	Not listed	Not listed	Not listed	Not listed	Not listed

**(g) reproductive toxicity;** No data available

**(h) STOT-single exposure;** Central nervous system (CNS)

**(i) STOT-repeated exposure;** No data available

**(j) aspiration hazard;** No data available

**Symptoms / effects, both acute and delayed;** No information available

Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 15 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

**SECTION 12: Ecological considerations**

No data available for ecological and wastewater treatment (sewage) systems.

---

Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 16 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

**SECTION 13: Disposal considerations**

**13.1 Waste treatment methods**

The used DnaCartridge should be disposed in a Clinical Waste stream and incinerated.

Product/ unused product recommendation: consultation with the disposal agency and relevant authorities.

---



Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 17 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

**SECTION 14: Transport information**

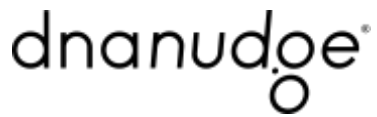
All reagents are either not regulated or, in the case of Ethanol (UN1170, PG3), shipped under the per container limit (0.45ml per container vs 5l limit).

No hazards are identified.

No Special precautions are required.

Packaged goods, no special requirements for bulk transport according to Annex II of MARPOL73/78 and the IBC Code.

---



## Safety Data Sheet

Trade name: DnaNudge Covid DnaCartridge™

Product No: CT-0001

Version: DN-MAN-DOC-003 rev1 Page 18 of 18

Print Date: 18.09.2020

Rev. Date: 18.09.2020

### **SECTION 15: Regulatory information**

DnaNudge has been assessed under Annex III (IVD 98/79/EC) as a General IVD. As such, it is in conformity with all requirements under applicable legislation.

---