

# SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)



## N-KITS

Version 1      Date of compilation: 12/02/2022

Page 1 of 8  
Print date: 15/02/2022

### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING.

#### 1.1 Product identifier.

N Latex <b>C1q</b> Kit	(REF: TD-42550),
N <b>C3Pa</b> Kit	(REF: TD-42720),
N <b>C5</b> Kit	(REF: TD-42570),
N Latex <b>IgD</b> Kit	(REF: TD-42650).

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

In Vitro diagnostic medical device, for laboratory professional use only.

#### Uses advised against:

Uses other than those recommended.

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

Company:	<b>Trimero Diagnostics SL</b>
Address:	Calle Valencia 558 4º 2ª
City:	08026 - Barcelona
Province:	Barcelona
Telephone:	+34 932448679
E-mail:	support@3diag.com
Web:	<a href="https://www.3diag.com">https://www.3diag.com</a>

#### 1.4 Emergency telephone number: (Available 24 hours)

UK and Scotland: Emergency Call 999

IRELAND - National Poisons Information Centre - WebSite <https://poisons.ie/>  
Phone No. Members of Public: +353 (01) 8092166 (8:00am to 10:00pm 7 days a week)  
Phone NO. Healthcare Professional : +353 (01) 8092566 (24 hours service)

For more information visit <https://www.3diag.com/Emergency-Numbers>

### SECTION 2: HAZARDS IDENTIFICATION.

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

The product is not classified as hazardous within the meaning of Regulation (EU) No 1272/2008.

#### 2.2 Label elements.

Not applicable

#### 2.3 Other hazards.

The product may have the following additional risks:

Since the absence of infectious agents can not be proven with absolute certainty, components containing materials of human or animal origin must be handled with caution, as potentially infectious, following the recommended safety standards for biological risk. Sodium Azide can react with lead or copper to give explosive compounds. For disposal it is recommended to rinse with plenty of running water to avoid accumulation in drains.

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

#### 3.1 Substances.

Not Applicable.

-Continued on next page.-

# SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)



## N-KITS

Version 1      Date of compilation: 12/02/2022

Page 2 of 8  
Print date: 15/02/2022

### 3.2 Mixtures.

This mixture does not contain substances that pose a danger to health or the environment in accordance with the Regulation (EC) No. 1272/2008, are not assigned a Community exposure limit in the workplace, and are not classified as PBT/vPvB or included in the Candidate List.

\* See Regulation (EC) No. 1272/2008, Annex VI, section 1.2.

## SECTION 4: FIRST AID MEASURES.

### 4.1 Description of first aid measures.

Due to the composition and type of the substances present in the product, no particular warnings are necessary.

#### Inhalation.

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

#### Eye contact.

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance.

#### Skin contact.

Remove contaminated clothing.

#### Ingestion.

Keep calm. NEVER induce vomiting.

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

No known acute or delayed effects from exposure to the product.

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

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

## SECTION 5: FIREFIGHTING MEASURES.

### 5.1 Extinguishing media.

#### Suitable extinguishing media:

Extinguisher powder or CO<sub>2</sub>. In case of more serious fires, also alcohol-resistant foam and water spray.

#### Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

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

#### Special risks.

Fire can cause thick, black smoke. As a result of thermal decomposition, dangerous products can form: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products can be harmful to your health.

### 5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account.

#### Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

-Continued on next page.-

# SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)



## N-KITS

Version 1      Date of compilation: 12/02/2022

Page 3 of 8  
Print date: 15/02/2022

### SECTION 6: ACCIDENTAL RELEASE MEASURES.

#### 6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

#### 6.2 Environmental precautions.

Product not classified as hazardous for the environment, avoid spillage as much as possible.

#### 6.3 Methods and material for containment and cleaning up.

Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations

#### 6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

### SECTION 7: HANDLING AND STORAGE.

#### 7.1 Precautions for safe handling.

The product does not require special handling measures, the following general measures are recommended:

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers.

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

The product does not require special storage measures. As general storage measures, sources of heat, radiation, electricity and contact with food should be avoided.

Keep away from oxidising agents and from highly acidic or alkaline materials.

Store the containers between 2 and 8 °C, in a dry and well-ventilated place.

Store according to local legislation. Observe indications on the label. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

#### 7.3 Specific end use(s).

Not available.

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

#### 8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

-Continued on next page.-

# SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)





## N-KITS

Version 1 Date of compilation: 12/02/2022

Page 4 of 8  
Print date: 15/02/2022

### 8.2 Exposure controls.

#### Measures of a technical nature:

<b>Concentration:</b>	<b>100 %</b>				
<b>Uses:</b>	<b>In Vitro diagnostic medical device, for laboratory professional use only.</b>				
<b>Breathing protection:</b>					
If the recommended technical measures are observed, no individual protection equipment is necessary.					
<b>Hand protection:</b>					
PPE:	Protective gloves.				
Characteristics:	«CE» marking, category II.				
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420				
Maintenance:	Keep in a dry place, away from any sources of heat, and avoid exposure to sunlight as much as possible. Do not make any changes to the gloves that may alter their resistance, or apply paints, solvents or adhesives.				
Observations:	Gloves should be of the appropriate size and fit the user's hand well, not being too loose or too tight. Always use with clean, dry hands.				
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.):	> 480	Material thickness (mm):	0,35
<b>Eye protection:</b>					
PPE:	Protective goggles against particle impacts.				
Characteristics:	«CE» marking, category II. Eye protector against dust and smoke.				
CEN standards:	EN 165, EN 166, EN 167, EN 168				
Maintenance:	Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions.				
Observations:	Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, scraping etc.				
<b>Skin protection:</b>					
PPE:	Protective clothing.				
Characteristics:	«CE» marking, category II. Protective clothing should not be too tight or loose in order not to obstruct the user's movements.				
CEN standards:	EN 340				
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.				
Observations:	The protective clothing should offer a level of comfort in line with the level of protection provided in terms of the hazard against which it protects, bearing in mind environmental conditions, the user's level of activity and the expected time of use.				
PPE:	Work footwear.				
Characteristics:	«CE» marking, category II.				
CEN standards:	EN ISO 13287, EN 20347				
Maintenance:	This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should not be used by other people.				
Observations:	Work footwear for professional use includes protection elements aimed at protecting users against any injury resulting from an accident				

Provide adequate ventilation, which can be achieved through good local extraction-ventilation and a good general extraction system.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

### 9.1 Information on basic physical and chemical properties.

Appearance: Liquid

Colour: White, colorless, yellowish or amber, depending on the product.

Odour: N.A./N.A.

Odour threshold: N.A./N.A.

-Continued on next page.-

# SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)



## N-KITS

Version 1      Date of compilation: 12/02/2022

Page 5 of 8  
Print date: 15/02/2022

pH: N.A./N.A.  
Melting point: N.A./N.A.  
Boiling Point: N.A./N.A.  
Flash point: N.A./N.A.  
Evaporation rate: N.A./N.A.  
Inflammability (solid, gas): N.A./N.A.  
Lower Explosive Limit: N.A./N.A.  
Upper Explosive Limit: N.A./N.A.  
Vapour pressure: N.A./N.A.  
Vapour density: N.A./N.A.  
Relative density: N.A./N.A.  
Solubility: Soluble  
Liposolubility: N.A./N.A.  
Hydrosolubility: N.A./N.A.  
Partition coefficient (n-octanol/water): N.A./N.A.  
Auto-ignition temperature: N.A./N.A.  
Decomposition temperature: N.A./N.A.  
Viscosity: N.A./N.A.  
Explosive properties: N.A./N.A.  
Oxidizing properties: N.A./N.A.  
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

### 9.2 Other information.

Dropping point: N.A./N.A.  
Blink: N.A./N.A.  
Kinematic viscosity: N.A./N.A.  
N.A./N.A. = Not Available/Not Applicable due to the nature of the product

## SECTION 10: STABILITY AND REACTIVITY.

### 10.1 Reactivity.

The product does not present hazards by their reactivity.

### 10.2 Chemical stability.

Stable under the recommended handling and storage conditions (see section 7).

### 10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

### 10.4 Conditions to avoid.

Avoid any improper handling.

### 10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

### 10.6 Hazardous decomposition products.

No decomposition if used for the intended uses.

## SECTION 11: TOXICOLOGICAL INFORMATION.

### 11.1 Information on toxicological effects.

There are no tested data available on the product.

a) acute toxicity;  
Not conclusive data for classification.

-Continued on next page.-

# SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)



## N-KITS

Version 1      Date of compilation: 12/02/2022

Page 6 of 8  
Print date: 15/02/2022

b) skin corrosion/irritation;  
Not conclusive data for classification.

c) serious eye damage/irritation;  
Not conclusive data for classification.

d) respiratory or skin sensitisation;  
Not conclusive data for classification.

e) germ cell mutagenicity;  
Not conclusive data for classification.

f) carcinogenicity;  
Not conclusive data for classification.

g) reproductive toxicity;  
Not conclusive data for classification.

h) STOT-single exposure;  
Not conclusive data for classification.

i) STOT-repeated exposure;  
Not conclusive data for classification.

j) aspiration hazard;  
Not conclusive data for classification.

### SECTION 12: ECOLOGICAL INFORMATION.

#### 12.1 Toxicity.

No information is available regarding the ecotoxicity of the substances present.

#### 12.2 Persistence and degradability.

No information is available regarding the biodegradability of the substances present.  
No information is available on the degradability of the substances present. No information is available about persistence and degradability of the product.

#### 12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation of the substances present.

#### 12.4 Mobility in soil.

No information is available about the mobility in soil.  
The product must not be allowed to go into sewers or waterways.  
Prevent penetration into the ground.

#### 12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

#### 12.6 Other adverse effects.

No information is available about other adverse effects for the environment.

-Continued on next page.-

# SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)



## N-KITS

Version 1      Date of compilation: 12/02/2022

Page 7 of 8  
Print date: 15/02/2022

### SECTION 13: DISPOSAL CONSIDERATIONS.

#### 13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.  
Follow the provisions of Directive 2008/98/EC regarding waste management.

### SECTION 14: TRANSPORT INFORMATION.

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

#### 14.1 UN number.

Transportation is not dangerous.

#### 14.2 UN proper shipping name.

Description:

ADR: Not classified as hazardous for transport.

IMDG: Not classified as hazardous for transport.

ICAO/IATA: Not classified as hazardous for transport.

#### 14.3 Transport hazard class(es).

Transportation is not dangerous.

#### 14.4 Packing group.

Transportation is not dangerous.

#### 14.5 Environmental hazards.

Transportation is not dangerous.

#### 14.6 Special precautions for user.

Transportation is not dangerous.

#### 14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code.

Transportation is not dangerous.

### SECTION 15: REGULATORY INFORMATION.

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

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

The product is not affected by Directive 2012/18/EU (SEVESO III).

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

#### 15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

-Continued on next page.-

# SAFETY DATA SHEET

(in accordance with Regulation (EU) 2015/830)



## N-KITS

Version 1      Date of compilation: 12/02/2022

Page 8 of 8  
Print date: 15/02/2022

### SECTION 16: OTHER INFORMATION.

#### Classification and procedure used to derive the classification for mixtures according to Regulation (EC)

##### 1272/2008 [CLP]:

Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

It is recommended that the product only be employed for the purposes advised.

#### Abbreviations and acronyms used:

CEN: European Committee for Standardization.  
PPE: Personal protection equipment.

#### Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>

<http://echa.europa.eu/>

Regulation (EU) 2015/830.

Regulation (EC) No 1907/2006.

Regulation (EU) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation 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.

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.