

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

The NGAL Test™ Reagent Kit

Catalog no.: ST001

The NGAL Test Reagent Kit contains:

Reaction Buffer (R1)

Immunoparticle Suspension (R2)

1.2 Relevant, identified uses - and uses advised against (if any)

The NGAL Test™ is a particle-enhanced turbidimetric immunoassay for the quantitative determination of human NGAL. The NGAL Test Reagent Kit is solely intended for use with The NGAL Test Control Kit and The NGAL Test Calibrator Kit. The products are intended for professional use only. Refer to the instructions for use for more information on the use of the product.

1.3 Supplier of this SDS



BioPorto Diagnostics A/S

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Responsible person: Niels Rosenkilde

Title: Development Manager

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1.4 Emergency phone numbers

Argentina	Buenos Aires	+54 412 5202/ +53 576 8624/ +54 11 4962 2247
	Ciudad de Buenos Aires	+54 11 4801 7767
	El Palomar	+54 46 58 777/ +54 46 54 6648
	Rosario	+54 341 448 0202
	Godoy Cruz	+54 261 4282020
Austria	+43 1 406 43 43	
Australia	131126	
Belgium	+32 70 245 245	
Bulgaria	+359 2 9154 233	
Croatia	+3851 2348 342.	
Cyprus	1401	
Czech Republic	+420 224 919 293 / +420 224 915 402	
Denmark	Danish Poison Center (Giftlinjen): +45 8212 1212	
Estonia	112 or 16662	
Finland	0800 147 111 or 09 471 977	
France	Angers	02 41 48 21 21
	Bordeaux	05 56 96 40 80
	Lille	0800 59 59 59
	Lyon	04 72 11 69 11
	Marseille	04 91 75 25 25
	Nancy	03 83 22 50 50
	Paris	01 40 05 48 48
	Strasbourg	03 88 37 37 37
Toulouse	05 61 77 74 47	
Germany	112/ +49 30192 40/ Erfurt: +49 361730730	
Greece	+30 21 07 79 37 77	
Hungary	+36 80 20 11 99	
Iceland	112/ +354 543 22 22	
Ireland	+353 1 837 9964 (medical professionals)	
	+353 1 809 2166 (public)	
Israel	+972 4 854 19 00	
Italy	Foggia:	71122 800183459
	Napoli:	80131 081-5453333
	Roma:	161 06-49978000 or 168 06-3054343 or 400165 06 68593726
	Firenze:	50134 0557947819
	Pavia:	27100 0382-24444
	Milano:	20612 02-66101029
Bergamo:	24127 800883300	
Latvia	112 or +371 67042473	
Liechtenstein	112	
Lithuania	8-5 2362052	
Luxembourg	(+352) 8002 5500	
The Netherlands	+31(0)30 274 8888	
Norway	22 59 13 00	

1.4 Emergency phone numbers, continued

Poland	Krakow:	+48 (12) 411 99 99
	Lodz	+48 42 63 14 724
	Sosnowiec	+48 32 266 11 45
	Warszawa	+48 22 619 66 54
	Wroclaw	+48 71 343 30 08
	Gdansk:	+48 (58) 682 04 04
Portugal		+351 800 250 250
Romania		+402 212 106 282
Russia	Ekaterinburg	+7 343 229 9857
	Moscow:	+7 495 628 1687
	Saint-Petersburg:	+7 921 757 3228
Slovakia		+421 2 5477 4166
Slovenia		112 or +386 41 635 500
Spain		+34 91 562 04 20
Sweden		112 (national callers); +46 (0)10 456 6700
Switzerland		+41 44 251 51 51 (in Switzerland dial 145)
Turkey		+90 0312 433 70 01 or 0 800 314 7900
United Kingdom		Non-emergency 111 number for specific information on poisons, or 999 in an emergency. (844 892 0111)
Other countries		See https://www.who.int/gho/phe/chemical_safety/poisons_centres/en/

2. Hazards identification
2.1 Classification of mixture

Not classified according to REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008.

None of the substances present in the mixtures listed in subsection 1.1 are present in a concentration that qualifies these mixtures to be classified as hazardous.

2.2 Label elements mixture

With reference to subsection 2.1: NA

2.3 Other hazards (if any) not resulting in classification

None of the substance or mixtures meets the criteria for PBT or vPvB in accordance with Annex XIII.

3. Composition/information on ingredients
3.1 Mixtures

Component	Substance	Concentration (in kit component)	CAS Reg. #	EC #	Classification (kit component)
Reaction Buffer (R1)	Tris-(hydroxymethyl) aminomethane	300 mM	77-86-1	201-064-4	NA
	Sodium chloride	1000 mM	7647-14-5	220-239-6	NA
	EDTA	10 mM	60-00-4	200-449-4	NA
	Sodium polystyrene sulfonate	2%	9080-79-9	635-475-9	NA
	2-methyl-4-isothiazolin-3-one (Methylisothiazolinone)	0.03%	2682-20-4	220-239-6	NA
Immunoparticle Suspension (R2)	Tris-(hydroxymethyl) aminomethane	10 mM	77-86-1	201-064-4	NA
	Polystyrene beads sensitized with anti-NGAL (neutrophil gelatinase associated lipocalin) antibody	0.125% w/v	NA	NA	NA
	Sucrose	15%	57-50-1	200-334-9	NA
	Sericin (Bombyx mori, Silkworm)	0.2%	NA	NA	NA
	2-methyl-4-isothiazolin-3-one (Methylisothiazolinone)	0.03%	2682-20-4	220-239-6	NA

4. First aid measures

4.1 First aid measures

After inhalation: Immediately remove the casualty from exposure and move to fresh air. If breathing stops, immediately apply mechanical ventilation and apply an oxygen mask if available. Arrange medical treatment.

After skin contact: Wash off with plenty of water. Remove contaminated clothing. If necessary, arrange medical treatment.

After eye contact: Rinse out with plenty of water with the eyelids held wide open. Arrange medical treatment.

After ingestion: Immediately make casualty drink plenty of water. Immediately arrange medical treatment.

4.2 Important symptoms and effects, acute and delayed

If first aid measures are adhered to: No acute or delayed effects.
Otherwise: Irritation of skin, eyes.

4.3 Indication of immediate medical attention and special treatment

Other than described in subsection 4.1: At the discretion of medical staff, depending on the casualty's condition.

5. Fire-fighting measures

5.1 Suitable extinguishing media

No extinguishing media requirements.

5.2 Special hazards arising from the substance or mixture

The mixtures are not flammable.

5.3 Advice for fire fighters

NA

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Do not inhale aerosols. Immediately change contaminated clothing.

6.2 Environmental precautions

Contain spillage. Prevent the mixtures from entering sewer systems.

6.3 Methods and material for containment and cleaning up

Clean with liquid-absorbent material and forward for disposal. Clean up affected area with appropriate detergents.

7. Handling and storage

7.1 Precautions for safe handling

General Good Laboratory Practice must be maintained.

The mixtures Reaction Buffer (R1) and Immunoparticle Suspension (R2) should not be present at the place of work in quantities above those required for carrying out the work.

7.2 Conditions for safe storage, including any incompatibilities

Adhere to storage recommendations and expiry date as indicated on product labels.

7.3 Specific end use(s)

The product is intended only for professional use and only for the uses described in subsection 1.2.

8. Exposure controls/personal protection
8.1 Personal protection/skin protection

Wear laboratory coat and protective gloves.

8.2 Respiratory protection

 In case of unintentional release of reagents in amounts where the possibility of aerosol formation exists:
Appropriate face mask.

8.3 Eye/face protection

Not required when handling as recommended.

9. Physical and chemical properties

Where nothing else is stated, data apply to both Reaction Buffer (R1) and Immunoparticle Suspension (R2).

Parameter	Value	Method/Reference	Comments
Appearance	R1: Pale-yellow liquid R2: White liquid (suspension of polystyrene particles)	Visual check	
Odor	R1: Odorless R2: Odorless	NA	
Odor threshold	NA	NA	No data available on the components. Not further investigated due to minimal relevance for these non-hazardous mixtures.
pH	R1: 8.0 ± 0.2 R2: 8.0 ± 0.1	Glass electrode @ 25°C	
Melting point/Freezing point	Data not available	NA	As c)
Initial boiling point and boiling range	Data not available	NA	As c)
Flash point	Data not available	NA	As c)
Evaporation rate	Data not available	NA	As c)
Flammability (solid, gas)	Data not available	NA	As c). Presumably not flammable.
Vapor pressure	Data not available	NA	As c)
Vapor density	Data not available	NA	As c)
Relative density	Data not available	NA	As c)
Solubility(ies)	Data not available	NA	As c)
Partition coefficient	Data not available	NA	As e)
Auto-ignition temperature	Data not available	NA	As c)
Decomposition temperature	Data not available	NA	As c)
Viscosity	Data not available	NA	As c)
Explosive properties	Data not available	NA	As c). Presumably not explosive
Oxidizing properties	Data not available	NA	As c)

10. Stability and reactivity**10.1 Reactivity**

Not reactive.

10.2 Chemical stability

Stable, no hazardous reaction when handled and stored according to provisions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

None when handling as recommended.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

None known.

11. Toxicological information**11.1 Information on toxicological effects**

No toxicological information on the kit components or their inherent substances in the relevant concentrations.

12. Ecological information

These mixtures are not classified as hazardous to human health or the environment.

No information on ecological hazards on the kit components or the substances they contain in the relevant concentrations

12.1 Toxicity: NA

12.2 Persistence and degradability: NA

12.3 Bioaccumulative potential: NA

12.4 Mobility in soil: NA

12.5 Results of PBT and vPvB assessment: NA

12.6 Other adverse effects: NA

13. Disposal considerations

National regulations for disposal must be adhered to, for both disposal of packaging material and any remaining product.

13.1 Waste treatment methods

No specific waste treatment methods required.

14. Transport information

No special transport regulations apply.

14.1 UN number: NA

14.2 UN proper shipping name: NA

14.3 Transport hazard class(es): NA

14.4 Hazard group: NA

14.5 Environmental hazards: NA

14.6 Special precautions for user: NA

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code: NA

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
None

15.2 Chemical safety assessment
Not found on any of the inherent substances in these mixtures.

16. Other information

NA