

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 19.11.2018

CER-000001/07 EN

Revision: 19.11.2018

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

- **1.1 Product identifier**
- **Trade name:** **Products with sodium azid ≤0.1 % (product list annex I)**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Medical product for in-vitro diagnostics
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Medion Grifols Diagnostics AG
Bonnstrasse 9
CH-3186 Düringen
Tel. + 41 (0)26 492 85 11
Fax + 41 (0)26 492 86 56
- **Further information obtainable from:** e-mail: info@medion-diagnostics.ch
- **1.4 Emergency telephone number:**
phone number +41 (0)26 492 85 11 (while office-time)
or
Tox Info Suisse
Freiestrasse 16 CH-8032 Zurich
Emergency Phone: 145 (24h)
Non urgent inquiry: + 41 44 251 66 66



SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified, according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

Dangerous components:

| | | | |
|-------------------|--------------|--|-------|
| CAS: 26628-22-8 | sodium azide |  Acute Tox. 2, H300 | <0.1% |
| EINECS: 247-852-1 | |  Aquatic Acute 1, H400; Aquatic Chronic 1, H410 | |

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:**
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
Immediately remove any clothing soiled by the product.
- **After inhalation:**
Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.

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- **After skin contact:**
Immediately rinse with water.
If skin irritation continues, consult a doctor.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**
Do not induce vomiting.
Seek medical treatment.
Rinse out mouth with water.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture**
In case of fire, the following can be released:
Nitrogen oxides (NO_x)
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**
Collect contaminated fire fighting water separately. It must not enter the sewage system.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Avoid contact with eyes and skin.
Ensure adequate ventilation
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Send for recovery or disposal in suitable receptacles.
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** No special measures required.

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- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Store receptacle in a well ventilated area.
Protect from heat and direct sunlight.
Store in cool, dry conditions in well sealed receptacles.
- **Recommended storage temperature:** 2 °C to 8 °C.
- **Storage class:** 10 (TRGS510) Flammable liquids.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

8.1 Control parameters

- **Ingredients with limit values that require monitoring at the workplace:**

26628-22-8 sodium azide (<0.1%)

| | |
|---------------------|---|
| WEL (Great Britain) | Short-term value: 0.3 mg/m ³ Long-term value: 0.1 mg/m ³ (as NaN ₃), Sk |
| IOELV (EU) | Short-term value: 0.3 mg/m ³ Long-term value: 0.1 mg/m ³ Skin |
| MAK (EU) | Long-term value: 200 mg/m ³ , 300 ppm |

- **Additional information:** The lists valid during the making were used as basis.

8.2 Exposure controls

For durable compliance with Occupational Exposure Limits (OEL, MAK) no special measures are required. Exposure measurements in the workplace are generally recommended.

- **Personal protective equipment:**
- **General protective and hygienic measures:**
Do not eat, drink, smoke or sniff while working.
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not necessary if room is well-ventilated.
- **Protection of hands:**
Chemical resistant gloves (EN 374)



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

Recommended thickness of the material: ≥ 0.11 mm

Nitrile rubber, NBR

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

For the mixture of chemicals mentioned below the penetration time has to be at least 480 minutes (Permeation according to EN 374 Part 3: Level 6).

· **Eye protection:**



Tightly sealed goggles

Safety glasses

· **Body protection:** Lab coat

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

| | |
|------------------|----------------------|
| · Form: | Fluid |
| · Colour: | Clear light amber |
| · Odour: | Characteristic |

· **pH-value at 20 °C:** 7.1-7.3

· **Change in condition**

· **Melting point/freezing point:** Undetermined.
· **Initial boiling point and boiling range:** 100 °C (DIN 51751)

· **Flash point:** Not applicable.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Vapour pressure at 20 °C:** 23 hPa

· **Density:** Not determined.

· **Solubility in / Miscibility with water:** Soluble.

· **Viscosity:**

· **Dynamic:** Not determined.
· **Kinematic:** Not determined.

· **Solvent content:**

· **Water:** 99.9 %
· **VOC (EC)** 0.00 %
· **VOC (CH)** 0.00 %

· **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.

· **10.2 Chemical stability**

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

· **10.3 Possibility of hazardous reactions** No dangerous reactions known.

· **10.4 Conditions to avoid** No further relevant information available.

· **10.5 Incompatible materials:** No further relevant information available.

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· **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

26628-22-8 sodium azide

| | | |
|--------|------|-------------------|
| Oral | LD50 | 27 mg/kg (rat) |
| Dermal | LD50 | 20 mg/kg (rabbit) |

- **Primary irritant effect:**
- **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 sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

26628-22-8 sodium azide

| | |
|------------|--|
| LC50 (96h) | 0.7 mg/l (<i>Lepomis macrochirus</i>) |
| IC50 (96h) | 272 mg/l (<i>Algen/Algues</i>) |
| EC50 | 38.5 mg/l (<i>Photobacterim phosphoreum</i>) |
| EC50 48 h | 4.2 mg/l (<i>Daphnia pulex</i>) |

- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**
Harmful to aquatic organisms
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

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Hand over to hazardous waste disposers.

| |
|-----------------------------------|
| · European waste catalogue |
|-----------------------------------|

| | |
|-----------|--|
| 18 01 06* | chemicals consisting of or containing hazardous substances |
|-----------|--|

- **Uncleaned packaging:**

- **Recommendation:**

Packagings that may not be cleansed are to be disposed of in the same manner as the product.

Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN-Number**

- **ADR, ADN, IMDG, IATA** Void

- **14.2 UN proper shipping name**

- **ADR, ADN, IMDG, IATA** Void

- **14.3 Transport hazard class(es)**

- **ADR, ADN, IMDG, IATA**

- **Class** Void

- **14.4 Packing group**

- **ADR, IMDG, IATA** Void

- **14.5 Environmental hazards:**

Not applicable.

- **14.6 Special precautions for user**

Not applicable.

- **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

- **UN "Model Regulation":**

Void

SECTION 15: Regulatory information

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

- **Labelling according to Regulation (EC) No 1272/2008** Void

- **Hazard pictograms** Void

- **Signal word** Void

- **Hazard statements** Void

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**

H300 Fatal if swallowed.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

- **Department issuing SDS:** product safety department

- **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

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ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 2: Acute toxicity – Category 2

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

*** Data compared to the previous version altered.**

GB



EN: Annex I - Products with sodium azid $\leq 0.1\%$
DE: Anhang I - Produkte mit Natriumazid $\leq 0.1\%$
FR: Annexe I - Produits avec azoture de sodium $\leq 0.1\%$
IT: Allegato I - Prodotti con azoturo de sodio $\leq 0.1\%$
ES: Anexo I - Productos con aziduro de sodio $\leq 0.1\%$
PT: Anexo I - Os produtos com azoteto de sódio $\leq 0.1\%$

| EN: Product name DE: Produkt Name FR: Nom du produit IT: Nome del prodotto ES: Nombre del producto PT: Nome do Produto | Quantity Menge Quantité Quantità Cantidad Quantidade | Cat. no. Kat. Nr. Cat. no. Art. n° N.° cat. Ref. |
|---|---|---|
| MDmulticard® ABO-D-Rh subgroups-K for patients | 1x10 | 210500 |
| MDmulticard® ABO-D-Rh subgroups-K for donors | 1x10 | 210501 |
| MDmulticard® Rh subgroups+K <i>DOUBLE</i> | 1x10 | 210502 |
| MDmulticard® ABO-D <i>CONFIRM</i> for patients | 1x10 | 210503 |
| MDmulticard® ABO-D <i>CONFIRM</i> for donors | 1x10 | 210505 |
| MDmulticard® Basic Extended Phenotype | 1x10 | 210506 |
| Diluent F | 1x50 mL | 210504 |
| Anti-A Mono-Type® Monoclonal | 1x10 mL | 213434 |
| | 6x10 mL | 213506 |
| | 100x10 mL | 213510 |
| Anti-B Mono-Type® Monoclonal | 1x10 mL | 213436 |
| | 6x10 mL | 213507 |
| | 100x10 mL | 213512 |
| Anti-A,B Mono-Type® Monoclonal | 1x10 mL | 213508 |
| | 6x10 mL | 213509 |
| | 100x10 mL | 213513 |
| Anti-A ₁ Lectin Dolichos biflorus | 1x5 mL | 213437 |
| Anti-C Mono-Type® (1) | 1x10 mL | 213526 |
| Anti-C Mono-Type® (2) | 1x10 mL | 213532 |
| Anti-c Mono-Type® (1) | 1x10 mL | 213528 |
| Anti-c Mono-Type® (2) | 1x10 mL | 213533 |
| Anti-C ^w Mono-Type® | 1x5 mL | 213536 |
| Anti-C ^w Mono-Type® Dual | 1x5 mL | 213296 |
| Anti-D IgG Mono-Type® | 1x5 mL | 213005 |
| Anti-Di ^a Dual | 1x2 mL | 213229 |
| Anti-E Mono-Type® (1) | 1x10 mL | 213530 |
| Anti-E Mono-Type® (2) | 1x10 mL | 213534 |
| Anti-e Mono-Type® (1) | 1x10 mL | 213531 |
| Anti-e Mono-Type® (2) | 1x10 mL | 213535 |
| Anti-Fy ^a | 1x3 mL | 213443 |
| Anti-Fy ^a for DG Gel | 1x5 mL | 213206 |
| Anti-Fy ^a Mono-Type® | 1x5 mL | 213208 |
| Anti-Fy ^b | 1x3 mL | 213444 |
| Anti-Fy ^b for DG Gel | 1x5 mL | 213207 |
| Anti-Fy ^b Mono-Type® Dual | 1x5 mL | 213293 |
| Anti-H Mono-Type® | 1x5 mL | 213633 |
| Anti-Jk ^a for DG Gel | 1x5 mL | 213204 |
| Anti-Jk ^a for DG Gel | 1x5 mL | 213290 |
| Anti-Jk ^a Mono-Type® | 1x3 mL | 213548 |
| Anti-Jk ^b for DG Gel | 1x5 mL | 213205 |
| Anti-Jk ^b for DG Gel | 1x5 mL | 213291 |
| Anti-Jk ^b Mono-Type® | 1x3 mL | 213549 |
| Anti-K Mono-Type® (1) | 1x5 mL | 213445 |
| Anti-K Mono-Type® (2) | 1x5 mL | 213557 |
| Anti-K Mono-Type® Dual (1) | 1x5 mL | 213297 |
| Anti-K polyclonal | 1x5 mL | 213542 |
| Anti-k | 1x3 mL | 213544 |
| Anti-k (Cellano) Mono-Type® | 1x5 mL | 213209 |
| Anti-Kp ^a Dual | 1x5 mL | 213995 |

| EN: Product name DE: Produkt Name FR: Nom du produit IT: Nome del prodotto ES: Nombre del producto PT: Nome do Produto | Quantity Menge Quantité Quantità Cantidad Quantidade | Cat. no. Kat. Nr. Cat. no. Art. n° N.° cat. Ref. |
|---|---|---|
| Anti-Kp ^b Dual | 1x5 mL | 213996 |
| Anti-Le ^a for DG Gel | 1x5 mL | 213283 |
| Anti-Le ^a (LEA2) Mono-Type [®] | 1x5 mL | 213537 |
| Anti-Le ^a Mono-Type [®] | 1x3 mL | 213540 |
| Anti-Le ^b for DG Gel | 1x5 mL | 213284 |
| Anti-Le ^b (LEB2) Mono-Type [®] | 1x5 mL | 213538 |
| Anti-Le ^b Mono-Type [®] | 1x3 mL | 213541 |
| Anti-Lu ^a | 1x3 mL | 213553 |
| Anti-Lu ^a for DG Gel | 1x5 mL | 213294 |
| Anti-Lu ^b | 1x3 mL | 213554 |
| Anti-Lu ^b Mono-Type [®] Dual | 1x5 mL | 213295 |
| Anti-M Mono-Type [®] Dual | 1x5 mL | 213008 |
| Anti-N (LN3/MN879) Mono-Type [®] | 1x5 mL | 213989 |
| Anti-P ₁ Mono-Type [®] | 1x5 mL | 213230 |
| Anti-P ₁ Mono-Type [®] Dual | 1x5 mL | 213292 |
| Anti-S | 1x3 mL | 213546 |
| Anti-S Mono-Type [®] | 1x5 mL | 213993 |
| Anti-s | 1x3 mL | 213547 |
| Anti-s Mono-Type [®] | 1x5 mL | 213994 |
| Combi Anti-D Mono-Type [®] IgM/IgG blend | 1x10 mL | 213514 |
| | 6x10 mL | 213586 |
| | 100x10 mL | 213515 |
| IgM Anti-D (MS-201) Mono-Type [®] | 1x10 mL | 213523 |
| | 6x10 mL | 213524 |
| | 100x10 mL | 213525 |
| IgM Anti-D (RUM-1) Mono-Type [®] | 1x10 mL | 213516 |
| | 6x10 mL | 213517 |
| | 100x10 mL | 213519 |
| Neutr-AB [®] II for the detection of immune antibodies of the ABO system (HDN) | 1x10 mL | 213424 |
| Rh-Control Mono-Type [®] | 1x10 mL | 213397 |
| Essential II Control | 2x2x6 mL | 213287 |
| Extended IV Control | 4x6 mL | 213286 |
| Sero-Control | 1x5 mL | 213398 |
| Sero ^{weak} -Control | 1x5 mL | 213399 |
| | | |
| Anti-Human Globulin Mono-Type [®] | 6x10 mL | 213567 |
| Anti-Human Globulin Mono-Type [®] | 1x10 mL | 213423 |
| | 6x10 mL | 213568 |
| | 1x50 mL | 213569 |
| | 100x10 mL | 213570 |
| Anti-C3 | 1x2 mL | 213564 |
| Anti-C3d | 1x2 mL | 213566 |
| Anti-C4 | 1x2 mL | 213565 |
| Anti-IgA | 1x2 mL | 213563 |
| Anti-IgG | 1x2 mL | 213559 |
| | 1x10 mL | 213560 |
| Anti-IgM | 1x2 mL | 213562 |
| Specific Albumin 22% | 1x10 mL | 213422 |
| | 100x10mL | 213572 |
| Specific Albumin 30% | 6x10 mL | 213573 |
| | 100x10 mL | 213575 |