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Revision Number 1

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

DG Gel Card / DG Gel 8 Cards

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

Specific use(s) DG Gel System

Recommended Use In vitro diagnostic

1.3. Details of the supplier of the safety data sheet

Manufacturer

 Diagnostic Grifols, S. A.
 Passeig Fluvial, 24
 08150 Paret del Valles
 Barcelona (Spain)
 +34 93 571 04 00

Supplier Address

 Diagnostic Grifols, S. A.
 Passeig Fluvial, 24
 08150 Paret del Valles
 Barcelona (Spain)
 +34 93 571 04 00

For further information, please contact

E-mail address service.emea@grifols.com

1.4. Emergency telephone number

Emergency Telephone - §45 - (EC)1272/2008	
Europe	CHEMTREC +1 703 741-5970
Belgium	+34 938 00 80 11
Bulgaria	+34 938 00 80 11
Croatia	+34 938 00 80 11
Czech Republic	00 4202 2223 1415
Denmark	+46 77 14 21 200
Finland	+46 77 14 21 200
France	+33 4 42 54 44 05
Germany	+34 938 00 80 11
Greece	+34 938 00 80 11
Hungary	+34 938 00 80 11
Italy	+39 050 875 5124
Lithuania	+34 938 00 80 11
Netherlands	+34 938 00 80 11
Norway	+46 77 1421 200
Poland	+34 938 00 80 11
Portugal	+35 19 33 02 11 48
Russia	+34 938 00 80 11
Spain	+ 34 93 571 04 00
Sweden	+46 77 14 21 200
Switzerland	+49(0)69 660-380
Turkey	+39 050 875 5124
United Kingdom	00 44 845 2413090

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture*Regulation (EC) No 1272/2008*

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.2. Label elements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

Hazard statements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.3. Other hazards

No information available

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS**3.1 Substances**

Not applicable

3.2 Mixtures

The product contains no substances which at their given concentration, are considered to be hazardous to health

Chemical name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Sodium azide	247-852-1	26628-22-8	0.09	Acute Tox. 2 (H300) (EUH032) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	No data available
sodium hydroxide 5N	215-185-5	1310-73-2	0.06	Skin Corr. 1A (H314)	No data available

Full text of H- and EUH-phrases: see section 16**Section 4: FIRST AID MEASURES****4.1. Description of first aid measures**

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a doctor.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

4.2. Most important symptoms and effects, both acute and delayed**Symptoms** No information available.**4.3. Indication of any immediate medical attention and special treatment needed**

Note to doctors Treat symptomatically.

Section 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media No information available.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical No information available.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling Ensure adequate ventilation.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Material Safety Data Sheet.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Control parameters****Exposure Limits**

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

Chemical name	European Union	United Kingdom	France	Spain	Germany
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ *	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ *	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ vía dérmica*	TWA: 0.2 mg/m ³
sodium hydroxide 5N 1310-73-2	-	STEL: 2 mg/m ³	TWA: 2 mg/m ³	STEL: 2 mg/m ³	-
Chemical name	Italy	Portugal	Netherlands	Finland	Denmark
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ pelle*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Ceiling: 0.29 mg/m ³ Ceiling: 0.11 ppm P*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ H*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ iho*	TWA: 0.1 mg/m ³ H*
sodium hydroxide 5N 1310-73-2	-	Ceiling: 2 mg/m ³	-	STEL: 2 mg/m ³ Ceiling: 2 mg/m ³	Ceiling: 2 mg/m ³
Chemical name	Austria	Switzerland	Poland	Norway	Ireland
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ STEL 0.3 mg/m ³ H*	TWA: 0.2 mg/m ³ STEL: 0.4 mg/m ³	STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Sk*
sodium hydroxide 5N 1310-73-2	TWA: 2 mg/m ³ STEL 4 mg/m ³	TWA: 2 mg/m ³ STEL: 2 mg/m ³	STEL: 1 mg/m ³ TWA: 0.5 mg/m ³	Ceiling: 2 mg/m ³	STEL: 2 mg/m ³

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls**Personal protective equipment**

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Appearance	No information available
Colour	Slightly colored
Odour	Odourless.
Odour threshold	No information available

Property	Values	Remarks • Method
pH	7.2	
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability limit:	No data available	
Lower flammability limit	No data available	
Vapour pressure	No data available	None known
Vapour density	No data available	None known
Relative density	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No information available	
 Oxidising properties	 No information available	
 9.2. Other information		
Softening point	No information available	
Molecular weight	No information available	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Numerical measures of toxicity

Acute toxicity

Unknown acute toxicity 13.66 % of the mixture consists of ingredient(s) of unknown toxicity.

13.66 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.

13.66 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

13.66 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).

13.66 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapour).

13.66 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium azide	= 27 mg/kg (Rat)	= 20 mg/kg (Rabbit) = 50 mg/kg (Rat)	Specific test data for the substance or mixture is not available
sodium hydroxide 5N	-	= 1350 mg/kg (Rabbit)	Specific test data for the substance or mixture is not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitisation	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity .

Unknown aquatic toxicity Contains 13.702 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium azide	-	LC50: =0.7mg/L (96h, Lepomis macrochirus) LC50: =0.8mg/L (96h, Oncorhynchus mykiss) LC50: =5.46mg/L (96h, Pimephales promelas)	-	-
sodium hydroxide 5N	-	LC50: =45.4mg/L (96h, Oncorhynchus mykiss)	-	-

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical name	PBT and vPvB assessment
sodium hydroxide 5N	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Other adverse effects

Other adverse effects No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

Section 14: TRANSPORT INFORMATION

IMDG

14.1 UN Number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing Group	Not regulated
14.5 Marine pollutant	Not applicable
14.6 Special Provisions	None
14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code	No information available

RID

14.1 UN Number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing Group	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special Provisions	None

ADR

14.1 UN Number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing Group	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special Provisions	None

IATA

14.1 UN Number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing Group	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special Provisions	None

Section 15: REGULATORY INFORMATION

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

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

TSCA	Does not comply
DSL/NDSL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AICS	Does not comply

Legend:

- TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory
- DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List
- EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
- ENCS** - Japan Existing and New Chemical Substances
- IECSC** - China Inventory of Existing Chemical Substances
- KECL** - Korean Existing and Evaluated Chemical Substances
- PICCS** - Philippines Inventory of Chemicals and Chemical Substances
- AICS** - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - Vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method

Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration toxicity	Calculation method
Ozone	Calculation method

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This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

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End of Safety Data Sheet