

Issuing Date 04-Mar-2019

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Revision Number 1

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

1.1. Product identifier

Red Blood Cell Reagents

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

| | |
|--|--|
| <p>Manufacturer Diagnostic Grifols, S. A. Passeig Fluvial, 24 08150 Parets del Valles Barcelona (Spain) +34 93 571 04 00</p> | <p>Supplier Diagnostic Grifols, S. A. Passeig Fluvial, 24 08150 Parets del Valles Barcelona (Spain) +34 93 571 04 00</p> |
|--|--|

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 |
| 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

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. |
| 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 | red |
| Odour | Odourless. |
| Odour threshold | No information available |

| <u>Property</u> | <u>Values</u> | <u>Remarks • Method</u> |
|---------------------------------------|-------------------|-------------------------|
| pH | 6.7 | |
| 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 0 % of the mixture consists of ingredient(s) of unknown toxicity.
0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.
0 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).
0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapour).
0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

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 The environmental impact of this product has not been fully investigated.

Unknown aquatic toxicity Contains 0.827 % of components with unknown hazards to the aquatic environment.

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.

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

Not regulated
 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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet