1 Identification of the substance/mixture and of the company/university undertaki

- **Product identifier**
  - **Trade name:** Blood Groups ABO and RhD with Monoclonal Antibodies
  - **Bio-Rad MSDS Number:** 2002M
  - **References and packagings (Id-N°):**
    - 50012 DiaClon ABO/Rh for Patients
    - 50053 DiaClon ABO/Rh for Newborns DVI+
    - 50071 DiaClon ABO/Rh for Newborns DVI-
    - 51011 DiaClon ABO/Rh for Donors
    - 51051 DiaClon ABO/Rh for Patients
    - 50481 DiaClon ABO/D
    - 50492 DiaClon ABO/D + DAT
    - 51160 DiaClon ABO/DVI+/DVI- + DAT
    - 50742 DiaClon ABO/D + Reverse Grouping
    - 50411 DiaClon ABO/Rh + épreuve sérique
    - 45470 DiaClon ABO/Rh + Epreuve Sérique
    - 50092 DiaClon ABO/Rh + Reverse Grouping
    - 50093 DiaClon ABO/D + Reverse Grouping for Patients
    - 51090 DiaClon ABO/D + Reverse Grouping for Donors
    - 50057 DiaClon ABO/D (DVI-) Confirmation for Patients
    - 50741 DiaClon ABO/D (DVI-, DVI-) + Reverse Grouping
    - 50981 DiaClon ABO/D (DVI+, DVI-) + Reverse Grouping

- **Relevant identified uses of the substance or mixture and uses advised against**
  No further relevant information available.

- **Application of the substance / the preparation**
  In vitro diagnostic medical device or component.

- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**
    DiaMed GmbH
    Pra Rond 23
    CH-1785 Cressier FR
    (Switzerland/Schweiz/Suisse/Swizzera)
    Tel: +41 (0)26 674 51 11
    Fax: +41 (0)26 674 51 45

  - **Further information obtainable from:** fds-msds.ch@bio-rad.com
  - **Emergency telephone number:** Tel.: 145 oder/or/ou +41 442 51 51 51

2 Hazards identification

- **Classification of the substance or mixture**
  The product is not classified according to the Globally Harmonized System (GHS).

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
  Not applicable.

(Contd. on page 2)
Sensitivity data sheet according to 1907/2006/EC, Article 31

Printing date 28.05.2013 Version number 1 Revision: 06.05.2013

(Contd. of page 1)

- Information concerning particular hazards for human and environment:
  The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

- Classification system:
  The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- Label elements
  - Labelling according to EU guidelines:
    Observe the general safety regulations when handling chemicals.
    The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).

- Other hazards
  - Results of PBT and vPvB assessment
    - PBT: Not applicable.
    - vPvB: Not applicable.

* 3 Composition/information on ingredients

- Chemical characterization: Mixtures
  - Description:
    Mixture of substances listed below with nonhazardous additions.
  - Additional information:
    Caution: The source materials from which these products were manufactured, were found non reactive for HBsAg, HCV and HIV (1+2) when tested with licensed reagents. However, no known test method can assure that infectious agents are absent. Products from human blood should be considered potentially infectious.
    Caution: All reagents should be treated as potentially infectious.
    For the wording of the listed risk phrases refer to section 16.

4 First aid measures

- Description of first aid measures
  - General information: No special measures required.
  - After inhalation:
    Supply fresh air; consult doctor in case of complaints.
  - After skin contact: Generally the product does not irritate the skin.
  - After eye contact:
    Rinse opened eye for several minutes under running water.
  - After swallowing: If symptoms persist consult doctor.
  - Information for doctor:
    - Most important symptoms and effects, both acute and delayed
      No further relevant information available.
    - Indication of any immediate medical attention and special treatment needed
      No further relevant information available.

(Contd. on page 3)
5 Firefighting measures

- **Extinguishing media**
  - Suitable extinguishing agents:
    - CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
    - Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture**
  No further relevant information available.
- **Advice for firefighters**
  - **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
  Not required.
- **Environmental precautions:** Dilute with plenty of water.
- **Methods and material for containment and cleaning up:**
  Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections**
  No dangerous substances are released.
  See Section 7 for information on safe handling.
  See Section 8 for information on personal protection equipment.
  See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
  - **Precautions for safe handling** No special measures required.
  - **Information about fire - and explosion protection:**
    No special measures required.
- **Conditions for safe storage, including any incompatibilities**
  - **Storage:**
    - Requirements to be met by storerooms and receptacles:
      No special requirements.
    - Information about storage in one common storage facility:
      Not required.
  - **Further information about storage conditions:**
    see related package insert
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:**
  No further data; see item 7.
- **Control parameters**
  - **Additional information:**
    The lists valid during the making were used as basis.
Exposure controls

- Personal protective equipment:
  - General protective and hygienic measures:
    The usual precautionary measures are to be adhered to when handling chemicals.
  - Respiratory protection:
    Not necessary if room is well-ventilated.
  - Protection of hands:
    Protective gloves

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

- Material of gloves
  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.

- 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.

- Eye protection: Safety glasses
- Body protection: Protective work clothing

9 Physical and chemical properties

- Information on basic physical and chemical properties
  - General Information
    - Appearance:
      - Form: Liquid
      - Colour: According to product specification
      - Odour:
      - Odour threshold:
    - pH-value: Not determined.
  - Change in condition
    - Melting point/Melting range: Undetermined.
    - Boiling point/Boiling range: Undetermined.
  - Flash point: Not applicable.
  - Flammability (solid, gaseous): Not applicable.
  - Ignition temperature:
  - Decomposition temperature: Not determined.
  - Self-igniting: Product is not self-igniting.
  - Danger of explosion: Product does not present an explosion hazard.
36.0.19

· Explosion limits:
  · Lower: Not determined.
  · Upper: Not determined.

· Vapour pressure at 20 °C: 23 hPa

· Density:
  · Relative density Not determined.
  · Vapour density Not determined.
  · Evaporation rate Not determined.

· Solubility in / Miscibility with water: Fully miscible.

· Partition coefficient (n-octanol/water): Not determined.

· Viscosity:
  · Dynamic: Not determined.
  · Kinematic: Not determined.

· Solvent content:
  · Organic solvents: 0,0 %
  · Water: 31,7 %
  · Other information No further relevant information available.

10 Stability and reactivity

· Reactivity
  · Chemical stability
    · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
  · Possibility of hazardous reactions No dangerous reactions known.
  · Conditions to avoid No further relevant information available.
  · Incompatible materials: No further relevant information available.
  · Hazardous decomposition products:
    No dangerous decomposition products known.

11 Toxicological information

· Information on toxicological effects
  · Acute toxicity:
    · LD/LC50 values relevant for classification:
      Sodium Azid is used as a preservative. (Concentration < 0.1%) 26628-22-8 Sodium Azide
    | Oral  | LD50  | 27 mg/kg (rat) |
    | Dermal| LD50  | 20 mg/kg (rabbit) |
  · Primary irritant effect:
    · on the skin: No irritant effect.
    · on the eye: No irritating effect.
  · Sensitization: No sensitizing effects known.
Additional toxicological information:
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

Toxicity
- Aquatic toxicity: No further relevant information available.
- Persistence and degradability: No further relevant information available.
- Behaviour in environmental systems:
  - Bioaccumulative potential: No further relevant information available.
  - Mobility in soil: No further relevant information available.
- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.
- Other adverse effects: No further relevant information available.

13 Disposal considerations

- Waste treatment methods
  - Recommendation: Smaller quantities can be disposed of with household waste.
- Uncleaned packaging:
  - Recommendation: Disposal must be made according to official regulations.
  - Recommended cleansing agents: Water, if necessary together with cleansing agents.

14 Transport information

- UN-Number
  - ADR, ADN, IMDG, IATA: Void
- UN proper shipping name
  - ADR, ADN, IMDG, IATA: Void
- Transport hazard class(es)
  - ADR, ADN, IMDG, IATA: Void
- Packing group
  - ADR, IMDG, IATA: Void
- Environmental hazards:
  - Marine pollutant: No
- Special precautions for user: Not applicable.
15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Labelling according to EU guidelines:
    Observe the general safety regulations when handling chemicals. The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).
  - Chemical safety assessment:
    A Chemical Safety Assessment has not been carried out.

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.

- Department issuing MSDS:
  DiaMed GmbH
  Pra Rond 23
  CH-1785 Cressier FR
  (Switzerland/Schweiz/Suisse/Svizzera)
- 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
  - GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
- * Data compared to the previous version altered.