Section 1 Identification of the substance/mixture and of the company/undertaking.
1.1 Product identifiers.

Product Name: Free 25OH Vitamin D ELISA
Item number: KAPF1991

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

Identified uses: For Research Use Only

1.3 Details of the supplier of the safety data sheet

Legal Manufacturer: Future Diagnostics Solutions B.V.
Nieuweweg 279
6603 BN Wijchen
The Netherlands
Tel: +31 (0) 24 6452900
Fax: +31 (0) 24 6452899
Monday to Friday, during office hours (UTC+1:00)
info@future-diagnostics.nl

Emergency Phone No.: EU: 112
US: 911

Section 2 Hazards Identification
2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008

FVD ELISA Anti-Vitamin D coated plate: Considered non-hazardous
FVD ELISA Sample diluent: Acute Toxicity Inhalation, Category 3, H331
FVD ELISA Biotinylated Vitamin D 100X concentrate: Considered non-hazardous
FVD ELISA Streptavidin-HRP reagent: Considered non-hazardous
FVD ELISA Calibrators (A–F): Considered non-hazardous
FVD ELISA Control 1 & 2: Considered non-hazardous
FVD ELISA PBS-T wash buffer tablet: Considered non-hazardous
FVD ELISA Substrate: Considered non-hazardous
FVD ELISA Stop reagent: Considered non-hazardous
FVD ELISA Biotinylated Vitamin D dilution buffer: Considered non-hazardous

For the full text of the H-Statements mentioned in this Section, see Section 16.
2.2 Labeling elements
Labeling according to Regulation (EC) 1272/2008
FVD ELISA Sample diluent
Pictogram: GHS06

Signal Word: Danger

Hazard statement:
H331: Toxic if inhaled

Precautionary statement(s)
P261: Avoid breathing dust/fume/gas/mist/vapours/spray
P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P403 + P233: Store in a well-ventilated place. Keep container tightly closed
P310: Immediately call a POISON CENTER or doctor/physician.

Supplemental Hazard information:
Not applicable.

2.3 Other hazards.
This product contains material of human source and animal origin. Therefore, this product should be considered potentially infectious.
FVD ELISA sample diluent contains Ammonium pentadecafluoroctanoate which is placed on the Candidate List of Substances of Very High Concern (SVHC).
Toxic for reproduction (Article 57c). PBT (Article 57d)
Section 3 Composition/Information of Ingredients.
3.1. Substance
Not applicable

3.2. Mixture
Synonyms: FVD ELISA Sample diluent
Chemical name: Ammonium pentadecafluorooctanoate mixture

Hazardous ingredients

<table>
<thead>
<tr>
<th>Ammonium pentadecafluorooctanoate</th>
<th>Included in the Candidate List of Substances of Very High Concern (SVHC) according to Regulation (EC) No. 1907/2006 (REACH)</th>
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<tr>
<td>Cas No.</td>
<td>Classification according to Regulation (EC) 1272/2008</td>
</tr>
<tr>
<td>3825-26-1</td>
<td>Acute Tox. 4; Acute Tox. 3; Eye Dam. 1; Carc. 2; Repr. 1B; Lact.; STOT RE 1</td>
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<tr>
<td>EG No.</td>
<td>H302, H331, H318, H351, H360, H362, H372</td>
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<tr>
<td>Art. No.</td>
<td>&lt;0,3</td>
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<tr>
<td>Reach. No.</td>
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<tr>
<td>3C-FVD-18</td>
<td></td>
</tr>
</tbody>
</table>

For the full text of the H-statements mentioned in this Section, see Section 16.

Section 4 First Aid Measures
4.1 Description of first aid measurers
Skin Contact:
In case of skin contact, wash thoroughly with soap and plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical attention.

Eye Contact:
If product enters eyes, wash gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.

Ingestion:
Never give anything by mouth to an unconscious person. If ingested, wash mouth out with water and seek medical attention.

Inhalation:
If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

4.2 Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labeling (see section 2.2) and/or in section 4.1.

4.3 Indication of any immediate medical attention and special treatment needed
For any immediate medical attention see section 4.1.
Section 5 Fire Fighting Measures
5.1 Extinguishing media
Suitable extinguishing media:
Use extinguishing media suitable for surrounding fire. Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture
Carbon oxides, Nitrogen oxides (NOx), Hydrogen fluoride

5.3 Advice for firefighters
Self-contained breathing apparatus is recommended.

Section 6 Accidental Release Measures
6.1 Personal precautions, protective equipment and emergency procedures
Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist, dust, or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. For personal protection see section 8.

6.2 Environmental precautions
Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up
Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations. As a precautionary measure, because some products contains materials from human or animal origin, treat spilled material with a 1:10 bleach water solution.

6.4 Reference to other sections
For disposal see section 13.

Section 7 Handling and Storage
7.1 Precautions for safe handling
Avoid contact with eyes or skin. Avoid formation of vapors, dust, mist or gas. Do not eat, drink or smoke during handling this product. Wash hands after handling. Use only outdoors or in a well-ventilated area. This product should be handled as tough capable of transmitting infectious diseases. Universal precautions should be followed when using this product. For further precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities
Keep away from incompatible material (see section 10). Keep container tightly closed in a dry well-ventilated place. To maintain efficacy, store according to the instructions on the product labeling.

7.3 Specific end use(s)
Apart from the uses mentioned in section 1.2 no other specific uses are defined.
Section 8 Exposure controls and personal protection

8.1 Control parameters
Not applicable

8.2 Exposure controls

*Engineering Controls*
Handle in accordance with good industrial hygiene and safety practice. Wash hands after handling this product.

*Personal protecting equipment*

**Respiratory Protection:**
Under normal conditions of use, as mentioned in section 1.2, the use of this product should not require respiratory protection.

**Eye Protection:**
Tightly fitting safety glasses or chemical goggles with side-shields. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EU Regulation 2016/425 and the standard EN 166 (EU) derived from it.

**Skin Protection:**
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove’s outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Regulation 2016/425 and the standard EN 374 derived from it.

**Full contact and splash contact:**
Material: Nitrile rubber
Minimum layer thickness: 0,11 mm
Break through time: 480 min

8.3 Environmental exposure controls
See section 6.
Section 9 Physical and Chemical Properties

Appearance:
FVD ELISA Sample diluent: Liquid

Odor:
No data available

Odor Threshold:
No data available

pH:
No data available

Melting point/Freezing Point:
No data available

Boiling Point/Boiling range:
No data available

Flash Point:
No data available

Evaporation rate:
No data available

Flammability (Solid, Gas):
Not applicable

Upper/lower flammability or explosion limits:
No data available

Vapor Pressure:
No data available

Vapor Density:
No data available

Relative density:
No data available

Solubility
No data available

Partition coefficient of Water/Oil:
No data available

Auto-ignition Temp.:
No data available

Decomposition Temp.:
No data available

Viscosity:
No data available

Explosive properties:
No data available

Oxidizing properties:
No data available

Section 10 Stability and reactivity

10.1 Reactivity
See subsection 10.3

10.2 Stability
Stable under normal temperatures and pressures

10.3 Possibility of hazardous reactions
Strong acids; Strong bases; Strong oxidizers

10.4 Conditions to avoid
Avoid contact with incompatible materials, see subsection 10.5.

10.5 Incompatible materials
Strong acids, strong bases, strong oxidizers

10.6. Hazardous Decomposition Products
No decomposition products posing significant hazards would be expected from this product
Section 11 Toxicological Information
11.1. Information on toxicological effects

**Acute Toxicity:**
No data available

**Skin corrosion and irritation:**
No data available

**Serious eye damage/irritation:**
No data available

**Respiratory or skin sensitization:**
No data available

**Germ cell mutagenicity:**
No data available

**Carcinogenicity:**
FVD ELISA sample diluent contains Ammonium pentadecafluorooccanoate and is suspected of causing cancer.

**Reproductive toxicity:**
No data available

**Specific target organ toxicity - single exposure:**
No data available

**Specific target organ toxicity - repeated exposure:**
No data available

**Aspiration hazard:**
No data available

**Primary routes of exposure:**
Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

**Additional Information:**
Ammonium pentadecafluorooccanoate is placed on the candidate List of Substances of Very High Concern (SVHC). Toxic for reproduction (Article 57c). Suspected of causing cancer.

This product contains materials of human source and animal origin and should be considered potentially infectious.
Section 12 Ecological Information

12.1 Toxicity:
No information available.

12.2 Persistence and degradability
No information available.

12.3. Bio accumulative potential
No information available.

12.4 Mobility in soil
No information available.

12.5. Results of PBT and vPvB assessment
No information available.

12.6 Other Adverse Effects
No information available.

12.7 Additional information
FVD ELISA Sample diluent contains ammonium pentadecafluoroocanate which is placed on the Candidate List of Substances of Very High Concern (SVHC) according to Regulation (EC) No. 1907/2006 (REACH). PBT (Article 57d).

Section 13 Disposable Considerations

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

Section 14 Transport regulations

<table>
<thead>
<tr>
<th>Ammonium pentadecafluoroocanate</th>
<th>UN number</th>
<th>Transport hazard class</th>
<th>PG</th>
<th>UN Proper shipping name</th>
<th>Environmental hazard</th>
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<tr>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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</tr>
</tbody>
</table>
Section 15 Regulatory Information
This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
FVD ELISA Sample diluent contains ammonium pentadecafluorooctanoate which is placed on the Candidate List of Substances of Very High Concern (SVHC) according to Regulation (EC) No. 1907/2006 (REACH). Toxic for reproduction (article 57c); PBT (Article 57d).

15.2 Chemical safety assessment
No chemical safety assessment has been carried out for this mixture by the supplier.

Section 16 Other Information

Complete text of the H-phrases as mentioned in paragraph 3.
H302: Harmful if swallowed.
H318: Causes serious eye damage.
H331: Toxic if inhaled.
H351: Suspected for causing cancer.
H360: May damage fertility or the unborn child.
H362: May cause harm to breast-fed children.
H372: Causes damage to organs through prolonged or repeated exposure.

Indications of changes.
Not applicable.

Further information.
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to the appropriate safety precautions. It does not represent any guarantee of the properties of this product. Future Diagnostics Solutions B.V. shall not be held liable for any damage resulting from handling or contact with the above product. The burden of safe use of these materials rests solely with the user.

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