1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Free 25OH Vitamin D ELISA

Catalog #: KAPF1991
KARF1991

Kit Components: Microtiterplate
Sample Diluent
Biot-VitD Reagent
SAV-HRP
Calibrators
Controls
Wash Tablet
Chromogenic Solution
Stop Reagent
Biot-ViD Dilution Buffer

1.2 Intended Use

In Vitro Diagnostic use (KAPF1991)
For Research Use Only (KARF1991)

1.3 Company

DIAsource ImmunoAssays S.A.
Rue du Bosquet, 2
B-1348 Louvain-la-Neuve
Belgium
Tel. Nr. +32 (0)10/84.99.11
E-mail: tech.support@diasource.be

1.4 Emergency telephone

DIAsource (only office hours): +32 (0)10/84.99.23
Centre Anti-Poisons (BE) 070 245 245
Please refer to your local Anti-Poison Center!

2 HAZARDS IDENTIFICATION

2.1 Classification of the mixture

Classification according to Regulation (EC) No 1272/2008

Microtiterplate	Considered non-hazardous
Sample diluent	Acute Toxicity Inhalation, Category 3, H331
Biot-VitD Reagent	Considered non-hazardous
SAV-HRP	Considered non-hazardous
Calibrators	Considered non-hazardous
Controls	Considered non-hazardous
Wash Tablet	Considered non-hazardous
Chromogenic Solution	Considered non-hazardous
Stop Reagent	Skin Corrosive, Category 1B, H314
Biot-VitD Dilution Buffer	Considered non-hazardous

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

2.2 Label elements

2.2.1 Sample diluent

Pictogram:

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.

2.2.2 Stop Reagent

Pictogram:

Signal Word: Danger

Hazard statement:
H314: Causes severe skin burns and eye damage

Precautionary statement(s)
P280: Wear protective gloves/ protective clothing/ eye protection/ face protection

P301+330+331:IF SWALLOWED: rinse mouth. Do NOT induce vomiting
P305+351+338:Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P309+310:IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician

2.2.3 Microtiterplate

Each well can only be used once 

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 pentadecafluorooctanoate Included in the Candidate List of Substances of Very High Concern (SVHC) according to Regulation (EC) No. 1907/2006 (REACH)

3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

3.1.1 Sample diluent

Ammonium pentadecafluorooctanoate

Component		Classification	concentration
CAS-No. EG No. Reach. No.	3825-26-1 223-320-4 -	Acute Tox. 4; Acute Tox. 3; Eye Dam. 1; Carc. 2; Repr. 1B; Lact.; STOT RE 1	< 0,3 %
		H302, H331, H318, H351, H360, H362, H372	

3.1.2 Stop Reagent

Hydrochloric acid

Component		Classification	concentration
CAS-No. EC-No. Index-No.	7647-01-0 231-595-7 017-002-01-X	Skin Corrosive CAT 1B, H314	< 5%

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

4 FIRST AID MEASURES

4.1 Description of first aid measures

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. Do NOT induce vomiting.

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.

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 Hazardous combustion products

Carbon oxides, Nitrogen oxides (NOx), Hydrogen fluoride

5.3 Advice for firefighters

Self-contained breathing apparatus is recommended.

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions

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. Discharge according to local regulations.

6.3 Methods for 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 contain materials from human or animal origin, treat spilled material with an appropriate disinfectant.

6.4 Reference to other sections

For disposal see Section 13.

7 HANDLING AND STORAGE

7.1 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 Storage

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.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters

Component	No. Value	Control parameters	Basis
Hydrochloric acid CAS 7647-01-0	TWA	5 ppm 8 mg/m3	Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values
	STEL	10 ppm 15 mg/m3	
	TWA	1 ppm 2 mg/m3	UK. EH40 WEL - Workplace Exposure Limits
	STEL	5 ppm 8 mg/m3	

8.2 Exposure controls

8.2.1 Engineering Controls

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

8.2.2 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.

9 PHYSICAL AND CHEMICAL PROPERTIES

Microtiterplate: plate
Calibrators, Controls, Wash Tablet: Lyophilized
Sample Diluent, Biot-Vit D Reagent, SAV-HRP,Chromogenic Solution TMB, Stop Reagent, Biot-Vit D Dilution Buffer: Liquid

10 STABILITY AND REACTIVITY

10.1 Chemical stability / reactivity

See subsection 10.3

10.2 Conditions to avoid

Stable under normal temperatures and pressures

10.3 Materials to avoid

Strong acids; Strong bases; Strong oxidizers

10.4 Dangerous decomposition products

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.

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute Toxicity : No data available
Skin corrosion and irritation:
Stop Reagent may cause irritation to skin
Serious eye damage/irritation:
Stop Reagent may cause irritation to eyes
Respiratory or skin sensitization: No data available
Germ cell mutagenicity: No data available
Carcinogenicity:
Sample diluent contains Ammonium pentadecafluorooctanoate and is suspected of causing cancer.
Reproductive toxicity: No data available
Specific target organ toxicity - single exposure:
Stop Reagent contains hydrochloric acid that is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.
Specific target organ toxicity - repeated exposure: No data available
Aspiration hazard: No data available
Repeated or prolonged exposure:
Avoid prolonged or repeated exposure.
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 pentadecafluorooctanoate 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.

12 ECOLOGICAL INFORMATION

12.1 Toxicity

HCl: Toxicity to fish LC50 - Gambusia affinis (Mosquito fish) - 282 mg/l - 96 h

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative 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

Sample diluent contains ammonium pentadecaflurooctanoate 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).

13 DISPOSAL 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.

14 TRANSPORT INFORMATION

	UN number	Transport hazard class	PG	UN Proper shipping name	Environmental hazard
IATA	N/A	N/A	N/A	N/A	N/A
ADR/RID	N/A	N/A	N/A	N/A	N/A
IMDG	N/A	N/A	N/A	N/A	N/A

15 REGULATORY INFORMATION

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

Sample diluent contains ammonium pentadecaflurooctanoate 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.

16 OTHER INFORMATION

Training advice
This product is designed for use by professionals.

Complete text of the H-phrases as mentioned in paragraph 3.
H302: Harmful if swallowed.
H314: Causes severe skin burns and eye damage.
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.

Further information.
NOTE: The safety analysis of the lyophilized components in this kit has been performed on the reconstituted components. Therefore, the information in this MSDS and product labeling relates to the components as they will be used, i.e. after reconstitution.

The human blood components included in this kit have been tested by European approved and/or FDA approved methods and found negative for HBsAg, anti-HCV and anti-HIV-1 and 2. No known method can offer complete assurance that human blood derivatives will not transmit hepatitis, AIDS or other infections. Therefore, handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.

All animal products and derivatives have been collected from healthy animals. Bovine components originate from countries where BSE has not been reported.

The information provided on this MSDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.
It remains the user's own responsibility to make sure that the information is appropriate and complete for his specific use of this product. The user is also responsible for observing any laws and applicable guidelines.

Notification:
English is acceptable for our MSDS as the following conditions are met:
- Medical specialists (users) are welle educated in the English language

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