GE Healthcare

SAFETY DATA SHEET

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II - Europe

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Peroxidase conjugate, lyophilized; part of '6-Keto-

prostaglandin F1a enzymeimmunoassay system'

Catalogue Number RPN221

Component Number RPN221HP

Product description Not available.

Product type Solid.

Other means of identification Not available.

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

Analytical chemistry. Laboratory chemicals Research and Development

1.3 Details of the supplier of the safety data sheet

SupplierGE Healthcare UK LtdHours of operationAmersham Place08.30 - 17.00

Little Chalfont Buckinghamshire HP7 9NA

England +44 0870 606 1921

Person who prepared the MSDS: msdslifesciences@ge.com

1.4 Emergency telephone number

Europe GE Healthcare Bio-Sciences GmbH +49 0761 4543 0

Munzinger Strasse 5 D-79111 Freiburg Germany / Deutschland

National advisory body/Poison Centre

Europe http://www.who.int/ipcs/poisons/centre/directory/euro/en/

Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Not classified.

Ingredients of unknown toxicity Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 2%

Ingredients of unknown ecotoxicity Percentage of the mixture consisting of ingredient(s) of unknown hazards to the aquatic environment:

47%

Classification according to Directive 1999/45/EC [DPD]



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Peroxidase conjugate, lyophilized; part of '6-Keto-prostaglandin F1a enzymeimmunoassay system' The product is not classified as dangerous according to Directive 1999/45/EC and its amendments.

Classification Not classified.

See Section 16 for the full text of the R phrases or H statements declared above. See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms

Signal word No signal word.

No known significant effects or critical hazards. Hazard statements

Precautionary statements

Prevention Not applicable. Not applicable. Response Storage Not applicable. Not applicable. Disposal

Hazardous ingredients

Supplemental label elements Safety data sheet available for professional user on request.

Special packaging requirements

Containers to be fitted with child-resistant fastenings

Not applicable.

Tactile warning of danger Not applicable.

2.3 Other hazards

Other hazards which do not result Not available.

in classification

SECTION 3: Composition/information on ingredients

Substance/mixture

Mixture

			<u>Classification</u>		
Product/ingredient name	Identifiers	%	67/548/EEC	Regulation (EC) No. 1272/2008 [CLP]	Туре
sucrose	EC: 200-334-9 CAS: 57-50-1	10-15	Not classified.	Not classified.	[2]
edetic acid	EC: 200-449-4 CAS: 60-00-4 Index: 607-429-00-8	1-5	Xi; R36	Eye Irrit. 2, H319	[1]
iron (II) sulfate (1:1) heptahydrate	EC: 231-753-5 CAS: 7782-63-0 Index: 026-003-01-4	1-3	Xn; R22 Xi; R36/38	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319	[1]
			See Section 16 for the full text of the R-phrases declared above.	See Section 16 for the full text of the H statements declared above.	

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

- [1] Substance classified with a health or environmental hazard
- [2] Substance with a workplace exposure limit
- [3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII
- [4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

Occupational exposure limits, if available, are listed in Section 8.



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SECTION 4: First aid measures

4.1 Description of first aid measures

In case of contact with eyes, rinse immediately with plenty of water. Get medical attention if irritation Eve contact

Inhalation If inhaled, remove to fresh air. Get medical attention if symptoms appear. Skin contact Wash with soap and water. Get medical attention if symptoms appear.

Do not ingest. Get medical attention if symptoms appear. Ingestion

No action shall be taken involving any personal risk or without suitable training. Protection of first-aiders

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

No known significant effects or critical hazards. Eve contact

Exposure to decomposition products may cause a health hazard. Serious effects may be delayed Inhalation

following exposure.

Skin contact No known significant effects or critical hazards. No known significant effects or critical hazards. Ingestion

Over-exposure signs/symptoms

Eye contact No specific data. Inhalation No specific data No specific data Skin contact No specific data. Ingestion

4.3 Indication of any immediate medical attention and special treatment needed

In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person Notes to physician

may need to be kept under medical surveillance for 48 hours.

Specific treatments No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media Use an extinguishing agent suitable for the surrounding fire.

None known Unsuitable extinguishing media

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or

mixture

No specific fire or explosion hazard.

Hazardous combustion products Decomposition products may include the following materials:

carbon dioxide carbon monoxide nitrogen oxides sulfur oxides metal oxide/oxides

5.3 Advice for firefighters

Special precautions for fire-

fighters

Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No

action shall be taken involving any personal risk or without suitable training.

Special protective equipment for

fire-fighters

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including

helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level

of protection for chemical incidents.



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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding

areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt

material. Put on appropriate personal protective equipment.

For emergency responders If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on

suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautionsAvoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and materials for containment and cleaning up

Small spill Move containers from spill area. Vacuum or sweep up material and place in a designated, labelled waste

container. Dispose of via a licensed waste disposal contractor.

Large spill Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas.

Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor. Note: see section 1 for emergency contact information and section

13 for waste disposal.

6.4 Reference to other sections See Section 1 for emergency contact information.

See Section 8 for information on appropriate personal protective equipment.

See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

Protective measures Put on appropriate personal protective equipment (see Section 8).

Advice on general occupational

hygiene

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for

additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store between the following temperatures: 2 to 8°C (35.6 to 46.4°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to

avoid environmental contamination.

7.3 Specific end use(s)

Recommendations Analytical chemistry. Laboratory chemicals Research and Development

Industrial sector specific solutions Not available.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
	ACGIH TLV (United States, 2/2010). Notes: 1996 Adoption Refers to Appendix A Carcinogens. TWA: 10 mg/m³ 8 hour(s).

Recommended monitoring procedures

If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to European Standard EN 689 for methods for the assessment of exposure by inhalation to chemical agents and national guidance documents for methods for the determination of hazardous substances.

Derived effect levels

No DELs available.

Predicted effect concentrations

No PECs available.



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8.2 Exposure controls

Appropriate engineering controls

No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

Individual protection measures

Hygiene measures

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that

eyewash stations and safety showers are close to the workstation location.

Safety eyewear complying with an approved standard should be used when a risk assessment indicates Eye/face protection

this is necessary to avoid exposure to liquid splashes, mists, gases or dusts.

Skin protection

Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times Hand protection

when handling chemical products if a risk assessment indicates this is necessary.

Personal protective equipment for the body should be selected based on the task being performed and **Body protection**

the risks involved and should be approved by a specialist before handling this product.

Appropriate footwear and any additional skin protection measures should be selected based on the task Other skin protection

being performed and the risks involved and should be approved by a specialist before handling this

Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk Respiratory protection

assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Emissions from ventilation or work process equipment should be checked to ensure they comply with the **Environmental exposure controls**

requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state Solid. Yellow. Colour Odourless Odour Odour threshold Not available. Not available рН Not available. Melting point/freezing point Not available. Initial boiling point and boiling

ranae

Flash point

[Product does not sustain combustion.]

Evaporation rate Not available. Flammability (solid, gas) Not available Not available **Burning time Burning** rate Not available

Upper/lower flammability or

explosive limits

Not available.

Not available. Vapour pressure Not available. Vapour density Not available. Relative density

Easily soluble in the following materials: cold water and hot water. Solubility(ies)

Partition coefficient: n-

octanol/water

Not available

Auto-ignition temperature Not available. Not available **Decomposition temperature** Not available. Viscosity

Non-explosive in the presence of the following materials or conditions: open flames, sparks and static **Explosive properties**

discharge, heat, shocks and mechanical impacts, oxidizing materials, reducing materials, combustible

materials, organic materials, metals, acids, alkalis and moisture.

Not available. Oxidising properties



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9.2 Other information

No additional information.

SECTION 10: Stability and reactivity

10.1 Reactivity No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability The product is stable.

10.3 Possibility of hazardous

reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to avoid No specific data.10.5 Incompatible materials No specific data.

10.6 Hazardous decomposition

products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
sucrose	LD50 Oral	Rat	29700 mg/kg	-
iron (II) sulfate (1:1) heptahydrate	LD50 Oral	Mouse	1520 mg/kg	

Conclusion/Summary

Not available.

Acute toxicity estimates

	Route	ATE value
Oral		25252.5 mg/kg

Irritation/Corrosion

Conclusion/Summary Not available.

<u>Sensitiser</u>

Conclusion/Summary Not available.

Mutagenicity

Conclusion/Summary Not available.

Carcinogenicity

Conclusion/Summary Not available.

Reproductive toxicity

Conclusion/Summary Not available.

<u>Teratogenicity</u>

Conclusion/Summary Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of Routes of entry anticipated:Oral, Dermal, Inhalation. **exposure**

Potential acute health effects

Inhalation Exposure to decomposition products may cause a health hazard. Serious effects may be delayed

following exposure.

IngestionNo known significant effects or critical hazards.Skin contactNo known significant effects or critical hazards.Eye contactNo known significant effects or critical hazards.



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Symptoms related to the physical, chemical and toxicological characteristics

Inhalation No specific data. No specific data. Ingestion No specific data. Skin contact No specific data. Eye contact

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects Not available.

Not available. Potential delayed effects

Long term exposure

Potential immediate effects Not available.

Potential delayed effects Not available.

Potential chronic health effects

Not available.

Conclusion/Summary Not available.

General No known significant effects or critical hazards. No known significant effects or critical hazards. Carcinogenicity No known significant effects or critical hazards. Mutagenicity No known significant effects or critical hazards. **Teratogenicity** No known significant effects or critical hazards. **Developmental effects** Fertility effects No known significant effects or critical hazards.

Other information Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
edetic acid	Acute EC50 113000 ug/L Fresh water	Daphnia - Daphnia magna - Neonate - <24 hours	48 hours
iron (II) sulfate (1:1) heptahydrate	Chronic NOEC 24000 ug/L Fresh water	Fish - Lepomis macrochirus Fish - Lepomis macrochirus Daphnia Fish	96 hours 96 hours 48 hours 96 hours

Not available. Conclusion/Summary

12.2 Persistence and degradability

Not available. Conclusion/Summary

12.3 Bioaccumulative potential

Product/ingredient name	LogPow	BCF	Potential
edetic acid	-3.34	1	low

12.4 Mobility in soil

Soil/water partition coefficient (Koc Not available.

Mobility

12.5 Results of PBT and vPvB assessment PBT

Not applicable. Not applicable. vPvB

No known significant effects or critical hazards. 12.6 Other adverse effects

Not available.



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SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal The generation of waste should be avoided or minimised wherever possible. Significant quantities of

waste product residues should not be disposed of via the foul sewer but processed in a suitable effluent treatment plant. Dispose of surplus and non-recyclable products via a licensed waste disposal

contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority

requirements.

Hazardous waste Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as

defined by EU Directive 91/689/EEC.

Packaging

Methods of disposal The generation of waste should be avoided or minimised wherever possible. Waste packaging should be

recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions This material and its container must be disposed of in a safe way. Empty containers or liners may retain

some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways,

drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN/ADNR	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.
14.6 Special precautions for user	Not available.	Not available.	Not available.	Not available.
Additional information	-	-	-	-

14.7 Transport in bulk according to Annex II of MARPOL

Not available.

73/78 and the IBC Code

SECTION 15: Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures

Not applicable.

and articles

Other EU regulations

Europe inventory All components are listed or exempted.

Black List Chemicals Not listed



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Priority List Chemicals Integrated pollution prevention and control list (IPPC) - Air

Listed Not listed

Integrated pollution prevention and control list (IPPC) - Water

Not listed

International regulations

Chemical Weapons Convention List Schedule I Chemicals

Not listed

Chemical Weapons Convention List Schedule II Chemicals

Not listed

Chemical Weapons Convention List Schedule III Chemicals

Not listed

15.2 Chemical Safety Assessment

This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

Indicates information that has changed from previously issued version.

Abbreviations and acronyms ATE = Acute Toxicity Estimate

CLP = Classification, Labelling and Packaging Regulation (Regulation (EC) No. 1272/2008)

DNEL = Derived No Effect Level

EUH statement = CLP-specific Hazard statement PNEC = Predicted No Effect Concentration RRN = REACH Registration Number

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Not classified.	

Full text of abbreviated H H302 Harmful if swallowed. H315 Causes skin irritation. statements H319

Causes serious eye irritation.

Full text of classifications Acute Tox. 4, H302 ACUTE TOXICITY: ORAL - Category 4 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2 Eye Irrit. 2, H319 [CLP/GHS]

SKIN CORROSION/IRRITATION - Category 2 Skin Irrit, 2, H315

R22- Harmful if swallowed.

Full text of abbreviated R phrases R36- Irritating to eyes.

R36/38- Irritating to eyes and skin.

Xn - Harmful Full text of classifications Xi - Irritant [DSD/DPD] Date of printing 27 April 2011 Date of issue/ Date of revision 27 April 2011 07 April 2011 Date of previous issue

Version

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.



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