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Revision Number 1

**1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING****GHS product identifier****Product Name** VITROS Immunodiagnostic Products Cortisol Range Verifiers**Other means of identification****Product Code(s)** OCDUK6800874**Synonyms** None**Recommended use of the chemical and restrictions on use****Recommended Use** Diagnostic agent**Uses advised against** No information available**Supplier's details****Supplier Address**Ortho-Clinical Diagnostics  
Felindre Meadows  
Pencoed  
Bridgend  
CF35 5PZ  
United Kingdom**Customer service telephone:**(800) 421-3311**Emergency telephone number****Emergency Telephone  
Number****Regional Emergency Telephone Number:**French 03 88 65 47 33  
Spanish 900 97 33 25**Transportation Emergencies:**US Telephone Number: (800) 424-9300  
International and Maritime Telephone Number: +1 (703) 527-3887**2. HAZARDS IDENTIFICATION****Classification**

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Skin Sensitization

Category 1

**GHS Label elements, including precautionary statements****Emergency Overview**

Signal Word

Warning

**Hazard Statements**

- May cause an allergic skin reaction

**Appearance** Off-white powder.**Physical State** Solid.**Odor** None.**Precautionary Statements****Prevention**

- Avoid breathing dust/fume/gas/mist/vapors/spray.
- Contaminated work clothing should not be allowed out of the workplace.
- Wear protective gloves.

**General Advice**

- Specific treatment (see supplemental instructions on the administration of antidotes on this label)

**Skin**

- IF ON SKIN: Wash with plenty of soap and water.
- If skin irritation or rash occurs: Get medical advice/attention.
- Wash contaminated clothing before reuse.

**Storage**

- None

**Disposal**

- Dispose of contents/container to an approved waste disposal plant.

**Hazard Not Otherwise Classified (HNOC)**

Not applicable.

**Other information**

This product contains human blood derivatives. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents. Therefore, all blood derivatives should be considered potentially infectious. It is recommended that these reagents be handled using established good laboratory working practices. May cause an allergic skin reaction. Product contains naturally-occurring hormones which are found in humans. Exposure may cause hormonal imbalance and effects to the endocrine system.

0% of the mixture consists of ingredient(s) of unknown toxicity.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

| Chemical Name         | CAS-No | Weight % |
|-----------------------|--------|----------|
| KATHON OR PROCLIN 200 | N/A    | 1        |

The listing of Kathon or Proclin 200 as a hazardous component is attributed to the percent of a mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one (3:1), CAS 55965-84-9, present in Kathon or Proclin 200 .

### 4. FIRST AID MEASURES

**Description of necessary first-aid measures****Eye Contact**

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention if irritation persists.

|                     |                                                                                                                                                                                                      |
|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Skin Contact</b> | Wash off immediately with soap and plenty of water for at least 15 minutes while removing all contaminated clothing and shoes. In the case of skin irritation or allergic reactions see a physician. |
| <b>Inhalation</b>   | IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention.                                                          |
| <b>Ingestion</b>    | Rinse mouth. Do NOT induce vomiting. Drink plenty of water. Never give anything by mouth to an unconscious person. Get medical attention.                                                            |

**Most important symptoms/effects, acute and delayed**

**Most Important Symptoms/Effects** May cause allergic skin reaction. Hives. Itching. Rashes.

**Indication of immediate medical attention and special treatment needed, if necessary**

**Notes to Physician** Treat symptomatically.

## 5. FIRE-FIGHTING MEASURES

**Suitable Extinguishing Media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable Extinguishing Media** None.

**Specific Hazards Arising from the Chemical**

No information available.

**Explosion Data**

**Sensitivity to Mechanical Impact**

None.

**Sensitivity to Static Discharge**

None.

**Protective Equipment and Precautions for Firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures**

**Personal Precautions** Ensure adequate ventilation. Wear suitable gloves and eye/face protection. Avoid contact with skin, eyes and clothing. Handle all blood and materials in contact with blood as if capable of transmitting infectious agents. It is recommended that blood and materials in contact with blood be handled using established good laboratory practices.

**Environmental Precautions**

**Environmental Precautions** Do not allow material to contaminate ground water system.

**Methods and materials for containment and cleaning up**

**Methods for Containment** Wipe up with absorbent material (e.g. cloth, fleece). Pick up and transfer to properly labeled containers.

**Methods for Cleaning Up** Clean contaminated surface thoroughly. Clean with disinfectants.

## 7. HANDLING AND STORAGE

**Precautions for safe handling**

**Handling** Ensure adequate ventilation. Avoid dust formation. Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Refer to Section 8. Wash thoroughly after handling.

**Conditions for safe storage, including any incompatibilities**

|                              |                                                                                                                 |
|------------------------------|-----------------------------------------------------------------------------------------------------------------|
| <b>Storage</b>               | Store according to label instructions. Keep containers tightly closed in a dry, cool and well-ventilated place. |
| <b>Incompatible Products</b> | None known.                                                                                                     |

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION****Control parameters**

|                            |                                                                                                                                               |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Exposure Guidelines</b> | This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies. |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|

**Appropriate engineering controls**

|                             |                                                    |
|-----------------------------|----------------------------------------------------|
| <b>Engineering Measures</b> | Showers<br>Eyewash stations<br>Ventilation systems |
|-----------------------------|----------------------------------------------------|

**Individual protection measures, such as personal protective equipment**

|                                 |                                           |
|---------------------------------|-------------------------------------------|
| <b>Eye/Face Protection</b>      | Safety glasses with side-shields.         |
| <b>Skin and Body Protection</b> | Long sleeved clothing. Impervious gloves. |
| <b>Respiratory Protection</b>   | None required under normal usage.         |

|                         |                                                                        |
|-------------------------|------------------------------------------------------------------------|
| <b>Hygiene Measures</b> | Handle in accordance with good industrial hygiene and safety practice. |
|-------------------------|------------------------------------------------------------------------|

**9. PHYSICAL AND CHEMICAL PROPERTIES****Information on basic physical and chemical properties**

|                       |        |                       |                           |
|-----------------------|--------|-----------------------|---------------------------|
| <b>Physical State</b> | Solid. | <b>Appearance</b>     | Off-white powder.         |
| <b>Odor</b>           | None.  | <b>Odor Threshold</b> | No information available. |

| <b>Property</b>                        | <b>Values</b>     | <b>Remarks/ - Method</b> |
|----------------------------------------|-------------------|--------------------------|
| pH                                     | No data available | None known               |
| Melting Point/Range                    | No data available | None known               |
| Boiling Point/Boiling Range            | No data available | None known               |
| Flash Point                            | Not determined.   | None known               |
| Evaporation rate                       | No data available | None known               |
| Flammability (solid, gas)              | No data available | None known               |
| Flammability Limits in Air             |                   |                          |
| upper flammability limit               | No data available |                          |
| lower flammability limit               | No data available |                          |
| Vapor Pressure                         | No data available | None known               |
| Vapor Density                          | No data available | None known               |
| Specific Gravity                       | No data available | None known               |
| Water Solubility                       | No data available | None known               |
| Solubility in other solvents           | No data available | None known               |
| Partition coefficient: n-octanol/water | No data available | None known               |
| Autoignition Temperature               | No data available | None known               |
| Decomposition Temperature              | No data available | None known               |
| Viscosity                              | No data available | None known               |

|                             |                   |
|-----------------------------|-------------------|
| <b>Flammable Properties</b> | Not flammable     |
| <b>Explosive Properties</b> | No data available |
| <b>Oxidizing Properties</b> | No data available |

**Other information**

|                        |                   |
|------------------------|-------------------|
| <b>VOC Content (%)</b> | No data available |
|------------------------|-------------------|

## 10. STABILITY AND REACTIVITY

### Reactivity

Not reactive under normal conditions.

### Chemical stability

Stable under recommended storage conditions.

### Possibility of hazardous reactions

None under normal processing.

### Hazardous Polymerization

Hazardous polymerization does not occur.

### Conditions to avoid

Heat.

### Incompatible materials

None known.

### Hazardous decomposition products

None known based on information supplied.

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

#### **Product Information**

|                     |                                               |
|---------------------|-----------------------------------------------|
| <b>Inhalation</b>   | May cause irritation.                         |
| <b>Eye Contact</b>  | May cause slight irritation.                  |
| <b>Skin Contact</b> | May cause sensitization by skin contact.      |
| <b>Ingestion</b>    | Not expected to be toxic following ingestion. |

### Symptoms related to the physical, chemical and toxicological characteristics

|                 |                                                                                                                                                                                        |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Symptoms</b> | Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain, or flushing |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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

|                          |                                                                             |
|--------------------------|-----------------------------------------------------------------------------|
| <b>Sensitization</b>     | May cause an allergic skin reaction.                                        |
| <b>Mutagenic Effects</b> | No information available.                                                   |
| <b>Carcinogenicity</b>   | Contains no ingredients above reportable quantities listed as a carcinogen. |

|                                 |                           |
|---------------------------------|---------------------------|
| <b>Reproductive Toxicity</b>    | No information available. |
| <b>STOT - single exposure</b>   | No information available. |
| <b>STOT - repeated exposure</b> | No information available. |
| <b>Target Organ Effects</b>     | Skin. Endocrine system.   |
| <b>Aspiration Hazard</b>        | No information available. |

### Numerical measures of toxicity - Product

**Acute Toxicity** 0% of the mixture consists of ingredient(s) of unknown toxicity.  
*The following values are calculated based on chapter 3.1 of the GHS document:*  
**LD50 Oral** > 5000 mg/kg; (ATE)

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

The environmental impact of this product has not been fully investigated. Contains a substance which is harmful to the aquatic environment with long lasting effects at very low concentrations.

**Persistence and Degradability** No information available.

**Bioaccumulation** No information available.

### Other Adverse Effects

No information available.

## 13. DISPOSAL CONSIDERATIONS

**Waste Disposal Methods** This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

**Contaminated Packaging** Do not re-use empty containers.

## 14. TRANSPORT INFORMATION

**DOT** Not regulated

**TDG** Not regulated

**IATA** Not regulated

**IMDG/IMO** Not regulated

## 15. REGULATORY INFORMATION

### International Inventories

|             |        |
|-------------|--------|
| <b>TSCA</b> | Exempt |
| <b>DSL</b>  | Exempt |
| <b>NDSL</b> | Exempt |

### Legend

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

### U.S. Federal Regulations

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

### SARA 311/312 Hazard Categories

|                              |     |
|------------------------------|-----|
| <b>Acute Health Hazard</b>   | Yes |
| <b>Chronic Health Hazard</b> | No  |
| <b>Fire Hazard</b>           | No  |

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|                                   |    |
|-----------------------------------|----|
| Sudden Release of Pressure Hazard | No |
| Reactive Hazard                   | No |

**Clean Water Act**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**U.S. State Regulations****California Proposition 65**

This product does not contain any Proposition 65 chemicals.

**U.S. State Right-to-Know Regulations**

This product does not contain any substances above threshold limits that are regulated by state right-to-know.

**U.S. EPA Label Information**

EPA Pesticide Registration Number Not applicable

**16. OTHER INFORMATION**

|                    |                 |                |                   |                                 |
|--------------------|-----------------|----------------|-------------------|---------------------------------|
| <b><u>NFPA</u></b> | Health Hazard 2 | Flammability 0 | Instability 0     | Physical and Chemical Hazards - |
| <b><u>HMIS</u></b> | Health Hazard 2 | Flammability 0 | Physical Hazard 0 | Personal Protection X           |

|               |                                                                                        |
|---------------|----------------------------------------------------------------------------------------|
| Prepared By   | Product Stewardship<br>23 British American Blvd.<br>Latham, NY 12110<br>1-800-572-6501 |
| Issuing Date  | 01-Jun-2015                                                                            |
| Revision Date | 16-Feb-2016                                                                            |
| Revision Note | (M)SDS sections updated. 1. 3.                                                         |

**General Disclaimer**

The information provided on this SDS 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 guide 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.

**End of Safety Data Sheet**