

MATERIAL SAFETY DATA SHEET

Section 1: IDENTIFICATION

Name: Human assayed Controls Level 1 & Level 2

Manufacturer: **Prestige Diagnostics U.K Ltd.,**
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Cat No. QCCHAN1 / QCCHAN2 / QCCHAN3 / QCCHAE1 / QCCHAE2 / QCCHAE3

Section 2: CHEMICAL COMPOSITION

All components contain preparations.

CAS NO.	DESCRIPTION	CONCENTRATION
CAS 56-87-1	Lysine	10-20%
CAS 7647-14-5	Sodium Chloride	2.5 – 5%
CAS 6131-90-4	Sodium Acetate 3-Hydrate	2.5 – 5%
CAS 50-99-7	Glucose	1.0 – 2.5%
CAS 57-88-5	Cholesterol	1.0 – 2.5%
CAS 57-13-6	Urea	0.1 – 1.0%

Section 3: HAZARDS IDENTIFICATION

This product is not classified according to the Globally Harmonized system (GHS).

Routes of Exposure: Ingestion, Inhalation, Skin

Special Hazards: Contains human sourced and/or potentially infectious components.

NFPA ratings (scale 0-4), Health = 0, Fire = 0, Reactivity = 0.

Results of PBT and vPvB assessment. PBT: Not Applicable, vPvB: Not applicable

Section 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: Immediately wash with water and soap and rinse thoroughly

Generally the product does not irritate the skin

After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing: Rinse mouth with water. Seek medical device and appropriate follow-up.

Information for doctor: Most important symptoms and effects, both acute and delayed

Skin irritation, Eye irritation.

Indication of any immediate medical attention and special treatment needed: No further relevant information available.

Section 5: FIRE FIGHTING MEASURES

Extinguishing media:

Suitable extinguishing agents: CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Special hazards arising from the substance or mixture: No further relevant information available

Advice for firefighters: Protective equipment: No special measures required.

Section 6: ACCIDENTAL RELEASE MEASURES

Handle as potentially infectious

Environmental precautions: Keep contaminated washing water and dispose of appropriately, Do not allow to enter sewers / surface or ground water

Methods and material for containment and cleaning up:

Absorb liquid components with liquid binding material, pick up mechanically, Clean the affected area carefully, Suitable cleaners are: Disinfectants. Refer to section 13 for disposal information.

Section 7: HANDLING AND STORAGE

Handling:

Precautions for safe handling: No Special precautions are necessary if used correctly

Information about protection against explosions and fires: No special measures required.

Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles: According to product specification

Information about storage in one common storage facility: Not required

Refer to the package insert for additional information regarding storage conditions

Specific end users: No further relevant information available.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Personal protective equipment, General and hygienic measures: the usual precautionary measures for handling chemicals should be followed. Follow the usual biosafety practices for handling potentially infectious materials.

Breathing equipment: Not required

Protection of hands: Gloves

Material of Gloves: The selection of 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 cannot be calculated in advance and has therefore to

be checked prior to the application. (Synthetic Gloves). 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.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

General information: Form: Solid, Colour: Light Yellow, Odour: Light

pH Value at 20°C: 7.55 – 7.65

Melting point/Melting range: Not determined

Boiling point / Boiling range: Not determined

Flash Point: Not applicable

Danger or explosion: product does not present an explosion hazard

Density: Not determined

Solubility: Soluble in water

Solvent content: Organic solvents: 0.0%

Solids content: 54.7%

Section 10: STABILITY AND REACTIVITY

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.

Section 11: TOXICOLOGICAL INFORMATION

Information on toxicological effects: Acute toxicity, Primary irritant effect on the skin: No irritant effect, on the eye: No irritant effect

Sensitization: No sensitizing effects known

Additional toxicological information: The product is not subject to classification according to the calculation of the General EU classification guidelines for preparation as issued in the latest version: when used and handled according to specifications, the product does not have any harmful effects according to our experience and information provided to us.

Carcinogenic categories: Cholesterol: 3, Paracetamol: 3, Phenobarbital: 2B, Theophylline: 3.

Section 12: ECOLOGICAL INFORMATION

Aquatic Toxicity: No information available

Persistence and degradability: No information available, Bioaccumulative potential: No information available, Mobility in soil: No information available

Water hazard class: 1, Slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Result of PBT and vPvB: Not applicable / No information available – respectively.

Section 13: DISPOSAL CONSIDERATIONS

Waste treatment methods: Recommendation: Dispose of waste in accordance to applicable national, regional or local regulations

Uncleaned packagings: Recommendation: Disposal must be made according to official regulations.

Recommended Cleansing agent: Water, if necessary with cleansing agents.

Section 14: TRANSPORT INFORMATION

Is not affected by the current rules for transport of hazardous goods (DOT, ADR, IMDG, IATA)

Section 15: REGULATORY INFORMATION

ISGA-Ca – None of the ingredients is listed.

Section 16: OTHER INFORMATION

The above mentioned information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Prestige Diagnostics UK Ltd shall not be held liable for any damage resulting from handling or from contact with the above product.