

# SAFETY DATA SHEET

ECO: 478121  
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## SECTION 1. ----- PRODUCT IDENTIFICATION -----

Inova Diagnostics, Inc.  
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San Diego, CA 92131 U.S.A.  
General information telephone number: 1-858-586-9900  
Emergency telephone numbers  
    National (USA, Canada): 1-800-424-9300  
    International: 1-703-527-3887

CATALOG #: **701333**

NAME: **QUANTA Flash® HMGCR Reagents**

USE: QUANTA Flash HMGCR is a chemiluminescent immunoassay for the semi-quantitative determination of IgG autoantibodies against HMGCR (3-hydroxy-3-methylglutaryl-coenzyme A reductase) antigens in human serum. The presence of anti-HMGCR antibodies, in conjunction with clinical findings and other laboratory tests, is an aid in the diagnosis of Immune-mediated necrotizing myopathy (IMNM).

## SECTION 2. ----- HAZARDS IDENTIFICATION -----

Emergency Overview

### OSHA Hazards

No known OSHA hazards

### Other hazards which do not result in classification

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS).

### GHS Classification

N/A

### GHS Label elements, including precautionary statements

Pictogram: None

Signal word: N/A

### Hazard Statements

None

### Precautionary statements

None

### Potential Health Effects

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Skin: May be harmful if absorbed through the skin. May cause skin irritation.

Eyes: May cause eye irritation.

Ingestion: May be harmful if swallowed.

Target Organs: None identified.

Human Source Material: None identified.

NOTE: Physical and health hazard information for this component has not been determined. Any physical and health information noted is based on evaluation of data for pure ingredients and concentration of ingredients as packaged.

NFPA: HEALTH = 0, FIRE = 0, REACTIVITY = 0

HMIS: HEALTH = 0, FLAMMABILITY = 0, PHYSICAL HAZARDS = 0 CHRONIC HEALTH HAZARD = \*

## SECTION 3. ----- COMPOSITION/INFORMATION ON INGREDIENTS -----

No ingredients are hazardous according to OSHA criteria

Kit components:

NOTE: P/N = Product Number

P/N 501014, Resuspension Buffer 2, 1 vial containing <0.1% Sodium Azide CAS# 26628-22-8, EINECS# 247-852-1

P/N 501333, HMGCR Beads, with recombinant antigen

P/N 501001, Assay Buffer, ≤0.02% Chloramphenicol CAS# 56-75-7, EINECS# 200-287-4 and <0.1% Sodium Azide CAS# 26628-22-8, EINECS# 247-852-1

P/N 501011, Tracer IgG, 1 vial containing <0.1% Sodium Azide CAS# 26628-22-8, EINECS# 247-852-1

Some reagents contain less than (<) 0.1% total weight of Sodium Azide (NaN<sub>3</sub>) as a preservative, CAS# 26628-22-8, EINECS# 247-852-1

Some reagents contain less than or equal to (≤) 0.02% total weight Chloramphenicol as a preservative, CAS# 56-75-7, EINECS# 200-287-4

#### SECTION 4. ----- FIRST-AID MEASURES -----

##### **Eye**

Rinse immediately with plenty of clean running water for at least 20 minutes, separating the eyelid.

##### **Skin Contact**

Wash off thoroughly with plenty of clean running water. Remove and wash contaminated clothing.

##### **Ingestion**

Obtain immediate medical attention.

##### **Inhalation**

Remove from exposure. If breathing is difficult, obtain medical attention if necessary.

IN CASE OF ACCIDENT OR IF YOU DO NOT FEEL WELL, IMMEDIATELY SEEK MEDICAL ADVICE.

#### SECTION 5. ----- FIRE FIGHTING MEASURES -----

*Non-flammable preparation.*

##### **Extinguishing media**

Use media in adaption to materials stored in the immediate neighborhood, such as dry chemical.

##### **Special firefighting procedures**

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

#### SECTION 6. ----- ACCIDENTAL RELEASE MEASURES -----

##### **After spillage**

Wipe up spills with inert absorbent materials and place in a suitable container. Use personal protective equipment (PPE), such as gloves, safety glasses/goggles to prevent exposure.

#### SECTION 7. ----- HANDLING AND STORAGE -----

##### **Handling**

Normal precautions for handling chemicals must be observed. Wash affected area after handling.

##### **Storage**

Keep containers tightly closed when not in use. Store in a dry, well ventilated storage area (2-8°C). Protect from physical damage.

#### SECTION 8. ----- EXPOSURE CONTROLS/PERSONAL PROTECTION -----

Contains no substances with occupational exposure limit values.

##### **Respiratory protection**

Where risk assessment shows air purifying respirators are appropriate use a full face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a back up to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

##### **Eye protection**

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

**Hand 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.

**Skin and body protection**

Impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

**Hygiene measures**

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of the workday.

SECTION 9. ----- PHYSICAL AND CHEMICAL PROPERTIES -----

Appearance:

Resuspension Buffer 2: clear liquid in screwcap tube.

Reagent Cartridge: solid plastic cartridge containing 3 individually sealed reagent tubes

HMGR Beads (space #1 in cartridge): solid brown/white lyophilized material in clear round tube

Assay Buffer (space #2 in cartridge): pink liquid in clear rectangular tube

Tracer IgG (space #3 in cartridge): clear liquid in white rectangular tube

Odor: N/A

Odor threshold: N/A

pH: No data available

Boiling point: N/A

Melting point: N/A

Flash point: N/A

Evaporation rate: N/A

Flammability (solid, gas): N/A

Upper/lower flammability or explosive limits: N/A

Ignition temperature: N/A

Explosion limits: N/A

Vapor pressure: N/A

Vapor density: N/A

Relative density: N/A

Partition coefficient n-octanol/water: N/A

Auto-ignition temperature: N/A

Decomposition temperature: N/A

Viscosity: N/A

Explosive properties: N/A

Oxidizing properties: N/A

Solubility in water: Solutions are soluble

SECTION 10. ----- STABILITY AND REACTIVITY -----

**Reactivity**

No data available

**Stability**

Stable under ordinary conditions of use and storage.

**Possibility of hazardous substances**

No data available

**Conditions and materials to avoid**

No data available

**Hazardous reactions**

No data available

**Incompatible materials**

No data available

**Hazardous decomposition products**

No data available

SECTION 11. ----- TOXICOLOGICAL INFORMATION -----

**Acute toxicity**

**Oral LD50**

No data available

**Inhalation LC50**

No data available

**Dermal LD50**

No data available

**Other information on acute toxicity**

No data available

**Skin corrosion/irritation**

No data available

**Serious eye damage/eye irritation**

No data available

**Respiratory or skin sensitization**

No data available

**Germ cell mutagenicity**

No data available

**Carcinogenicity**

**IARC**

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**ACGIH**

No component of this product at levels greater than or equal to 0.1% is identified as a carcinogen by ACGIH.

**NTP**

No component of this product present at levels greater than or equal to 0.1% is identified as known or anticipated carcinogen by NTP.

**OSHA**

No component of this product present at levels greater than or equal to 0.1% is identified as carcinogen or potential carcinogen by OSHA.

**Reproductive toxicity**

No data available

**Teratogenicity**

No data available

**Specific target organ toxicity – single exposure (Globally Harmonized System)**

No data available

**Specific target organ toxicity – repeated exposure (Globally Harmonized System)**

No data available

**Aspiration hazard**

No data available

**Potential health effects**

**Inhalation**

May be harmful if inhaled. May cause respiratory tract irritation.

**Ingestion**

May be harmful if swallowed.

**Skin**

May be harmful if absorbed by the skin. May cause skin irritation.

**Eyes**

May cause eye irritation.

**Signs and Symptoms of Exposure**

No data available

**Synergistic effects**

No data available

**Additional Information**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been fully investigated.

**RTECS**

Not available

## SECTION 12. ----- ECOLOGICAL INFORMATION -----

**Toxicity**

No data available

**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

**Results of PBT and vPvB Assessment**

PBT/vPvB assessment not available as chemical safety assessment not required/conducted

**Other adverse effects**

No data available. However, an environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Toxic to aquatic life.

## SECTION 13. ----- DISPOSAL CONSIDERATIONS -----

Observe all Governmental environmental regulations for waste disposal. Chemical waste generators must determine if a discarded chemical is classified as a hazardous waste. Contact a licensed professional waste disposal service for disposal of unused product.

Some reagents in this kit contain Sodium Azide as a preservative. Sodium Azide has been reported to form lead or Copper Azide in laboratory plumbing which may explode on percussion. Use proper disposal procedures.

**Product**

Offer surplus and non-recyclable solutions to a licensed company.

**Contaminated packaging**

Disposed of as an unused product.

Remains of biological samples, reagents and controls should be collected in a suitable container for this purpose and autoclaved for 1 hour at 121°C.

RCRA P-Series: None listed.

RCRA U-Series: None listed.

## SECTION 14. ----- TRANSPORT INFORMATION -----

**DOT (US)**

Not dangerous goods.

**IMDG**

Not dangerous goods.

**IATA**

Not dangerous goods.

## SECTION 15. ----- REGULATORY INFORMATION -----

According to 1999/45/EC Directive and 91/155/EEC Directive and following modifications.

**OSHA Hazards**

No known OSHA hazards.

**TSCA Status**

Not on TSCA Inventory.

Antibody, liquid CAS# None, EINECS# None

**DSL Status**

This product contains the following components that are not on the Canadian DSL nor NDSL lists.

Antibody, liquid CAS# None, EINECS# None

**SARA 302 Components**

The following components are subject to the reporting requirements of SARA Title III, Section 302.

Sodium azide, CAS# 26628-22-8, EINECS# 247-852-1

**SARA 313 Components**

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**SARA 311/312 Hazards**

Acute Health Hazard, Chronic Health Hazard

**Massachusetts Right To Know Components**

Sodium azide, CAS# 26628-22-8, EINECS# 247-852-1

Chloramphenicol, CAS# 56-75-7, EINECS# 200-287-4

**Pennsylvania Right To Know Components**

Water, CAS# 7732-18-5, EINECS# 231-791-2

Chloramphenicol, CAS# 56-75-7, EINECS# 200-287-4

Sodium azide, CAS# 26628-22-8, EINECS# 247-852-1

**New Jersey Right To Know Components**

Water, CAS# 7732-18-5, EINECS# 231-791-2

Chloramphenicol, CAS# 56-75-7, EINECS# 200-287-4

**California Prop. 65 Components**

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

**SECTION 16. ----- OTHER INFORMATION -----**

Inova Diagnostics, Inc. provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by properly trained personnel using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. Inova Diagnostics, Inc. makes no representations or warranties, either expressed or implied, including without limitation any warranties of merchantability, fitness for a particular purpose with the respect to the information set forth herein or the product to which the information refers. Accordingly, Inova Diagnostics, Inc. will not be liable for any claims, losses or damages resulting from use of or reliance upon this information.

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