

SAFETY DATA SHEET

Issuing Date: 2018-08-03
Revision Date: 2018-08-03
Revision: 002

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Supplier:

Aalto Scientific, Ltd.
230 Technology Parkway
Eatonton, GA 31024
U.S.

Product name: Control FD Glycohemoglobin A1c
Product code: K061M-6
Pure substance/preparation: Preparation
Intended Use: For In Vitro Diagnostic use only.

Customer service telephone: (760) 431-7922
Email: ehs@aaltoscientific.com

Emergency telephone number: 1-800-748-6674

SECTION 2 - HAZARDS IDENTIFICATION

2.1 Classification: This product contains no hazardous chemicals in reportable quantities according to Regulation (EC) No 1272/2008 (CLP). This product is not classified according to the Globally Harmonized System (GHS). This product contains no hazardous chemicals in reportable quantities according to EU Directives 67/548/EEC or 1999/45/EC

2.2 Label Elements

Product name Control FD Glycohemoglobin A1c
Hazard pictograms None assigned
Signal word(s) None assigned

Hazard statements None assigned
Precautionary statement(s) None assigned

2.3 Other hazard information:

Some components of this kit contain 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. Contains anti-microbial materials that could be toxic in large doses.

Carcinogenicity rating

IARC: Not classified.

European Union: Not classified.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Component(s)	CAS Number	% w/w	OSHA PEL:	OSHA STEL:
Human Serum	N/A	99-100%	N/A	N/A
Tetrachloroethylene	127-18-4	<0.1%	25 ppm	100 ppm

SECTION 4 – FIRST AID MEASURES

Eye contact: May Cause irritation. In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical attention.

Skin contact: May cause slight skin irritation. If a person feels unwell or symptoms of skin irritation appear, consult a physician. Wash off immediately with soap and plenty of water.

Ingestion: May cause gastrointestinal irritation, nausea, vomiting and diarrhea

Inhalation: May cause irritation of respiratory tract

Protection of first-aiders: Wear suitable gloves and eye/face protection.

SECTION 5 – FIRE FIGHTING MEASURES

Suitable extinguishing media: Use any extinguishing media which is suitable for the surrounding fire.

Extinguishing media which must not be used for safety reasons: None.

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases:

None reasonably foreseeable.

Combustion products or resulting gases:

None.

Special protective equipment for firefighters:

Wear self-contained breathing apparatus and protective suit.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal precautions:

Wear suitable gloves and eye/face protection. 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:

Waste disposal must be in accordance with appropriate US, Federal, State and International regulations.

Methods for cleaning up:

Wipe up with absorbent material (e.g. cloth, fleece). Clean with disinfectants. Clean contaminated surface thoroughly.

SECTION 7 – HANDLING AND STORAGE

Handling:

Technical measures/precautions:

Wear protective safety glasses, gloves and clothing.

Safe handling advice:

Always replace cap after use. Wear disposable gloves while handling reagents. Thoroughly wash hands afterwards.

Storage:

Technical measures/storage conditions:

Store opened and unopened containers in accordance with COA or package insert.

Incompatible products:

Keep away from sources of ignition.

Specific use(s):

In vitro diagnostic use only.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limits:

No information available.

Exposure controls / personal protection

Engineering controls:	Ensure adequate ventilation.
Respiratory protection:	None required.
Hand protection:	Wear disposable gloves while handling. Thoroughly wash hands afterwards.
Eye protection:	Wear eye/face protection
Skin and body protection:	Wear suitable protective clothing. Wear suitable gloves and eye/face protection.
Environmental exposure controls:	No information available.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Freeze-dried powder.	Vapor Pressure:	No information available.
Appearance:	No information available.	Specific gravity:	No information available.
Colour:	No information available.	Density (20/4):	No information available.
Odour:	No information available.	Water solubility:	No information available.
Flash Point:	No information available.	Solubility in other solvents:	No information available.
pH:	Neutral.	Partition coefficient:	No information available.
Flammability (solid, gas):	No information available.	Viscosity:	No information available.
Explosive properties:	No information available.	Vapor density:	No information available.
Oxidizing properties:	No information available.	Evaporation rate:	No information available.
Autoignition temperature:	No information available.	Fat solubility (g/l)	No information available.
Miscibility:	No information available.	Gas group:	No information available.
Volume resistivity:	No information available.		

SECTION 10 – STABILITY AND REACTIVITY

Chemical stability:	Stable under recommended storage conditions.
Materials to avoid:	No information available.
Conditions to avoid:	Keep away from heat and sources of ignition.

Hazardous polymerisation:	No information available.
Possibility of hazardous reactions:	No information available.
Hazardous incompatibilities/decomposition products:	Thermal decomposition of tetrachloroethylene can lead to release of irritating/toxic gases and vapors. Tetrachloroethylene reacts with strong oxidizers and chemically active metals such as barium, lithium, and beryllium.

SECTION 11 – TOXICOLOGICAL INFORMATION

Toxicity data for hazardous Ingredients:	Tetrachloroethylene: LC50 Inhalation-rat-4h-5200 ppm LD50 Dermal-rabbit-24h-500 mg-Mild LD50 Oral-rat-8100 mg/kg
Primary routes of exposure:	The most likely routes of exposure are skin and eye contact and inhalation. Material may be absorbed through the skin.
Symptoms of overexposure:	No specific symptoms identified
Eye contact:	May cause eye irritation.
Skin contact:	May cause skin irritation.
Ingestion:	Not expected to be toxic if swallowed.
Inhalation:	Not expected to be toxic if inhaled.
Target organ(s):	Not available.
Reproductive effects:	Not available.
Developmental effects:	Not available.
Carcinogenicity:	Not available.
Genotoxic effects:	Not available.

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects:	No data available.
Aquatic toxicity effects:	No data available.
Mobility:	No data available.
Persistence/degradability:	No data available.
Bioaccumulation:	No data available.
Degradation:	No data available.

SECTION 13– DISPOSAL CONSIDERATIONS

Waste from residues/unused products:

Waste disposal must be in accordance with appropriate US, Federal, State and International regulations.

Contaminated packaging:

Waste disposal must be in accordance with appropriate US, Federal, State and International regulations.

SECTION 14 – TRANSPORT INFORMATION

Product not regulated by DOT, IATA/ICAO, IMO/IMDG, ADR/RID, or TDG.

SECTION 15– REGULATORY INFORMATION

U.S. Federal Regulations:	
U.S. CERCLA/SARA/TSCA Regulatory Information:	This Product does not contain any chemicals currently listed on the Section 302/312, SARA Title III above the OSHA de minimis concentration. This product does not contain any chemicals currently listed with a CERCLA RQ above the OSHA de minimis concentration.
California Proposition 65	This product contains trace amounts of the following substances known to the State of California to cause Cancer and/or reproductive harm: Tetrachloroethylene.

SECTION 16 – OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):

All sections revised to meet GHS/CLP SDS formatting requirements.

Section 1 - Product code changed from K061M-8 to K061M-6

Restrictions on use:

This product is not for human consumption. In vitro diagnostic use only.

Additional advice:

None.

Full text of R-phrases referred to under sections 2 and 3

N/A

Disclaimer:

The information and recommendations contained herein are based upon tests believed to be reliable.

However, Aalto Scientific, Ltd., does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. Aalto Scientific, Ltd. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.

End of Safety Data Sheet