



K-CHECK® CONTROLS FOR SERUM and PLASMA DETERMINATIONS

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Issue Date:09/02/2018 Date of Revision: 09/02/2018

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Name: K-CHECK Controls for serum or plasma

Product Code: B1777-0, B1777-01, B1777-02

1.2. Intended Use of the Product

Quality Control Materials for use by Clinical Laboratory Professionals.

Name, Address, and Telephone of the Responsible Party

Company

BIOREX LABS LLC.

194 E WALLINGS RD. Ste 1

CLEVELAND, OH 44147

1.3. www.biorexlabs.com

1.4. Emergency Telephone Number : 440-824-3000

SECTION 2: HAZARD IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US classification

Skin Sens. 1 H317

Full text of H-phrases: see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :



Signal Word (GHS-US) :

Warning

Hazard Statements (GHS-US) :

H317 - May cause an allergic skin reaction.

Precautionary Statements (GHS-US) : P261 - Avoid breathing vapors, mist, or spray.

P272 - Contaminated work clothing must not be allowed out of the workplace. P280 - Wear protective gloves, protective clothing, and eye protection.

P302+P352 - If on skin: Wash with plenty of water.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P363 - Wash contaminated clothing before reuse.

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

No additional information available

2.4. Unknown Acute Toxicity (GHS-US) No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixture

Name	Product Identifier	% (V/V)	GHS-US classification
2,4-Pentanedione	(CAS No) 123-54-6	0.1 – 0.4	Flam. Liq. 3, H226 Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation: vapour), H331 Aquatic Acute 3, H402

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: When symptoms occur: go into open air and ventilate suspected area.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes.

Eye Contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Ingestion: Rinse mouth. Do NOT induce vomiting.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: May cause an allergic reaction in sensitive individuals.

Inhalation: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

Skin Contact: May cause sensitisation of susceptible persons by skin contact.

Eye Contact: May cause eye irritation.

Ingestion: If a large quantity has been ingested: May cause nausea, vomiting, and diarrhea.

Chronic Symptoms: None expected under anticipated conditions of normal use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Carbon dioxide, dry chemical powder, alcohol foam, polymer foam, water spray, fog.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire. Under fire conditions, hazardous fumes will be present.

Firefighting Instructions: Exercise caution when fighting any chemical fire.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection. **Hazardous Combustion Products:** The product is not flammable. However, under fire conditions, decomposition may produce carbon monoxide and carbon dioxide.

Reference to Other Sections

Refer to section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid breathing vapor, mist, or spray. Avoid contact with skin, eyes, or clothing.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Absorb and/or contain spill with inert material, then place in suitable container.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely.

6.4. Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Storage Conditions: Store in a dry, cool and well-ventilated place. Keep container closed when not in use.

Incompatible Materials: Strong acids. Strong bases. Strong oxidizers.

7.3. Specific End Use(s)

Laboratory Quality Control Material. For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established Exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), Canadian provincial governments, or the Mexican government.

2,4-Pentanedione (123-54-6)		
USA ACGIH	ACGIH TWA (ppm)	25 ppm
USA ACGIH	ACGIH chemical category	Skin-potential significant contribution to overall exposure by the cutaneous route

8.2. Exposure Controls

Appropriate Engineering Controls: Emergency eyewash fountains should be available in the immediate vicinity of any potential exposure.

Personal Protective Equipment: Protective goggles. Gloves. Protective clothing.



Materials for Protective Clothing: Chemically resistant fabrics and materials.

Hand Protection: Wear chemically resistant protective gloves.

Eye Protection: Chemical goggles or safety glasses.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: Use a NIOSH-approved respirator or self-contained breathing apparatus whenever exposure may exceed established Occupational Exposure Limits.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Liquid

Appearance : Amber Yellow

Odor : Odorless

Odor Threshold : Not available

pH : 6

Evaporation Rate : Not available

Melting Point	: Not available
Freezing Point	: Not available
Boiling Point	: Not available
Flash Point	: Not available
Auto-ignition Temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Lower Flammable Limit	: Not available
Upper Flammable Limit	: Not available
Vapor Pressure	: Not available
Relative Vapor Density at 20°C	: Not available
Specific Gravity	: 1
Solubility	: Not available
Partition Coefficient: N-Octanol/Water	: Not available
Viscosity	: Not available
Explosion Data – Sensitivity to Mechanical Impact	: Not expected to present an explosion hazard due to mechanical impact.
Explosion Data – Sensitivity to Static Discharge	: Not expected to present an explosion hazard due to static discharge.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:	Hazardous reactions will not occur under normal conditions.
10.2. Chemical Stability:	Product is stable.
10.3. Possibility of Hazardous Reactions:	Hazardous polymerization will not occur.
10.4. Conditions to Avoid:	Direct sunlight. Extremely high or low temperatures.
10.5. Incompatible Materials:	Strong acids. Strong bases. Strong oxidizers.
10.6. Hazardous Decomposition Products:	The product is not flammable. However, under fire conditions, decomposition may produce carbon monoxide and carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity: Not classified

LD50 and LC50 Data: Not available

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified Teratogenicity: Not

available Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Not expected to present as significant inhalation hazard under anticipated conditions of normal use.

Symptoms/Injuries After Skin Contact: May cause sensitisation of susceptible persons by skin contact.

Symptoms/Injuries After Eye Contact: May cause eye irritation.

Symptoms/Injuries After Ingestion: If a large quantity has been ingested : May cause nausea, vomiting, and diarrhea

Chronic Symptoms: None expected under anticipated conditions of normal use.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

2,4-Pentanedione (123-54-6)	
LD50 Oral Rat	760 mg/kg
LD50 Dermal Rabbit	770 mg/kg
LC50 Inhalation Rat	5.01 mg/l/4h
LC50 Inhalation Rat	

SECTION 12: ECOLOGICAL INFORMATION

12.2 Toxicity

2,4-Pentanedione (123-54-6)

LC50 Fish 1	98.3-110mg/l (Exposure time: 96h - Species: Pimephales promelas [flow-through])
EC50 Daphnia 1	34.4 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC 50 Fish 2	50.3-71.8mg/l (Exposure time: 96h - Species: Lepomis macrochirus [flow-through])

12.1. Persistence and Degradability

K-CHECK[®] CONTROLS FOR SERUM and PLASMA

Persistence and Degradability	Not established.
-------------------------------	------------------

12.2. Bioaccumulative Potential

Urinalysis Dipstick Controls-Dipper[®]/Dropper[®]/Dropper[®] Plus, Level 2

Bioaccumulative Potential	Not established.
---------------------------	------------------

2,4-Pentanedione (123-54-6)	
Log Pow	0.34

12.3. Mobility in Soil Not available

12.4. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

14.4. In Accordance with TDG Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

2,4-Pentanedione (123-54-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	S-S-indicates a substance that is identified in a proposed or final Significant New Uses Rule.

15.2 US State Regulations

2,4-Pentanedione (123-54-6)

U.S. - Massachusetts - Right To Know List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 09/02/2018

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation: dust, mist)	Acute toxicity (inhalation: dust, mist) Category 3
Acute Tox. 3 (Inhalation: vapour)	Acute toxicity (inhalation: vapour) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Flam. Liq. 3	Flammable liquids Category 3
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Corr. 1B	Skin corrosion/irritation Category 1B
Skin Sens. 1	Skin sensitization Category 1

STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H226	Flammable liquid and vapor
H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H331	Toxic if inhaled
H335	May cause respiratory irritation

H400	Very toxic to aquatic life
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H410	Very toxic to aquatic life with long lasting effects

Party Responsible for the Preparation of This Document

BIOREX LABS LLC.
194 E WALLINGS RD. Ste 1
CLEVELAND, OH 44147
440-824-3000

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential, or exemplary damages howsoever arising, even if the company has been advised of the possibility of such damages.