

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: KOVA-Trol® III Normal (60mL and 15mL)

Product Component: 87327, 87328, 87331, 87528, 87327E, 87328E, 87331E, 87528E, 87327M, 87331M

1.2. Intended Use of the Product

Use of the Substance/Mixture: For in vitro diagnostic use only.

1.3. Name, Address, and Telephone of Manufacturer/Supplier

Kova International, Inc.

7272 Chapman Avenue, Suite B

Garden Grove, CA 92841

Tel: 1-714-902-1700

Fax: 1-714-908-7945

Business hours: (8:00 a.m. - 5:00 p.m., PST, Monday - Friday)

1.4. Emergency Telephone Number

Emergency Number Contact your local Poison Center.

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Repr. 2 H361

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :



GHS08

Signal Word (GHS-US) :

Warning

Hazard Statements (GHS-US) :

H361 - Suspected of damaging fertility or the unborn child.

Precautionary Statements (GHS-US) :

P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves, protective clothing, and eye protection.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions. May cause an allergic reaction in sensitive individuals.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	GHS-US classification
Urine, Human	(CAS No) Not applicable	50	Not classified
Water	(CAS No) 7732-18-5	49.44	Not classified
Sodium phosphate dibasic	(CAS No) 7558-79-4	0.25	Not classified
Gonadotropin, chorionic	(CAS No) 9002-61-3	0.12	Repr. 2, H361
Phosphoric acid, potassium salt (1:1)	(CAS No) 7778-77-0	0.1	Not classified

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Sodium hydroxide*	(CAS No) 1310-73-2	< 0.1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402
Hydrochloric acid*	(CAS No) 7647-01-0	< 0.1	Met. Corr. 1, H290 Skin Corr. 1B, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401
4H-Imidazol-4-one, 2-amino-1,5-dihydro-1-methyl-	(CAS No) 60-27-5	0.055	Not classified
Gentamicin	(CAS No) 1403-66-3	0.016	Resp. Sens. 1A, H334 Skin Sens. 1A, H317 Repr. 1B, H360
D-erythro-Hex-2-enonic acid, .gamma.-lactone	(CAS No) 89-65-6	0.01	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335

Full text of H-phrases: see section 16

* These components are added to adjust pH as necessary.

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

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).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Suspected of damaging fertility or the unborn child.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation. May cause exacerbation of asthma if mist is inhaled.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation. May cause an allergic reaction in sensitive individuals.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child.

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

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

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.

Firefighting Instructions: Use water spray or fog for cooling exposed containers. Remove containers from fire area if this can be done without risk. Do not breathe fumes from fires or vapors from decomposition.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Thermal decomposition generates: Carbon oxides (CO, CO₂). Nitrogen oxides. Sodium oxides. Hydrogen chloride. Potassium oxides.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist or spray.

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: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Ventilate area. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not get in eyes, on skin, or on clothing. Do NOT breathe (dust, vapor, mist, gas).

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash contaminated clothing before reuse.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep only in original container. Store in a dry, cool and well-ventilated place. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up.

Incompatible Products: Strong acids, strong bases, strong oxidizers. Water reactive materials.

Storage Temperature: 2 - 8 °C (35.6 to 46.4°F)

7.3. Specific End Use(s)

For in vitro diagnostic 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), or OSHA (PEL).

Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³
USA IDLH	US IDLH (mg/m ³)	10 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³
Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	7 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m ³)	7 mg/m ³
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm

8.2. Exposure Controls

Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Local exhaust and general ventilation must be adequate to meet exposure standards. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing. In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact is possible.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Environmental Exposure Controls

: Avoid release to the environment.

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	: No data available
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials: Strong acids, strong bases, strong oxidizers. Water reactive materials.

10.6. Hazardous Decomposition Products: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Not classified

Gentamicin (1403-66-3)	
LD50 Oral Rat	6600 mg/kg
Sodium phosphate dibasic (7558-79-4)	
LD50 Oral Rat	> 2000 mg/kg
LD50 Dermal Rat	> 2000 mg/kg
D-erythro-Hex-2-enonic acid, .gamma.-lactone (89-65-6)	
LD50 Oral Rat	18 g/kg
ATE (Oral)	18,000.00 mg/kg body weight
Hydrochloric acid (7647-01-0)	
LD50 Dermal Rabbit	> 5010 mg/kg

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Hydrochloric acid (7647-01-0)	
IARC group	3

Reproductive Toxicity: Suspected of damaging fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation. May cause exacerbation of asthma if mist is inhaled.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation. May cause an allergic reaction in sensitive individuals.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	40 mg/l
Hydrochloric acid (7647-01-0)	
LC50 Fish 1	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)

12.2. Persistence and Degradability

KOVA-Trol® III Normal (60mL and 15mL)	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

KOVA-Trol® III Normal (60mL and 15mL)	
Bioaccumulative Potential	Not established.

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

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

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Kova-Trol III Normal (60mL and 15mL)	
SARA Section 311/312 Hazard Classes	Delayed (chronic) health hazard
Sodium phosphate dibasic (7558-79-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	5000 lb
Phosphoric acid, potassium salt (1:1) (7778-77-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
D-erythro-Hex-2-enonic acid, .gamma.-lactone (89-65-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
4H-Imidazol-4-one, 2-amino-1,5-dihydro-1-methyl- (60-27-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	1000 lb
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
EPA TSCA Regulatory Flag	T - T - indicates a substance that is the subject of a Section 4 test rule under TSCA
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1.0 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

15.2. US State Regulations

Sodium phosphate dibasic (7558-79-4)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Sodium hydroxide (1310-73-2)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Hydrochloric acid (7647-01-0)	
U.S. - Massachusetts - Right To Know List	

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U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
U.S. - Pennsylvania - RTK (Right to Know) List

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

Revision Date : 09/16/2016
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:

Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Met. Corr. 1	Corrosive to metals Category 1
Repr. 1B	Reproductive toxicity Category 1B
Repr. 2	Reproductive toxicity Category 2
Resp. Sens. 1A	Respiratory sensitisation Category 1A
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Corr. 1B	Skin corrosion/irritation Category 1B
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1A	Skin sensitization Category 1A
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H290	May be corrosive to metals
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation
H360	May damage fertility or the unborn child
H361	Suspected of damaging fertility or the unborn child
H401	Toxic to aquatic life
H402	Harmful to aquatic life

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)