

SAFETY DATA SHEET (Europe)

SECTION 1: IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1. Product identifier:
KOVA -TROL® URINE CONTROLS – NORMAL WITH HCG
Product type: Powder
Component: 87327, 87328, 87331, 87528, 87327E, 87328E, 87331E, 87528E, 87327M, 87331M
- 1.2. Relevant identified uses of the mixture and uses advised against:
For *in vitro* diagnostic and professional use.
- 1.3. Details of the supplier of the safety data sheet:
Kova International, Inc.
7272 Chapman Avenue, Suite B
Garden Grove, CA 92841
United States
Tel: +1-714-902-1700
www.kovaintl.com
- 1.4. Emergency telephone number: **Public Toxicological Health Service (ETTSZ)**
1096 Budapest, Nagyvárad tér 2.
Tel.: 06 1 476 6464, 06 80 201 199 (0-24 h)
or
Contact your local poison center.

SECTION 2: HAZARDS IDENTIFICATION

- 2.1. Classification of the mixture:
Classification according to Regulation 1272/2008/EC (CLP):
Not considered as hazardous mixture.
Warning **H statements:** None.
- 2.2. Label elements:
Warning **H statements:** None.
Precautionary **P statements:**
P280 – Wear protective clothing.
- 2.3. Other hazards:
The product has no other known specific hazards for human or environment.
Results of PBT and vPvB assessment: no data available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1. Substance:
Not applicable.
- 3.2. Mixture:
The product does not contain any substances which considered as hazardous, or the concentration of hazardous substances does not reach the extent stated in the relevant regulation. Therefore, it is not necessary to indicate them in the safety data sheet.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures:

IN CASE OF INGESTION:

Measures:

- Do not induce vomiting unless directed to do so by medical personnel.
- Never give anything by mouth to an unconscious person.
- Get medical attention if adverse health effects persist or are severe.

IN CASE OF INHALATION:

Measures:

- If inhaled, remove to fresh air.
- If breathing is difficult, give oxygen.
- If not breathing, give artificial respiration.
- Get medical attention if adverse health effects persist or are severe.

IN CASE OF SKIN CONTACT:

Measures:

- In case of contact, immediately flush skin with plenty of water.
- Remove contaminated clothing and shoes.
- Wash clothing before reuse.
- Clean shoes thoroughly before reuse.
- Get medical attention if adverse health effects persist or are severe.

IN CASE OF EYE CONTACT:

Measures:

- In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
- Get medical attention if adverse health effects persist or are severe.

4.2. Most important symptoms and effects, both acute and delayed:

No data available.

4.3. Indication of any immediate medical attention and special treatment needed:

No specific treatment. Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media:

5.1.1. Suitable extinguishing media:

Choose extinguishing media depending on surrounding fire.

5.1.2. Unsuitable extinguishing media:

None known.

5.2. Special hazards arising from the substance or mixture:

The formation of dangerous decomposition products greatly depends on the circumstances of the combustion. A complex mixture of airborne solid, liquid and gas substances may occur, such as carbon monoxide, carbon dioxide and unidentified compounds.

5.3. Advise for fire fighters:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures:

6.1.1. For non-emergency personnel:

Keep unprotected people away, allow only well trained experts wearing suitable protective clothing to abide in the field of accident.

6.1.2. For emergency responders:

No action shall be taken involving any personal risk or without suitable training.

Evacuate surrounding areas.

Keep unnecessary and unprotected personnel from entering.

Do not touch or walk through spilled material.

Avoid breathing dust.

Provide adequate ventilation.

Wear appropriate respirator when ventilation is inadequate.

Put on appropriate personal protective equipment (see section 8).

- 6.2. Environmental precautions:
Dispose the spillage and the resulting waste according to the applicable environmental regulations. Do not allow the product and the resulting waste to enter sewers/soil/surface or ground water. Notify the respective authorities in accordance with local law in the case of environmental pollution immediately.
- 6.3. Methods and material for containment and cleaning up:
Move containers from spill area. Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor.
- 6.4. Reference to other sections:
For further and detailed information see section 8 and 13.

SECTION 7: HANDLING AND STORAGE

- 7.1. Precautions for safe handling:
Observe conventional hygiene precautions.
Wash thoroughly after handling.
Technical measures:
No special measures required.
Precautions against fire and explosion:
No special measures required.
- 7.2. Conditions for safe storage, including any incompatibilities:
Technical measures and storage condition:
Store between the following temperatures: 2 °C to 8 °C (35.6 °F to 46.4 °F).
Store in accordance with local regulations.
Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink.
Keep container tightly closed and sealed until ready for use.
Containers that have been opened must be carefully resealed and kept upright to prevent leakage.
Do not store in unlabelled containers.
Use appropriate containment to avoid environmental contamination.
Incompatible materials: see section 10.
Packaging material: original container recommended.
- 7.3. Specific end use(s):
No specific instructions available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1. Control parameters:
Occupational exposure limit values:
The components of the mixture are not regulated with exposure limit value.

If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to European Standard EN 689 for methods for the assessment of exposure by inhalation to chemical agents and national guidance documents for methods for the determination of hazardous substances.

DNEL		Routes of exposure	Exposure frequency:	Remarks:
Worker	Consumer			
no data available	no data available	Dermal	Short term (acute) Long term (repeated)	no data available
no data available	no data available	Inhalative	Short term (acute) Long term (repeated)	no data available
no data available	no data available	Oral	Short term (acute) Long term (repeated)	no data available

PNEC			Exposure frequency:	Remarks:
Water	Soil	Air		
no data available	no data available	no data available	Short term (single use) Long term (continuous)	no data available
no data available	no data available	no data available	Short term (single use) Long term (continuous)	no data available
no data available	no data available	no data available	Short term (single use) Long term (continuous)	no data available

8.2. Exposure controls:

In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.

8.2.1. Appropriate engineering controls:

In pursuance of work is proper foresight needed to avoid spilling onto clothes and floors and to avoid contact with eyes and skin.

No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory I limits.

8.2.2. Individual protection measures, such as personal protective equipment:

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period.

Appropriate techniques should be used to remove potentially contaminated clothing.

Wash contaminated clothing before reusing.

Ensure that eyewash stations and safety showers are close to the workstation location.

1. Eye/face protection: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dust (EN 166).
2. Skin protection:
 - a. Hand protection: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary (EN 374).
 - b. Other: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
3. Respiratory protection: Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.
4. Thermal hazard: None known.

8.2.3. Environmental exposure controls:

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

The requirements detailed in Section 8 assume skilled work under normal conditions and usage of the product for appropriate aims. If conditions differ from normal or work is carried out under extreme conditions an expert's advice should be sought out before deciding upon further protective measures.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties:

Parameter		Test method:	Remarks:
1. Appearance:	Yellow solid (Powder. Lyophilised)		
2. Odour:	Odourless.		
3. Odour threshold:	no data available		
4. pH value:	7 to 9 (Basic)		
5. Melting point/ freezing point:	no data available		
6. Initial boiling point/boiling range:	~ 100 °C (212 °F)		
7. Flash point:	no data available		
8. Evaporation rate:	no data available		
9. Flammability:	no data available		
10. Upper/lower flammability or explosive limits:	no data available		
11. Vapour pressure:	no data available		
12. Vapour density:	no data available		
13. Relative density:	no data available		

14. Solubility(ies):	Easily soluble in the following materials: cold water and hot water.		
15. Partition coefficient: n-octanol/water:	no data available		
16. Self-ignition temperature:	no data available		
17. Degradation temperature:	no data available		
18. Viscosity:	no data available		
19. Explosive properties:	no data available		
20. Oxidizing properties:	no data available		

9.2. Other information:

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

None known.

10.2. Chemical stability:

Stable within normal temperature and general work conditions.

10.3. Possibility of hazardous reactions:

Under normal conditions of storage and use, hazardous polymerisation will not occur.

10.4. Conditions to avoid:

None known.

10.5. Incompatible materials:

Oxidizing materials, metals, acids and alkalis.

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: None known.

Skin corrosion/irritation: None known.

Serious eye damage/eye irritation: None known..

Respiratory or skin sensitisation: None known.

Germ cell mutagenicity: None known.

Carcinogenicity: None known.

Reproductive toxicity: None known.

STOT-single exposure: None known.

STOT-repeated exposure: None known..

Aspiration hazard: None known.

11.1.1. For substances subject to registration, brief summaries of the information derived from the test conducted:
No data available.

11.1.2. Relevant toxicological properties of the hazardous substances:
No data available.

11.1.3. Information on likely routes of exposure:
Ingestion, inhalation, skin contact, eye contact.

11.1.4. Symptoms related to the physical, chemical and toxicological characteristics:
Inhalation: exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs.
Ingestion: no known significant effects or critical hazards.
Skin contact: no known significant effects or critical hazards.
Eye contact: exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the eyes.

11.1.5. Delayed and immediate effects as well as chronic effects from short and long-term exposure:
Chronic effects: repeated or prolonged inhalation of dust may lead to chronic respiratory irritation.
Inhalation: adverse symptoms may include the following: respiratory tract irritation, coughing.
Eyes: adverse symptoms may include the following: irritation, redness.

11.1.6. Interactive effects:
No data available.

11.1.7. Absence of specific data:
No information.

11.1.8. Other information:
To the best of our knowledge, the toxicological properties of this product have not been thoroughly investigated.

SECTION 12: ECOLOGICAL INFORMATION

- 12.1. Toxicity:
No known significant effects or critical hazards.
- 12.2. Persistence and degradability:
No data available.
- 12.3. Bioaccumulation potential:
This product is not expected to bioaccumulate through food chains in the environment.
- 12.4. Mobility in soil:
No data available.
- 12.5. Results of PBT and vPvB assessment:
No data available.
- 12.6. Other adverse effects:
No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

- 13.1. Waste treatment methods:
Disposal according to the local regulations.
- 13.1.1. Information regarding the disposal of the product:
The generation of waste should be avoided or minimised wherever possible. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.
European Waste Code:
For this product no waste disposal key according the European Waste Catalogue (EWC) can be determined, as only the purpose of application defined by the user enables an allocation. The European waste code number has to be determined after a discussion with a specialist dealing with waste disposal.
- 13.1.2. Information regarding the disposal of the packaging:
Dispose according to the relevant regulations.
- 13.1.3. Physical/chemical properties that may affect waste treatment options shall be specified:
None known.
- 13.1.4. Sewage disposal:
None known.
- 13.1.5. Special precautions for any recommended waste treatment:
No data available.

SECTION 14: TRANSPORT INFORMATION

Not dangerous good in sense of the transport regulations.

- 14.1. UN Number:
None.
- 14.2. UN proper shipping name:
None.
- 14.3. Transport hazard class(es):
None.
- 14.4. Packaging group:
None.
- 14.5. Environmental hazard:
No relevant information available.
- 14.6. Special precautions for user:
No relevant information available.
- 14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code:
Not applicable.

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

15.2. Chemical safety assessment: No information available.

SECTION 16: OTHER INFORMATION

Information regarding the revision of the safety data sheet:

The safety data sheet has been revised according to Regulation 830/2015/EU (Section 1-16).

The classification of the components and the mixture have been amended according to Regulation 1272/2008/EC (CLP) and its amendments.

Full text of the abbreviations in the safety data sheet:

DNEL: Derived no effect level. PNEC: Predicted no effect concentration. CMR effects: carcinogenicity, mutagenicity and toxicity for reproduction. PBT: Persistent, bioaccumulative and toxic. vPvB: Very Persistent, Very Bioaccumulative. n.d.: not defined. n.a.: not applicable.

Data sources:

Safety data sheet previously issued by the manufacturer was on October 15, 2015.

Methods used for the classification according to Regulation 1272/2008/EC: Not considered as hazardous mixture.

Relevant H-Phrases (number and full text) of Section 2 and 3: None.

Training advice: No data available.

This safety data sheet (SDS) had been prepared on the basis of information provided by the manufacturer/supplier and conform to the relevant regulations.

The information, data and recommendations contained herein are provided in good faith, obtained from reliable sources and believed to be true and accurate as of the date issued. However, no representation is made as to the comprehensiveness of the information. The safety data sheet (SDS) shall be used only as a guide for handling the product; in the course of handling and using the product, other considerations may arise or be required.

Users are cautioned to determine the appropriateness and applicability of the above information to their particular circumstances and purposes and assume all risk associated with the use of this product. It is the responsibility of the user to fully comply with local, national and international regulations concerning the use of this product

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