

SDS – ARK™ Pregabalin Urine Calibrator/Control**1. IDENTIFICATION**

(a) Product Identifier: ARK™ Pregabalin Urine Calibrator/Control
Product Code: 5035-0002-00 and 5035-0003-00

(b) Other means of identification/synonyms

<u>Component Name</u>	<u>Internal Code</u>
Calibrator A-E	4035-0004-00 through 4035-0004-04 (5035-0002-00)
Low and High Control	4035-0006-01 through 4035-0006-02 (5035-0003-00)
Product Type:	Liquid

(c) Relevant identified uses of the substance or mixture and uses advised against:
In vitro diagnostic kit

(d) Manufactured/Supplied: ARK Diagnostics, Inc.
48089 Fremont Blvd.
Fremont, CA 94538 USA
1-510-270-6270
Email: customersupport@ark-tdm.com

2. HAZARDS IDENTIFICATION**OSHA/HCS Status:**

Regulation (EC)
1272/2008 [GHS]

ARK™ Pregabalin Urine Calibrator and Control
This material is not considered hazardous by the OSHA Hazard
Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture:

ARK™ Pregabalin Urine Calibrator/Control Not classified.

GHS Label Elements:

Signal word:	ARK™ Pregabalin Urine Calibrator/Control	No signal word.
Hazard statements:	ARK™ Pregabalin Urine Calibrator/Control	No known significant effects or critical hazards.

Precautionary statements

Prevention:	ARK™ Pregabalin Urine Calibrator/Control	Not applicable.
Response:	ARK™ Pregabalin Urine Calibrator/Control	Not applicable.
Storage:	ARK™ Pregabalin Urine Calibrator/Control	Not applicable.
Disposal:	ARK™ Pregabalin Urine Calibrator/Control	Not applicable.
Supplemental label elements:	ARK™ Pregabalin Urine Calibrator/Control	Not applicable.

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Hazards not otherwise classified: ARK™ Pregabalin Urine Calibrator/Control Not applicable.

3. COMPOSITIONS/INFORMATION ON INGREDIENTS

Substance/mixture: ARK™ Pregabalin Urine Calibrator Liquid Mixture
ARK™ Pregabalin Urine Control Liquid Mixture

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

ARK Pregabalin Urine Calibrator and Control are composed of a non-sterile, processed human urine matrix that was determined as non-reactive in tests for HIV 1/2, HBsAg, HCV, HIV-1 (NAT), HCV (NAT) and RPR.

There are no ingredients which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section. Occupational exposure limits, if available, are listed in Section 8.

4. FIRST AID MEASURES**Description of necessary first aid measures**

Eye contact: If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.

Skin contact: Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

Inhalation: Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours. Immediately notify medical personnel and supervisor.

Ingestion: If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

Protection of first aid Responders: See Section 8 for Exposure Controls/Personal Protection Recommendations.

Most important symptoms and effects, both acute and delayed: See Sections 2 and 11.

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Indication of immediate medical attention and special treatment needed if necessary:

Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

Most important symptoms/effects, acute and delayed**Potential acute health effects**

Eye contact: No known significant effects or critical hazards.
Inhalation: Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
Skin contact: No known significant effects or critical hazards.
Ingestion: No known significant effects or critical hazards.

Overexposure signs/symptoms

Eye Contact: No specific data.
Inhalation: No specific data.
Skin contact: No specific data.
Ingestion: No specific data.

Indication of immediate medical attention and special treatment needed if necessary

Notes to physician: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested.
Specific treatments: No specific treatment.
Protection of first-aiders: No action shall be taken involving any personal risk or without suitable training.

5. FIREFIGHTING MEASURES**Extinguishing media**

Suitable extinguishing media: In case of fire, use water spray (fog), foam, carbon dioxide or dry chemical as appropriate for surrounding fire and materials.
Unsuitable extinguishing media: None known
Hazardous thermal decomposition products: No specific data.

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Special protective actions for fire-fighters:	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
Special protective equipment for fire fighters:	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece

6. ACCIDENTAL RELEASE MEASURES**Personal precautions, protective equipment and emergency procedures**

For non-emergency personnel:	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. Put on appropriate personal protective equipment.
For emergency responders:	If specialized clothing is required to deal with the spillage, take note of any in Section 8 on suitable and unsuitable materials. See also the information in “For non-emergency personnel”.
Environmental precautions:	Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleanup

Small spill:	Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
Large spill:	Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

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Protective measures:	Put on appropriate personal protective equipment (see Section 8).
Advice on general occupational hygiene:	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.
Conditions for safe storage, including any incompatibilities:	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 unlabeled containers. Use appropriate containment to avoid environmental contamination.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**Control Parameters**

Occupational exposure limits:	None
Appropriate engineering controls:	Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear Liquid
Color	Colorless
Odor	No information identified
Odor threshold	No information identified
pH	5-8

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Melting point/freezing point	No information identified
Initial boiling point and boiling range	No information identified
Flash point	No information identified
Evaporation rate	No information identified
Flammability (solid, gas)	No information identified
Upper/lower flammability or explosive limits	No information identified
Vapor pressure	No information identified
Vapor density	No information identified
Relative density	No information identified
Water solubility	Miscible in water
Solvent solubility	No information identified
Partition Coefficient (n-octanol/water)	No information identified
Auto-Ignition temperature	No information identified
Decomposition temperature	No information identified
Viscosity	No information identified
Explosive properties	No information identified
Oxidizing properties	No information identified

Other information

Molecular weight	No information identified
Molecular formula	No information identified

10. STABILITY AND REACTIVITY

Reactivity	No specific test data related to reactivity available for this product or its ingredients
Chemical Stability	The product is stable when stored as recommended.
Possibility of hazardous reactions	Not expected to occur.
Conditions to avoid	No thermal hazard. Avoid temperatures $\geq 32^{\circ}\text{C}$ to preserve biochemical integrity.
Incompatible materials	No information identified.

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Hazardous decomposition products: No information identified.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity Not available
Conclusion Summary:

Irritation/Corrosion Not available
Conclusion Summary:

Sensitization Not available
Conclusion Summary:

Mutagenicity Not available
Conclusion Summary:

Carcinogenicity Not available
Conclusion Summary:

Reproductive Toxicity Not available
Conclusion Summary:

Teratogenicity Not available
Conclusion Summary:

Specific target organ toxicity (single exposure) Not available

Specific target organ toxicity (multiple exposure) Not available

Aspiration hazard Not available.

Potential acute health effects:

Eye contact No known significant effects or critical hazards.

Inhalation No known significant effects or critical hazards.

Skin contact No known significant effects or critical hazards.

Ingestion No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact No known significant effects or critical hazards.

Inhalation No known significant effects or critical hazards.

Skin contact No known significant effects or critical hazards.

Ingestion No known significant effects or critical hazards.

SDS – ARK™ Pregabalin Urine Calibrator/Control**Delayed and immediate effects and also chronic effects from short and long term exposure****Short term exposure**

Potential immediate effects Not available

Potential delayed effects Not available

Long term exposure

Potential immediate effects Not available

Potential delayed effects Not available

Potential chronic health effects Not available

Conclusion/Summary

General No known significant effects or critical hazards

Carcinogenicity No known significant effects or critical hazards

Mutagenicity No known significant effects or critical hazards

Teratogenicity No known significant effects or critical hazards

Developmental effects No known significant effects or critical hazards

Fertility effects No known significant effects or critical hazards

Numerical measures of toxicity

Acute toxicity measurement Not available.

12. ECOLOGICAL INFORMATION

Toxicity Not available

Conclusion summary:

Persistence and degradability Not available

Conclusion summary:

Bioaccumulative potential Not available

Mobility in soil

Soil/water partition coefficient (K_{oc})

Mobility

Other adverse effects No known significant effects or critical hazards.

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Disposal methods 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. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residue. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. Products contain $\leq 0.09\%$ sodium azide. As a precaution, affected plumbing including instrumentation should be flushed adequately with water to mitigate the potential accumulation of explosive metal azides.

14. TRANSPORT INFORMATION

Transport Based on available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID US DOT, Canada TDG, IATA or IMDG.

UN Number None assigned.

UN Proper Shipping Name None assigned

Transport hazard classes and packaging group None assigned

Special precautions for users Mixture not fully tested – avoid exposure.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code Not applicable

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance and mixture

This SDS complies with the requirements under the US, EU and GHS (EU CLP – Regulation EC No 1272/2008) guidelines. Consult your local or regional authorities for more information.

U.S. Federal regulations TSCA 8(a) CDR Exempt/Partial exemption: Not determined

United States inventory TSCA 8(b) Not determined

Clean Air Act Section 112: Not listed

(b) Hazardous Air pollutants (HAPs)

Clean Air Act Section 602

Class I Substances Not listed

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Clean Air Act Section 602

Class II Substances Not listed

DEA List I Chemicals

Precursor Chemicals Not listed

DEA List II Chemicals

Essential Chemicals Not listed

SARA 302/304:

Name	%	EHS	SARA 302 TPQ		SARA 304 RQ	
			(lbs)	(gallons)	(lbs)	(gallons)
ARK™ Pregabalin Urine Calibrator						
sodium azide	0.09%	Yes	500	-	1000	
ARK™ Pregabalin Urine Control						
sodium azide	0.09%	Yes	500	-	1000	

SARA 304RQ: 1000000 lbs/454000kg

SARA 311/312

Classification: Not applicable

Composition/information on ingredients: No products were found.

State regulations

Massachusetts None of the components are listed.

New York None of the components are listed.

New Jersey None of the components are listed.

Pennsylvania None of the components are listed.

California None of the components are listed.

Canada inventory:

International regulations

International lists:	Australia inventory (AICS):	Not determined
	China inventory (IECSC):	Not determined
	Japan inventory:	Not determined
	Korea inventory:	Not determined
	Malaysia inventory (EHS Register):	Not determined
	New Zealand Inventory of Chemicals (NZIoC):	Not determined
	Philippines inventory (PICCS):	Not determined
	Taiwan inventory (CSNN):	Not determined

Chemical Weapons

Convention List Schedule 1 Chemicals:

Convention List Schedule 2 Chemicals:

Convention List Schedule 3 Chemicals:

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Revision #, Date of Effectivity: See Header of this document

Key to Abbreviations:

ACGIH=American Conference of Governmental Industrial Hygienists
ADR/RID=European Agreement Concerning the International Carriage of Dangerous goods by Road/Rail;
AIHA=American Industrial Hygiene Association
ATE=Acute Toxicity Estimate
BCF=Bioconcentration Factor
CAS=Chemical Abstract Services
CLP=Classification, Labelling and Packaging of Substances and Mixtures
DNEL=Derived No Effect Level
EINECS=European Inventory of New and Existing Chemical Substances
EU=European Union
GHS=Global Harmonized System of Classification and Labelling of Chemicals
IARC=International Agency for Research on Cancer
IATA=International Air Transport Association
IBC=Intermediate Bulk Container
IDLH=Immediately Dangerous to Life or Health
IMDG=International Maritime Dangerous Goods
LOEL=Lowest Observed Effect Level
LOAEL=Lowest Observed Adverse Effect Level
LogPow=logarithm of the octanol/water partition coefficient
MARPOL 73/78=International Convention for the Prevention of Pollution from Ships, 1973 as modified by the Protocol of 1978. (Marpol=marine pollution)
NIOSH=National Institute of Occupational Health and Safety
NOEL=No Observed Effect Level
NOAEL=No Observed Adverse Effect Level
NTP=National Toxicology Program
OEL=Occupational Exposure Limit
OSHA=Occupational Safety and Health Administration
PNEC=Predicted No Effect Concentration
SARA=Superfund Amendments and Reauthorization Act
STEL=Short Term Exposure Limit
TDG=Transportation of Dangerous Goods
TSCA=Toxic Substances Control Act
TWA=Time Weighted Average
UN= United Nations
WHMIS=Workplace Hazardous Materials Information System



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Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.