

**SDS – ARK™ Ethyl Glucuronide (EtG) Calibrator/Control****1. IDENTIFICATION**

(a) Product Identifier: ARK™ Ethyl Glucuronide Calibrator/Control  
Product Code: 5036-0002-00, 5036-0002-01, 5036-0002-02, 5036-0002-03,  
5036-0003-00, 5036-0003-01

(b) Other means of identification/synonyms

<u>Component Name</u>	<u>Internal Code</u>
Calibrator A-E	4036-0004-00 through 4036-0004-04 (5036-0002-00)
Calibrator A (Negative) Only	4036-0004-00 (5036-0002-01)
Calibrator C (500 ng/mL Cutoff) Only	4036-0004-02 (5036-0002-02)
Calibrator D (1000 ng/mL Cutoff) Only	4036-0004-03 (5036-0002-03)
Low (375 ng/mL) and High (625 ng/mL) Controls	4036-0006-01 & 4036-0006-02 (5036-0003-00)
Low (750 ng/mL) and High (1250 ng/mL) Controls	4036-0006-03 & 4036-0006-04 (5036-0003-01)
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™ Ethyl Glucuronide 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™ Ethyl Glucuronide Calibrator/Control Not classified.

**GHS Label Elements:**

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

**SDS – ARK™ Ethyl Glucuronide (EtG) Calibrator/Control**Precautionary statements

Prevention:	ARK™ Ethyl Glucuronide Calibrator/Control	Not applicable.
Response:	ARK™ Ethyl Glucuronide Calibrator/Control	Not applicable.
Storage:	ARK™ Ethyl Glucuronide Calibrator/Control	Not applicable.
Disposal:	ARK™ Ethyl Glucuronide Calibrator/Control	Not applicable.
Supplemental label elements:	ARK™ Ethyl Glucuronide Calibrator/Control	Not applicable.
Hazards not otherwise classified:	ARK™ Ethyl Glucuronide Calibrator/Control	Not applicable.

**3. COMPOSITIONS/INFORMATION ON INGREDIENTS**

Substance/mixture:	ARK™ Ethyl Glucuronide Calibrator	Liquid Mixture
	ARK™ Ethyl Glucuronide Control	Liquid Mixture

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

**ARK Ethyl Glucuronide 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.

**SDS – ARK™ Ethyl Glucuronide (EtG) Calibrator/Control**

## 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.

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.

**SDS – ARK™ Ethyl Glucuronide (EtG) Calibrator/Control****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.
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

**SDS – ARK™ Ethyl Glucuronide (EtG) Calibrator/Control**

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.

**7. HANDLING AND STORAGE****Precautions for safe handling**

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

**SDS – ARK™ Ethyl Glucuronide (EtG) Calibrator/Control**

Color	Colorless
Odor	No information identified
Odor threshold	No information identified
pH	5-8
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.

**SDS – ARK™ Ethyl Glucuronide (EtG) Calibrator/Control**

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.

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.

**SDS – ARK™ Ethyl Glucuronide (EtG) Calibrator/Control**

Skin contact	No known significant effects or critical hazards.
Ingestion	No known significant effects or critical hazards.

**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	



**SDS – ARK™ Ethyl Glucuronide (EtG) Calibrator/Control**

Other adverse effects                      No known significant effects or critical hazards.

**13. DISPOSAL CONSIDERATIONS**

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 ≤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

## SDS – ARK™ Ethyl Glucuronide (EtG) Calibrator/Control

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™ Ethyl Glucuronide Calibrator						
sodium azide	0.09%	Yes	500	-	1000	
ARK™ Ethyl Glucuronide 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:

**SDS – ARK™ Ethyl Glucuronide (EtG) Calibrator/Control****16. OTHER INFORMATION**

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

Neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy and completeness of the information contained herein. No representation, warranty or guarantee, expressed or implied (including warranty of fitness or merchantability for a particular purpose), is made with respect to the materials. The above information is offered in good faith and with the belief that it is accurate.



Doc. No. 0900-0007-70

Rev. No. 01

Safety Data Sheet

Effective Date: 06/20/17

CN No. 17-091

Page 12 of 12

**SDS – ARK™ Ethyl Glucuronide (EtG) Calibrator/Control**

---

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.