

SDS – ARK™ EDDP Calibrator/Control**1. IDENTIFICATION**

- (a) Product Identifier: ARK™ EDDP Calibrator/Control
Product Code: 5051-0002-00, 5051-0002-01, 5051-0002-02, 5051-0002-03,
5051-0003-00, 5051-0003-01
- (b) Other means of identification/synonyms
- | <u>Component Name</u> | <u>Internal Code</u> |
|---|--|
| Calibrator A-E | 4051-0004-00 through 4051-0004-04 (5051-0002-00) |
| Calibrator A (Negative) Only | 4051-0004-00 (5051-0002-01) |
| Calibrator B (100 ng/mL Cutoff) Only | 4051-0004-01 (5051-0002-02) |
| Calibrator C (300 ng/mL Cutoff) Only | 4051-0004-02 (5051-0002-03) |
| Low (75 ng/mL) and High (125 ng/mL) Controls | 4051-0008-01 & 4051-0008-02 (5051-0003-00) |
| Low (225 ng/mL) and High (375 ng/mL) Controls | 4051-0009-01 & 4051-0009-02 (5051-0003-01) |
| 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™ EDDP 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™ EDDP Calibrator/Control Not classified.

GHS Label Elements:

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

SDS – ARK™ EDDP Calibrator/ControlPrecautionary statements

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

3. COMPOSITIONS/INFORMATION ON INGREDIENTS

Substance/mixture:	ARK™ EDDP Calibrator	Liquid Mixture
	ARK™ EDDP Control	Liquid Mixture

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

ARK EDDP 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 MEASURESDescription 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.

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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™ EDDP 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

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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.

SDS – ARK™ EDDP Calibrator/Control**9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance:	Clear Liquid
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

SDS – ARK™ EDDP Calibrator/Control**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.
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.

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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.

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.
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SDS – ARK™ EDDP Calibrator/Control**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.

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 $\leq 0.09\%$ 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

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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

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

SDS – ARK™ EDDP Calibrator/ControlInternational 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:

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

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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.