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# SDS – ARK<sup>TM</sup> Methotrexate Calibrator/Control/Dilution Buffer

### 1. IDENTIFICATION

(a) Product Identifier: ARK<sup>TM</sup> Methotrexate Calibrator/Control/Dilution Buffer

Product Code: 5026-0002-00, 5026-0003-01, 5026-0003-02 and

5026-0004-00

(b) Other means of identification/synonyms

<u>Component Name</u> <u>Internal Code</u>

Calibrator A-F 4026-0004-00 through 4026-0004-05 (5026-0002-00)

Control 6 Levels 4026-0006-01 through 4026-0006-09

Dilution Buffer 4026-0007-01 (5026-0004-00)

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<sup>TM</sup> Methotrexate Calibrator/Control/Dilution Buffer

This material is not considered hazardous by the OSHA Hazard

Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture:

ARK<sup>TM</sup> Methotrexate Calibrator/Control/Dilution Buffer

Not classified.

# **GHS Label Elements:**

Signal word: ARK<sup>TM</sup> Methotrexate Calibrator/Control/Dilution Buffer No signal word.

Hazard statements: ARK<sup>TM</sup> Methotrexate Calibrator/Control/Dilution Buffer

No known significant effects or critical hazards.

### Precautionary statements

Prevention:	ARK <sup>TM</sup> Methotrexate Calibrator/Control/Dilution Buffer	Not applicable.
Response:	ARK <sup>TM</sup> Methotrexate Calibrator/Control/Dilution Buffer	Not applicable.
Storage:	ARK <sup>TM</sup> Methotrexate Calibrator/Control/Dilution Buffer	Not applicable.
Disposal:	ARK <sup>TM</sup> Methotrexate Calibrator/Control/Dilution Buffer	Not applicable.



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Supplemental label

elements: ARK<sup>TM</sup> Methotrexate Calibrator/Control/Dilution Buffer Not applicable.

Hazards not otherwise

classified: ARK<sup>TM</sup> Methotrexate Calibrator/Control/Dilution Buffer Not applicable.

# 3. COMPOSITIONS/INFORMATION ON INGREDIENTS

Substance/mixture: ARK<sup>TM</sup> Methotrexate Calibrator Liquid Mixture

ARK<sup>TM</sup> Methotrexate Control Liquid Mixture ARK<sup>TM</sup> Methotrexate Dilution Buffer Liquid Mixture

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

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**

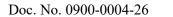
Suitable extinguishing media: In case of fire, use water spray (fog), foam, carbon

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

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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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### 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

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 ≥32°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 a

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.

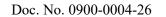
## Symptoms related to the physical, chemical and toxicological characteristics

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.





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# 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<sub>oc</sub>)

Mobility

Other adverse effects No known significant effects or critical hazards.



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### 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.

### 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

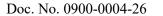
United States inventory TSCA 8(b) Not determined

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:

Composition/information on ingredients: No products were found.

SARA 304RQ: Not applicable

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 Pennsylvania California None of the components are listed.
None of the components are listed.
None of the components are listed.

Canada inventory:

International regulations

International lists: Australia inventory (AICS): Not determined

China inventory (IECSC):

Japan inventory:

Korea inventory:

Malaysia inventory (EHS Register):

Not determined

Not determined

Not determined

New Zealand Inventory of Chemicals (NZloC): 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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### 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

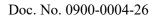
TDG=Transportation of Dangerous Goods

TSCA=Toxic Substances Control Act

TWA=Time Weighted Average

UN= United Nations

WHMIS=Workplace Hazardous Materials Information System





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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.

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.