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SDS – ARKTM HS Benzodiazepine II Calibrator/Control

IDENTIFICATION 1.

ARKTM HS Benzodiazepine II Calibrator/Control (a) Product Identifier:

5073-0002-00, 5073-0002-01, 5073-0002-02, 5073-0002-03 Product Code:

5073-0003-00, 5073-0003-01

(b) Other means of identification/synonyms

Component Name Internal Code

Calibrator A-E 4073-0004-00 through 4073-0004-04 (5073-0002-00)

Calibrator A (Negative) Only 4073-0004-00 (5073-0002-01) Calibrator B (100 ng/mL Cutoff) Only 4073-0004-01 (5073-0002-02) Calibrator C (200 ng/mL Cutoff) Only 4073-0004-02 (5073-0002-03)

Low (75 ng/mL) and High (125 ng/mL) Controls 4073-0007-01 & 4073-0007-02 (5073-0003-00) Low (150 ng/mL) and High (250 ng/ml) Controls 4073-0007-03 & 4073-0007-04 (5073-0003-01)

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)

ARKTM HS Benzodiazepine II Calibrator and Control 1272/2008 [GHS]

This material is not considered hazardous by the OSHA Hazard

Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture:

ARKTM HS Benzodiazepine II Calibrator/Control Not classified.

GHS Label Elements:

ARKTM HS Benzodiazepine II Calibrator/Control Signal word: No signal word. No known

ARKTM HS Benzodiazepine II Calibrator/Control Hazard statements:

significant effects or critical hazards.



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Precautionary statements

Prevention: ARKTM HS Benzodiazepine II Calibrator/Control Not applicable. Response: ARKTM HS Benzodiazepine II Calibrator/Control Not applicable. Storage: ARKTM HS Benzodiazepine II Calibrator/Control Not applicable. Disposal: ARKTM HS Benzodiazepine II Calibrator/Control Not applicable.

Supplemental label

elements: ARKTM HS Benzodiazepine II Calibrator/Control Not applicable.

Hazards not otherwise

classified: ARKTM HS Benzodiazepine II Calibrator/Control Not applicable.

3. COMPOSITIONS/INFORMATION ON INGREDIENTS

Substance/mixture: ARKTM HS Benzodiazepine II Calibrator Liquid Mixture

ARKTM HS Benzodiazepine II Control Liquid Mixture

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

ARK HS Benzodiazepine II 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.



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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.

5. FIREFIGHTING MEASURES

Extinguishing media



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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 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



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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

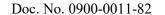
engineering modifications to the process equipment will be necessary to

reduce emissions to acceptable levels.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear Liquid
Color Colorless

Odor No information identified



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No information identified

Odor threshold No information identified

5-8 pН

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)

Upper/lower flammability or

explosive limits No information identified No information identified Vapor pressure Vapor density No information identified Relative density No information identified

Water solubility Miscible in water

Solvent solubility No information identified

Partition Coefficient

No information identified (n-octanol/water) Auto-Ignition temperature No information identified Decomposition temperature No information identified No information identified Viscosity Explosive properties No information identified Oxidizing properties No information identified

Other information

No information identified Molecular weight Molecular formula No information identified

10. STABILITY AND REACTIVITY

No specific test data related to reactivity available for this product or its Reactivity

ingredients

Chemical Stability The product is stable when stored as recommended.

Possibility of hazardous

reactions Not expected to occur.



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Conditions to avoid No thermal hazard. Avoid temperatures ≥32°C to preserve biochemical integrity.

Incompatible materials No information identified.

Hazardous decomposition

No information identified. products:

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

No known significant effects or critical hazards. Eye contact Inhalation No known significant effects or critical hazards. Skin contact No known significant effects or critical hazards.



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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

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.

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

Clean Air Act Section 602



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Class II Substances Not listed

DEA List I Chemicals

Precursor Chemicals Not listed

DEA List II Chemicals

Essential Chemicals Not listed

SARA 302/304:

			SARA 302 TPQ		SARA 304 RQ	
Name	%	EHS	(lbs)	(gallons)	(lbs)	(gallons)
ARK TM HS Benzodiazepine II						
Calibrator						
sodium azide	0.09%	Yes	500	-	1000	
ARK TM HS Benzodiazepine II						
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 Pennsylvania None of the components are listed.
California None of the components are listed.
None of the components are listed.

Canada inventory:

<u>International regulations</u>

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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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.