SDS – ARK™ Pregabalin II Calibrator/Control

Meets the requirements of Regulation (EC) No. 1907/2006 (REACH), Annex II, with changes introduced by Commission Regulation (EU) 2020/878, and Occupational Safety and Health Administration Standard Number 1910.1200 App D.

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY INDERTAKING

1.1. Product Identifier: ARK™ Pregabalin II Calibrator/Control

Product Code: 5059-0002-00, 5059-0003-00

Component Name	Internal Code
Calibrator A-E	4059-0004-00 through 4059-000404 (5059-0002-00)
Low and High Control	4059-0007-01 & 4059-0007-02 (5059-0003-00)

Product Type: Liquid

1.2. Relevant identified uses of the substance or mixture and uses advised against:
Invitro Diagnostic Kit Reagents for Professional users only

1.3. Details of the supplier of the safety data sheet

Company: ARK Diagnostics, Inc.
48089 Fremont Blvd.
Fremont, CA 94538
USA

Telephone: 1-510-270-6270
Fax: 1-510-270-6298

Email: customersupport@ark-tdm.com

1.4 Emergency Telephone 800-424-9300 CHEMTREC (USA)
+1-703-527-3887 CHEMTREC (International)
24 Hours/day; 7 Days/week

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

This product is a reagent kit consisting of individual ingredients. The classification of material is not considered hazardous by the EC Regulation 1272/2008 and OSHA Hazard Communication (29CFR 1910.1200)

2.2. OSHA/HCS Status:

Regulation (EC) 1272/2008 [GHS]	ARK™ Pregabalin II Calibrator and Control This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

GHS Label Elements:

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

Precautionary statements

Prevention:	ARK™ Pregabalin II Calibrator and Control	Not applicable.
Response:	ARK™ Pregabalin II Calibrator and Control	Not applicable.
Storage:	ARK™ Pregabalin II Calibrator and Control	Not applicable.
Disposal:	ARK™ Pregabalin II Calibrator and Control	Not applicable.
Supplemental label elements:	ARK™ Pregabalin II Calibrator and Control	Not applicable.
Hazards not otherwise classified:	ARK™ Pregabalin II Calibrator and Control	Not applicable.

3. COMPOSITIONS/INFORMATION ON INGREDIENTS

ARK™ Pregabalin II Calibrator and Control

GHS Classification

The GHS classification of the mixture has not been determined. Not a hazardous mixture based on bridging principles of GHS classification (2005) of individual components and ingredients and regulation EC No 1272/2008

Not a hazardous substance or mixture

Any concentration shown as a range is to protect confidentiality or is due to batch variation. Concentrations below 0.1%w/w for other ingredients are excluded per EC 1907/2006 and amended Annex II 2020/878. Occupational Exposure limits are listed in Section 8.

4. FIRST AID MEASURES

4.1. 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:	The first aid procedure should be established in consultation with medical personnel responsible for industrial medicine. No action shall be taken involving any personal risk or without suitable training. It may be dangerous to perform mouth to mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.
Responders:	See Section 8 for Exposure Controls/Personal Protection Recommendations.

4.2. Most important symptoms and effects both acute and delayed: See also 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.

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.

4.3. 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. The first aid procedure should be established in consultation with physician responsible for industrial medicine

5. FIREFIGHTING MEASURES

5.1. 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

5.2. Special hazards arising from the substance or mixture

Hazards from the substance or mixture	In a fire or if heated a pressure increase could occur resulting in the container to burst
Hazardous thermal decomposition products:	No specific data.

5.3. Advice for firefighters

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

6.1. 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".

6.2. 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).

6.3. 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.

6.4. Reference to other section(s)

See section 1 for emergency contact information
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information and disposal

7. HANDLING AND STORAGE

7.1. 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.

7.2. 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.

7.3. Specific End Uses Laboratory Reagents for Clinical Chemistry Analyzers

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control Parameters

ARK™ Pregabalin II Calibrator and Control

Contains no substances with occupational exposure limit values.

8.2. Exposure Controls

Appropriate engineering Controls	Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
Personal protective equipment	The selected protective equipment have to satisfy the specifications of Regulations EU 2016/425 and the standard EN 374 derived from it.
Hand	Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly. Please observe the instructions regarding the permeability and breakthrough time provided by the supplier of gloves.
Eye	Wear Safety Glasses complying with approved standards commensurate with risk assessment indicating possibility of liquid splashes.
Skin and Body	Appropriate clothing preferably a lab coat as protective suit. Personal protective equipment for the body should be selected based on the task being performed and the risks involved in handling the product. Appropriate footwear and any additional skin protection should be selected during the performance of the tasks.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practice. Wash hands, forearms and face thoroughly after handling chemical products before eating and using the lavatory/toilet at the end of the working period. Wash contaminated clothing before reusing. Ensure eyewash stations and safety showers are in the vicinity and functional.
Respiratory Protection	Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Ensure proper training and fitting before use. No personal respiratory protective equipment is normally required during the handling of this product.

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

9.1. Information on basic physical and chemical properties

ARK™ Pregabalin II Calibrator and Control

Appearance:	Clear Liquid	
Color	Colorless	
Odor	Odorless	
Odor threshold	Not relevant due to nature of product information identified	
pH	5.0 to 8.0	
Melting point/freezing point	Not relevant due to nature of product	Initial boiling point and
boiling range Does not Flash	Not relevant due to nature of product	Flash point
Evaporation rate	No data available	
Flammability (liquids)	Does not sustain Combustion	
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 data available
Explosive properties	Not Explosive
Oxidizing properties	The substance or mixture is not classified as oxidizing
Other information	
Molecular weight	Not Applicable, Homogeneous Mixture
Molecular formula	Not Applicable Homogeneous Mixture
Particle Characteristics	Particle size not applicable
Burning Time	Not relevant due to nature of product
Burning Rate	Not relevant due to nature of product
Heat of reaction	Not relevant due to nature of product
Heat of combustion	Not relevant due to nature of product
Flow time (ISO 2431)	Not relevant due to nature of product

10. STABILITY AND REACTIVITY

10.1. Reactivity No specific test data related to reactivity available for this product or its ingredients. No dangerous reaction known under conditions of normal use.

10.2. Chemical Stability The product is stable when stored as recommended.

10.3 Possibility of hazardous reactions Not expected to occur

10.4 Conditions to avoid No thermal hazard.

Avoid temperatures ≥32ºC to preserve biochemical integrity.

10.5 Incompatible materials: No information identified.

10.6 Hazardous decomposition products No information identified.

11. TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes

Acute Toxicity	Not classified based on available information
Irritation/Skin Corrosion	Not classified based on available information
Serious Eye damage/Injury	Not classified based on available information
Sensitization	Not classified based on available information
Mutagenicity	Not classified based on available information
Carcinogenicity	Not classified based on available information
IARC	No ingredient of this product present at levels greater than or equal to 0.1% w/w is identified as probable, possible, or confirmed human carcinogen
OSHA	No component of this product present at levels greater than or equal to 1% w/w is on OSHA's list of regulated carcinogens
NTP	No ingredient of this product present at levels greater than or equal to 0.1% w/w is identified as a known or potential carcinogen.

Conclusion Summary:

Reproductive Toxicity	Not available
Teratogenicity	Not available

Conclusion Summary:

Specific target organ toxicity (STOT) (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.

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.

11.2. Information on other hazards

Endocrine disrupting properties	Not available

To the best of our knowledge, the chemical, physical and toxicological properties of the mixtures have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

12.1. Toxicity **ARK™ Pregabalin II Calibrator and Control**

Toxicity to daphnia and other aquatic invertebrates	Static test EC50- Dapnia magna (water flea) >100mg/L 48h (OECD Test Guideline 202)
Toxicity to algae	Static test NOEC – Pseudokirchneriella subcapitata (green algae) > 100mg/L 72h (OECD Test Guideline 201)

Remarks – refers to pure substance not mixture

12.2 Persistence and degradability Biodegradability Aerobic exposure 28d Results 0% Not readily biodegradable (OECD Test Guideline 301D)

Remarks: Refers to pure substance data not available for mixture.

12.3 Bio accumulative potential Data not available

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc})	Data not available

12.5 Results of PBT a vPvB assessment PBT/vPvB assessment not available

12.6 Endocrine disrupting properties No data available

12.7 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.

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.

14.1. UN Number None assigned.

14.2. UN Proper Shipping Name None assigned, not regulated as a dangerous good

14.3. Transport hazard classes and packaging group None assigned, not regulated as a dangerous good
UNRTDG, IATA-DGR, IMDG-Code Not regulated as a dangerous good

14.4. Packing Group No packing group assigned

14.5. Environmental Hazards Not determined for mixture

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

14.7. Maritime transport in bulk Not applicable

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

14.9. Domestic regulation 49 CFR Not assigned, Not regulated as a dangerous good in the meaning of ADR/RID, AND, IMDG-Code, ICAO and IATA-DGR

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15. REGULATORY INFORMATION

15.1. 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.

REACH – Candidate List of Substances of very High Concern for Authorization (Article 59) – Not Applicable
REACH – List of Substances subject to Authorization (Annex XIV) - Not Applicable
REACH – Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) -Not Applicable

Regulation EC No 1005/2009 on substances that deplete the ozone layer -Not Applicable

Regulation EC No 850/2004 on persistent organic pollutants -Not Applicable

Regulation(EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals -Not Applicable

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

Hazardous Air pollutants (HAPs)

Clean Air Act
Class I and II Substances This product neither contains nor was manufactured with a Class I or Class II ODS as defined by the US Clean Air Act Section 602 (40 CFR 82)
This product does not contain any hazardous air pollutants (HAP) as identified by the US clean Air Act Section 112 (40 CFR 11).
This product does not contain any chemicals listed under the US Clean Air Act Section 112® for Accidental Release Prevention (40 CFR 68)
This product does not contain any chemicals listed under the US Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60).

Clean Water Act

This product does not contain any Hazardous Substances listed under the US Clean Water Act Section 311
This product does not contain any toxic pollutants listed under US Clean Water Act Section 307
This product does not contain any priority pollutants related to the US Clean Water Act

15.2. Chemical Safety Assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified application.

DEA List I Chemicals	Not listed
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.

US State regulations

Massachusetts	None of the components are listed
Maine	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: The substances are listed in the DSL and do not meet the criteria of CEPA

European Inventory: On the C&L inventory of ECHA

International regulations

International lists:	Australia inventory (AIIC):	Not determined
	Brazil:	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

16. OTHER INFORMATION

Revision #, Date of Effectivity: Refer to the Header of this document (The effective Date is the same as the Revision Date.)

Key to Abbreviations:
AIIC = Australian Inventory of Chemicals
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
CEPA = Canadian Environmental protection Agency
CLP=Classification, Labelling and Packaging of Substances and Mixtures
DNEL=Derived No Effect Level
DSL = Domestic Substances List
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

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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.

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.