

SAFETY DATA SHEET

SDS No. : 105730EU-1
Issue Date : 24 Jun. 2019
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Ver.2.0

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name : CALIBRATOR 90 High/Low

1.2 Relevant identified uses of the substance or mixture and uses advised against

The product is applicable for the following purpose of use only. Use exclusive reagents for ADAMS A1c HA-8190V.

1.3 Details of the supplier of the safety data sheet

ARKRAY FACTORY, Inc.

Address : 1480 Koji, Konan-cho, Koka-shi, Shiga 520-3306, JAPAN

Phone : +81-748-86-6901

Facsimile : +81-748-86-5347

European representative

ARKRAY Europe, B. V.

Address : Prof. J. H. Bavincklaan 2, 1183 AT Amstelveen, THE NETHERLANDS

Phone : +31-20-545-2450

Facsimile : +31-20-545-2459

1.4 Emergency telephone number

Emergency phone : +31-20-545-2450 (9:00~17:00)

2. Hazards Identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to REGULATION (EC) No 1272/2008.

2.2 Label elements

The product does not need to be labeled in accordance with EC directives or respective national laws.

2.3 Other hazards

This product contains material derived from human sources. All human source components in this product have been tested and found negative for Hepatitis B surface Antigen, Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV) Antibody, and Adult T-cell Leukemia (ATL) Antibody. However, as infectiousness is not tested except the four viruses above, this product should be considered potentially capable of transmitting infectious disease, and handled with care as well as patient samples.

May cause irritation, inflammation, or eczema by skin contact.

3. Composition/information on ingredients

3.2 Mixtures

Component	Conc. [wt%]	Formula	EINECS No.	CAS No.	Classification Regulation(EC) 1272/2008(CLP)
Human source hemoglobin	—	—	—	—	—

4. First aid measures

4.1 Description of first aid measures

General notes

Consult a physician. Show this safety data sheet to the doctor in attendance.

Following inhalation

Rinse mouth, nose, and throat with water and remove to fresh air and keep comfortable for breathing. Get medical attention if you feel unwell.

Following skin contact

Immediately wash thoroughly with water and soap. Immediately get medical attention if itchiness and inflammation occurs.

Following eye contact

Immediately wash eyes with plenty of clean water for several minutes and get medical attention.

Following ingestion

Immediately rinse mouth and get medical attention.

Self-protection of the first aider

Wear protective gloves/protective clothing/eye protection/face protection.

4.2 Most important symptoms and effects, both acute and delayed

No relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No relevant information available.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water

Unsuitable extinguishing media

Not specified.

5.2 Special hazards arising from the substance or mixture

May form irritating, toxic or corrosive gas in fire.

5.3 Advice for firefighters

Fire-fighters should wear proper protective equipment.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Wear suitable protective equipment.

6.1.2 For emergency responder

Avoid contact skin and eyes.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up**6.3.1 For containment:**

Stop leak if possible without risk.

6.3.2 For cleans up:

Wipe with damp cloth and wipe off using alcohol or sodium hypochlorite solution.

6.3.3 Other information:

No relevant information available.

6.4 Reference to other sections

For protective equipment see Section 8.

For disposal see Section 13.

7. Handling and storage**7.1 Precautions for safe handling****Preventive measures (Exposure Control for handling personnel)**

Wear suitable protective equipment. For personal protection see Section 8.

See the package insert for further information for handling.

7.2 Conditions for safe storage, including any incompatibilities

Store the product in a refrigerator at temperature of 2 to 8 °C. Keep container tightly closed.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

8. Exposure controls/personal protection**8.1 Control parameters**

The product does not contain any substances for which the allowable concentration has been set.

8.2 Exposure controls**8.2.1 Appropriate engineering controls**

Handle in a well-ventilated area.

8.2.2 personal protection equipment:**8.2.2.1 Eye/face protection**

Use protective goggles.

8.2.2.2 Skin protection

Hand protection

Use protective gloves.

Other skin protection:

Use protective clothing.

8.2.2.3 Respiratory protection

Use dust mask, if necessary.

8.2.2.4 Thermal hazards

No information available.

8.2.3 Environmental exposure controls

For environmental exposure controls, see Section 6.2.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	solid (lyophilized powder)
Colour	Red
Odour	No data available
Odour threshold	No data available
Melting point/freezing point	No data available
Boiling point and boiling range	No data available
Flammability	No data available
Lower and upper explosion limit	Not applicable
Flash Point	Not applicable
Auto-ignition temperature	Not applicable
Decomposition temperature	No data available
pH	No data available
Kinematic viscosity	No data available
Solubility	No data available
Partition coefficient n-octanol/water(log value)	No data available
Vapour pressure	No data available
Density and/or relative density	No data available
Relative vapour density	Not applicable
Particle characteristics	No data available

9.2 Other information

No further relevant information.

10. Stability and reactivity

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Stable under recommended storage conditions.

10.4 Conditions to avoid

High temperature and humidity

10.5 Incompatible materials

Store at a distance from incompatible materials.

10.6 Hazardous decomposition products

Does not decompose when used for intended uses.

11. Toxicological information

11.1 Information on hazard classes as defined in Regulation(EC) No 1272/2008

Acute toxicity	
Oral	Based on available data, the classification criteria are not met.
Dermal	Based on available data, the classification criteria are not met.
Inhalation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Serious eye damage/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
STOT-single exposure	Based on available data, the classification criteria are not met.
STOT-repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

11.2 Information on other hazards

No product available.

12. Ecological information

12.1 Toxicity

Based on available data, the classification criteria are not met.

12.2 Persistence and degradability

Based on available data, the classification criteria are not met.

12.3 Bioaccumulative potential

Based on available data, the classification criteria are not met.

12.4 Mobility in soil

Based on available data, the classification criteria are not met.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Endocrine disrupting properties

This substance does not have endocrine disrupting properties with respect to non-target organisms as it does not meet the criteria set out in section B of Regulation (EU) No 2017/2100.

12.7 Other adverse effects

No product available.

13. Disposal considerations

13.1 Waste treatment methods

13.1.1 Product/Packaging disposal

Dispose of as biohazardous waste in accordance with regulations.

13.1.2 Waste treatment-relevant information

Remove the product from the container completely, dispose of as unused product.

13.1.3 Sewage disposal-relevant information

Do not dump this product into sewers, on the ground or into any body of water.

Further information

The above information contained herein is based on the data available to us and is believed to be correct. However, ARKRAY, Inc. bears no warranty expresses or implies regarding the accuracy of these data or the results to be obtained from the use thereof.

ARKRAY, Inc. assumes no responsibility for injury caused from the use of the product described herein.