

## SAFETY DATA SHEET

SDS No. : 71266EU-1  
Issue Date : 01 Jun. 2009  
Revision Date : 20 Jun. 2022  
Ver.5.0

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

#### 1.1 Product identifier

Product name : CALIBRATOR 80 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-8180 series.

#### 1.3 Details of the supplier of the safety data sheet

ARKRAY FACTORY, Inc.

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#### 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 at least 15 minutes and get medical attention.

##### Following ingestion

Immediately rinse mouth and get medical attention.

##### Self-protection of the first aider

Wear protective equipment to avoid contact with skin and eyes.

#### 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**

It is desirable to install local exhaust ventilations.

#### **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	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	No data available
Flash Point	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
pH	No data available
Kinematic viscosity	No data available
Solubility	Water miscible freely
Partition coefficient	No data available
n-octanol/water(log value)	
Vapour pressure	No data available
Density and/or relative density	No data available
Relative vapour density	No data available
Particle characteristics	No data available

**9.2 Other information**

No relevant information available.

**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 (gas)	Based on available data, the classification criteria are not met.
Inhalation (vapours)	Based on available data, the classification criteria are not met.
Inhalation (dust/mist)	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 relevant information 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 relevant information 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.

##### 13.1.4 Other disposal recommendations

Observe all federal, state, and local environmental regulation.

### 14. Transport information

#### 14.1 UN number or ID number

ADR/RID: N/A

IMDG: N/A

IATA: N/A

#### 14.2 UN proper shipping name

ADR/RID: N/A

IMDG: N/A

IATA: N/A

#### 14.3 Transport hazard class(es)

ADR/RID: N/A

IMDG: N/A

IATA: N/A

#### 14.4 Packing group

ADR/RID: N/A

IMDG: N/A

IATA: N/A

#### 14.5 Environmental hazards

ADR/RID: N/A

IMDG Marine pollutant: N/A

IATA: N/A

#### 14.6 Special precautions for user

Maintain the product at the temperature of 2 to 8 °C.

#### 14.7 Maritime transport in bulk according to IMO instruments

No relevant information available.

### 15. Regulatory information

#### 15.1 Safety, health, and environmental regulations/legislation specific for the substance or mixture

(EC) No 1907/2006 (REACH).

(EC) No 1272/2008 (CLP).

(EU) No 453/2010.

(EU) No 2015/ 830

(EU) 2020/878

#### 15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

### 16. Other information

#### The date of preparation and revision of the SDS

Ver.1.0	Prepared on 1 June 2009.	
Ver.2.0	Revised on 24 August 2012:	Added a postscript to the following words in the document beginning, "This material safety data sheet is according to (ES) No. 1907/2006 REACH."

Ver.3.0	Revised on 10 June 2015:	Modified in accordance with the requirements of Regulation (EC) No. 1907/2006.
Ver.3.1	Revised on 8 June 2016:	European representative's address has changed.
Ver.3.2	Revised on 25 January 2017:	Corrected the wording in 15.1.
Ver.4.0	Revised on 25 May 2020:	Changed Revision Date.
Ver.5.0	Revised on 20 June 2022:	Revised a new format in accordance with Regulation(EU) 2020/878.

**Key literature references**

Package insert

IMDG Code

IATA Dangerous Goods Regulations

**Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:**

Not applicable

**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.