

SAFETY DATA SHEET (SDS)

SDS – 093

Revision number: 1

Rev. 11/17

Calibrator 80 Low/High

Part Numbers: 103400

For use with the ADAMS A1c HA-8180V

ARKRAY USA, Inc.

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SAFETY DATA SHEET

SDS No. : 71266EU-1
Issue Date : 01 Jun. 2009
Revision Date : 25 Jan. 2017

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.

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

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 regulations 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. [%] | 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

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.

Skin contact

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

Eye contact

Immediately wash eyes with plenty of clean water for at least 15 minutes and get medical attention.

Ingestion

Immediately rinse mouth and get medical attention.

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

None

5.2 Special hazards arising from the substance or mixture

No relevant information available

5.3 Advice for firefighters

No relevant information available

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear suitable protective equipment.

For emergency responder

Avoid contact skin and eyes.

6.2 Environmental precautions

No relevant information available

6.3 Methods and material for containment and cleaning up

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

6.4 Reference to other sections

For personal protection 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

No data available

8.2 Exposure controls

Appropriate engineering controls

No information available

Individual protection measures, such as personal protective equipment

Eye/face protection

Use protective goggles.

Skin protection

Hand protection

Use protective gloves.

Other

Use protective clothing.

Respiratory protection

Use dust mask, if necessary.

Thermal hazards

No information available

Environmental exposure controls

No relevant information available

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | |
|---------------------------------|------------------------------------|
| Appearance | Reddish solid (lyophilized powder) |
| Odour | None |
| Odour threshold | — |
| pH | — |
| Melting point/freezing point | No data available |
| Boiling point and boiling range | No data available |
| Flash Point | No data available |
| Evaporation rate | No data available |

| | |
|--|-----------------------|
| Flammability | No data available |
| Upper/lower flammability or explosive limits | No data available |
| Vapor pressure | No data available |
| Vapor density | No data available |
| Solubility in | Water miscible freely |
| Partition coefficient: n-octanol/water | No data available |
| Auto-ignition temperature | No data available |
| Decomposition temperature | No data available |
| Viscosity | 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

None

10.4 Conditions to avoid

High temperature and humidity

10.5 Incompatible materials

No information available

10.6 Hazardous decomposition products

None

11. Toxicological information

11.1 Information on toxicological effects

| | |
|-----------------------------------|--------------------------|
| Acute toxicity | No information available |
| Skin corrosion/irritation | No information available |
| Serious eye damage/irritation | No information available |
| Respiratory or skin sensitization | No information available |
| Germ cell mutagenicity | No information available |
| Carcinogenicity | |
| IARC: — | NTP: — |
| Reproductive toxicity | No information available |
| STOT-single exposure | No information available |
| STOT-repeated exposure | No information available |
| Aspiration hazard | No information available |

OSHA: —

ACGUH: —

12. Ecological information

12.1 Toxicity

No information available

12.2 Persistence and degradability

No information available

12.3 Bioaccumulative potential

No information available

12.4 Mobility in soil

No information available

12.5 Results of PBT and vPvB assessment

No information available

12.6 Other adverse effects

No information available

13. Disposal considerations**13.1 Waste treatment methods****Product**

Dispose of as biohazardous waste in accordance with regulations.

Contaminated packaging

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

Others

Observe all federal, state, and local environmental regulation.

14. Transport information**14.1 UN number**

ADR/RID: —

IMDG: —

IATA: —

14.2 UN proper shipping name

ADR/RID: —

IMDG: —

IATA: —

14.3 Transport hazard class(es)

ADR/RID: —

IMDG: —

IATA: —

14.4 Packing group

ADR/RID: —

IMDG: —

IATA: —

14.5 Environmental hazards

ADR/RID: no

IMDG Marine pollutant: no

IATA: no

14.6 Special precautions for user

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

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

15. Regulatory information

The safety datasheet compiles with the requirements of Regulation (EC) No. 1907/2006.

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

No information available

15.2 Chemical safety assessment

No information available

16. Other information

The date of preparation and revision of the SDS

Prepared on 1 June 2009.

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."

Revised on 10 June 2015: Modified in accordance with the requirements of Regulation (EC) No. 1907/2006.

Revised on 8 June 2016: European representative's address has changed.

Revised on 25 January 2017: Corrected the wording in 15.1.

Key literature references

Insert

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.