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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Minneapolis, Minnesota 55439

Technical Customer Service Phone:
1-855.646.3108
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

<table>
<thead>
<tr>
<th>Component</th>
<th>Conc. [%]</th>
<th>Formula</th>
<th>EINECS No.</th>
<th>CAS No.</th>
<th>Classification Regulation(EC) 1272/2008(CLP)</th>
</tr>
</thead>
</table>
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.
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

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Reddish solid (lyophilized powder)</td>
</tr>
<tr>
<td>Odour</td>
<td>None</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>—</td>
</tr>
<tr>
<td>pH</td>
<td>—</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash Point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Flammability
Upper/lower flammability or explosive limits
Vapor pressure
Vapor density
Solubility in
Partition coefficient: n-octanol/water
Auto-ignition temperature
Decomposition temperature
Viscosity

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

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 complies 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.

Key literature references

Insert

Further information

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