SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product code:	A371-011
Product name:	Calibrator set – Level 0 – 6 for PEth from whole blood
REACH	
Registration number:	not relevant (mixture)

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

Relevant identified use:	Product for in vitro diagnostics
Uses advised against:	
	Do not use for private purposes.

1.3 Details of the supplier of the safety data sheet

Address:	ARCHImedline GmbH
	Leberstraße 20/2, 1110 Wien, Austria
E-Mail:	info@archimedline.com
Tel:	+43 1 3940020
Web:	www.archimedline.com

1.4 Emergency telephone number

Austria:	0043 14064343	24 hours
Germany:	0049 3019240 (Berlin)	24 hours
	0049 22819240 (Bonn)	24 hours
	0049 361 730730 (Göttingen)	24 hours
	0049 613119240 (Mainz)	24 hours
	0049 8919240 (München)	24 hours
Switzerland:	0041 442515151 (Zürich) (from abroad)	24 hours
	145 (national)	24 hours

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

This mixture does not meet the criteria for classification in accordance with Regulation (EC) No 1272/2008.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

Not required

2.3 Other hazards

The human blood used to manufacture the calibrator was tested for the absence of various pathogens (see the product package insert). Nevertheless, the material should be regarded as potentially infectious and handled with appropriate care.

Results of PBT and vPvB assessment

Does not contain any PBT/vPvB substance at a concentration of ≥ 0.1%.

Endocrine-disrupting properties

Does not contain an endocrine disruptor (EDC) at a concentration of ≥ 0.1%.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not relevant (mixture)

3.2 Mixtures

Description of the mixture

Dried blood, spiked with various analytes.

Hazardous components according to EU legislation; other information to be considered

None

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes

Do not leave affected persons unattended. Remove the casualty from the danger area. Keep the affected person at rest, covered and warm. Remove contaminated, soaked clothing immediately. Seek medical advice if symptoms occur or if in doubt. If unconscious, place in the recovery position and do not give anything by mouth.

Following inhalation

If breathing is irregular or has stopped, seek medical assistance immediately and initiate first aid measures. Provide fresh air.

Following skin contact

Wash with plenty of water and soap.

Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Hold the eyelids open and rinse with plenty of clean, flowing water for at least 10 minutes.

Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

No symptoms or effects are known to date.

4.3 Indication of any immediate medical attention and special treatment needed

None

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Water, foam, ABC powder

Unsuitable extinguishing media

Water jet

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

Carbon monoxide (CO), carbon dioxide (CO2)

5.3 Advice for firefighters

Do not breathe explosion and combustion gases. Coordinate firefighting measures with the surroundings. Do not allow firefighting water to enter drains or watercourses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Non-emergency personnel

Move persons to safety.

Emergency responders

Wear respiratory protection in the event of exposure to vapours, dusts, aerosols and gases.

6.2 Environmental precautions

Prevent entry into drains, surface water and groundwater. Retain and dispose of contaminated wash water.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Cover drains and collect mechanically.

Advice on how to clean up a spill

Collect mechanically.

Other information relating to spills and releases

Place in suitable containers for disposal. Ventilate the affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Recommendations

- Measures to prevent fire and aerosol and dust generation

Use local and general ventilation. Use only in well-ventilated areas. Earth the container and receiving equipment.

- Specific notes/information

Dust deposits may accumulate on all deposition surfaces in a work area. The product as supplied is not capable of a dust explosion; however, accumulation of fine dust creates a dust explosion hazard.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink or smoke in work areas. Remove contaminated clothing and protective equipment before entering areas where food is consumed. Do not store food and beverages together with chemicals. Do not use containers normally intended for food for chemicals. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Management of the following risks

- Explosive atmospheres

Removal of dust deposits.

Control of effects

Protect from sunlight. Protect from moisture.

7.3 Specific end use(s)

For a general overview, see section 16.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

National limit values

No information available.

8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear safety goggles/face protection.

Skin protection

- Hand protection

Wear protective gloves.

- Other protective measures

Allow recovery periods for skin regeneration. Preventive skin protection (protective creams/ointments) is recommended. Wash hands thoroughly after use.

Respiratory protection

Wear respiratory protection if ventilation is inadequate.

Environmental exposure controls

Use an appropriate container to avoid environmental contamination. Prevent entry into drains, surface water and groundwater.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	Solid (freeze-dried)
Colour	reddish brown
Odour	No information is available on this property
Melting point/freezing point	Not determined
Boiling point or initial boiling point and boiling range	Not determined
Flammability	This material is combustible but not readily flammable
Lower and upper explosion limit	Not determined
Flash point	Not applicable
Auto-ignition temperature	Not determined
Decomposition temperature	Not relevant
pH	Not applicable
Kinematic viscosity	Not relevant
Solubility	Not determined

Partition coefficient

Partition coefficient n-octanol/water (log value)	no information available

Vapour pressure	Not determined

Density and/or relative density

Density	Not determined
Relative vapour density	No information is available on this property

Particle characteristics	No data are available

9.2 Other information

Information with regard to physical hazard classes	Hazard classes according to GHS (physical hazards): not relevant

Other safety characteristics

Solvent content	0%
Solids content	100%

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Regarding incompatibilities: see "Conditions to avoid" and "Incompatible materials" below.

10.2 Chemical stability

The material is stable under normal ambient conditions and under the temperature and pressure conditions anticipated during storage and handling.

10.3 Possibility of hazardous reactions

No hazardous reactions are known.

10.4 Conditions to avoid

No specific conditions to avoid are known.

Information on how fires or explosions can be prevented

The product as supplied is not capable of a dust explosion; however, accumulation of fine dust creates a dust explosion hazard.

10.5 Incompatible materials

Oxidising agents

10.6 Hazardous decomposition products

No hazardous decomposition products that may reasonably be expected to arise as a result of use, storage, spillage or heating are known. Hazardous combustion products: see section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

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

No test data are available for the complete mixture.

Classification procedure

The procedure for classification of the mixture is based on the mixture components (additivity formula).

Classification according to GHS (1272/2008/EC, CLP)

This mixture does not meet the criteria for classification in accordance with Regulation (EC) No 1272/2008.

Acute toxicity

Not classified as acutely toxic.

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Not classified as causing serious eye damage or eye irritation.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as toxic for reproduction.

Specific target organ toxicity - single exposure

Shall not be classified as specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

11.2 Information on other hazards

No additional information is available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

According to Regulation (EC) No 1272/2008: shall not be classified as hazardous to the aquatic environment.

Ordinance on Installations for Handling Substances Hazardous to Water (AwSV): water hazard class (WGK) 1, slightly hazardous to water (Germany)

12.2 Persistence and degradability

No data are available.

12.3 Bioaccumulative potential

No data are available.

12.4 Mobility in soil

No data are available.

12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is neither a PBT nor a vPvB substance.
Does not contain any PBT/vPvB substance at a concentration of ≥ 0.1%.

12.6 Endocrine-disrupting properties

Does not contain an endocrine disruptor (EDC) at a concentration of ≥ 0.1%.

12.7 Other adverse effects

No data are available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Sewage disposal-relevant information

Do not allow to enter drains. Avoid release to the environment. Obtain special instructions/consult the safety data sheet.

Waste treatment of containers/packaging

Completely emptied packaging may be recycled. Contaminated packaging must be treated in the same manner as the substance.

13.2 Remarks

Observe the relevant national or regional provisions. Waste should be separated so that it can be handled separately by municipal or national waste disposal facilities. Product waste should be collected and disposed of in the same manner as patient samples.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number

Not subject to transport regulations.

14.2 UN proper shipping name

Not relevant.

14.3 Transport hazard class(es)

None.

14.4 Packing group

Not assigned.

14.5 Environmental hazards

Not environmentally hazardous according to the dangerous goods regulations.

14.6 Special precautions for user

No additional information is available.

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not transported in bulk.

14.8 Information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN)

Additional information

Not subject to the provisions of ADR, RID or ADN.

International Maritime Dangerous Goods Code (IMDG) -

Not subject to the provisions of the IMDG Code.

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Not subject to the provisions of ICAO-IATA.

SECTION 15: REGULATORY INFORMATION

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

Relevant provisions of the European Union (EU)

Decopaint Directive (2004/42/EC)

VOC content	0%

Industrial Emissions Directive (VOCs, 2010/75/EU)

VOC content	0%

National regulations (Germany)

Water hazard class (WGK) 1, slightly hazardous to water

Technical Instructions on Air Quality Control (Germany)

Number	Substance group	Class	Conc.	Mass flow	Mass concentration	Note
	Not assigned		≥ 25 Wt.-%			

Storage of hazardous substances in non-stationary containers (TRGS 510) (Germany)

Storage class (LGK) 11 (combustible solids)

15.2 Chemical safety assessment

Chemical safety assessments have not been carried out for substances in this mixture.

SECTION 16: OTHER INFORMATION

Abbreviations and acronyms

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals", developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
LGK	Storage class according to TRGS 510, Germany
PBT	Persistent, bioaccumulative and toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
TRGS	Technical Rules for Hazardous Substances (Germany)
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No 1907/2006 (REACH), as amended by Regulation (EU) 2020/878.

Transport of dangerous goods by road, rail or inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for air transport (IATA).

Classification procedure

Physical and chemical properties: classification is based on test results for the mixture.

Health hazards, environmental hazards: the procedure for classification of the mixture is based on the mixture components (additivity formula).

Disclaimer

The information provided is based on our current state of knowledge. This SDS has been compiled exclusively for this product and is intended exclusively for this product.