



Release Date: 15.08.2018

Product Name

Calibrator for use with AUTOF MS

Components:

Calibrator

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** Calibrator
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture:** Only for in vitro diagnostic
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
AUTOBIO DIAGNOSTICS CO., LTD
No.87 Jingbei Yi Road National Eco & Tech Development Area, Zhengzhou, China,
450016 Tel: +86 0371-66785303
E-mail: liudandan@autobio.com.cn
- **Only Representative / other EU contact point :** Not available
- **Further information obtainable from:** AUTOBIO DIAGNOSTICS CO., LTD
- **1.4 Emergency telephone number:**
Tel: 400-056-9995-3

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
- **Information concerning particular hazards for human and environment:**
The product has to be labelled due to the calculation procedure of Regulation (EC) No. 1272/2008.
- **Classification system:**
The classification is according to the latest edition of EU Regulation 1272/2008/EC, and extended by company and literature data.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to CLP Regulation.

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- 2.3 Other hazards
- Results of PBT and vPvB assessment
- PBT: Not applicable
- vPvB: Not applicable

SECTION 3: Composition/information on ingredients

Not applicable.

SECTION 4: First aid measures

·4.1 Description of first aid measures

·After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

·After skin contact:

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

·After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

·After swallowing:

Never give anything by mouth to an unconscious person.

Rinse out mouth with water.

Seek medical treatment.

·4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

·4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

·5.1 Extinguishing media

·Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.

·5.2 Special hazards arising from the substance or mixture No further relevant information available.

·5.3 Advice for firefighters

·Protective equipment:

Wear fully protective suit.

Mouth respiratory protective device.

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SECTION 6: Accidental release measures

·6.1 Personal precautions, protective equipment and emergency procedures

- Avoid contact with skin.
- Avoid contact with eyes.
- Ensure adequate ventilation.
- Use respiratory protective device against the effects of fumes/dust/aerosol.
- Wear protective equipment. Keep unprotected persons away.

·6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

·6.3 Methods and material for containment and cleaning up:

- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- Dispose contaminated material as waste according to item 13.

·6.4 Reference to other sections

- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.

SECTION 7: Handling and storage

·7.1 Precautions for safe handling

- Avoid contact with eyes and skin.
- Ensure good ventilation/exhaustion at the workplace.
- Keep away from heat and direct sunlight. Prevent formation of aerosols.
- Keep receptacles tightly sealed.
- For the general occupational hygienic measures refer to section 8.
- Information about fire - and explosion protection:** Normal measures for preventive fire protection.

·7.2 Conditions for safe storage, including any incompatibilities:

·Requirements to be met by storerooms and receptacles:

- Store in a cool location.
- Store only in the original receptacle.
- Information about storage in one common storage facility:** Store away from foodstuffs.

·Further information about storage conditions:

- Keep container tightly sealed.
- Store in cool, dry conditions in well sealed receptacles.

·7.3 Specific end use(s) No further relevant information available.

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SECTION 8: Exposure controls/personal protection

- **Regulatory information MAK (Germany):** MAK- und BAT-Liste
- **DNELs:** Data not applicable.
- **PNECs:** Data not applicable.
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- **Additional information:** The lists valid during the making were used as basis.
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8.2 Exposure controls

· **Based on composition shown in Section 3, the following measures are suggested for occupational safety measure:**

- **Appropriate engineering controls:**
 - Keep away from foodstuffs, beverages and feed.
 - Immediately remove all soiled and contaminated clothing.
 - Wash hands before breaks and at the end of work.
 - Avoid contact with the eyes and skin.
 - See Section 7 for information about design of technical facilities.
- **Personal protective equipment:**
 - **Respiratory protection:** Suitable respiratory protective device recommended.
 - **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves:

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material:

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.



Tightly sealed goggles

- **Environmental exposure controls:**
 - Control measures must be made in accordance with Community environmental protection legislation.

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SECTION 9: Physical and chemical properties

·9.1 Information on basic physical and chemical properties	
·General information	
·Appearance:	
Form:	Lyophilized
Colour:	colorless
·Odour:	Odourless
·Odour threshold:	Data not available.
·pH-value:	Data not available.
·Change in condition	
Melting point/freezing point:	Data not available.
Initial boiling point and boiling range:	Data not available.
·Flash point:	Data not available
·Flammability (solid, gaseous):	Not applicable
·Auto-Ignition temperature:	Data not available
·Decomposition temperature:	Date not available.
·Self-igniting:	Product is not selfigniting.
·Explosive properties:	Product does not present an explosion hazard.
·Explosion limits:	
Lower:	Data not available.
Upper:	Data not available.
·Oxidising properties	Data not available.
·Vapour pressure:	Data not available.
·Density:	Data not available.
·Relative density	Data not available.
·Vapour density	Data not available.
·Evaporation rate	Data not available.
·Solubility in / Miscibility with water:	Data not available
·Partition coefficient (n-octanol/water):	Data not available.
·Viscosity:	
Dynamic:	Data not available.
Kinematic:	Data not available.
·9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

- 10.1 Reactivity No decomposition if used according to specification.
- 10.2 Chemical stability Stable under recommended storage conditions.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: No dangerous decomposition products known.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

·Acute toxicity

·LD50 Oral- Rat- 730 mg/kg (Formic acid)

·(OECD Test Guideline 401)

·LC50 Inhalation - Rat - 4h- 7.4 mg/l (Formic acid)

·Skin corrosion/irritation:

Causes skin irritation.

·Serious eye damage/irritation:

Causes serious eye irritation.

·Respiratory or skin sensitization:

May cause an allergic skin reaction.

·**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.

SECTION 12: Ecological information

·12.1 Toxicity

·**Aquatic toxicity:** No further relevant information available.

·**12.2 Persistence and degradability** No further relevant information available.

·**12.3 Bioaccumulative potential** No further relevant information available.

·**12.4 Mobility in soil** No further relevant information available.

·12.5 Results of PBT and vPvB assessment

·**PBT:** Not applicable.

·**vPvB:** Not applicable.

·**12.6 Other adverse effects** No further relevant information available.

·12.7 Additional ecological information:

·General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.



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SECTION 13: Disposal considerations

·13.1 Waste treatment methods

·Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

·Uncleaned packaging:

·Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

· 14.1 UN-Number	
· ADR,RID,ADN, IMDG, IATA	Not applicable
·14.2 UN proper shipping name	
·ADR/RID/AND, IMDG, IATA	Not applicable
·14.3 Transport hazard class(es)	Not applicable
·ADR/RID/ADN, IMDG, IATA	
·Class	Not applicable
·Label	Not applicable
·14.4 Packing group	
·ADR,RID,ADN, IMDG, IATA	Not applicable
·14.5 Environmental hazards	Not applicable
·14.6 Special precautions for user	Not applicable
·14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
·UN "Model Regulation":	Not applicable



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SECTION 15: Regulatory information

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

MAK (German Maximum Workplace Concentration)

None of the ingredients is listed.

Directive 2012/18/EU

·Named dangerous substances - ANNEX I None of the ingredients is listed.

·National regulations:

·Water hazard class: Water hazard class 2 (Self-assessment): hazardous for water.

Other regulations, limitations and prohibitive regulations

·SVHC Candidate List of REACH Regulation Annex XIV Authorisation (15/1/2018)

None of the ingredients is listed.

REACH Regulation Annex XVII Restriction (18/4/2018) See Section 16 for information about restriction of use.

None of the ingredients is listed.

·REACH Regulation Annex XIV Authorization List (13/6/2017)

None of the ingredients is listed.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Relevant hazard statements

H300 Fatal if swallowed.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H331 Toxic if inhaled.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

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

Skin corrosion/irritation

Serious eye damage/eye

irritation Skin sensitisation

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

The contents and format of this SDS are in accordance with Regulation (EC) No 1907/2006, 1272/2008 and Regulation (EU) No 2015/830.

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-Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH) LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 2: Acute toxicity, Hazard Category 2

Acute Tox. 3: Acute toxicity, Hazard Category 3

Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Aquatic Acute 1: Hazardous to the aquatic environment – Acute Hazard, Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

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