

Safety Data Sheet

according to 1907/2006/EC, Article 31

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Release date 29.04.2023

Version number 18 (replaces version 17)

Last alteration on 20.04.2023

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

1.1 Product identifier

· Trade name: **Hemoglobin A1c Calibrators 1-2 For Use With ARCHITECT**

· Article number:

4P52 CAL 1 LYO

4P52 CAL 2 LYO

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

No further relevant information available.

· Product category PC0 Other

· Application of the substance / the preparation: For In Vitro Diagnostic Use

1.3 Details of the supplier of the safety data sheet

· Supplier:

Abbott GmbH

Max-Planck-Ring 2

65205 Wiesbaden

Tel.: (+49)-6122-58-0

MSDS-Support@Abbott.com

1.4 Emergency telephone number

(+49)-6122-58-0 (English only)

Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675805.

- Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.

- Telephone +1 (703) 527-3887, the international and maritime number (collect calls accepted), if you are calling from outside the United States or from a ship at sea.

- Telephone 09 8010034 if you are calling from New Zealand.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

The classification is in alignment with current European regulations. It incorporates information from technical literature and information provided by supplier companies.

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

This product has been evaluated per the classification criteria in Regulation (EC) No 1272/2008 (CLP) and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). This product does not meet the criteria for classification in accordance with either CLP or GHS.

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2.2 Label elements

· Labelling according to Regulation (EC) No 1272/2008: None

· Hazard pictograms: None

· Signal word: None

· Hazard statements: None

· Routes of Exposure:

For bloodborne pathogens and potentially infectious materials:

- non-intact skin

- mucous membranes (which includes, but is not limited to, the lining of the nose, mouth and throat)

- parenteral contact (e.g. by injection, puncture)

2.3 Other hazards

This product contains human-sourced components. No known test method can offer complete assurance that products derived from human sources will not transmit infection. Therefore, all human-sourced materials should be considered potentially infectious.

· Results of PBT and vPvB assessment:

· PBT: Not applicable

· vPvB: Not applicable

· Determination of endocrine-disrupting properties

CAS: 26027-38-3 Ethoxylated p-nonylphenol

List I

SECTION 3: Composition/information on ingredients

3.2 Mixtures

· Dangerous components according to EC criteria:

CAS: 26027-38-3

Reg.nr.: 01-2120118827-51-xxxx

Ethoxylated p-nonylphenol

Acute Tox. 4, H302; Eye Irrit. 2, H319

1.999%

· SVHC

CAS: 26027-38-3 Ethoxylated p-nonylphenol

· Additional information: For the complete text of Hazard (H) codes displayed in this section, refer to Section 16.

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SECTION 4: First aid measures

4.1 Description of first aid measures

- **After inhalation:** Remove from source of exposure. Seek medical attention and appropriate follow-up.
- **After skin contact:**
Take off any clothing that the product touched. Wash affected area with soap and water. Seek medical attention and appropriate follow-up.
- **After eye contact:**
Rinse open eye(s) cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention and appropriate follow-up. Wash hands after handling.
- **After swallowing:** Rinse mouth with water. Seek medical attention and appropriate follow-up.
- **Information for Medical Personnel:**
This product contains human-sourced and/or potentially infectious material. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced material should be considered potentially infectious.

The human-sourced material used in this product has been tested and found to be:

- Nonreactive for HBsAg (hepatitis B surface antigen)
- Nonreactive for HCV (hepatitis C virus)
- Nonreactive for HIV-1 Ag (human immunodeficiency virus type 1 antigen)
- Nonreactive for anti-HIV-1 (antibodies to human immunodeficiency virus type 1)
- Nonreactive for anti-HIV-2 (antibodies to human immunodeficiency virus type 2)

4.2 Most important symptoms and effects, both acute and delayed:

Liver effects
Cramps
Gastric or intestinal disorders
Nausea

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

No additional relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- **Suitable extinguishing agents:**
Dry chemical, carbon dioxide (CO₂), water spray or regular foam.
 - Caution: CO₂ will displace air in confined spaces and may cause an oxygen-deficient atmosphere.
 - For larger fires: There are no unique chemical or reactivity hazards that would impact firefighting decisions related to this product. Use firefighting measures that suit the environment.

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• 5.2 Special hazards arising from the substance or mixture

There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.

No further relevant information available.

• 5.3 Advice for firefighters

• Protective equipment:

For large fires, wear appropriate heat- and flame-resistant personal protective equipment and an approved positive-pressure, self-contained breathing apparatus.

SECTION 6: Accidental release measures

• 6.1 Personal precautions, protective equipment and emergency procedures

Handle as a potentially infectious material.

Avoid causing dust.

If material is released or spilled, minimize exposure by using appropriate personal protective equipment as listed in Section 8. Keep unprotected persons away.

• 6.2 Environmental precautions

Do not allow to enter the ground/soil.

Prevent from entering sewage system, storm drains, surface waters, or soil.

• 6.3 Methods and material for containment and cleaning up

Damp down dust with water spray.

Sweep up material and place into a suitable disposal container.

Vacuum (HEPA filter or equivalent recommended) or wet sweep products that are powders to avoid dust dispersal.

Clean the affected area. Suitable cleaners are:

- warm water and detergent or similar cleansing agent

Apply a suitable disinfectant. Select a disinfectant that is effective against bloodborne infectious agents, as well as other microbial agents that you might expect to be prevalent in your population. A disinfectant that is effective against *Mycobacterium tuberculosis* is generally effective against all known viruses and non-sporeforming bacteria, and is suitable for most clinical laboratory situations.

NOTE: Commercial disinfectants must be used according to manufacturer directions. Disinfectants are typically hazardous chemicals that react with many chemicals, materials and living tissues. Obtain and review the manufacturer's safety information before using the disinfectant.

Dispose of spilled and contaminated material in accordance with Federal, State, and Local regulations. See Section 13 for information that may impact disposal of materials contaminated with this product.

• 6.4 Reference to other sections

See Section 7 for information on safe handling.

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See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling:** Handle as a potentially infectious material.
- **7.2 Conditions for safe storage, including any incompatibilities**
 - **Storage:**
 - **Requirements to be met by storerooms and containers:** Store only in the original container.
 - **Information about storage in one common storage facility:** Store in original packaging.
 - **Further information about storage conditions:**
Refer to the package insert or product label for additional information on storage conditions for product quality.
- **7.3 Specific end use(s):** No additional relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

- **Components with limit values that require monitoring at the workplace:**

CAS: 1310-73-2 Sodium hydroxide (0.1999 %)

WEL (Great Britain) Short-term value: 2 mg/m³

· 8.2 Exposure controls

- **Individual protection measures, such as personal protective equipment**

- **General protective and hygienic measures:**

Always maintain good housekeeping and follow general precautionary measures. Do not eat, drink or store food and beverages in areas where chemicals or specimens are used. Wash hands before breaks, after handling reagents and specimens, and at the end of the workshift.

Observe universal precautions and other appropriate biosafety practices for handling potentially infectious material.

- **Breathing equipment:**

Normal use and storage of product - respiratory protection is not necessary if room is well ventilated.

Small-volume spills (e.g. small enough to clean up with a paper towel or small sorbent pad) - respiratory protection should not be necessary if room is well ventilated.

Other unusual conditions (e.g. volume spilled too big to clean up with materials in arm's reach) - Use appropriate
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air-purifying respirator if airborne chemical concentrations may exceed the exposure limit (if any) listed above.

Hazardous Materials Emergencies or Firefighting - use approved respiratory protection.

Take precautions if chemical concentrations exceed the exposure limits (if any) listed above.

· Hand protection

Wear impervious gloves if hand contact with the material is anticipated. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

· Material of gloves and breakthrough time of the glove material:

The glove material must be suitable for use in a microbiological laboratory and have a measured breakthrough time of at least 30 minutes, such as those with a Class 2 protection index per EN374 (or equivalent standard applicable in your region). NOTE: This recommendation applies only to the product stated in this Safety Data Sheet. When dissolving in or mixing with other substances, contact the supplier of approved gloves.

· Eye/face protection

Wear safety glasses or other protective eyewear. If splash potential exists, wear full face shield or goggles.

· Body protection:

Normal use: protect personal clothing from splatters and small spills. Wear a laboratory coat (or other protective clothing required by your institution). Larger spills (e.g. that can saturate cloth): wear appropriate water-repellant covering over clothing.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

| | |
|--|----------------|
| · Physical state | Solid |
| · Colour: | Brown |
| · Odour: | Odourless |
| · Odour threshold: | Not determined |
| · Melting point/freezing point: | Not determined |
| · Boiling point or initial boiling point and boiling range | Not determined |
| · Flammability | Not applicable |
| · Lower and upper explosion limit | |
| · Lower: | Not determined |
| · Upper: | Not determined |
| · Flash point: | Not applicable |
| · pH | Not applicable |

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- **Viscosity:**
 - **dynamic:** Not applicable
- **Solubility**
 - **Water:** Soluble
- **Vapour pressure:** Not applicable
- **Density and/or relative density**
 - **Density** Not determined
 - **Relative density:** Not determined
- **Particle characteristics** See item 3.

· 9.2 Other information

- **Appearance:**
 - **Form:** Lyophilized powder
 - **Auto igniting:** Product is not self-igniting.
 - **Explosive properties:** Product is a carbon-rich organic solid, and is presumed to be capable of producing a combustible dust.
 - **Solids content:** 100.0 %
- **Change in condition:**
 - **Evaporation rate:** Not applicable

- **Information with regard to physical hazard classes**
 - **Explosives** None
 - **Flammable gases** None
 - **Aerosols** None
 - **Oxidising gases** None
 - **Gases under pressure** None
 - **Flammable liquids** None
 - **Flammable solids** None
 - **Self-reactive substances and mixtures** None
 - **Pyrophoric liquids** None
 - **Pyrophoric solids** None
 - **Self-heating substances and mixtures** None
 - **Substances and mixtures, which emit flammable gases in contact with water** None
 - **Oxidising liquids** None
 - **Oxidising solids** None
 - **Organic peroxides** None
 - **Corrosive to metals** None
 - **Desensitised explosives** None

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SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability:**
 - **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
- **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.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
 - **Acute toxicity** Based on available data, the classification criteria are not met.
 - **LD/LC50 values that are relevant for classification:**

• **Ingredients (100% pure substance/s):**

CAS: 26027-38-3 Ethoxylated p-nonylphenol

| | | |
|------------|----------------------|--|
| Oral | LD50 | 1,310 mg/kg (rat) |
| Dermal | LD50 | >2,000 mg/kg (rabbit) |
| Inhalation | LC50 1 h | >200 mg/l species unknown |
| | Target Organ Effects | In reproductive studies in rats and rabbits it showed effects on fertility including pre-implantation mortality, reduced pup weight as well as some maternal effects. A 22 day subchronic mouse study indicated changes in liver and spleen weights, and weight loss in animals. |

- **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.
- **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.

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- **Target organs/systems:**

- Liver
- Gastrointestinal tract
- Spleen
- Reproductive system

- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

Endocrine disrupting effects caused by this substance have been observed in the environment. No adverse human health effects are known. See Section 12 for more information.

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 Endocrine disrupting properties**

4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO) degrade to 4-Nonylphenol, branched and linear, either already in wastewater treatment plants, or via further degradation processes in sediments (e.g. of aquatic bodies receiving the wastewater effluents) and soils (e.g. receiving sewage sludge). Available information for 4-NPnEO indicate that 4-NPnEO contribute to the 4-NP concentration in the environment. A significant amount is either degraded to 4-NP itself in waste water treatment plants or is released to rivers in a form which may undergo further degradation to 4-NP.

- **12.7 Other adverse effects:**

- **General notes:**

Do not allow product to reach ground water, water course, or sewage system.
Refer to applicable local regulations for limit values of discharge into sewage system.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**

There are no uniform EU regulations for the disposal of laboratory waste. In general, laboratory waste is under special supervision of the authorities.

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• **Recommendation for disposal of unused product:**

Dispose in accordance with federal, state and local regulations and institutional requirements. The following may be particularly important when identifying appropriate disposal:

- Potentially infectious. See Section 4, Information for Medical Personnel, for more information.
- See Section 6, Measures for cleaning/collecting for information when institutional or regulatory requirements include any sort of treatment of potentially infectious waste.

• **European waste catalogue:**

HP6 Acute Toxicity

• **The following waste disposal key numbers are possible:**

18 01 07: chemicals other than those mentioned in 18 01 06

• **Uncleaned packagings**

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

• **Recommendation for disposal of packaging:**

Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

- **Recommended cleaning agent:** Water with cleansing agents, if necessary.

SECTION 14: Transport information

• **14.1 UN number or ID number**

• ADR, ADN, IMDG, IATA None

• **14.2 UN proper shipping name**

• ADR, ADN, IMDG, IATA None

• **14.3 Transport hazard class(es)**

• ADR, ADN, IMDG, IATA
• Class None

• **14.4 Packing group**

• ADR, IMDG, IATA None

• **14.5 Environmental hazards**

• Marine pollutant: No

• **14.6 Special precautions for user** Not applicable

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14.7 Maritime transport in bulk according to IMO instruments

Transport/Additional information

ADR

Remarks:

Not restricted for transportation.

IMDG

Remarks:

Not restricted for transportation.

IATA

Remarks:

Not restricted for transportation.

SECTION 15: Regulatory information

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

Directive 2012/18/EU

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

LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV)

CAS: 26027-38-3 Ethoxylated p-nonylphenol

Sunset date: 2021-01-04

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 46b

Regulation (EU) No 649/2012

CAS: 26027-38-3 Ethoxylated p-nonylphenol

Annex I Part 1
Annex I Part 2

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Annex II

None of the ingredients is listed.

REGULATION (EU) 2019/1148

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

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- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

- **National regulations:**

- **Other regulations, limitations and prohibitive regulations:**

- **Substances of very high concern (SVHC) according to REACH, Article 57**

CAS: 26027-38-3 Ethoxylated p-nonylphenol

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

SECTION 16: Other information

The information and recommendations contained herein are based upon information or tests believed to be reliable. Abbott Laboratories does not guarantee the accuracy or completeness of this information or recommendations contained herein, NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE.

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The information in this Safety Data Sheet (SDS) reflects the most current hazard information for this product.

- **Complete text for H (Hazard) codes displayed in Section 3:**

Note: The respective H statements apply to the pure substances.

H302 Harmful if swallowed.

H319 Causes serious eye irritation.

- **Contact supplier**

Environmental Affairs & Product Safety

Tel.: +49 (0) 6122 58 0

- **Date of previous version:** 06.12.2022

- **Version number of previous version:** 17

- **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

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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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
SVHC: Substance of Very High Concern (REACH)
Acute Tox. 4: Acute toxicity ☐ Category 4
Eye Irrit. 2: Serious eye damage/eye irritation ☐ Category 2

· * **Data compared to the previous version altered.**

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