

ALP2

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : ALP2
Mat.-No./ Genisys-No. : 03333752190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
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Address : 9115 Hague Road
46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone number:

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or
Canada)
1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

GHS Label element

Hazard pictograms :



Signal word : Warning

Hazard statements : H315 Causes skin irritation.
H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 Take off contaminated clothing and wash before reuse.

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Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**R1(A / B)****GHS Classification**

Skin irritation, Category 2

H315: Causes skin irritation.

Eye irritation, Category 2A

H319: Causes serious eye irritation.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
2-amino-2-methylpropanol	124-68-5	≥ 10 - < 20

R2(C)**GHS Classification**

Eye irritation, Category 2A

H319: Causes serious eye irritation.

Hazardous components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.
Do not leave the victim unattended.
- If inhaled : Move to fresh air.
If unconscious place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- In case of skin contact : If skin irritation persists, call a physician.
If on skin, rinse well with water.
If on clothes, remove clothes.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Rinse mouth with water.
- Most important symptoms and effects, both acute and : No information available.

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delayed

Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during firefighting : Do not allow run-off from fire fighting to enter drains or water courses.
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Refer to protective measures listed in sections 7 and 8.
- Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : Do not breathe vapours/dust.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Electrical installations / working materials must comply with

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the technological safety standards.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**R1(A / B)****Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

R2(C)**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

Personal protective equipment**Hand protection**

In case of contact through splashing:

Material	: Gloves
Break through time	: > 480 min
Glove thickness	: 0.1 mm
Remarks	: The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Eye protection	: Eye wash bottle with pure water Tightly fitting safety goggles Wear face-shield and protective suit for abnormal processing problems.
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Skin and body protection	: impervious clothing Choose body protection according to the amount and concentration of the dangerous substance at the work place.
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Hygiene measures	: When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.
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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**R1(A / B)**

Appearance	: liquid
pH	: 10.44, (20 °C)
Flash point	: does not flash
Flammability (solid, gas)	: The product is not flammable.

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Density : 1.003 - 1.0053 g/cm³

Solubility(ies)
Water solubility : completely miscible

Thermal decomposition : No data available

Oxidizing properties : The substance or mixture is not classified as oxidizing.

R2(C)

Appearance : liquid

pH : ca. 8.5, (25 °C)

Flash point : does not flash

Flammability (solid, gas) : The product is not flammable.

Density : 1.0 - 1.0175 g/cm³

Solubility(ies)
Water solubility : completely miscible

Thermal decomposition : No data available

Oxidizing properties : The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : No decomposition if stored and applied as directed.

Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION**R1(A / B)****Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg
Method: Calculation method

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Components:**2-amino-2-methylpropanol:**

Acute oral toxicity : LD50 Oral (Rat): 2,900 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): > 2,000 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Product:

Remarks: May cause skin irritation in susceptible persons.

Components:**2-amino-2-methylpropanol:**

Result: Irritating to skin.

Remarks: May cause skin irritation in susceptible persons.

Serious eye damage/eye irritation

Causes serious eye irritation.

Product:

Remarks: May cause irreversible eye damage.

Components:**2-amino-2-methylpropanol:**

Result: Irritating to eyes.

Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:**2-amino-2-methylpropanol:**

Species: Guinea pig

Method: OECD Test Guideline 406

Remarks: Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity

Not classified based on available information.

Components:**2-amino-2-methylpropanol:**

Genotoxicity in vitro : Test Type: Ames test

Result: negative

Carcinogenicity

Not classified based on available information.

IARC

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

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ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

Components:**2-amino-2-methylpropanol:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

Not classified based on available information.

Components:**2-amino-2-methylpropanol:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

Components:**2-amino-2-methylpropanol:**

No aspiration toxicity classification

R2(C)**Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: May cause skin irritation in susceptible persons.

Serious eye damage/eye irritation

Causes serious eye irritation.

Product:

Result: Irritating to eyes.

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Remarks: May cause irreversible eye damage.

Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION**R1(A / B)****Ecotoxicity****Product:**

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Components:

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2-amino-2-methylpropanol:

- Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 190 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : (Daphnia magna (Water flea)): 193 mg/l
Exposure time: 48 h

(Daphnia magna (Water flea)): 65 mg/l
Exposure time: 24 h
Method: OECD Test Guideline 202
- Toxicity to algae : IC50 (Desmodesmus subspicatus (green algae)): 520 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
- Toxicity to bacteria : EC50 (Bacteria): 132 mg/l
- Ecotoxicology Assessment
Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

Persistence and degradability**Components:****2-amino-2-methylpropanol:**

- Biodegradability : Result: Not readily biodegradable.
Biodegradation: 40 %
Exposure time: 28 d
Method: OECD Test Guideline 301
Remarks: According to the results of tests of biodegradability this product is not readily biodegradable.
- Biodegradation: 50 %
Exposure time: 28 d
Method: OECD Test Guideline 302

Bioaccumulative potential**Components:****2-amino-2-methylpropanol:**

- Bioaccumulation : Remarks: Does not bioaccumulate.
- Partition coefficient: n-octanol/water : log Pow: -0.63

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation

40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances

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Remarks

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological information

: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.

Components:**2-amino-2-methylpropanol:****Additional ecological information**

: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

R2(C)**Ecotoxicity****Product:****Ecotoxicology Assessment****Toxicity Data on Soil**

: Not expected to adsorb on soil.

Other organisms relevant to the environment

: No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

Product:**Regulation**

40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods****Waste from residues**

: The product should not be allowed to enter drains, water courses or the soil.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.

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Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION**International Regulation****IATA-DGR**

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

National Regulations**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**R1(A / B)****EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

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This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

2-amino-2-methylpropanol	124-68-5	10 - 20 %
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Pennsylvania Right To Know

water	7732-18-5	70 - 90 %
2-amino-2-methylpropanol	124-68-5	10 - 20 %

New Jersey Right To Know

water	7732-18-5	70 - 90 %
2-amino-2-methylpropanol	124-68-5	10 - 20 %

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

R2(C)**EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium hydroxide	1310-73-2	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

sodium hydroxide	1310-73-2	0.6 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

sodium hydroxide	1310-73-2	0.6 %
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This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

sodium azide	26628-22-8	0 - 0.1 %
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Pennsylvania Right To Know

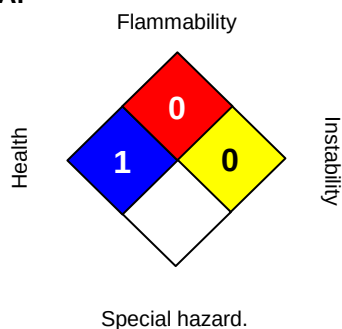
water	7732-18-5	90 - 100 %
p-nitrophenyl dihydrogen phosphate, compound with 2-amino-2- (hydroxymethyl)propane-1,3-diol (1:2)	68189-42-4	5 - 10 %
sodium hydroxide	1310-73-2	0.1 - 1 %
sodium azide	26628-22-8	0 - 0.1 %

New Jersey Right To Know

water	7732-18-5	90 - 100 %
p-nitrophenyl dihydrogen phosphate, compound with 2-amino-2- (hydroxymethyl)propane-1,3-diol (1:2)	68189-42-4	5 - 10 %

California Prop 65

: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

SECTION 16. OTHER INFORMATION**Further information****R1(A / B)****NFPA:****HMIS III:**

HEALTH	2
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

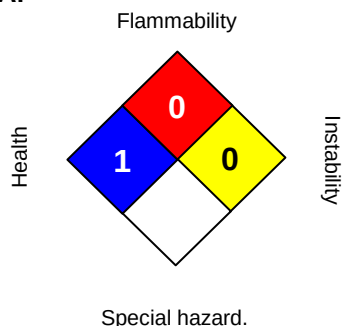
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NFPA:**HMIS III:**

HEALTH	2
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.