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

1.1 Product identifier

Commercial Product Name : ALP2
Mat.-No./ Genisys-No. : 03333752190

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

Recommended restrictions on use : For professional users only.

1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH
-
Sandhoferstrasse 116
68305 Mannheim
E-mail address : mannheim.umweltschutz@roche.com
Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-2012+49(0)621-759-4848+49(0)8856-60-2629

1.4 Emergency telephone number

In case of emergencies:	:	Central Works Security Roche Diagnostics GmbH	+49(0)621-759-2203
Centre for detoxification:	:	Mainz Munich	+49(0)6131-19240 +49(0)89-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Warning

Hazard statements	:	H315	Causes skin irritation.
		H319	Causes serious eye irritation.
		H412	Harmful to aquatic life with long lasting effects.
Precautionary statements	:	**Prevention:**	
		P273	Avoid release to the environment.

P280	Wear eye protection/ face protection.
P280	Wear protective gloves.
Response:	
P362 + P364	Take off contaminated clothing and wash it before reuse.

2.3 Other hazards

No information available.

SECTION 3: Composition/information on ingredients

R1(A / B)

Classification (REGULATION (EC) No 1272/2008)

Skin irritation, Category 2	H315: Causes skin irritation.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Chronic aquatic toxicity, Category 3	H412: Harmful to aquatic life with long lasting effects.

Classification (67/548/EEC, 1999/45/EC)

Irritant	R36/38: Irritating to eyes and skin.

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
2-amino-2-methylpropanol	124-68-5 204-709-8	Xi; R36/38 R52-R53	Skin Irrit. 2; H315 Eye Irrit. 2; H319 Aquatic Chronic 3; H412	>= 10 - < 20
zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate)	7446-20-0 231-793-3	Xn; Xn; R22 Xi; Xi; R41 N; R50/53	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	< 0,1

For explanation of abbreviations see section 16.

R2(C)

Classification (REGULATION (EC) No 1272/2008)

Skin irritation, Category 2	H315: Causes skin irritation.
Eye irritation, Category 2	H319: Causes serious eye irritation.

Classification (67/548/EEC, 1999/45/EC)

Irritant	R36/38: Irritating to eyes and skin.

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
sodium hydroxide	1310-73-2 215-185-5	C; R35	Met. Corr. 1; H290 Skin Corr. 1A; H314	>= 0,5 - < 1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

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

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Do not allow run-off from fire fighting to enter drains or water courses.

5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Refer to protective measures listed in sections 7 and 8.

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Hygiene measures : When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : 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 the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

Storage class (TRGS 510) : 12, Non Combustible Liquids

Other data : No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

R1(A / B)

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
2-amino-2-methylpropanol	124-68-5	AGW (Vapour and aerosols)	1 ppm 4,6 mg/m3	DE TRGS 900
Peak-limit: excursion factor (category)	2;(I)			
Further information	Commission for dangerous substances, Sum of vapor and aerosols.			

R2(C)

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Personal protective equipment

Eye protection : Eye wash bottle with pure water

Tightly fitting safety goggles
Wear face-shield and protective suit for abnormal processing problems.

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.

Skin and body protection : impervious clothing
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

R1(A / B)

Appearance	:	liquid
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	10,44 (20 °C)
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	The product is not flammable., Does not sustain combustion.
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	1,003 - 1,0053 g/cm3

Solubility(ies)
Water solubility : completely miscible

Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available

Viscosity : No data available
Explosive properties : No data available
Oxidizing properties : The substance or mixture is not classified as oxidizing.

R2(C)

Appearance : liquid

Colour : No data available
Odour : No data available
Odour Threshold : No data available
pH : ca. 8,5 (25 °C)

Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : does not flash

Evaporation rate : No data available
Flammability (solid, gas) : The product is not flammable., Does not sustain combustion.

Upper explosion limit : No data available
Lower explosion limit : No data available
Vapour pressure : No data available
Relative vapour density : No data available
Relative density : No data available
Density : 1,0 - 1,0175 g/cm3

Solubility(ies)
Water solubility : completely miscible

Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available

Viscosity : No data available
Explosive properties : No data available
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

R1(A / B)

No data available

R2(C)

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : No decomposition if stored and applied as directed.

10.4 Conditions to avoid

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : No data available

10.6 Hazardous decomposition products

No data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

R1(A / B)

Acute toxicity

Not classified based on available information.

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

zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate):

Acute oral toxicity : LD50 Oral (Rat): 1.260 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Components:

2-amino-2-methylpropanol:

Result: Irritating to skin.

Remarks: May cause skin irritation in susceptible persons.

zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate):
Remarks: No data available

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

2-amino-2-methylpropanol:
Result: Irritating to eyes.
Remarks: May cause irreversible eye damage.

zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate):
Result: Risk of serious damage 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.

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, repeat-

ed exposure.

Aspiration toxicity

Not classified based on available information.

Components:

2-amino-2-methylpropanol:
No aspiration toxicity classification

R2(C)

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Causes skin irritation.

Components:

sodium hydroxide:
Remarks: Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

sodium hydroxide:
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.

Components:

sodium hydroxide:
Genotoxicity in vitro : Test Type: Ames test
Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

sodium hydroxide:
Effects on fertility :
Remarks: No data available

STOT - single exposure

Not classified based on available information.

Components:

sodium hydroxide:
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:

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

Aspiration toxicity

Not classified based on available information.

SECTION 12: Ecological information

12.1 Toxicity

R1(A / B)

Components:

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

zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate):

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 0,1 mg/l Exposure time: 96 h
Toxicity to algae	:	IC50 (Scenedesmus quadricauda (Green algae)): 0,52 mg/l Exposure time: 120 h Test substance: anhydrous substance
Ecotoxicology Assessment Acute aquatic toxicity	:	Very toxic to aquatic life.

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

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

Other organisms relevant to the environment : No data available

R2(C)

Components:

sodium hydroxide:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 45,4 mg/l
Exposure time: 96 h

LC50 (Leuciscus idus (Golden orfe)): ca. 7 mg/l

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 40,38 mg/l
Exposure time: 48 h

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

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

Other organisms relevant to the environment : No data available

12.2 Persistence and degradability

R1(A / B)

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

R2(C)

No data available

12.3 Bioaccumulative potential

R1(A / B)

Components:

2-amino-2-methylpropanol:

Bioaccumulation : Remarks: Does not bioaccumulate.

Partition coefficient: n-octanol/water : log Pow: -0,63

R2(C)

No data available

12.4 Mobility in soil

R1(A / B)

No data available

R2(C)

No data available

12.5 Results of PBT and vPvB assessment

R1(A / B)

Not relevant

R2(C)

Not relevant

12.6 Other adverse effects

R1(A / B)

Components:

2-amino-2-methylpropanol:

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

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

zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate):

Additional ecological information : Remarks: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Very toxic to aquatic life with long lasting effects.

R2(C)

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : 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.

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

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADNR, IMDG-Code, ICAO/IATA-DGR

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

Remarks : Not applicable

SECTION 15: Regulatory information

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

Seveso II - Directive 2003/105/EC amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances
Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Water contaminating class (Germany) : WGK 1 slightly water endangering

R1(A / B)

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Warning

Hazard statements	:		
		H315	Causes skin irritation.
		H319	Causes serious eye irritation.
		H412	Harmful to aquatic life with long lasting effects.

Precautionary statements	:		
		Prevention:	
		P264	Wash skin thoroughly after handling.
		P273	Avoid release to the environment.
		P280	Wear eye protection/ face protection.
		P280	Wear protective gloves.
		Response:	
		P337 + P313	If eye irritation persists: Get medical advice/ attention.
		Disposal:	
		P501	Dispose of contents/ container to an approved waste disposal plant.

R2(C)

Labelling (REGULATION (EC) No 1272/2008)

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 eye protection/ face protection.
		P280	Wear protective gloves.
		Response:	
		P332 + P313	If skin irritation occurs: Get medical advice/ attention.
		P337 + P313	If eye irritation persists: Get medical advice/ attention.
		P362 + P364	Take off contaminated clothing and wash it before reuse.

15.2 Chemical Safety Assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

SECTION 16: Other information

Full text of R-Phrases

R22	:	Harmful if swallowed.
R35	:	Causes severe burns.
R36/38	:	Irritating to eyes and skin.
R41	:	Risk of serious damage to eyes.
R50/53	:	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R52	:	Harmful to aquatic organisms.
R53	:	May cause long-term adverse effects in the aquatic environment.

Full text of H-Statements

H290	:	May be corrosive to metals.
H302	:	Harmful if swallowed.
H314	:	Causes severe skin burns and eye damage.
H315	:	Causes skin irritation.
H318	:	Causes serious eye damage.
H319	:	Causes serious eye irritation.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.
H412	:	Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Acute aquatic toxicity
Aquatic Chronic	:	Chronic aquatic toxicity
Eye Dam.	:	Serious eye damage
Eye Irrit.	:	Eye irritation
Met. Corr.	:	Corrosive to metals
Skin Corr.	:	Skin corrosion
Skin Irrit.	:	Skin irritation

Further information

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.

DE / EN