



09/07/2016

Kit Components

Product code	Description
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12003121	PIK3CA Rare Mutation Detection Kit
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Components:

12003214	PIK3CA Deletions Screening Assay
1863023	ddPCR™ Supermix for Probes (no dUTP)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/07/2016

Reviewed on 06/20/2016

1 Identification

- **Product identifier**
- **Trade name:** PIK3CA Deletions Screening Assay
- **Catalog or product number:** 12003214
- **Application of the substance / the mixture** Laboratory chemicals
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Bio-Rad Laboratories, Life Science Group
2000 Alfred Nobel Drive
Hercules, California 94547 (510)741-1000
- **Information department:**
Technical services, customer support
lsg_techserv_us@bio-rad.com
- **Emergency telephone number:**
1(800)424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT.
510-741-1000

2 Hazard(s) identification

- **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:** Contact with acids may cause release of toxic gases
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with non-hazardous additions.
- **Listing of dangerous and non-hazardous components:** Void
- **Additional information** For the wording of the listed risk phrases refer to section 15.

4 First-aid measures

- **Description of first aid measures**
- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing** Induce vomiting and call for medical help.
- **Information for doctor**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.

(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/07/2016

Reviewed on 06/20/2016

Trade name: **PIK3CA Deletions Screening Assay**

(Contd. of page 1)

· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling**
- **Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** According to product specification
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures** The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not required.

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/07/2016

Reviewed on 06/20/2016

Trade name: PIK3CA Deletions Screening Assay

(Contd. of page 2)

- **Protection of hands:** Protective gloves.
- **Material of gloves:** Synthetic gloves
- **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.
- **Eye protection:** Safety glasses

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

- **Form:** Liquid
- **Color:** Pink
- **Odor:** Odorless
- **Odor threshold:** Not determined.

· **pH-value at 20 °C:** 7

· **Change in condition**

- **Melting point/Melting range:** undetermined
- **Boiling point/Boiling range:** 100 °C

· **Flash point:** Not applicable

· **Flammability (solid, gaseous):** Not applicable.

· **Ignition temperature:**

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

- **Lower:** Not determined.
- **Upper:** Not determined.

· **Vapor pressure at 20 °C:** 23 hPa

- **Density:** Not determined
- **Relative density:** Not determined.
- **Vapor density:** Not determined.
- **Evaporation rate:** Not determined.

· **Solubility in / Miscibility with**

· **Water:** Not determined.

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

- **dynamic:** Not determined.
- **kinematic:** Not determined.

· **Solvent content:**

· **Organic solvents:** 0.0 %

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/07/2016

Reviewed on 06/20/2016

Trade name: PIK3CA Deletions Screening Assay

(Contd. of page 3)

Water:	99.8 %
Solids content:	0.2 %
Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.
- **NTP (National Toxicology Program)**
None of the ingredients is listed.
- **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.
- **Target organs:** Not applicable.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water.

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/07/2016

Reviewed on 06/20/2016

Trade name: PIK3CA Deletions Screening Assay

(Contd. of page 4)

- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Hand over to hazardous waste disposers.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Void
- **UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** Void
- **Transport hazard class(es)**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class** Void
- **Packing group**
- **DOT, ADR, IMDG, IATA** Void
- **Environmental hazards:** Not applicable.
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
- **UN "Model Regulation":** Void

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **SARA (Superfund Amendants and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**

None of the ingredients is listed.

· **Section 313 (40CFR372.65):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

77-86-1 Tris(hydroxymethyl)aminomethane

60-00-4 ethylenediaminetetraacetic acid

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/07/2016

Reviewed on 06/20/2016

Trade name: PIK3CA Deletions Screening Assay

(Contd. of page 5)

7732-18-5 water

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **MAK (German Maximum Workplace Concentration)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Generally not hazardous for water.

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

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.

· **Contact:**

Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000

· **Date of preparation / last revision** 09/07/2016 / -

· **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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

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

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/07/2016

Reviewed on 06/06/2016

1 Identification

- **Product identifier**
- **Trade name:** ddPCR™ Supermix for Probes (no dUTP)
- **Catalog or product number:**
1863023, 1863024, 1863025, 10026768, 10026710, 29011720, 10033082, 10033083, 10026767, 10026708, 10026709, 10033081
- **Application of the substance / the mixture** Laboratory chemicals
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Bio-Rad Laboratories, Life Science Group
2000 Alfred Nobel Drive
Hercules, California 94547 (510)741-1000
- **Information department:**
Technical services, customer support
lsg_techserv_us@bio-rad.com
- **Emergency telephone number:**
1(800)424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT.
510-741-1000

2 Hazard(s) identification

- **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:** Contact with acids may cause release of toxic gases
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:**

Proprietary Reagent K	Eye Irrit. 2A, H319	1.0-2.5%
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- **Additional information** For the wording of the listed risk phrases refer to section 15.

4 First-aid measures

- **Description of first aid measures**
- **After inhalation** Supply fresh air; consult doctor in case of complaints.

(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/07/2016

Reviewed on 06/06/2016

Trade name: ddPCR™ Supermix for Probes (no dUTP)

(Contd. of page 1)

- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing** Induce vomiting and call for medical help.
- **Information for doctor**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling**
- **Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** According to product specification
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/07/2016

Reviewed on 06/06/2016

Trade name: ddPCR™ Supermix for Probes (no dUTP)

(Contd. of page 2)

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures** The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not required.
- **Protection of hands:** Protective gloves.
- **Material of gloves** Synthetic gloves
- **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.
- **Eye protection:** Safety glasses

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:	Liquid
Color:	Colorless
Odor:	Odorless
Odor threshold:	Not determined.

· **pH-value at 20 °C:** 8.3

· **Change in condition**

Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined

· **Flash point:** Not applicable

· **Flammability (solid, gaseous)** Not applicable.

· **Ignition temperature:** 400 °C

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower:	0.9 Vol %
Upper:	0.0 Vol %

· **Vapor pressure at 20 °C:** 23 hPa

· **Density:** Not determined

· **Relative density** Not determined.

· **Vapor density** Not determined.

· **Evaporation rate** Not determined.

· **Solubility in / Miscibility with**

Water: Fully miscible

· **Partition coefficient (n-octanol/water):** Not determined.

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/07/2016

Reviewed on 06/06/2016

Trade name: ddPCR™ Supermix for Probes (no dUTP)

(Contd. of page 3)

- **Viscosity:**
 - dynamic:** Not determined.
 - kinematic:** Not determined.
- **Solvent content:**
 - Organic solvents:** 15.4 %
 - Water:** 77.0 %
- **Solids content:** 4.1 %
- **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.
- **NTP (National Toxicology Program)**
None of the ingredients is listed.
- **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.
- **Target organs:** Not applicable.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/07/2016

Reviewed on 06/06/2016

Trade name: ddPCR™ Supermix for Probes (no dUTP)

(Contd. of page 4)

- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

US
(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/07/2016

Reviewed on 06/06/2016

Trade name: ddPCR™ Supermix for Probes (no dUTP)

(Contd. of page 5)

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- SARA (Superfund Amendments and Reauthorization Act of 1986 - USA)

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**

Proprietary Reagent D

· **Section 313 (40CFR372.65):**

Proprietary Reagent SR 2

Proprietary Reagent D

· **TSCA (Toxic Substances Control Act):**

Proprietary Reagent J11

Proprietary Ingredient PW2

Proprietary Reagent K

Proprietary Reagent PW1

Proprietary Reagent MK10

Proprietary Reagent KL

Proprietary Reagent SR 2

Proprietary Reagent D

7732-18-5 water

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **MAK (German Maximum Workplace Concentration)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **National regulations**

· **Technical instructions (air):**

Class	Share in %
NK	10-20

- **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:** Environmental Health and Safety.

(Contd. on page 7)

Safety Data Sheet
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Trade name: ddPCR™ Supermix for Probes (no dUTP)

(Contd. of page 6)

· Contact:

Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000

· Date of preparation / last revision 09/07/2016 / -**· 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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

· * Data compared to the previous version altered.