



11/06/2018

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
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1863023	ddPCR™ Supermix for Probes (no dUTP)
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Safety Data Sheet

acc. to OSHA HCS

Printing date 11/06/2018

Reviewed on 03/08/2018

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:** 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
- **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**
- **General information** No special measures required.
- **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** Rinse mouth with water. Seek medical attention and appropriate follow-up.
- **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 11/06/2018

Reviewed on 03/08/2018

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** Use fire fighting measures that suit the environment.
- **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.
- **Protective Action Criteria for Chemicals**

· **PAC-1:**

None of the ingredients is listed.

· **PAC-2:**

None of the ingredients is listed.

· **PAC-3:**

None of the ingredients is listed.

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.

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/06/2018

Reviewed on 03/08/2018

Trade name: PIK3CA Deletions Screening Assay

(Contd. of page 2)

- **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.
- **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.

· **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.

(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/06/2018

Reviewed on 03/08/2018

Trade name: PIK3CA Deletions Screening Assay

(Contd. of page 3)

- **Solubility in / Miscibility with Water:** *Not determined.*
- **Partition coefficient (n-octanol/water):** *Not determined.*
- **Viscosity:**
 - dynamic:** *Not determined.*
 - kinematic:** *Not determined.*
- **Solvent content:**
 - 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.*
 - on the eye:** *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.

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/06/2018

Reviewed on 03/08/2018

Trade name: PIK3CA Deletions Screening Assay

(Contd. of page 4)

· **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.
- **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** Dispose of waste in accordance to applicable national, regional, or local regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | Void |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | Void |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | Void |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Class | Void |
| · Packing group | Void |
| · 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 |

US

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/06/2018

Reviewed on 03/08/2018

Trade name: PIK3CA Deletions Screening Assay

(Contd. of page 5)

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

7732-18-5 water

· **California Proposition 65:**

None of the ingredients is listed.

· **Chemicals known to cause cancer:**

The product does not contain listed components.

· **Developmental Toxicity**

None of the ingredients is listed.

· **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** 11/06/2018 / -

(Contd. on page 7)

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/06/2018

Reviewed on 03/08/2018

Trade name: PIK3CA Deletions Screening Assay

(Contd. of page 6)

· 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 11/06/2018

Reviewed on 11/06/2018

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:** 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
- **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 | 1-2.5% |
|-----------------------|---------------------|--------|
- **Additional information** For the wording of the listed risk phrases refer to section 15.

4 First-aid measures

- **Description of first aid measures**
- **General information** No special measures required.
- **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** Rinse mouth with water. Seek medical attention and appropriate follow-up.

(Contd. on page 2)

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/06/2018

Reviewed on 11/06/2018

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

(Contd. of page 1)

- **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** Use fire fighting measures that suit the environment.
- **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.
- **Protective Action Criteria for Chemicals**

· **PAC-1:**

None of the ingredients is listed.

· **PAC-2:**

None of the ingredients is listed.

· **PAC-3:**

None of the ingredients is listed.

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.

US

(Contd. on page 3)

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/06/2018

Reviewed on 11/06/2018

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

(Contd. of page 2)

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.
Not necessary if room is well-ventilated. Adequate ventilation 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
Not determined.
- **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.
Not determined.
- **Explosion limits:**

Lower:	0.9 Vol %
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(Contd. on page 4)

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/06/2018

Reviewed on 11/06/2018

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

(Contd. of page 3)

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.
· 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.
- **on the eye:** 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.

(Contd. on page 5)

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/06/2018

Reviewed on 11/06/2018

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

(Contd. of page 4)

· **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:**

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.

Dispose of waste in accordance to applicable national, regional, or local regulations.

· **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

(Contd. on page 6)

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/06/2018

Reviewed on 11/06/2018

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

(Contd. of page 5)

- **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

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):**

None of the ingredients is listed.

· **Section 313 (40CFR372.65):**

None of the ingredients is listed.

· **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

· **California Proposition 65:**

None of the ingredients is listed.

· **Chemicals known to cause cancer:**

The product does not contain listed components.

· **Developmental Toxicity**

None of the ingredients is listed.

· **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.

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS

Printing date 11/06/2018

Reviewed on 11/06/2018

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

(Contd. of page 6)

· **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.

· **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** 11/06/2018 / -

· **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.**