

SAFETY DATA SHEETS

This SDS packet was issued with item:

074576963

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

074576930 074576948 075217724


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

- **Product identifier**
- **Trade name:** CLEARFIL SE Protect ; PRIMER
- **Article number:** US092-P
- **Application of the substance / the preparation** Dental bonding material
- **Details of the supplier of the safety data sheet**
- **Manufacturer:**
Kuraray Noritake Dental Inc.
1621 Sakazu, Kurashiki, Okayama 710-0801,
Japan
- **Contact information:**
Kuraray America, Inc.
33 Maiden Lane, 6th Floor, New York,
NY 10038 U.S.A.
Tel: 800-879-1676
Fax: 888-700-5200
Website: www.kuraraydental.com

2 Composition/information on ingredients

- **Chemical characterization:** Single Component
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

868-77-9	2-hydroxyethyl methacrylate	 H315; H319; H317	25-45%
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- **Other ingredients:**
10-Methacryloyloxydecyl dihydrogen phosphate
12-Methacryloyloxydodecylpyridinium bromide
Hydrophilic aliphatic dimethacrylate
Water
Initiators
Accelerators
Dyes
Others

3 Hazards identification

· **Classification of the substance or mixture**



GHS05 Corrosion

H314 Causes severe skin burns and eye damage.



GHS07

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



Irritant

Irritating to eyes and skin. May cause sensitisation by skin contact.

· **Information concerning particular hazards for human and environment:**

The product has to be labelled due to the calculation procedure of international guidelines.

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USA

Trade name: CLEARFIL SE Protect ; PRIMER

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· **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· **Label elements**

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonized System (GHS).

· **Hazard pictograms** GHS05, GHS07

· **Signal word** Danger

· **Hazard-determining components of labelling:**

2-hydroxyethyl methacrylate

· **Hazard statements**

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

· **Precautionary statements**

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or doctor/physician.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 1

Fire = 1

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 1

Fire = 1

Reactivity = 0

4 First aid measures

· **After inhalation:**

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:**

Do not induce vomiting; immediately call for medical help.

If symptoms persist consult doctor.

5 Firefighting measures

· **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.

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Printing date 05/07/2012

Reviewed on 04/01/2012

Trade name: CLEARFIL SE Protect ; PRIMER

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- **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **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**
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**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about protection against explosions and fires:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a refrigerator (2-8°C).
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **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.
- **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.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the

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USA

Trade name: CLEARFIL SE Protect ; PRIMER

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application.

· **Penetration time of glove material**

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

9 Physical and chemical properties

· **General Information**

· **Appearance:**

Form: Liquid
Color: Transparent
Blue

· **Odor:** Odorless

· **pH-value:** 2.0

· **Change in condition**

Melting point/Melting range: -12 °C (2-hydroxyethyl methacrylate)
Boiling point/Boiling range: 205 °C (2-hydroxyethyl methacrylate)

· **Flash point:** 97 °C (2-hydroxyethyl methacrylate)

· **Ignition temperature:** Not applicable

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

· **Explosion limits:**

Lower: Not applicable
Upper: Not applicable

· **Vapor pressure:** Not applicable

· **Density:** 1.1 g/cm³ (9.18 lbs/gal)

· **Vapour density:** Not applicable

· **Solubility in / Miscibility with**

Water: Not miscible or difficult to mix.

· **Segregation coefficient (n-octanol/water):** Not applicable

· **Other information:** No further relevant information available.

10 Stability and reactivity

· **Thermal decomposition / conditions to be avoided:**

No decomposition if used and stored according to specifications.

· **Incompatible materials:** No further relevant information available.

· **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

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Trade name: CLEARFIL SE Protect ; PRIMER

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11 Toxicological information

· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

868-77-9 2-hydroxyethyl methacrylate

Oral	LD50	4680 mg/kg (guinea pig)
		3275 mg/kg (mouse)
		5050 mg/kg (rat)

· **Primary irritant effect:**

· **on the skin:** Irritant to skin and mucous membranes.

· **on the eye:** Irritating effect.

· **Sensitization:** Sensitization possible through skin contact.

· **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

12 Ecological information

· **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.

· **Additional ecological information:**

· **General notes:**

Water hazard class 1 (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.

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** Void

· **Class**

Void

· **Packing group**

· **DOT, ADR, IMDG, IATA** Void

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Trade name: CLEARFIL SE Protect ; PRIMER

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- **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":** -

15 Regulatory information

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredient is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

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

All ingredients are listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogeny categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

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.

· **Version: 2**

· **Relevant phrases**

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

1 Identification

- **Product identifier**
- **Trade name:** CLEARFIL SE Protect ; PRIMER
- **Article number:** US092-P
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Dental bonding material
- **Details of the supplier of the safety data sheet**
- **Manufacturer:**
Kuraray Noritake Dental Inc.
1621 Sakazu, Kurashiki, Okayama 710-0801,
Japan
- **Contact information:**
Kuraray America, Inc.
33 Maiden Lane, 6th Floor, New York,
NY 10038 U.S.A.
Tel: 800-879-1676
Fax: 888-700-5200
Website: www.kuraraydental.com
- **Emergency telephone number:**
For chemical emergency spill, leak, fire, exposure or accident
Call CHEMTREC day and night
Within USA and Canada: 1-800-424-9300 CCN706984 or
+1 703-527-3887 (collect calls accepted)

2 Hazard(s) identification

- **Classification of the substance or mixture**



- Skin Irrit. 2 H315 Causes skin irritation.
- Eye Irrit. 2A H319 Causes serious eye irritation.
- Skin Sens. 1 H317 May cause an allergic skin reaction.

- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labeling:**
2-hydroxyethyl methacrylate
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
- **Precautionary statements**

P261	Avoid breathing dust/fume/gas/mist/vapors/spray
P264	Wash thoroughly after handling.
P280	Wear protective gloves / eye protection / face protection.
P302+P352	IF ON SKIN: Wash with plenty of 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.
P321	Specific treatment (see on this label).
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.

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Trade name: CLEARFIL SE Protect ; PRIMER

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- P363 Wash contaminated clothing before reuse.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Substances** None
- **Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

Dangerous components:

868-77-9	2-hydroxyethyl methacrylate	25-45%
	⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317	

- **Other ingredients:**
- 10-Methacryloyloxydecyl dihydrogen phosphate
- 12-Methacryloyloxydodecylpyridinium bromide
- Hydrophilic aliphatic dimethacrylate
- Water
- Initiators
- Accelerators
- Dyes

4 First-aid measures

- **Description of first aid measures**
- **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**
Do not induce vomiting; immediately call for medical help.
If symptoms persist consult doctor.
- **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:**
Wear self-contained respiratory protective device.

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Printing date 08/08/2017

Version 3

Reviewed on 08/08/2017

Trade name: CLEARFIL SE Protect ; PRIMER

Wear fully protective suit.

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6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** See Section 8.
- **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**
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**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **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:** Store in a refrigerator (2-8 °C).
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.
- **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:**
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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Trade name: CLEARFIL SE Protect ; PRIMER

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Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

· Form:	Liquid
· Color:	Blue
· Odor:	Odorless

· **pH-value:** <2.5

· **Change in condition**

· Melting point/Melting range:	-12 °C (2-hydroxyethyl methacrylate)
· Boiling point/Boiling range:	205 °C (2-hydroxyethyl methacrylate)

· **Flash point:** 97 °C (2-hydroxyethyl methacrylate)

· **Ignition temperature:** Not determined

· **Decomposition temperature:** Not determined

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

· **Explosion limits:**

· Lower:	Not determined
· Upper:	Not determined

· **Oxidizing properties** Not determined

· **Vapor pressure:** Not determined

· **Density:** 1.1 g/cm³

· **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:** Not determined

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Trade name: CLEARFIL SE Protect ; PRIMER

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· **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 and stored 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:** Carbon monoxide and carbon dioxide

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

868-77-9 2-hydroxyethyl methacrylate

Oral	LD50	4680 mg/kg (guinea pig)
		3275 mg/kg (mouse)
		5050 mg/kg (rat)

- **Primary irritant effect:**
- **on the skin:** Irritating effect
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant
- **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.

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 (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.

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Trade name: CLEARFIL SE Protect ; PRIMER

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- **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

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

· Section 355 (extremely hazardous substances):
None of the ingredient is listed.
· Section 313 (Specific toxic chemical listings):
None of the ingredients is listed.
· TSCA (Toxic Substances Control Act):
All ingredients are listed.
· Proposition 65
· Chemicals known to cause cancer:
None of the ingredients is listed.
· Chemicals known to cause reproductive toxicity for females:
None of the ingredients is listed.

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Trade name: CLEARFIL SE Protect ; PRIMER

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· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

· **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.

· **Relevant phrases**

- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.

· **NFPA ratings (scale 0 - 4)**



Health = 1
Fire = 1
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 1
Fire = 1
Reactivity = 0

· **Abbreviations and acronyms:**

- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
- Skin Sens. 1: Skin sensitisation – Category 1

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