

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 09.09.2016

Version number 6

Revision: 01 09 2016

nting date 09.09.2016	Version number 6	Revision: 01.09.2016
SECTION 1: Identificati	on of the substance/mixture and of	the company/undertaking
1.1 Product identifier		
Trade name: CLEARFIL SE	Protect ; BOND	
No further relevant information	the substance or mixture and uses advised	d against
1.3 Details of the supplier of the	he safety data sheet	
1.4 Emergency telephone num National Poisons information Se Guy's & St. Thomas' Hospital T Medical Toxicology Unit Avonley Road LONDON SE14 5ER	le from: Manufacturer or Supplier ber: ervice (London Centre) Trust 870 600 6266 or +44 20 7771 5394 20 7 771 53 10	
SECTION 2: Hazards id	antification	
	entitication	

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

· 2.2 Label elements

· Labelling according to Regulation (EC) No 1272/2008

- The product is classified and labelled according to the CLP regulation.
- Hazard pictograms GHS07 Signal word Warning
- · Hazard-determining components of labelling:

2-hydroxyethyl methacrylate

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Trade name: CLEARFIL SE Protect ; BOND

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· Hazard stateme	
H315 Causes sk	
	rious eye irritation.
	e an allergic skin reaction.
· Precautionary	
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P264	Wash thoroughly after handling.
P305+P351+P33	38 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).
P362	Take off contaminated clothing.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P302+P352	IF ON SKIN: Wash with plenty of water.
Additional Info	
	t with acids liberates very toxic gas.
	ckages where the contents do not exceed 125 ml
· Hazard-determ	ining components of labelling:
bisphenol A dig	lycidylmethacrylate
sodium fluoride	
· 2.3 Other hazar	rds
· Results of PBT	and vPvB assessment
• PBT: Not applie	cable.
vPvB: Not appli	icable.
SECTION 3	: Composition/information on ingredients
- 3.1 Chemical cl	haracterisation: Substances None
	haracterisation: Mixtures
	ixture of substances listed below with nonhazardous additions.

 Dangerous compone 	ents:	
	bisphenol A diglycidylmethacrylate	25-45%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319	
	2-hydroxyethyl methacrylate	20-40%
EINECS: 212-782-2	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
CAS: 7681-49-4	sodium fluoride	<1%
EINECS: 231-667-8	🔗 Acute Tox. 3, H301; 🚸 Skin Irrit. 2, H315; Eye Irrit. 2, H319	
• Other ingredients•		

Other ingredients:

10-Methacryloyloxydecyl dihydrogen phosphate Hydrophobic aliphatic methacrylate Colloidal silica dl-Camphorquinone Initiators Accelerators

· Additional information: EUH032: Contact with acids liberates very toxic gas.(sodium fluoride)

SECTION 4: First aid measures

4.1 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.

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Trade name: CLEARFIL SE Protect ; BOND

• After eye contact:

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

· After swallowing:

Do not induce vomiting; call for medical help immediately.

- If symptoms persist consult doctor.
- · 4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

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

SECTION 5: Firefighting measures

- 5.1 Extinguishing media

· Suitable extinguishing agents:

- CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- 5.3 Advice for firefighters
- Protective equipment:

Wear self-contained respiratory protective device.

Wear fully protective suit.

SECTION 6: Accidental release measures

• 6.1 Personal precautions, protective equipment and emergency procedures See Section 8.

• 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:

- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- 6.4 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.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

· Information about fire - and explosion protection: No special measures required.

· 7.2 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 container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

Protect from heat and direct sunlight.

• 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

• Additional information about design of technical facilities: No further data; see item 7.

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(Contd. of page 3) -8.1 Control parameters · Ingredients 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 valid during the making were used as basis. - 8.2 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. · Respiratory protection: Not required. · Protection of hands: Neoprene 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 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 **SECTION 9: Physical and chemical properties** · 9.1 Information on basic physical and chemical properties · General Information • Appearance: Form: Liquid Transparent **Colour:** Yellow

Odour:	Odourless	
· pH-value:	Not determined	
 Change in condition Melting point/Melting range: Boiling point/Boiling range: 	-12 °C (2-hydroxyethyl methacrylate) 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.	
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• Explosion limits:		
Lower:	Not determined	
Upper:	Not determined	
· Oxidising properties	Not determined	
· Vapour pressure:	Not determined	
Density:	1.1 g/cm^3	
Relative density	Not determined	
Vapour density	Not determined	
Evaporation rate	Not determined	
Solubility in / Miscibility with		
water:	Not miscible or difficult to mix.	
Partition coefficient (n-octanol/wa	ter): Not applicable	
Viscosity:	Not determined	
9.2 Other information	No further relevant information available.	

SECTION 10: Stability and reactivity

• 10.1 Reactivity No further relevant information available.

10.2 Chemical stability

• Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

· Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

868-77-9 2-hydroxyethyl methacrylate

Oral LD50 4680 mg/kg (guinea pig)

3275 mg/kg (mouse)

5050 mg/kg (rat)

7681-49-4 sodium fluoride

Oral LD50 44 mg/kg (mouse)

52 mg/kg (rat)

Primary irritant effect:

- · Skin corrosion/irritation
- Causes skin irritation.
- · Serious eye damage/irritation
- Causes serious eye irritation.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

• Acute effects (acute toxicity) Not classified

 \cdot CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

· Germ cell mutagenicity Based on available data, the classification criteria are not met.

• Carcinogenicity Based on available data, the classification criteria are not met.

 \cdot Reproductive toxicity Based on available data, the classification criteria are not met.

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- STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1 Toxicity

- Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 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.

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

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· Uncleaned packaging:

• Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

· 14.1 UN-Number		
· ADR, ADN, IMDG, IATA	Void	
 14.2 UN proper shipping name ADR, ADN, IMDG, IATA 	Void	
14.3 Transport hazard class(es)		
ADR, ADN, IMDG, IATA Class	Void	
14.4 Packing group ADR, IMDG, IATA	Void	
14.5 Environmental hazards: Marine pollutant:	No	
· 14.6 Special precautions for user	Not applicable.	
• 14.7 Transport in bulk according to Anne Marpol and the IBC Code	ex II of Not applicable.	
· UN "Model Regulation":	Void	

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SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3 • **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· Relevant phrases

*

- H301 Toxic if swallowed.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.

· Abbreviations and acronyms:

Acute Tox. 3: Acute toxicity – Category 3 Skin Irrit. 2: Skin corrosion/irritation – Category 2

- Eye Irrit. 2: Serious eye damage/eye irritation Category 2
- Skin Sens. 1: Skin sensitisation Category 1
- * Data compared to the previous version altered.

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SECTION 1: Identification of the substance/mixture and of the company/undertaking
· 1.1 Product identifier
Trade name: CLEARFIL SE Protect ; PRIMER
 Article number: 092-P Registration number Not applicable 1.2 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
1.3 Details of the supplier of the safety data sheet
 Manufacturer: Kuraray Europe GmbH Philipp-Reis-Str. 4, 65795 Hattersheim am Main Germany Phone:+49 (0)69 305 35 840 Fax:+49 (0)69 305 35 640 E-mail: dental@kuraray.de Supplier: J & S Davis 5 Whitworth Road, Stevenage, Hertfordshir, SG1 4QS Great Britain Tel: +44- (0) 1438 747344 Fax: +44- (0) 1438 758909 E-mail: jsdsales@js-davis.co.uk Further information obtainable from: Manufacturer or Supplier 1.4 Emergency telephone number: National Poisons information Service (London Centre) Guy's & St. Thomas' Hospital Trust Medical Toxicology Unit Avonley Road LONDON SE14 5ER Emergency telephone: (local) 0870 600 6266 or +44 20 7771 5394 Administrative telephone: +44 20 7 771 53 10 Facsimile number: +44 20 7 771 53 09
SECTION 2: Hazards identification
• 2.1 Classification of the substance or mixture • Classification according to Regulation (EC) No 1272/2008 GHS07
Skin Irrit. 2H315 Causes skin irritation.Eye Irrit. 2H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

· 2.2 Label elements

· Labelling according to Regulation (EC) No 1272/2008

- The product is classified and labelled according to the CLP regulation.
- Hazard pictograms GHS07 Signal word Warning
- · Hazard-determining components of labelling:

2-hydroxyethyl methacrylate

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· Hazard stateme	nts
H315 Causes ski	n irritation.
H319 Causes ser	ious eye irritation.
H317 May cause	an allergic skin reaction.
Precautionary s	tatements
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P264	Wash thoroughly after handling.
P305+P351+P33	8 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).
P362	Take off contaminated clothing.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P302+P352	IF ON SKIN: Wash with plenty of water.
- 2.3 Other hazar	ds
· Results of PBT a	and vPvB assessment
• PBT: Not application	able.
• vPvB: Not applie	cable.

SECTION 3: Composition/information on ingredients

· 3.1 Chemical characterisation: Substances None

- 3.2 Chemical characterisation: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

8	1		
CAS: 868-7	7-9	2-hydroxyethyl methacrylate	25-45%
EINECS: 21	2-782-2	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
• Other ingre	dients:		

Other ingredients:

10-Methacryloyloxydecyl dihydrogen phosphate

12-Methacryloyloxydodecylpyridinium bromide Hydrophilic aliphatic dimethacrylate

- Hydrophilic alipha
- Water

Initiators Accelerators

Dyes

SECTION 4: First aid measures

· 4.1 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; call for medical help immediately.
- If symptoms persist consult doctor.
- 4.2 Most important symptoms and effects, both acute and delayed
- No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed
- No further relevant information available.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

· Suitable extinguishing agents:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- 5.3 Advice for firefighters
- Protective equipment:
- Wear self-contained respiratory protective device.

Wear fully protective suit.

SECTION 6: Accidental release measures

• 6.1 Personal precautions, protective equipment and emergency procedures See Section 8.

• 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

• 6.3 Methods and material for containment and cleaning up:

- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- · 6.4 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.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols.

· Information about fire - and explosion protection: No special measures required.

· 7.2 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 container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

Protect from heat and direct sunlight.

• 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

• Additional information about design of technical facilities: No further data; see item 7.

- 8.1 Control parameters

Ingredients 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 valid during the making were used as basis.

- 8.2 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.
- Respiratory protection: Not required.



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Trade name: CLEARFIL SE Protect ; PRIMER

· 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 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

SECTION 9: Physical and ch	emical properties	
• 9.1 Information on basic physical a • General Information • Appearance:	nd chemical properties	
Form:	Liquid	
Colour:	Blue	
Odour:	Odourless	
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	
• Oxidising properties	Not determined	
· Vapour pressure:	Not determined	
· Density:	1.1 g/cm ³	
Relative density	Not determined	
· Vapour density	Not determined	
• Evaporation rate	Not determined	
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· Solubility in / Miscibility with		
water:	Not miscible or difficult to mix.	
· Partition coefficient (n-octanol/water	:): Not determined	
· Viscosity:	Not determined	
9.2 Other information	No further relevant information available.	

SECTION 10: Stability and reactivity

• 10.1 Reactivity No further relevant information available.

10.2 Chemical stability

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

• Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values 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:

Skin corrosion/irritation

Causes skin irritation.

· Serious eye damage/irritation

Causes serious eye irritation.

· Respiratory or skin sensitisation

May cause an allergic skin reaction.

· Acute effects (acute toxicity) Not classified

· CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

· Germ cell mutagenicity Based on available data, the classification criteria are not met.

· Carcinogenicity Based on available data, the classification criteria are not met.

• Reproductive toxicity Based on available data, the classification criteria are not met.

• STOT-single exposure Based on available data, the classification criteria are not met.

- STOT-repeated exposure Based on available data, the classification criteria are not met.
- Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· 12.1 Toxicity

- Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.

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Trade name: CLEARFIL SE Protect ; PRIMER

· 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.

• 12.5 Results of PBT and vPvB assessment

• **PBT:** Not applicable. • **vPvB:** Not applicable.

• 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· Uncleaned packaging:

• Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

· 14.1 UN-Number · ADR, ADN, IMDG, IATA	Void	
• 14.2 UN proper shipping name • ADR, ADN, IMDG, IATA	Void	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	Void	
· 14.4 Packing group · ADR, IMDG, IATA	Void	
· 14.5 Environmental hazards: · Marine pollutant:	No	
· 14.6 Special precautions for user	Not applicable.	
• 14.7 Transport in bulk according to Anne: Marpol and the IBC Code	x II of Not applicable.	
· UN "Model Regulation":	Void	

SECTION 15: Regulatory information

• 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture • REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

• 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 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.

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H319 Causes serious eye irritation.

Abbreviations and acronyms:

Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

* Data compared to the previous version altered.

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