

Printing date 28.11.2017 Version number 6 Revision: 28.11.2017

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

· 1.1 Product identifier

· Trade name: CLEARFIL NEW BOND; CATALYST

· Article number: 022-C

· 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



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

benzoyl peroxide

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#### · Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

#### **Precautionary statements**

P264 Wash thoroughly after handling.

P280 Wear protective gloves/protective clothing/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).

P332+P313 If skin irritation occurs: Get medical advice/attention. P337+P313 If eye irritation persists: Get medical advice/attention.

P362 Take off contaminated clothing.

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

#### **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:			
	bisphenol A diglycidylmethacrylate	20-40%	
EINECS: 216-367-7	♦ 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		
	benzoyl peroxide	<3%	
EINECS: 202-327-6	Unst. Expl., H200;  Eye Irrit. 2, H319; Skin Sens. 1, H317; Org. Perox. E, H242		

#### Other ingredients:

10-Methacryloyloxydecyl dihydrogen phosphate

Hydrophobic aliphatic dimethacrylate

#### **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 eve 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** Not required.
- **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). Ensure adequate ventilation.

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:

Store away from oxidising agents.

Store away from reducing agents.

· 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

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Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

#### **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

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 chemical properties**

- 9.1 Information on basic physical and chemical properties
- · General Information
- Appearance:

Form: Liquid Colour: Transparent · Odour: Odourless

Not determined pH-value:

· Change in condition

Melting point/freezing point: -12 °C (2-hydroxyethyl methacrylate) Initial boiling point and boiling range: 205 °C (2-hydroxyethyl methacrylate)

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

Ignition temperature: **Decomposition temperature:** Not determined.

Product does not present an explosion hazard. Explosive properties:

Not determined

· Explosion limits:

Lower: Not determined Upper: Not determined · Oxidising properties Not determined.

· Vapour pressure: Not determined

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Density:	1.1 g/cm <sup>3</sup>
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/water:	Not determined
· Viscosity: · 9.2 Other information	Not determined 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)	
		nzoyl peroxide	
Oral	LD50	5700 mg/kg (mouse)	
		7710 mg/kg (rat)	

LD50 250 mg/kg (mouse - intraperitoneal)

• Primary irritant effect:

· Skin corrosion/irritation

Causes skin irritation.

Serious eve damage/irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

- 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.

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### **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.

Void		
Void		
Void		
Void		
No		
Not applicable.		
· 14.7 Transport in bulk according to Annex II of		
Not applicable.		
	Void  Void  Void  No  Not applicable.	

### **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

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· 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

H200 Unstable explosives.

H242 Heating may cause a fire.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

#### Abbreviations and acronyms:

Unst. Expl.: Explosives – Unstable explosive Org. Perox. E: Organic peroxides – Type E/F

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 NEW BOND; UNIVERSAL
- Article number:022-U
- · 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



GHS02 flame

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

- · 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 GHS02
- · Signal word Danger
- · Hazard statements

H225 Highly flammable liquid and vapour.

**Precautionary statements** 

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

smoking.

P241 Use explosion-proof electrical/ventilating/lighting/equipment.

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>90%

🍑 Flam. Liq. 2, H225

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P240 Ground/bond container and receiving equipment.

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

water/shower.

P370+P378 In case of fire: Use for extinction: CO2, powder or water spray.

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

regulations.

· Labelling of packages where the contents do not exceed 125 ml

· Hazard-determining components of labelling: ethanol

2.3 Other hazards Not applicable

· Results of PBT and vPvB assessment

· **PBT:** Not applicable. · **vPvB:** Not applicable.

### **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:

CAS: 64-17-5 ethanol

EINECS: 200-578-6

Other ingredients:

Catalysts Accelerators

### **SECTION 4: First aid measures**

- 4.1 Description of first aid measures
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
- After eye contact: Rinse opened eye for several minutes under running water.
- 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.

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#### **SECTION 6: Accidental release measures**

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

- 6.2 Environmental precautions:

Dilute with plenty of water.

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).

Ensure adequate ventilation.

· 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.
- · Information about fire and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- 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:

Store away from oxidising agents.

Store away from reducing agents.

· 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:

64-17-5 ethanol

WEL Long-term value: 1920 mg/m³, 1000 ppm

- Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures: Wash hands before breaks and at the end of work.
- Respiratory protection: Not required.
- · Protection of hands:

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

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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**

**General Information** 

· Appearance:

Liquid Form: Transparent Colour: · Odour: Alcohol-like · pH-value: Not determined

· Change in condition

Melting point/Melting range: -114.5 °C (ethanol) **Boiling point/Boiling range:** 78 °C (ethanol) · Flash point: 13 °C (ethanol)

425.0 °C (ethanol) · Ignition temperature:

**Decomposition temperature:** Not determined

· Danger of explosion: Product is not explosive. However, formation of explosive air/

vapour mixtures are possible.

· Explosion limits:

3.5 Vol % (ethanol) Lower: 15.0 Vol % (ethanol) **Upper:** · Oxidising properties Not determined

59.0 hPa (20 °C, ethanol) · Vapour pressure:

0.79 g/cm<sup>3</sup> **Density:** Not determined · Relative density

· Vapour density 1.6 g/cm<sup>3</sup> (ethanol, air=1)

Not determined · Evaporation rate

· Solubility in / Miscibility with

water: Fully miscible.

· Partition coefficient (n-octanol/water): -0.32 (ethanol)

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. (Contd. on page 5)



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- 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 i	for cla	assificat	ion:

64-17-5 et	64-17-5 ethanol		
Oral	LD50	3450 mg/kg (mouse)	
		7060 mg/kg (rat)	
Inhalative	LC50/4 h	20000 mg/l (rat)	
	LD50	3600 mg/kg (rat - intraperioneal)	

- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · 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.
- · 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.

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· Recommended cleansing agents: Water, if necessary together with cleansing agents.

<b>SECTION 14: Transport informa</b>	tion
· 14.1 UN-Number · ADR, IMDG, IATA	1170
· 14.2 UN proper shipping name	
· ADR	1170 ETHANOL SOLUTION (ETHYL ALCOHOL
· IMDG	SOLUTION) ETHANOL SOLUTION (ETHYL ALCOHOL
	SOLUTION)
· IATA	ETHANOL SOLUTION
14.3 Transport hazard class(es)	
ADR, IMDG, IATA	
· Class · Label	3 Flammable liquids.
14.4 Packing group	
· ADR, IMDG, IATA	II
14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user	Warning: Flammable liquids.
Danger code (Kemler):	33
· EMS Number:	F-E,S-D
· 14.7 Transport in bulk according to Annex II of	
Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	UN1170; ETHANOL SOLUTION (ETHYL ALCOHO SOLUTION); 3; II

### **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

H225 Highly flammable liquid and vapour.

Abbreviations and acronyms:

Flam. Liq. 2: Flammable liquids – Category 2

\* Data compared to the previous version altered.