

Safety Data Sheet

according to Regulation (EC) No 1907/2006

C-Prime S plus

Revision date: 06.09.2018

Product code: 2PRIMS-P

Page 1 of 12

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

1.1. Product identifier

C-Prime S plus

Product group: Composite

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

Enamel- and dentin-bonding agent for the bonding of dental-composites.

Uses advised against

Application of eugenol containing material, specifically base liners, is not indicated, it will inhibit the polymerization.

1.3. Details of the supplier of the safety data sheet

Company name:	MEGADENTA Dentalprodukte GmbH	
Street:	Carl-Eschebach-Str. 1A	
Place:	01454 Radeberg, Germany	
Telephone:	+49-3528 4530	Telefax: +49-3528 45321
e-mail:	info@megadenta.de	
Internet:	www.megadenta.de	

1.4. Emergency telephone number: +49-3528 453-0 (just during usual office time: GMT+1)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Flammable liquid: Flam. Liq. 2

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Dam. 1

Respiratory or skin sensitisation: Skin Sens. 1A

Hazardous to the aquatic environment: Aquatic Chronic 2

Hazard Statements:

Highly flammable liquid and vapour.

Causes skin irritation.

Causes serious eye damage.

May cause an allergic skin reaction.

Toxic to aquatic life with long lasting effects.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

2-hydroxyethyl methacrylate

Triethylene glycol dimethacrylate

Adhesive Monomer

Glycerol dimethacrylate

Bisphenol-A-bis-(2-hydroxypropyl)methacrylate

diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Signal word: Danger

Safety Data Sheet

according to Regulation (EC) No 1907/2006

C-Prime S plus

Revision date: 06.09.2018

Product code: 2PRIMS-P

Page 2 of 12

Pictograms:**Hazard statements**

H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H411	Toxic to aquatic life with long lasting effects.

Precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
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/doctor.
P403+P235	Store in a well-ventilated place. Keep cool.

Special labelling of certain mixtures

- 10 - < 15 % of the mixture consists of ingredient(s) of unknown acute toxicity (dermal).
- 10 - < 15 % of the mixture consists of ingredient(s) of unknown acute toxicity (inhalation).
- Contains 10 - < 15 % of components with unknown hazards to the aquatic environment.

Additional advice on labelling

Medical devices (93/42/EWG) which are invasive or used in direct phys. contact with the human body, are exempted from provisions of Reg. (EC) No 1272/2008 (CLP/GHS) if they are in finished state and intended for the final user.

2.3. Other hazards

The non-polymerized material could irritate skin due to longer contact.

Wassergefährdungsklasse 3 - stark wassergefährdend

SECTION 3: Composition/information on ingredients**3.2. Mixtures**

Safety Data Sheet

according to Regulation (EC) No 1907/2006

C-Prime S plus

Revision date: 06.09.2018

Product code: 2PRIMS-P

Page 3 of 12

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
868-77-9	2-hydroxyethyl methacrylate			20 - < 25 %
	212-782-2	607-124-00-X		
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H315 H319 H317			
109-16-0	Triethylene glycol dimethacrylate			15 - < 20 %
	203-652-6		01-2119969287-21	
	Skin Sens. 1; H317			
148019-46-9	Adhesive Monomer			10 - < 15 %
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1A, STOT SE 3; H315 H319 H317 H335			
1830-78-0	Glycerol dimethacrylate			5 - < 10 %
	217-388-4			
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1A, STOT SE 3; H315 H319 H317 H335			
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate			5 - < 10 %
	Acute Tox. 4, Eye Dam. 1, Skin Sens. 1, Aquatic Chronic 1; H302 H318 H317 H410			
21245-02-3	2-Ethylhexyl-p-dimethylaminobenzoate			< 1 %
	244-289-3		01-2120766649-35	
	Repr. 1B, Aquatic Acute 1; H360 H400			
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			< 1 %
	278-355-8	015-203-00-X		
	Repr. 2; H361f			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
868-77-9	212-782-2	2-hydroxyethyl methacrylate	20 - < 25 %
		oral: LD50 = 5050 mg/kg	
109-16-0	203-652-6	Triethylene glycol dimethacrylate	15 - < 20 %
		dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg	
148019-46-9		Adhesive Monomer	10 - < 15 %
		inhalation: Data lacking (gases); dermal: Data lacking; oral: LD50 = >2000 mg/kg	
1830-78-0	217-388-4	Glycerol dimethacrylate	5 - < 10 %
		dermal: LD50 = 480 mg/kg; oral: LD50 = >2000 mg/kg	
1565-94-2		Bisphenol-A-bis-(2-hydroxypropyl)methacrylate	5 - < 10 %
		oral: LD50 = >5000 mg/kg	
21245-02-3	244-289-3	2-Ethylhexyl-p-dimethylaminobenzoate	< 1 %
		dermal: LD50 = >2000 mg/kg; oral: LD50 = 14900 mg/kg	
75980-60-8	278-355-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	< 1 %
		inhalation: Data lacking (gases); oral: LD50 = >5000 mg/kg	

SECTION 4: First aid measures**4.1. Description of first aid measures**

Safety Data Sheet

according to Regulation (EC) No 1907/2006

C-Prime S plus

Revision date: 06.09.2018

Product code: 2PRIMS-P

Page 4 of 12

General information

Polymerized material is non-hazardous.

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

After contact with eyes

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink plenty of water. @000000000029

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water spray jet, Carbon dioxide (CO₂), Foam, Extinguishing powder.

5.2. Special hazards arising from the substance or mixture

Highly flammable. Vapours can form explosive mixtures with air.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures

Remove all sources of ignition. Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow uncontrolled discharge of product into the environment. Danger of explosion

6.3. Methods and material for containment and cleaning up

Other information

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Safety Data Sheet

according to Regulation (EC) No 1907/2006

C-Prime S plus

Revision date: 06.09.2018

Product code: 2PRIMS-P

Page 5 of 12

Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray. The unprotected substance must not be exposed to the light before processing, because it polymerizes. Only adequately trained personnel should handle this product. For use in dentistry only.

Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking. Take precautionary measures against static discharges. Vapours can form explosive mixtures with air.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations. Keep in a cool, well-ventilated place. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Light-sensitive substance. Protect from exposure to the light. Store not above 25°C.

Hints on joint storage

Do not store together with: Oxidizing agent. Pyrophoric or self-heating substances.

7.3. Specific end use(s)

As adhesion promoter for composites at the dentist.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
128-37-0	2,6-Di-tert-butyl-p-cresol	-	10		TWA (8 h)	WEL
64-17-5	Ethanol	1000	1920		TWA (8 h)	WEL

DNEL/DMEL values

CAS No	Substance	Exposure route	Effect	Value
21245-02-3	2-Ethylhexyl-p-dimethylaminobenzoate			
	Worker DNEL, long-term	inhalation	systemic	0,5 mg/m ³
	Worker DNEL, long-term	dermal	systemic	6,7 mg/kg bw/day
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			
	Worker DNEL, long-term	dermal	systemic	0,233 mg/kg bw/day
	Consumer DNEL, long-term	inhalation	systemic	0,145 mg/m ³
	Consumer DNEL, long-term	dermal	systemic	0,0833 mg/kg bw/day
	Consumer DNEL, long-term	oral	systemic	0,0833 mg/kg bw/day

Safety Data Sheet

according to Regulation (EC) No 1907/2006

C-Prime S plus

Revision date: 06.09.2018

Product code: 2PRIMS-P

Page 6 of 12

PNEC values

CAS No	Substance	
Environmental compartment		Value
21245-02-3	2-Ethylhexyl-p-dimethylaminobenzoate	
Freshwater		0 mg/l
Freshwater (intermittent releases)		0 mg/l
Marine water		0 mg/l
Freshwater sediment		0,042 mg/kg
Marine sediment		0,004 mg/kg
Micro-organisms in sewage treatment plants (STP)		100 mg/l
Soil		0,008 mg/kg

8.2. Exposure controls**Appropriate engineering controls**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

Eye/face protection

Suitable eye protection: goggles.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Skin protection

Flame-retardant protective clothing. Wear anti-static footwear and clothing . .

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state:	liquid	
Colour:	yellow	
Odour:	characteristic: like ethanol	
pH-Value:		not determined

Changes in the physical state

Melting point:		not determined
Boiling point or initial boiling point and boiling range:		78 °C
Flash point:		12 °C

Flammability

Solid/liquid:		not applicable
Gas:		not applicable

Safety Data Sheet

according to Regulation (EC) No 1907/2006

C-Prime S plus

Revision date: 06.09.2018

Product code: 2PRIMS-P

Page 7 of 12

Lower explosion limits:	3,5 vol. %
Upper explosion limits:	15 vol. %
Auto-ignition temperature:	255 °C
Self-ignition temperature	
Solid:	not applicable
Gas:	not applicable
Decomposition temperature:	not determined
Oxidizing properties	
Not oxidising.	
Vapour pressure: (at 20 °C)	58 hPa
Density (at 20 °C):	0,95 g/cm ³
Water solubility:	partially soluble
Solubility in other solvents	
not determined	
Partition coefficient n-octanol/water:	not determined
Flow time:	Daten nicht verfügbar
Relative vapour density:	not determined
Evaporation rate:	not determined
Solvent content:	60,21 %

9.2. Other information

Solid content:	not determined
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SECTION 10: Stability and reactivity**10.1. Reactivity**

Highly flammable.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Keep away from sources of heat (e.g. hot surfaces), sparks and open flames. Vapours can form explosive mixtures with air. Direct light.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

With incomplete combustion toxic gases such as carbon monoxide may be generated.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

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

ATEmix tested

	Dose	Species	Source
LD50, oral	5000 mg/kg	Rat	

Safety Data Sheet

according to Regulation (EC) No 1907/2006

C-Prime S plus

Revision date: 06.09.2018

Product code: 2PRIMS-P

Page 8 of 12

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
868-77-9	2-hydroxyethyl methacrylate				
	oral	LD50 mg/kg	5050	Rat	
109-16-0	Triethylene glycol dimethacrylate				
	oral	LD50 mg/kg	>5000	Rat	
	dermal	LD50 mg/kg	>2000	mouse	
148019-46-9	Adhesive Monomer				
	oral	LD50 mg/kg	>2000	Rat	OECD423
	dermal	Data lacking			
	inhalation	Data lacking			
1830-78-0	Glycerol dimethacrylate				
	oral	LD50 mg/kg	>2000	Rat	Manufacturer
	dermal	LD50 mg/kg	480	Rabbit	
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate				
	oral	LD50 mg/kg	>5000	Rat	Manufacturer
21245-02-3	2-Ethylhexyl-p-dimethylaminobenzoate				
	oral	LD50 mg/kg	14900	Rat	
	dermal	LD50 mg/kg	>2000	Rat	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide				
	oral	LD50 mg/kg	>5000	Rat	
	inhalation	Data lacking			

Irritation and corrosivity

Causes skin irritation.

Causes serious eye damage.

Sensitising effects

May cause an allergic skin reaction. (2-hydroxyethyl methacrylate; Triethylene glycol dimethacrylate; Adhesive Monomer; Glycerol dimethacrylate; Bisphenol-A-bis-(2-hydroxypropyl)methacrylate)

Carcinogenic/mutagenic/toxic effects for reproduction

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.

Additional information on tests

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

Safety Data Sheet

according to Regulation (EC) No 1907/2006

C-Prime S plus

Revision date: 06.09.2018

Product code: 2PRIMS-P

Page 9 of 12

Practical experience

When used and handled according to specifications, the product gives to the present knowledge and experience no adverse health effects .

SECTION 12: Ecological information**12.1. Toxicity**

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
868-77-9	2-hydroxyethyl methacrylate					
	Acute fish toxicity	LC50 227 mg/l	96 h	Pimephales promelas		
109-16-0	Triethylene glycol dimethacrylate					
	Acute fish toxicity	LC50 16,4 mg/l	96 h	Danio rerio	OECD-Test Nr. 203	
	Acute algae toxicity	ErC50 >100 mg/l		Pseudokirchneriella subcapitata	OECD-Test Nr. 201	
148019-46-9	Adhesive Monomer					
	Aquatic toxicity	Data lacking				
1830-78-0	Glycerol dimethacrylate					
	Acute fish toxicity	LC50 43,2 mg/l	96 h	Guppy (Poecilia reticulata)	Manufacturer	
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate					
	Acute fish toxicity	LC50 >100 mg/l	96 h	Poecilia reticulata (Guppy)	Manufacturer	
21245-02-3	2-Ethylhexyl-p-dimethylaminobenzoate					
	Acute fish toxicity	LC50 0,235 mg/l	96 h		Manufacturer	
	Acute algae toxicity	ErC50 >0,015 mg/l	72 h	Pseudokirchneriella subcapitata		
	Acute crustacea toxicity	EC50 >0,031 mg/l	48 h	Daphnia magna		
	Acute bacteria toxicity	(>1000 mg/l)	3 h			
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide					
	Acute fish toxicity	LC50 6,53 mg/l	96 h	Oryzias latipes		
	Acute algae toxicity	ErC50 2,01 mg/l	72 h	Pseudokirchneriella subcapitata	OECD 201	
	Acute crustacea toxicity	EC50 3,53 mg/l	48 h	Daphnia magna	OECD Guideline 202	

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

C-Prime S plus

Revision date: 06.09.2018

Product code: 2PRIMS-P

Page 10 of 12

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
868-77-9	2-hydroxyethyl methacrylate	0,47
109-16-0	Triethylene glycol dimethacrylate	2,3
1830-78-0	Glycerol dimethacrylate	2,05
1565-94-2	Bisphenol-A-bis-(2-hydroxypropyl)methacrylate	4,63
21245-02-3	2-Ethylhexyl-p-dimethylaminobenzoate	>6,2
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	3,257

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The product has not been tested.

12.7. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.
Wassergefährdungsklasse 3 - stark wassergefährdend

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

List of Wastes Code - residues/unused products

200139 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); Plastics

List of Wastes Code - used product

200139 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); Plastics

List of Wastes Code - contaminated packaging

200139 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); Plastics

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information**Land transport (ADR/RID)**

- 14.1. UN number:** UN number
- 14.2. UN proper shipping name:** No dangerous good in sense of this transport regulation.
- 14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.
- 14.4. Packing group:** No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

- 14.1. UN number:** UN 1170

Safety Data Sheet

according to Regulation (EC) No 1907/2006

C-Prime S plus

Revision date: 06.09.2018

Product code: 2PRIMS-P

Page 11 of 12

14.2. UN proper shipping name: 1170 ETHANOL; LÖSUNG (ETHYLALKOHOL; LÖSUNG)**Marine transport (IMDG)****14.1. UN number:** UN 1170**14.2. UN proper shipping name:** 1170 ETHANOL; LÖSUNG (ETHYLALKOHOL; LÖSUNG)**Air transport (ICAO-TI/IATA-DGR)****14.1. UN number:** UN 1170**14.2. UN proper shipping name:** 1170 ETHANOL; LÖSUNG (ETHYLALKOHOL; LÖSUNG)**14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulatory information**

Restrictions on use (REACH, annex XVII):

Entry 3

2010/75/EU (VOC): 65,314 % (620,483 g/l)

2004/42/EC (VOC): 60,222 % (572,109 g/l)

Information according to 2012/18/EU (SEVESO III): E2 Hazardous to the Aquatic Environment

Additional information: P5c

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D): 3 - highly hazardous to water

Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information**Changes**

This data sheet contains changes from the previous version in section(s): 2,6,8,9,11,15.

Abbreviations and acronymsADR: 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

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

Safety Data Sheet

according to Regulation (EC) No 1907/2006

C-Prime S plus

Revision date: 06.09.2018

Product code: 2PRIMS-P

Page 12 of 12

Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Classification procedure
Flam. Liq. 2; H225	On basis of test data
Skin Irrit. 2; H315	Calculation method
Eye Dam. 1; H318	Calculation method
Skin Sens. 1A; H317	Calculation method
Aquatic Chronic 2; H411	Calculation method

Relevant H and EUH statements (number and full text)

H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H360	May damage fertility or the unborn child.
H361f	Suspected of damaging fertility.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)