

according to Regulation (EC) No 1907/2006

Rapid - Rapid soft - Rapid Liner Base

Revision date: 20.04.2015

Print date: 20.04.2015

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

1.1. Product identifier

Rapid - Rapid soft - Rapid Liner Base

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

Use of the substance/mixture

for dental use only

1.3. Details of the supplier of the safety data sheet

| Company name: | Coltène/Whaledent AG |
|-------------------------|--|
| Street: | Feldwiesenstrasse 20 |
| Place: | CH-9450 Altstätten |
| Telephone: | +41 (71) 75 75 300 |
| Telefax: | +41 (71) 75 75 301 |
| e-mail: | info.ch@coltene.com |
| Internet: | www.coltene.com |
| Responsible Department: | Regulatory Affairs msds@coltene.com |

Further Information

Only supplied to dentists and dental laboratories or upon their instructions

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

This mixture is classified as not hazardous according to Regulation (EC) 1272/2008 [GHS]. The preparation is not dangerous in the sense of Directive 1999/45/EC. Preparation/mixture without hazards for human health or environment

2.2. Label elements

Hazardous components which must be listed on the label

According to EC directive 1999/45/EC or annex VI of directive 67/548/EEC the preparation does not have to be labelled.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Polymer preparations and compounds

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

No special measures are necessary.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water. Foam. Extinguishing powder. Carbon dioxide (CO2). Sand.



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Additional information

Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Wipe up with absorbent material (eg. cloth, fleece). Clear contaminated areas thoroughly.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

No special precautionary measures are necessary. Observe instructions for use.

7.2. Conditions for safe storage, including any incompatibilities

Further information on storage conditions

Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity. Recommended storage temperature: 15 - 23 °C

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Protective and hygiene measures

When using do not eat, drink or smoke.

Hand protection

Single-use gloves. Unsuitable material: NR (Natural rubber (Caoutchouc), Natural latex).

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| Physical state: Colour: | Paste | |
|---|-------|-------------|
| | | Test method |
| Changes in the physical state Initial boiling point and boiling ra | nge: | >150 °C |
| Water solubility: (at 23 °C) | | insoluble |

Solubility in other solvents

ketone.

SECTION 10: Stability and reactivity

Further information

No special measures are necessary.

SECTION 11: Toxicological information

11.1. Information on toxicological effects



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Acute toxicity

LD50: >2000 mg/kg (Rat)

The statement is derived from products of similar composition.

Irritation and corrosivity

Irritant effect on the skin: (Rabbit) Not an irritant. The statement is derived from products of similar composition.

Sensitising effects

Guinea-pig.

no danger of sensitization.

The statement is derived from products of similar composition.

SECTION 12: Ecological information

Further information

No special environmental measures are necessary.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Can be burnt together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge.

SECTION 14: Transport information

Other applicable information

Not a hazardous material with respect to these transportation regulations.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulatory information

Additional information

SECTION 16: Other information

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal.

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



| Rapid Activator | |
|-----------------|--|
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Print date: 25.06.2015

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

1.1. Product identifier

Rapid Activator

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

Use of the substance/mixture

Activator.

1.3. Details of the supplier of the safety data sheet

| Company name: | Coltène/Whaledent AG |
|-------------------------|--|
| Street: | Feldwiesenstrasse 20 |
| Place: | CH-9450 Altstätten |
| Telephone: | +41 (71) 75 75 300 |
| Telefax: | +41 (71) 75 75 301 |
| e-mail: | info.ch@coltene.com |
| Internet: | www.coltene.com |
| Responsible Department: | Regulatory Affairs msds@coltene.com |

Further Information

Only supplied to dentists and dental laboratories or upon their instructions

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Indications of danger: Xn - Harmful, Xi - Irritant R phrases: Irritating to eyes, respiratory system and skin. Harmful: danger of serious damage to health by prolonged exposure if swallowed. May cause long-term adverse effects in the aquatic environment.

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazard categories: Skin corrosion/irritation: Skin Irrit. 2 Serious eye damage/eye irritation: Eye Irrit. 2 Specific target organ toxicity - single exposure: STOT SE 3 Specific target organ toxicity - repeated exposure: STOT RE 2 Hazardous to the aquatic environment: Aquatic Chronic 4 Hazard Statements: Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation. May cause damage to organs through prolonged or repeated exposure. May cause long lasting harmful effects to aquatic life.

2.2. Label elements

Hazardous components which must be listed on the label

Alkyl silicates

| Signal word: | Warning |
|--------------|-------------|
| Pictograms: | GHS07-GHS08 |



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Print date: 25.06.2015 Revision date: 18.06.2015 Page 2 of 6 Hazard statements H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H373 May cause damage to organs through prolonged or repeated exposure. H413 May cause long lasting harmful effects to aquatic life. **Precautionary statements** P280 Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 IF ON SKIN: Wash with plenty of water. P332+P313 If skin irritation occurs: Get medical advice/attention. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P314 Get medical advice/attention if you feel unwell. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention. Avoid release to the environment. P273 Additional advice on labelling Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical

contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

| EC No | Chemical name | Quantity |
|------------|--|-------------|
| CAS No | Classification according to Directive 67/548/EEC | |
| Index No | Classification according to Regulation (EC) No. 1272/2008 [CLP] | |
| REACH No | | |
| | Alkyl silicates | 20 - < 25 % |
| | Xn - Harmful, Xi - Irritant R10-20-36/37/38-48/22-53 | |
| | Flam. Liq. 3, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, STOT RE 2, Aquatic Chronic 4; H226 H332 H315 H319 H335 H373 H413 | |
| 246-325-3 | Dioctyltin dicarboxylate | 5 - < 10 % |
| 24577-34-2 | Xn - Harmful R48/22-53 | |
| | STOT RE 2, Aquatic Chronic 4; H373 H413 | |

Full text of R-, H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

After contact with skin

After contact with skin, wash immediately with: Water and soap.

After contact with eyes

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.



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After ingestion

Seek medical attention if problems persist.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water. Foam. Extinguishing powder. Carbon dioxide (CO2). Sand.

Additional information

Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Wipe up with absorbent material (eg. cloth, fleece). Clear contaminated areas thoroughly.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Avoid contact with skin and eyes. Observe instructions for use.

Further information on handling

After use replace the closing cap immediately.

7.2. Conditions for safe storage, including any incompatibilities

Further information on storage conditions

Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity. Recommended storage temperature: 15 - 23 °C

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Protective and hygiene measures

When using do not eat, drink or smoke.

Eye/face protection

Framed glasses.

Hand protection

Single-use gloves.

Skin protection

Lab apron.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| Physical state: | Paste |
|-----------------|----------------|
| Colour: | blue |
| Odour: | characteristic |

Test method



according to Regulation (EC) No 1907/2006

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|--|------------------------|-------------|
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| Changes in the physical state | | |
| Initial boiling point and boiling range: | >150 °C | |
| Density (at 23 °C): | 1.0 g/cm³ | |
| Water solubility: (at 23 °C) | insoluble | |
| Solubility in other solvents ketone. | | |

SECTION 10: Stability and reactivity

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.4. Conditions to avoid

Air, humid.

Further information

Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

LD50: >2000 mg/kg (Rat)

The statement is derived from products of similar composition.

| CAS No | Chemical name | | | | | |
|------------|----------------------------|--------|------------|---------|--------|--|
| | Exposure routes | Method | Dose | Species | Source | |
| | Alkyl silicates | | | | | |
| | inhalative vapour | ATE | 11 mg/l | | | |
| | inhalative aerosol | ATE | 1.5 mg/l | | | |
| 24577-34-2 | 2 Dioctyltin dicarboxylate | | | | | |
| | oral | LD50 | 2764 mg/kg | Rat | | |
| | dermal | LD50 | 2764 mg/kg | Rabbit | | |

Irritation and corrosivity

Causes serious eye irritation.

Irritant effect on the skin: (Rabbit)

Not an irritant.

The statement is derived from products of similar composition.

Sensitising effects

Guinea-pig. no danger of sensitization.

The statement is derived from products of similar composition.

STOT-single exposure

May cause respiratory irritation.

Severe effects after repeated or prolonged exposure

May cause damage to organs through prolonged or repeated exposure.

SECTION 12: Ecological information

12.1. Toxicity



according to Regulation (EC) No 1907/2006

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|---------------------------|------------|---|--------|-----------|-----------|---------------|--------|
| | CAS No | Chemical name | | | | | |
| | | Aquatic toxicity | Method | Dose | [h] [d] | Species | Source |
| | 24577-34-2 | Dioctyltin dicarboxylate | | | | | |
| | | Acute fish toxicity | LC50 | 22.8 mg/l | 96 h | | |
| | | Acute crustacea toxicity | EC50 | 12.2 mg/l | 48 h | Daphnia magna | |

Further information

May cause long-term adverse effects in the aquatic environment. Do not allow uncontrolled leakage of product into the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Can be burnt together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge.

SECTION 14: Transport information

| Land transport (ADR/RID) | |
|--------------------------|--|
| 14.1. UN number: | |
| Marine transport (IMDG) | |
| <u>14.1. UN number:</u> | |
| Air transport (ICAO) | |
| <u>14.1. UN number:</u> | |

Other applicable information

Not a hazardous material with respect to these transportation regulations.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulatory information

Additional information

SECTION 16: Other information

Relevant R-phrases (Number and full text)

| 10 | Flammable. | | | | | | |
|-----------------|---|--|--|--|--|--|--|
| 20 | Harmful by inhalation. | | | | | | |
| 36/37/38 | Irritating to eyes, respiratory system and skin. | | | | | | |
| 48/22 | Harmful: danger of serious damage to health by prolonged exposure if swallowed. | | | | | | |
| 53 | May cause long-term adverse effects in the aquatic environment. | | | | | | |
| Relevant H- and | I EUH-phrases (Number and full text) | | | | | | |
| H226 | Flammable liquid and vapour. | | | | | | |
| H315 | Causes skin irritation. | | | | | | |
| H319 | Causes serious eye irritation. | | | | | | |
| H332 | Harmful if inhaled. | | | | | | |

- H332 Harmful if inhaled. H335 May cause respiratory irritation.
 - H373 May cause damage to organs through prolonged or repeated exposure.
 - H413 May cause long lasting harmful effects to aquatic life.



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Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal.

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



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

1.1. Product identifier

Rapid Liner Activator

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

Use of the substance/mixture

Activator.

1.3. Details of the supplier of the safety data sheet

| Company name: | Coltène/Whaledent AG |
|-------------------------|--|
| Street: | Feldwiesenstrasse 20 |
| Place: | CH-9450 Altstätten |
| Telephone: | +41 (71) 75 75 300 |
| Telefax: | +41 (71) 75 75 301 |
| e-mail: | info.ch@coltene.com |
| Internet: | www.coltene.com |
| Responsible Department: | Regulatory Affairs msds@coltene.com |

Further Information

Only supplied to dentists and dental laboratories or upon their instructions

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Indications of danger: Xn - Harmful, Xi - Irritant R phrases: Flammable. Harmful by inhalation. Irritating to eyes, respiratory system and skin. Harmful: danger of serious damage to health by prolonged exposure if swallowed. May cause long-term adverse effects in the aquatic environment.

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazard categories: Flammable liquid: Flam. Liq. 3 Skin corrosion/irritation: Skin Irrit. 2 Serious eye damage/eye irritation: Eye Irrit. 2 Specific target organ toxicity - single exposure: STOT SE 3 Specific target organ toxicity - repeated exposure: STOT RE 2 Hazardous to the aquatic environment: Aquatic Chronic 4 Hazard Statements: Flammable liquid and vapour. Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation. May cause damage to organs through prolonged or repeated exposure.

May cause long lasting harmful effects to aquatic life.

2.2. Label elements

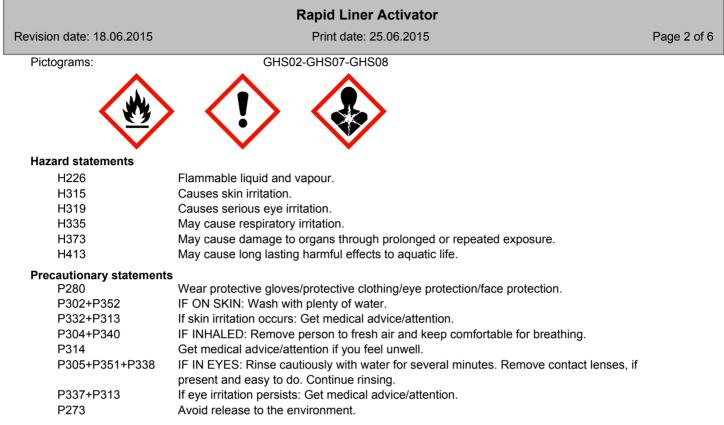
Hazardous components which must be listed on the label

Alkyl silicates Signal word:

Warning



according to Regulation (EC) No 1907/2006



Additional advice on labelling

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

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

| EC No | Chemical name | Quantity |
|------------|--|-------------|
| CAS No | Classification according to Directive 67/548/EEC | |
| Index No | Classification according to Regulation (EC) No. 1272/2008 [CLP] | |
| REACH No | | |
| | Alkyl silicates | 25 - < 30 % |
| | Xn - Harmful, Xi - Irritant R10-20-36/37/38-48/22-53 | |
| | Flam. Liq. 3, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, STOT RE 2, Aquatic Chronic 4; H226 H332 H315 H319 H335 H373 H413 | |
| 246-325-3 | Dioctyltin dicarboxylate | 1 - < 5 % |
| 24577-34-2 | Xn - Harmful R48/22-53 | |
| | STOT RE 2, Aquatic Chronic 4; H373 H413 | |

Full text of R-, H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

After contact with skin

After contact with skin, wash immediately with: Water and soap.



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After contact with eyes

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

After ingestion

Seek medical attention if problems persist.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water. Foam. Extinguishing powder. Carbon dioxide (CO2). Sand.

Additional information

Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Wipe up with absorbent material (eg. cloth, fleece). Clear contaminated areas thoroughly.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Avoid contact with skin and eyes. Observe instructions for use.

Further information on handling

After use replace the closing cap immediately.

7.2. Conditions for safe storage, including any incompatibilities

Further information on storage conditions

Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity. Recommended storage temperature: 15 - 23 °C

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Protective and hygiene measures

When using do not eat, drink or smoke.

Eye/face protection

Framed glasses.

Hand protection

Single-use gloves.

Skin protection

Lab apron.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| Physical state: | liquid |
|-----------------|--------|
| Colour: | red |



according to Regulation (EC) No 1907/2006

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| Odour: | characteristic | | |
| | | Test m | nethod |
| Changes in the physical state | | | |
| Initial boiling point and boiling range: | | >150 °C | |
| Density (at 23 °C): | | 1.0 g/cm³ | |
| Water solubility: (at 23 °C) | | insoluble | |
| Solubility in other solvents | | | |

ketone.

SECTION 10: Stability and reactivity

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.4. Conditions to avoid

Air, humid.

Further information

Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

LD50: >2000 mg/kg (Rat)

The statement is derived from products of similar composition.

| CAS No | Chemical name | | | | | |
|------------|--------------------------|--------|------------|---------|--------|--|
| | Exposure routes | Method | Dose | Species | Source | |
| | Alkyl silicates | - | | | | |
| | inhalative vapour | ATE | 11 mg/l | | | |
| | inhalative aerosol | ATE | 1.5 mg/l | | | |
| 24577-34-2 | Dioctyltin dicarboxylate | | | | | |
| | oral | LD50 | 2764 mg/kg | Rat | | |
| | dermal | LD50 | 2764 mg/kg | Rabbit | | |

Irritation and corrosivity

Causes serious eye irritation.

Irritant effect on the skin: (Rabbit) Not an irritant. The statement is derived from products of similar composition.

Sensitising effects

Guinea-pig.

no danger of sensitization.

The statement is derived from products of similar composition.

STOT-single exposure

May cause respiratory irritation.

Severe effects after repeated or prolonged exposure

May cause damage to organs through prolonged or repeated exposure.



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SECTION 12: Ecological information

12.1. Toxicity

| CAS No | Chemical name | | | | | |
|------------|--------------------------|--------|-----------|-----------|---------------|--------|
| | Aquatic toxicity | Method | Dose | [h] [d] | Species | Source |
| 24577-34-2 | Dioctyltin dicarboxylate | | | | | |
| | Acute fish toxicity | LC50 | 22.8 mg/l | 96 h | | |
| | Acute crustacea toxicity | EC50 | 12.2 mg/l | 48 h | Daphnia magna | |

Further information

May cause long-term adverse effects in the aquatic environment. Do not allow uncontrolled leakage of product into the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Can be burnt together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge.

| SECTION 14: Transport informa | ition | |
|--|--|--|
| Land transport (ADR/RID) | | |
| <u>14.1. UN number:</u> | | |
| Marine transport (IMDG) | | |
| <u>14.1. UN number:</u> | | |
| Air transport (ICAO) | | |
| <u>14.1. UN number:</u> | | |
| Other applicable information | | |
| Not a hazardous ma | terial with respect to these transportation regulations. | |
| SECTION 15: Regulatory inform | nation | |
| 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture | | |

National regulatory information

Additional information

SECTION 16: Other information

Relevant R-phrases (Number and full text)

| 10 | Flammable. |
|-----------------|---|
| 20 | Harmful by inhalation. |
| 36/37/38 | Irritating to eyes, respiratory system and skin. |
| 48/22 | Harmful: danger of serious damage to health by prolonged exposure if swallowed. |
| 53 | May cause long-term adverse effects in the aquatic environment. |
| Relevant H- and | EUH-phrases (Number and full text) |
| H226 | Flammable liquid and vapour. |
| LI245 | Courses akin irritation |

- H315 Causes skin irritation.
- H319 Causes serious eye irritation.



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| H332 | | Harmful if inhaled. | | | |
| H335 | | May cause respiratory irritation. | | | |
| H373 May cause damage to organs through prolonged or repeated exposure. | | | | | |
| H413 May cause long lasting harmful effects to aquatic life. | | | | | |
| Further Infe | ormation | | | | |
| | our present-da | ormation describes exclusively the safety requirements of the product and is based on ay knowledge. The information is intended to give you advice about the safe handling of amed in this safety data sheet, for storage, processing, transport and disposal. | | | |

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