

Safety Data Sheet

Spot It

Issued on: March 16, 2015

Version No.: 1

Revised:-

Page: 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

PRODUCT IDENTIFIER

Spot IT – angled and straight.

To mark areas of proximal contacts on crowns and bridges to adjacent tooth. For direct invasive use.

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Supplier: Directa AB, Box 723, SE-194 27 Upplands Väsby, Sweden.

Phone: +46 (0)8-506 505 75

Website: www.directadental.se

E-mail: info@directadental.se

EMERGENCY TELEPHONE

Position centre 112 (in acute emergencies) (EU, EES, GSM networks), + 46 (0)8-33 12 31 (office hours)

2. HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR THE MIXTURE

In accordance with CLP (Regulation (EC) No 1272/2008): –

In accordance with the Swedish regulation KIFS 2005:7: –

LABEL ELEMENTS

The labelling requirements of the above regulations do not apply as this is a direct invasive medical device.

Classification in accordance with the Swedish regulation KIFS 2005:7:

R PHRASES

-

S PHRASES

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ADDITIONAL INFORMATION (LABEL)

This safety data sheet is available on request to professional users.

The labelling requirements of the above regulations do not apply as this product is a direct Invasive medical device.

OTHER HAZARDS

No hazard expected under normal conditions of use.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substances

Composition in accordance with CLP (Regulation (EC) No 1272/2008).

| Chemical name | EC No | Reg. No | CAS No | Pct./Conc. | Pictogram | H code(s)* | Category |
|---------------|-------|---------|--------|------------|-----------|------------|----------|
|---------------|-------|---------|--------|------------|-----------|------------|----------|

* For full wording of R phrases and H codes refer to section 16.

**Substance with exposure limit.

Composition in accordance with the Swedish regulation KIFS 2005:7

| Chemical name | EC No | CAS No | Pct./Conc. | Symbol(s) | R phrase(s)* |
|---------------|-------|--------|------------|-----------|--------------|
|---------------|-------|--------|------------|-----------|--------------|

* For full wording of R phrases and H codes refer to section 16.

**Substance with exposure limit.

This product is manufactured entirely without toluene.

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4. FIRST AID MEASURES

SKIN CONTACT

Wash affected area with plenty of soad and water.

EYE CONTACT

If substance has got into eyes, immediately wash out with plenty of water.

INGESTION

Not expected to be harmful by ingestion. Seek medical advice if ill effects occur.

INHALATION

Inhalation is unlikely to occur.

OTHER INFORMATION

Possible irritation of affected areas.

5. FIREFIGHTING MEASURES

EXTINGUISHING MEDIA

Use water, foam or dry agent (S43).

SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

Not flammable but will support

In case of fire, do not breathe fumes.

Decomposition products may include acidic and toxic gases.

ADVICE FOR FIREFIGHTERS

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6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

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ENVIRONMENTAL PRECAUTIONS

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METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Place in appropriate container.

7. HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

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CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep in cool, dry place.

SPECIFIC END USE(S)

-

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 GENERAL

Use good personal hygiene practices.

8.2 EXPOSURE LIMITS

None assigned.

9. PHYSICAL AND CHEMICAL PROPERTIES

Article as described above.

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10. STABILITY AND REACTIVITY

This product is considered stable under normal conditions.

11. TOXICOLOGICAL INFORMATION

No experimental data available.

12. ECOLOGICAL INFORMATION

Presents no hazards to the environment.
Water Hazard Class NA (Company)

13. DISPOSAL CONSIDERATIONS

Bury on an authorised landfill site.
Incineration by an approved method could be considered.
Disposal should be in accordance with local, state or national legislation.

14. TRANSPORT INFORMATION

Not classified as dangerous goods under international transportation regulations (ADR/RID/IMO/DGR).

15. REGULATORY INFORMATION

Safety data sheet and classification in accordance with CLP (regulation (EC) No 1272/2008 and regulation (EU) No 453/2010, Annex I) and Swedish regulation KIFS 2005:7.

Not classified as hazardous for users.

16. OTHER INFORMATION

Classification in accordance with CLP (Regulation (EC) No 1272/2008)

Pictogram:

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Signal words:

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Precautionary statements:

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Hazard statements:

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The information contained in this safety data sheet is a complement to other information. The user must decide if the given information is adequate. The responsibility for product safety and the information contained in this safety data sheet rests with Directa AB.