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

### 1.1. Product identifier

- **Product code**: F/G 5101
- **Product name**: Universal Impression Tray Adhesive
- **Product description**: Dental Impression Tray Adhesive

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

**Relevant identified uses**: Professional Dental Impression Tray Adhesive

### 1.3. Details of the supplier of the safety data sheet

**Manufacturer**
Ultradent Products, Inc.
505 W. 10200 S.
South Jordan, UT 84095

**Distributor**
Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany
Email: infoDE@ultradent.com

**Emergency Phone**: +49(0)2203-35-92-0

### 1.4. Emergency telephone number

- CHEMTREC (NORTH AMERICA) : (800) 424 - 9300
- (INTERNATIONAL) : +1(703) 527-3887

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

**Classification according to Directive 1999/45/EC**

- The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.
  - **Danger symbols**: F,Xn
  - **R phrases**: R11,R61,R20/21

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

- **Health**
  - Skin Irritation, Category 2
  - Reproductive Toxicity, Category 2
  - Acute Toxicity (Dermal), Category 4
  - Aspiration Hazard, Category 1
  - Target Organ Toxicity (Repeated exposure), Category 2
  - Eye Irritation, Category 2
  - Target Organ Toxicity (Single exposure), Category 3

- **Physical**
  - Flammable Liquids, Category 3

### 2.2. Label elements

- This mixture contains ETHYLBENZENE, TOLUENE, and XYLENE (MIXTURE OF ISOMERS)

**Classification according to Directive 1999/45/EC**

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**SAFETY DATA SHEET**

designed to Regulation (EC) No. 453/2010

**Dental Use**

**Date Issued**: 01/25/2007
**SDS No**: 141-001.4
**Date Revised**: 02/17/2016
**Revision No**: 4
Universal Impression Tray Adhesive

Hazard pictogram(s) : F Xn
- Highly flammable
- Harmful

R& statement(s) : R11: Highly flammable.
R61: May cause harm to the unborn child.
R20/21: Harmful by inhalation and in contact with skin.

Classification according to Regulation(EC) No 1272/2008 [CLP]
Hazard pictogram(s) :
- Exclamation mark
- Health hazard
- Flame

Signal Word : DANGER

Hazard statement(s) : H315: Causes skin irritation.
H335: May cause respiratory irritation.
H319: Causes serious eye irritation.
H373: May cause damage to organs through prolonged or repeated exposure.
H304: May be fatal if swallowed and enters airways.
H226: Flammable liquid and vapour.
H361d: Suspected of damaging the unborn child.

Precautionary statement(s)

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

Response : P305: IF IN EYES:
P351: Rinse cautiously with water for several minutes.
P315: Get immediate medical advice/attention.
P302: IF ON SKIN:
P353: Rinse skin with water [or shower].
P362: Take off contaminated clothing.
P332+P313: If skin irritation occurs: Get medical advice/attention.
P363: Wash contaminated clothing before reuse.
P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P331: Do NOT induce vomiting.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Storage : P273: Avoid release to the environment.
P233: Keep container tightly closed.

Disposal : P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-
### Universal Impression Tray Adhesive

20/11/2003)

2.3. Other hazards

<table>
<thead>
<tr>
<th>Immediate concerns</th>
<th>Highly Flammable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health hazards</td>
<td>Warning! This product contains a chemical that causes birth defects or reproductive harm. Toluene.</td>
</tr>
<tr>
<td>Additional information</td>
<td>On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0.1%.</td>
</tr>
</tbody>
</table>

### SECTION 3: Composition / information on ingredients

#### 3.1. Substances

Not Applicable

#### 3.2. Mixtures

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Directive 67/548/EEC</th>
<th>Classification according to Regulation(EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xylene</td>
<td>1330-20-7</td>
<td>215-535-7</td>
<td>≤ 30</td>
<td>Xi; R10; R20/21; R38</td>
<td>Flam. Liq.,Cat 3; Acute Tox. (D),Cat. 4; Acute Tox. (I),Cat. 4; Asp. Tox.,Cat. 1; STOT RE,Cat. 2; Eye Irr.,Cat. 2; Skin Irr.,Cat. 2; STOT SE,Cat. 3; H226; H312; H315; H332; H304; H373; H319; H335</td>
</tr>
<tr>
<td>Toluene</td>
<td>108-88-3</td>
<td>203-625-9</td>
<td>≤ 20</td>
<td>F; Xn; R11; R38; R48/20; R63; R65; R67</td>
<td>Flam. Liq.,Cat. 2; Skin Irr.,Cat. 2; Asp. Tox.,Cat. 1; Rep. Tox.,Cat. 2; STOT SE,Cat. 3; STOT RE,Cat. 2; H225; H315; H336; H373; H361d</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Ethyl Benzene</th>
<th>100-41-4</th>
<th>202-849-4</th>
<th>≤ 19</th>
<th>Flam. Liq., Cat. 2; Acute Tox. (I), Cat. 4; Asp. Haz., Cat. 1; STOT RE, Cat. 2; Aquatic Chronic, Cat 3; H225; H332; H304; H373; H412</th>
</tr>
</thead>
</table>

For full text of H-statements and R-phrases: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

Following skin: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention immediately. Wash contaminated clothing before using it again.

Following ingestion: Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

Following inhalation: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately.

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

Eyes: Acute effects: stinging eyes Symptoms may include: rubescence, edema, pain and lachrymation.

Skin: Acute effects: contact with skin may cause: irritation, erythema, edema, dryness and chapped skin.

Ingestion: Ingestion may cause health disorders, including stomach pain and sting, nausea and sickness.

Inhalation: Acute effects: inhalation of this product may irritate the lower and upper respiratory tract and cause cough and respiratory disorders, at higher concentrations it can also cause pulmonary edema.

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

Notes to physician: Harmful if swallowed and inhaled.

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media: SUITABLE EXTINGUISHING EQUIPMENT
Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.
UNIVERSAL IMPRESSION TRAY ADHESIVE

5.2. Special hazards arising from the substance or mixture

General hazard:
- HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE
  - Excess pressure may form in containers exposed to fire at a risk of explosion.
  - Do not breathe combustion products.

Hazardous combustion products:
- In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

5.3. Advice for firefighters

Fire fighting procedures:
- GENERAL INFORMATION
  - Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

Fire fighting equipment:
- SPECIAL PROTECTIVE EQUIPMENT FOR FIRE - FIGHTERS
  - Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A20) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General procedures:
- Block the leakage if there is no hazard.
  - Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

Water spill:
- The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

- Collect the leaked product into a suitable container. Evacuate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.
  - Make sure the leakage site is well aired. Check incompatibility for container material in section 7. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Reference to other sections:
- Any information on personal protection and disposal is given in sections 8 and 13.
7.1. Precautions for safe handling

**Handling**

: Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Vapours may catch fire and an explosion may occur; vapour accumulation is therefore to be avoided by leaving windows and doors open and ensuring good cross ventilation. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. When performing transfer operations involving large containers, connect to an earthing system and wear antistatic footwear. Vigorous stirring and flow through the tubes and equipment may cause the formation and accumulation of electrostatic charges. In order to avoid the risk of fires and explosions, never use compressed air when handling. Open containers with caution as they may be pressurised. Do not eat, drink or smoke during use. Avoid leakage of the product into the environment.

**Storage**

: Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Store in a well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. Keep containers away from any incompatible materials, see Section 10 for details.

7.2. Conditions for safe storage, including any incompatibilities

7.3. Specific end use(s)

: Professional Dental Impression Tray Adhesive

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

**Control parameters**

: XYLENE (MIXTURE OF ISOMERS)

<table>
<thead>
<tr>
<th>Type Country</th>
<th>TWA/8h</th>
<th>STEL/15min</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg/m³ ppm</td>
<td>mg/m³ ppm</td>
<td></td>
</tr>
<tr>
<td>MAK AUS</td>
<td>221 50 442 100 SKIN.</td>
<td></td>
</tr>
<tr>
<td>VLEP BEL</td>
<td>221 50 442 100 SKIN.</td>
<td></td>
</tr>
<tr>
<td>TLV CZE</td>
<td>200 400 SKIN</td>
<td></td>
</tr>
<tr>
<td>AGW DEU</td>
<td>440 100 880 200 SKIN.</td>
<td></td>
</tr>
<tr>
<td>MAK DEU</td>
<td>440 100 880 200 SKIN.</td>
<td></td>
</tr>
<tr>
<td>VLA ESP</td>
<td>221 50 442 100 SKIN.</td>
<td></td>
</tr>
<tr>
<td>HTP FIN</td>
<td>220 50 440 100 SKIN.</td>
<td></td>
</tr>
<tr>
<td>VLEP FRA</td>
<td>221 50 442 100 SKIN.</td>
<td></td>
</tr>
<tr>
<td>WEL GRB</td>
<td>220 50 441 100</td>
<td></td>
</tr>
<tr>
<td>OEL IRL</td>
<td>221 50 442 100 SKIN.</td>
<td></td>
</tr>
<tr>
<td>TLV ITA</td>
<td>221 50 442 100 SKIN.</td>
<td></td>
</tr>
<tr>
<td>OEL NLD</td>
<td>210 442 SKIN.</td>
<td></td>
</tr>
<tr>
<td>TLV NOR</td>
<td>108 25 SKIN.</td>
<td></td>
</tr>
<tr>
<td>NDS POL</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>MAK SWE</td>
<td>221 50 442 100 SKIN.</td>
<td></td>
</tr>
</tbody>
</table>
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OEL EU 221 50 442 100 SKIN.
TLV-ACGIH 434 100 651 150
Predicted no-effect concentration - PNEC.
Normal value in fresh water 0,327 mg/l
Normal value in marine water 0,327 mg/l
Normal value for fresh water sediment 12,46 mg/kg
Normal value for marine water sediment 12,46 mg/kg
Normal value for water, intermittent release 0,327 mg/l
Normal value of STP microorganisms 6,58 mg/l
Health - Derived no-effect level - DNEL / DMEL
Effects on consumers.
Effects on workers
Route of exposure Acute local Acute systemic Chronic local Chronic systemic
Acute local Acute systemic
Chronic local Chronic systemic
Oral. VND 1,6 mg/kg
Inhalation. VND 174 mg/m3 174 mg/m3 14,8 mg/m3 VND 289 mg/m3 VND 77 mg/m3
Skin. VND 108 mg/kg VND 180 mg/kg
TOLUENE
Threshold Limit Value.
Type Country TWA/8h STEL/15min
mg/m3 ppm mg/m3 ppm
MAK AUS 190 50 380 100 SKIN.
VLEP BEL 77 20 384 100 SKIN.
TLV CZE 200 500 SKIN.
AGW DEU 190 50 760 200 SKIN.
MAK DEU 190 50 760 200
TLV DNK 94 25 SKIN.
VLA ESP 192 50 384 100 SKIN.
HTP FIN 81 25 380 100 SKIN.
VLEP FRA 76,8 20 384 100 SKIN.
WEL GRB 191 50 384 100 SKIN.
OEL IRL 192 50 384 100 SKIN.
TLV ITA 192 50 SKIN.
OEL NLD 150 384
TLV NOR 94 25 SKIN.
NDS POL 100 350
MAK SWE 192 50 384 100 SKIN.
OEL EU 192 50 384 100 SKIN
TLV-ACGIH 75,4 20
ETHYLBENZENE
Threshold Limit Value.
Universal Impression Tray Adhesive

Type Country TWA/8h STEL/15min
mg/m³ ppm mg/m³ ppm
MAK AUS 440 100 880 200 SKIN.
VLEP BEL 442 100 551 125 SKIN.
TLV CZE 200 500 SKIN.
AGW DEU 440 100 880 200 SKIN.
MAK DEU 88 20 176 40 SKIN.
TLV DNK 217 50
VLA ESP 441 100 884 200 SKIN.
HTP FIN 220 50 880 200 SKIN.
VLEP FRA 88.4 20 442 100 SKIN.
WEL GRB 441 100 552 125 SKIN.
OEL IRL 442 100 884 200 SKIN.
TLV ITA 442 100 884 200 SKIN.
OEL NLD 215 430 SKIN.
TLV NOR 20 5 SKIN.
NDS POL 200 400
MAK SWE 200 50 450 100
OEL EU 442 100 884 200 SKIN.
TLV-ACGIH 87 20
Legend:
(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ;
THORA = Thoracic Fraction.
VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure
expected ; NPI = no hazard identified

8.2. Exposure controls

Engineering controls
: As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local ventilation. Personal protective equipment must be CE marked, showing that it complies with applicable standards.
Provide an emergency shower with face and eye wash station.
Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).

Eye/face protection
: Wear airtight protective goggles (see standard EN 166)

Skin protection
: HAND PROTECTION
Protect hands with category III work gloves (see standard EN 374).
The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.
The work gloves’ resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves’ wear time depends on the duration and type of use.

SKIN PROTECTION
Wear category II professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.
Universal Impression Tray Adhesive

Consider the appropriateness of providing antistatic clothing in the case of working environments in which there is a risk of explosion.

Respiratory protection: If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required. Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited. If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529

Other precautions: ENVIRONMENTAL EXPOSURE CONTROLS. The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>Red</td>
</tr>
<tr>
<td>Odour</td>
<td>characteristic of solvent</td>
</tr>
<tr>
<td>Boiling temperature</td>
<td>113°C</td>
</tr>
<tr>
<td>Flash point</td>
<td>27°C</td>
</tr>
<tr>
<td>Density</td>
<td>1,011 Kg/l</td>
</tr>
<tr>
<td>Solubility in water</td>
<td>Partially miscible</td>
</tr>
</tbody>
</table>

9.2. Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent volatile</td>
<td>Not Determined</td>
</tr>
</tbody>
</table>

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity: There are no particular risks of reaction with other substances in normal conditions of use. TOLUENE: breaks down in sunlight.

10.2. Chemical stability

Chemical stability: The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions
Possibility of hazardous reactions: The vapours may also form explosive mixtures with the air. TOLUENE: risk of explosion on contact with fuming sulphuric acid, nitric acid, silver perclorates, nitrogen dioxide, non-metal halogenides, acetic acid, organic nitrocompounds. Can form explosive mixtures with the air. May react dangerously with strong oxidizing agents, strong acids, sulphur (in the presence of heat).

10.4. Conditions to avoid
Conditions to avoid: Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition.

10.5. Incompatible materials
Incompatible materials: Information not available.

10.6. Hazardous decomposition products
Hazardous decomposition products: In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

SECTION 11: Toxicological information
11.1. Information on toxicological effects
Acute
Notes: In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification. It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product. This product must be handled carefully because of its possible teratogenic effects, which may be toxic and damage the foetus development. The introduction of even small quantities of this liquid into the respiratory system in case of ingestion or vomit may cause bronchopneumonia and pulmonary edema. This product may cause functional disorders or morphological mutations after repeated or prolonged exposure and/or may accumulate inside the human body and is thus graded as dangerous. Acute effects: stinging eyes. Symptoms may include: rubescence, edema, pain and lachrymation. Ingestion may cause health problems, including stomach pain and sting, nausea and sickness. Acute effects: contact with skin may cause: irritation, erythema, edema, dryness and chapped skin. Ingestion may cause health disorders, including stomach pain and sting, nausea and sickness. Acute effects: inhalation of this product may irritate the lower and upper respiratory tract and cause cough and respiratory disorders; at higher concentrations it can also cause pulmonary edema. Ingestion may cause health problems, including stomach pain and sting, nausea and sickness.
ETHYLBENZENE
LD50 (Oral).3500 mg/kg Rat
LD50 (Dermal).15354 mg/kg Rabbit
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LC50 (Inhalation).17,2 mg/l/4h Rat
Irritation/Corrosion
Skin irritation: Slightly irritating (publication, rabbit, in vivo, ECHA dossier).
Eye irritation: Slightly irritating (publication, rabbit, in vivo, ECHA dossier).
Skin Sensitization: No data available.
Genotoxicity: Negative (OECD 473, in vitro mammalian chromosome aberration test and OECD 486, in vivo, ECHA dossier).
Carcinogenicity: Insufficient data. According to NTP there was some evidence of carcinogenicity in a test conducted on mice (lung tumors and hepatocellular neoplasms) (NTP study, GLP, ECHA dossier).
Toxicity to reproduction: Negative (OECD 415, rat, ECHA dossier).
STOT Repeated exposure: Insufficient data. Liver, lung, thyroid and pituitary pathology was observed in mice that inhaled >= 250 ppm ethylbenzene for 2 years.(ECHA dossier).
ETHYLBENZENE: like the benzene homologues, may exert an effect on the CNS with depression, narcosis, often preceded by dizziness and accompanied by headache. It is irritating to the skin, conjunctivae and respiratory apparatus.
XYLENE (MIXTURE OF ISOMERS)
LD50 (Oral).3523 mg/kg (EU Method B.1, GLP, rat, ECHA dossier).
LD50 (Dermal).> 4200 mg/kg (rabbit, ECHA dossier).
LC50 (Inhalation).6350 ppm (EU Method B.2, rat, ECHA dossier).
Acute toxicity:
Dermal: No data available.
Irritation/Corrosion
Skin irritation: Slightly irritating (weight of evidence approach, in vivo, rabbit, ECHA dossier).
Eye irritation: Slightly irritating (weight of evidence approach, in vivo, rabbit, ECHA dossier).
Skin Sensitization: Insufficient data (ECHA dossier).
STOT - Repeated exposure: There was no evidence of treatment-related systemic toxicity or carcinogenicity following gavage administration of mixed xylenes (oral and inhalation exposure, ECHA dossier).
Genotoxicity in vitro: Negative (in vitro mammalian chromosome aberration test, ECHA dossier).
Genotoxicity in vivo: Negative (similar to OECD 478, mixed xylenes, chromosome aberration, ECHA dossier).
Carcinogenicity: Negative (EU Method B.32, rat, ECHA dossier).
Toxicity to reproduction: Negative (EPA OPPTS 870.3800, rat, ECHA dossier).
TOLUENE
LD50 (Oral).5580 mg/kg (rat, ECHA dossier).
LD50 (Dermal).12124 mg/kg (rabbit, ECHA dossier).
LC50 (Inhalation).28,1 mg/l/4h (rat, ECHA dossier).
Irritation/Corrosion
Skin irritation: Irritating (OECD 404, in vivo, rabbit, ECHA dossier).
Eye irritation: Not irritating (OECD 405, in vivo, rabbit, ECHA dossier).
Skin Sensitization: Not sensitising (OECD 406, Magnusson-Kligman, ECHA dossier).
Universal Impression Tray Adhesive

STOT - Repeated/single exposure: Target organ: central nervous system (inhalation exposure, tests on animals, ECHA dossier).
Genotoxicity in vitro: Negative (OECD 471, OECD 476, mutation assay, ECHA dossier).
Genotoxicity in vivo: Negative (Chromosome aberration assay, rat, ECHA dossier).
Carcinogenicity: No data available.
Toxicity to reproduction: Possible adverse effects on fetal development (OECD 416 and EPA OTS 798.4350, rat, ECHA dossier).
Aspiration toxicity: Possible chemical pneumonitis (ECHA dossier).

TOLUENE: it has a toxic effect on the central and peripheral nervous system (with encephalopathies and polyneuritis). Irritating to the skin, conjunctivae, cornea and respiratory apparatus.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity Parameter</th>
<th>Concentration</th>
<th>Species/Environmental Conditions</th>
<th>ECHA dossier</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOLUENE</td>
<td>LC50 - for Fish.</td>
<td>5.5 mg/l/96h</td>
<td>Oncorhynchus kisutch, dynamic, freshwater</td>
<td>ECHA dossier</td>
</tr>
<tr>
<td></td>
<td>EC50 - for Crustacea</td>
<td>3.78 mg/l/48h</td>
<td>Daphnia magna, semi-static, freshwater</td>
<td>ECHA dossier</td>
</tr>
<tr>
<td></td>
<td>EC50 - for Algae / Aquatic Plants</td>
<td>134 mg/l/72h</td>
<td>(ECHA dossier)</td>
<td></td>
</tr>
<tr>
<td>XYLENE (MIXTURE OF ISOMERS)</td>
<td>LC50 - for Fish.</td>
<td>7.6 mg/l/96h</td>
<td>Oncorhynchus mykiss, OECD 203</td>
<td>ECHA dossier</td>
</tr>
<tr>
<td></td>
<td>EC50 - for Crustacea</td>
<td>3.82 mg/l/48h</td>
<td>Daphnia magna, ECHA dossier</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC50 - for Algae / Aquatic Plants</td>
<td>4.36 mg/l/72h</td>
<td>(OECD 201, Pseudokirchneriella subcapitata)</td>
<td>ECHA dossier</td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability

<table>
<thead>
<tr>
<th>Substance</th>
<th>Persistence and degradability</th>
<th>ECHA dossier</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHYLBENZENE</td>
<td>Solubility in water. mg/l 1000 - 10000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rapidly biodegradable.</td>
<td></td>
</tr>
<tr>
<td>XYLENE (MIXTURE OF ISOMERS)</td>
<td>Solubility in water. mg/l 100 - 1000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rapidly biodegradable.</td>
<td></td>
</tr>
<tr>
<td>TOLUENE</td>
<td>Solubility in water. mg/l 1000 - 10000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rapidly biodegradable.</td>
<td></td>
</tr>
</tbody>
</table>

12.3. Bioaccumulative potential

<table>
<thead>
<tr>
<th>Substance</th>
<th>Bioaccumulative potential</th>
<th>ECHA dossier</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHYLBENZENE</td>
<td>Partition coefficient: n-octanol/water</td>
<td></td>
</tr>
</tbody>
</table>
Universal Impression Tray Adhesive

3.6
TOLUENE
Partition coefficient: n-octanol/water.
2.73
BCF. 90

12.4. Mobility in soil
Mobility in soil: Information not available

12.5. Results of PBT and vPvB assessment
Results of PBT and vPvB assessment: On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0.1%.

12.6. Other adverse effects
Environmental data: Information not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Disposal method: Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations. Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations. Waste transportation may be subject to ADR restrictions. CONTAMINATED PACKAGING Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14: Transport information

14.1. UN number
UN number: 1133

14.2. UN proper shipping name
UN proper shipping name: Adhesives (containing flammable liquid);

14.3. Transport hazard class(es)
Hazard classification: 3

14.4. Packing group
Packing group: III

14.5. Environmental hazards
Marine pollutant #1: N/A

14.6. Special precautions for user
ADR - road: HIN - Kemler: 30 Limited Quantities 5L (D/E) Tunnel restriction code Special Provision: 640E
SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

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IMDG - sea
: EMS: F-E, S-D
Limited Quantities 5L

IATA - air
: Cargo: Maximum quantity: 220 L Packaging instructions: 366
Pass.: Maximum quantity: 60 L Packaging instructions: 355
Special Instructions: A3

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
Transport in bulk
: Information not relevant.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
RoHS
: Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment
Chemical safety assessment
: No chemical safety assessment has been processed for the mixture and the substances it contains.

Additional information
: WARNING! This product contains a chemical known to cause birth defects or other reproductive harm. Toluene.

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text)
: R10: Flammable.
R11: Highly flammable.
R20/21: Harmful by inhalation and in contact with skin.
R36: Irritating to eyes.
R38: Irritating to skin.
R48/20: Harmful: danger of serious damage to health by prolonged exposure through inhalation.
R63: Possible risk of harm to the unborn child.
R65: Harmful: may cause lung damage if swallowed.
R67: Vapors may cause drowsiness and dizziness.
Acute Tox. (D), Cat. 4: Acute Toxicity (Dermal), Category 4
Acute Tox. (I), Cat. 4: Acute Toxicity (Inhalation), Category 4
Aquatic Chronic, Cat 3: Chronic Hazards to the Aquatic Environment, Category 3
Asp. Haz., Cat. 1: Aspiration Hazard, Category 1
Asp. Tox., Cat. 1: Aspiration Toxicity, Category 1
Eye Irr., Cat. 2: Eye Irritation, Category 2
Flam. Liq., Cat 3: Flammable Liquids, Category 3
Flam. Liq., Cat. 2: Flammable Liquids, Category 2
Rep. Tox., Cat. 2: Reproductive Toxicity, Category 2
STOT RE, Cat 2: Target Organ Toxicity (Repeated exposure), Central nervous system, Category 2
STOT RE, Cat 2: Target Organ Toxicity (Repeated exposure), Category 2
STOT SE, Cat 3: Target Organ Toxicity (Single exposure), Category 3
STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Category 3
Skin Irr., Cat. 2: Skin Irritation, Category 2
H225: Highly flammable liquid and vapour.
H226: Flammable liquid and vapour.
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H304: May be fatal if swallowed and enters airways.
H312: Harmful in contact with skin.
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H332: Harmful if inhaled.
H335: May cause respiratory irritation.
H336: May cause drowsiness or dizziness.
H361d: Suspected of damaging the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.
H412: Harmful to aquatic life with long lasting effects.

Prepared by : Anu Kattoju
Revision summary : This SDS replaces the 12/18/2014 SDS. Revised: Section 1: Date-Revised.
General statements : N/A= Not Applicable
Manufacturer disclaimer : FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer’s knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.