

Safety Data Sheet

According to Regulation (EU) 2015/830

IMPORTANT

Read this MSDS before handling and disposing of this product and pass this information on to employees, customers and users of this product.

1. IDENTIFICATION

1.1 Product Identifier

Product Name	Fix II Tray Adhesive
--------------	----------------------

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

Product Use	(SU22) professional uses: Public domain (administration, education, entertainment, services, craftsmen); (SU20) Health services;
Restricted Use	(SU21) Consumer Uses: Private households (=general public = consumers);
Description	Dental Product

1.3 Supplier of the Safety Data Sheet

Company Name	Perfection Plus Ltd
Company Address	6 Westwood Court, Brunel Road, Totton, Hants. SO40 3WX. UK
Company Phone No.	+44 (0) 2380 866 677
Website	www.perfectionplus.com
Telephone	0044 (0) 2380 866677
Email	Regulatory@perfectionplus.com
Email address of Competent Person	Regulatory@perfectionplus.com

1.4 Emergency telephone number


Emergency telephone number	0044 (0) 230 866 677 (8am – 5pm Monday to Friday)
----------------------------	--

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.2. Classification - EC 1272/2008	H225 – Flammable Liquid 2 H304 - Aspiration Hazard 1 H315 - Skin Irritant 2 H319 - Eye Irritant 2 Specific Target Organ Toxicity H373 - Single exposure 3 Specific Target Organ Toxicity H373 - Repeated Exposure 2 H361 - Reproductive Toxicity 2
--------------------------------------	--

2.2 Label Elements

Hazard Pictograms	
Signal Word	Danger
Hazard Statement	H225 – Highly flammable liquid and vapour H304 – May be fatal if swallowed and enters airways H315 – Causes skin irritation H319 – Causes serious eye irritation H335 – May cause respiratory inflammation H373 – May cause damage to organs through prolonged or repeated exposure H361 – Suspected of damaging fertility or the unborn child
Precautionary Statement: Prevention	P201 – Obtain special instructions before use. P202 – Do not handle until all safety precautions have been read and understood.

	P210 – Keep away from heat/sparks/open flames/hot surfaces – no Smoking P240 – Ground/bond container and receiving equipment P241 – use explosion-proof equipment P242 – Use only non-sparking tools. P243 – Take precautionary measures against static discharge. P260 – Do not breathe dust/fumes/gas/mist/vapours/spray. P261 – Avoid breathing dust /fumes/gas/mist/vapours/spray. P264 – Wash hands thoroughly after handling. P271 – Use only outdoors or in a well-ventilated area. P280 – Wear protective gloves/protective clothing/eye protection/face protection. P281 – Use personal protective equipment as required.
Precautionary Statement: Response	P301+P310 – IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician. P302+P352 – IF ON SKIN: wash with plenty of soap and water. P303+P361+P353 – IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse SKIN with water/shower. P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308+P313 – IF exposed or concerned: Get medical advice/attention. P314 – Get medical advice/attention if you feel unwell. P321 – Specific treatment (section 4 on this SDS sheet). P331 – Do NOT Induce vomiting. P337+P313P – IF eye irritation persists: Get medical advice/attention. P363 – Wash contaminated clothing before reuse. P370+P378 – In case of fire: use carbon dioxide, foam, or dry chemical for extinction.
Precautionary Statements: Storage	P403+P233 – Store in a well-ventilated place. Keep container tightly closed. P403+P235 – Store in a well-ventilated place. Keep cool. P405 – Store locked up.
Precautionary Statements: Disposal	P501 – Dispose of contents/container to appropriate location in accordance with local and national regulations.

2.3 Other hazards

Other hazards	None known.
---------------	-------------

2.4 Unknown acute toxicity

	No data available.
--	--------------------

Further information

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	CONC. (%w/w)	Classification
Isopropyl Alcohol		67-63-0	200-661-7		25-50%	H225, H319, H335
Polyamide Curing Agent		108-88-3/ 68139-75-3/ 67-63-0	203-625-9 614-310-4 200-661-7		50-75%	H225, H304, H315, H319, H335, H336, H373, H361

4. FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	Move to fresh air. If breathing is laboured, administer oxygen.
Eye Contact	Flush with plenty of water for at least 15 minutes. Call a physician.
Skin contact	Wash exposed areas thoroughly with soap and water. Remove contaminated clothing.
Ingestion	Do not induce vomiting. Give large quantities of milk or water. Call physician.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation	Respiratory irritation, dizziness, nausea.
Eye Contact	Severe eye irritation, redness, tearing or blurred vision.
Skin contact	Irritation, defatting or dermatitis.

4.3 Indication of any immediate medical attention and special treatment needed

Inhalation	Seek medical attention if irritation or symptoms persist.
Eye Contact	Seek medical attention if irritation or symptoms persist.
Skin contact	Seek medical attention if irritation or symptoms persist.
Ingestion	Seek medical attention in case of high quantities of ingestion.

General information

	Note to physicians (Treatment, Testing and Monitoring): Treat symptomatically.
--	--

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

	Carbon dioxide, dry chemical or appropriate foam.
--	---

5.2 Special hazards arising from the substance or mixture

	May produce hazardous fumes.
--	------------------------------

5.3 Advice for firefighters

Firefighting procedures	General: Evacuate all personnel. Use protective equipment for fire-fighting. Wear full protective equipment including self-contained breathing apparatus, use water only as a blanket. Water may spread fire (product floats on water).
Precautions for fire fighters	Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

	Remove all ignition sources such as open flames, spark producing equipment, pilot lights etc. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.
--	--

6.2 Environmental precautions

	Prevent entry into sewers and waterways. Report releases as required by local, state and national authorities. Avoid contact with skin, eyes and clothing. Wear appropriate protective clothing as described in Section 8.
--	--

6.3 Methods and material for containment and cleaning up

	Clean up with absorbent material and remove residue with alcohol damp wipe. Rinse spill area with water. Use non-sparking tools and equipment.
--	--

6.4 Reference to other sections

	See section 13 for disposal information. See section 8 for exposure controls/personal protection.
--	---

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

	Avoid contact with eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Wash thoroughly after handling. Keep away from heat, sparks, flames and other sources of ignition.
--	--

7.2 Conditions for safe storage, including any incompatibilities

	Keep in a cool, dry, well-ventilated area away from heat, direct sunlight and all sources of ignition. Store away from incompatible materials. Keep containers tightly closed.
--	--

7.3 Specific end use(S)

	No specific end use other than that mentioned in Section 1.2.
--	---

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

	No additional information available.
--	--------------------------------------

8.2 Exposure controls



8.2.1 Appropriate engineering controls

	None required under normal product handling conditions.
--	---

8.2.2 Individual protection measures

Eye/face protection	Chemical safety goggles should be worn if needed to avoid eye contact.
Specific Skin protection	Wear impervious gloves such as natural rubber or neoprene if needed to avoid skin contact. Consult glove supplier for thickness and breakthrough times. Wash hands thoroughly after using.
Specific Respiratory protection	Wear respirator with organic vapour cartridge. No extra protection is necessary with local exhaust.
Specific Thermal Hazards	Non required.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Viscous liquid	Clarity	Slightly Turbid
Colour	Blue Green	Specific gravity	0.855-0.865
Odour	No data available	Refractive index	1.4365-1.4404
Odour threshold	No data available	Vapour pressure	No data available
pH	No data available	Vapour density	>1
Melting/Freezing point	No data available	Solubility	No data available
Initial boiling point	No data available	Partition coefficient	No data available
Flash point	14°C/57°F	Autoignition temperature	No data available
Evaporation rate	No data available	Decomposition temperature	No data available
Flammability (solid/gas)	No data available	Viscosity	No data available
Explosive properties	No data available	Oxidising properties	No data available

9.2. Other information

Conductivity	No data available
Surface tension	No data available
Gas group	No data available
Benzene content	No data available
Lead content	No data available
VOC (Volatile organic compounds)	No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

	Volatile at ambient temperature and under normal conditions of use.
--	---

10.2 Chemical stability

	Stable at standard temperature and pressure.
--	--

10.3 Possibility of hazardous reactions

	None known.
--	-------------

10.4 Conditions to avoid

	Keep away from heat, sparks, incompatible materials, flames and other sources of ignition.
--	--

10.5 Incompatible materials

	High temperatures, strong oxidising agents. Keep away from sunlight and open flames.
--	--

10.6 Hazardous decomposition products

	Toxic fumes of carbon monoxide, carbon dioxide.
--	---

11. TOXICOLOGICAL INFORMATION
11.1 Information on toxicological effects

Chronic effects	No chronic health effects reported.
Target Organs	No target organs reported
Carcinogenicity	Not classified

12. ECOLOGICAL INFORMATION
12.1 Toxicity

	No data available
--	-------------------

12.2 Persistence and degradability

	No data available
--	-------------------

12.3 Bio accumulative potential

	No data available
--	-------------------

12.4 Mobility in soil

	No data available
--	-------------------

12.5 Results of PBT and vPvB assessment

	No data available
--	-------------------

12.6 Other adverse effects

	No data available
--	-------------------

13. DISPOSAL CONSIDERATIONS
13.1 Waste treatment methods

Regulations	Dispose of in compliance with all local and national regulations.
Properties (Physical/Chemical) Affecting disposal	None currently known
Waste treatment recommendations	Dispose in accordance with national and local regulations.

General information

	18 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care). 18 01 wastes from natal care, diagnosis, treatment or prevention of disease in humans. 18 01 06 chemicals consisting of or containing dangerous substances.
--	---

Disposal Methods

	Do not empty in to drains. For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used.
--	---

Disposal of packaging

	Do NOT reuse empty canisters. Empty containers can be sent for disposal or recycling.
--	---

14. TRANSPORT INFORMATION
14.1 UN number

	UN1993
--	--------

14.2 UN proper shipping name

	Flammable liquids, N.O.S.
--	---------------------------

14.3 Transport hazard class(es)

	3
--	---

14.4 Packing group

	Not applicable
--	----------------

14.5 Environmental hazards

	Not applicable
14.6 Special precautions for user	
	Not applicable
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	
	Not applicable

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

Regulations	COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.
-------------	--

15.2 Chemical Safety Assessment

	No data available.
--	--------------------

16. OTHER INFORMATION
HMIS Hazard Rating

Health: 3	Flammability: 3	Reactivity: 0
-----------	-----------------	---------------

Other information

Text of Hazard Statements in Section 2 and 3	H225 – Highly flammable liquid and vapour H304 – May be fatal if swallowed and enters airways H315 – Causes skin irritation H319 – Causes serious eye irritation H335 – May cause respiratory irritation H336 – May cause drowsiness or dizziness H373 – May cause damage to organs through prolonged or repeated exposure H361 – Suspected of damaging fertility or the unborn child
--	--

Further information

This product is manufactured by Dental Technologies, Inc., 6901 N. Hamlin Avenue, Lincolnwood, IL 60712, USA and the contained SDS information is supplied by them.

The information used in this SDS is believed to be correct however, the information is provided without any warranty, neither expressed nor implied, regarding its correctness.

The conditions or methods of handling, storage, use alone or in combination with other products, or disposal of the product are beyond our control and may be beyond our knowledge.

For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.

This SDS was prepared and is to be used only for this product. If the product is used as a component in or in combination with another product, this SDS information may not be applicable.