

ESTEC EM II PLUS PASTE B

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2020/878

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**1.1 Product identifier**

Product Name ESTEC EM II PLUS PASTE B

1.2 Relevant identified uses of the substance or mixture and uses advised againstIdentified Use(s) **【Medical Device】** Adhesive resin cement. For dental professionals only.

Uses Advised Against Use only for intended applications.

1.3 Details of the supplier of the safety data sheet**Manufacturer**

Company Identification Tokuyama Dental Corporation
 Address of Manufacturer 38-9, Taitou 1-chome, Taitou-ku, Tokyo, Japan
 Postal code 110-0016
 Telephone: +81-3-3835-2261
 Fax +81-3-3835-2265
 E-mail <https://tokuyama-dental.com/contact/>

Supplier

Company Identification Tokuyama Dental Italy S.r.l.
 Address of Supplier Via Chizzalunga, 1, 36066 Sandrigo, Vicenza, Italy
 Postal code 36066
 Telephone: +39-0444-659650
 Fax +39-0444-750345
 E-mail <https://tokuyama-dental.com/contact/>

1.4 Emergency telephone number

Emergency Phone No.

018 092 566

Contact

The National Poisons Information Centre of Ireland
 Beaumont Hospital

PO Box 1297, Beaumont Road, Dublin, Ireland.

Members of Public : +353 (1) 809 2166.

(8.00 a.m. to 10.00 p.m. 7 days a week)

Healthcare Professionals : +353 (1) 809 2566 (24 hour service)

Email : chemicalsinfo@beaumont.ie

National response centre

Address

Poisons Information Centre of Ireland Beaumont Hospital, PO Box 1297, Beaumont Road,
 Dublin, Ireland.

Emergency Phone No.

+353 01 809 2566 (24 hours)

SECTION 2: HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture**

Regulation (EC) No. 1272/2008 (CLP)

Skin Irrit. 2 : Causes skin irritation.

Skin Sens. 1 : May cause an allergic skin reaction.

Eye Irrit. 2 : Causes serious eye irritation.

Aquatic Chronic 2 : Toxic to aquatic life with long lasting effects.

2.2 Label elements

Product Name

According to Regulation (EC) No. 1272/2008 (CLP)

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(Contains: dibenzoyl peroxide)

(1-methylethylidene)bis (4,1-phenyleneoxy- 2,1-ethanedioxy-2,1-ethanediyl) bismethacrylate;
 2,2'-ethylenedioxydiethyl dimethacrylate;

(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate;

Hazard Pictogram(s)



GHS07



GHS09

Signal Word(s)

Warning

Hazard Statement(s)

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

H411: Toxic to aquatic life with long lasting effects.

Precautionary Statement(s)

P261: Avoid breathing vapours.

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P273: Avoid release to the environment.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
P337+P313: If eye irritation persists: Get medical advice/attention.
P501: Dispose of contents in accordance with local, state or national legislation.
Not applicable.

Unique Formula Identifier (UFI):

2.3 Other hazards

PBT assessment : This product does not contain any substances classified as PBT or vPvB.
Endocrine disrupting properties : 128-37-0 (Under evaluation) (<0.1%)

2.4 Additional Information

For full text of H/P Statements see section 16.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**3.1 Substances**

Not applicable.

3.2 Mixtures

HAZARDOUS INGREDIENT(S)	CAS No.	EC No. / REACH Registration No.	W/W %	Hazard Statement(s)	Hazard Pictogram(s)
SILICA-ZIRCONIA FILLER	-	910-388-1 01-2119860534-36-0000	60-80	Not classified	None
(1-methylethylidene)bis (4,1-phenyleneoxy-2,1-ethanedioxy-2,1-ethanediyl) bismethacrylate;	41637-38-1	609-946-4	5-15	Skin Irrit. 2 H315 Skin Sens. 1 H317 Eye Irrit. 2 H319 STOT SE 3 H335	GHS07
2,2'-ethylenedioxydiethyl dimethacrylate	109-16-0	203-652-6	5-15	Skin Irrit. 2 H315 Skin Sens. 1B H317 Eye Irrit. 2 H319	GHS07
(1-methylethylidene)bis[4,1-phenyleneoxy (2-hydroxy-3,1-propanediyl)] bismethacrylate	1565-94-2	216-367-7	1-5	Skin Sens. 1 H317 Aquatic Chronic 3 H412	GHS07
AMORPHOUS SILICA	112945-52-5	231-545-4	1-5	Not classified	None
dibenzoyl peroxide	94-36-0	202-327-6	<1	Org. Perox. B H241 Skin Sens. 1 H317 Eye Irrit. 2 H319 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	GHS07 GHS09
dl-bornane-2,3-dione	10373-78-1	233-814-1	<0.5	Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT SE 3 H335	GHS07
2,6-di-tert-butyl-p-cresol	128-37-0	204-881-4	<0.1	Aquatic Chronic 1 H410	GHS09
1,1'-(1,1-dimethyl-3-methylene-1,3-propanediyl)bisbenzene	6362-80-7	228-846-8	<0.1	Acute Tox. 4 H302 Skin Sens. 1 H317 STOT RE 2 H373 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	GHS08 GHS07 GHS09
mequinol	150-76-5	205-769-8	<0.1	Acute Tox. 4 H302 Skin Sens. 1 H317 Eye Irrit. 2 H319	GHS07

HAZARDOUS INGREDIENT(S)	CAS No.	Specific Concentration Limit	M-factor	ATE
dibenzoyl peroxide	94-36-0		Aquatic Acute 1: 10 Aquatic Chronic 1: 10	
1,1'-(1,1-dimethyl-3-methylene-1,3-propanediyl)bisbenzene	6362-80-7		Aquatic Acute 1: 10	Acute Tox. 4 (H302) : 500
mequinol	150-76-5			Acute Tox. 4 (H302) : 500

Contains no non-classified vPvB substances.

Contains no non-classified substances with a Union workplace exposure limit.

For full text of H/P Statements see section 16.

SECTION 4: FIRST AID MEASURES**4.1 Description of first aid measures**

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General	Remove to fresh air immediately. Get medical advice/attention if you feel unwell.
Inhalation	Remove to fresh air immediately. Keep warm and at rest. Get medical advice/attention if you feel unwell.
Skin Contact	Wash affected area with plenty of soap and water. Take off immediately all contaminated clothing and wash it before reuse. If skin irritation or rash occurs: Get medical advice/attention.
Eye Contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Ingestion	Rinse mouth. Give plenty of water to drink. If signs/symptoms continue, get medical attention.
Advice for first aider	Rescuers should take suitable precautions to avoid becoming casualties themselves.
4.2 Most important symptoms and effects, both acute and delayed	
Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation.	
4.3 Indication of any immediate medical attention and special treatment needed	
No specific recommendations. Treat symptomatically.	

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing media	Alcohol resistant foam. Carbon dioxide. Water fog or dry powder.
Unsuitable extinguishing media	No information available

5.2 Special hazards arising from the substance or mixture

In case of fire: Toxic gas may be formed. Combustion or thermal decomposition will evolve toxic vapours. Toxic gases/vapours : Carbon monoxide, Carbon dioxide

5.3 Advice for firefighters

Avoid breathing gas. Avoid breathing vapours. Keep upwind. Portable containers should be moved if possible and without risk. Keep fire exposed containers cool by spraying with water. No open flames, no sparks and no smoking. Fire fighters should wear complete protective clothing including self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective clothing as per section 8. No open flames, no sparks and no smoking.

6.2 Environmental precautions

Do not allow to enter drains, sewers or watercourses.

6.3 Methods and material for containment and cleaning up

Eliminate sources of ignition. No open flames, no sparks and no smoking. Provide adequate ventilation. Keep away from clothing and other combustible materials. Adsorb spillages onto sand, earth or any suitable adsorbent material. Place in appropriate container. Avoid run off to waterways and sewers. Use non-sparking tools.

6.4 Reference to other sections

See Also Section 8, 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Use only in well-ventilated areas. Avoid breathing vapours. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Wear protective clothing as per section 8. Wash hands before breaks and after work. Wash the contaminated area of body with soap and fresh water. Take any precaution to avoid mixing with combustibles.

7.2 Conditions for safe storage, including any incompatibilities

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep cool. Protect from sunlight.

Storage temperature

0 - 10°C

Storage life

Stable under the prescribed storage conditions.

Incompatible materials

Flammable or combustible materials. Strong reducing agent.

7.3 Specific end use(s)

【Medical Device】 Adhesive resin cement. For dental professionals only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits

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Occupational Exposure Limits						
SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m³)	STEL (ppm)	STEL (mg/m³)	Note
2,6-Ditertiary-butyl-para- cresol (Butylated hydroxytoluene (BHT))	10373-78-1		2			
4-Methoxyphenol (Mequinol)	150-76-5		5			
Dibenzoyl peroxide (Benzoyl peroxide)	94-36-0		5			Sens

Region	Source
EU	Indicative Occupational Exposure Limit Value
Ireland	Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations (2001-2021) and Safety, Health and Welfare at Work (Carcinogens) Regulations 2024, Ireland
Remark	Notes
Sens	In the workplace, respiratory or dermal exposures to sensitising agents may occur. Sensitisers may evoke respiratory or dermal reactions, e.g. asthma, rhinitis and allergic contact dermatitis. The "sens" notation alone does not distinguish between respiratory or dermal sensitisation. Chemical agents that are sensitisers present special problems in the workplace. Should an employee become sensitised, subsequent exposure may cause intense responses, even at low exposure concentrations well below the OELV. Exposure should be eliminated or significantly reduced through control measures such as engineering and process controls and use of personal protective equipment (PPE). The absence of a "Sens." note does not signify that the chemical agent lacks the ability to produce a sensitisation but may reflect the lack of, or inconclusiveness of, scientific evidence.

8.2 Exposure controls

8.2.1. Appropriate engineering controls Provide adequate ventilation, including appropriate local extraction. Provide adequate ventilation to ensure that the occupational exposure limit is not exceeded.

8.2.2. Personal protection equipment

	Eye Protection	Wear eye protection with side protection (EN ISO 16321-1). Wear chemical resistant protective eye glasses. Goggles.
	Skin protection	Wear protective clothing and gloves: Impervious gloves (EN 374). Breakthrough time of the glove material: refer to the information provided by the gloves' producer. Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible. Gloves should be changed regularly to avoid permeation problems. Wear suitable protective clothing. (Avoid contact with skin.)
	Respiratory protection	Wear a suitable respirator if the ventilation is not sufficient to keep the solvent vapour concentration below the occupational limit values.
	Thermal hazards	A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.
	Hygiene Measures	Provide adequate ventilation, including appropriate local extraction, to ensure that the occupational exposure limit is not exceeded. A washing facility/water for eye and skin cleaning purposes should be present. Remove contaminated clothing immediately. After contact with skin, wash immediately with plenty of soap and water. Wash hands before eating, drinking or smoking. Wash hands before breaks and after work. Do not eat, drink or smoke when using this product.

8.2.3. Environmental Exposure Controls

Avoid release to the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on basic physical and chemical properties**

Physical state	paste. (Liquid.)
Colour	Clear
Odour	Characteristic
Melting point/freezing point	Not known.
Boiling point or initial boiling point and boiling	Not known.

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range	
Flammability	Not applicable.
Lower and upper explosion limit	Not known.
Flash Point	Not applicable.
Auto-ignition temperature	Not known.
Decomposition Temperature	Not known.
pH	Not known.
Kinematic Viscosity	Not known.
Solubility	Solubility (Water) : Not known. Solubility (Other) : Not known.
Partition coefficient n-octanol/water (log value)	Not known.
Vapour pressure	Not known.
Density and/or relative density	Not known.
Relative vapour density	Not known.
Particle characteristics	Not known.
9.2 Other information	None.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	None anticipated. See the other subsections of this section for further details.
10.2 Chemical Stability	Stable under the prescribed storage conditions.
10.3 Possibility of hazardous reactions	Not known.
10.4 Conditions to avoid	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep away from direct sunlight.
10.5 Incompatible materials	Flammable or combustible materials. Strong reducing agent.
10.6 Hazardous decomposition products	Combustion or thermal decomposition will evolve toxic vapours. Toxic gases/vapours : Carbon monoxide, Carbon dioxide

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008	
Acute toxicity - Ingestion	Calculation method : Not classified. Based on available data, the classification criteria are not met.
Acute toxicity - Skin Contact	Calculation method : Not classified. Based on available data, the classification criteria are not met.
Acute toxicity - Inhalation	Calculation method : Not classified. Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Calculation method : Causes skin irritation.
Serious eye damage/irritation	Calculation method : Causes serious eye irritation.
Skin sensitization data	Calculation method : May cause an allergic skin reaction.
Respiratory sensitization data	Calculation method : Not classified. Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Calculation method : Not classified. Based on available data, the classification criteria are not met.
Carcinogenicity	Calculation method : Not classified. Based on available data, the classification criteria are not met. dibenzoyl peroxide (94-36-0) IARC Classification: Group 3. NTP carcinogenicity : Not listed . 2,6-di-tert-butyl-p-cresol (128-37-0) IARC Classification: Group 3. NTP carcinogenicity : Not listed .
Reproductive toxicity	Calculation method : Not classified. Based on available data, the classification criteria are not met.
Lactation	Calculation method : Not classified.

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STOT - single exposure	Based on available data, the classification criteria are not met. Calculation method : Not classified.
STOT - repeated exposure	Based on available data, the classification criteria are not met. Calculation method : Not classified.
Aspiration hazard	Based on available data, the classification criteria are not met. Calculation method : Not classified.
11.2 Information on other hazards	Based on available data, the classification criteria are not met.
Route(s) of entry	Skin, Eyes, Ingestion, Inhalation, Health effects: See section 4.2.
Endocrine disrupting properties	128-37-0 (Under evaluation) (<0.1%)

SECTION 12: ECOLOGICAL INFORMATION**12.1 Toxicity**

Calculation method : Toxic to aquatic life. Toxic to aquatic life with long lasting effects.

Toxicity - Aquatic invertebrates	Data lacking.
Toxicity - Fish	Data lacking.
Toxicity - Algae	Data lacking.
Toxicity - Sediment Compartment	Data lacking.
Toxicity - Terrestrial Compartment	Data lacking.

12.2 Persistence and degradability

Not known.

12.3 Bioaccumulative potential

Not known.

12.4 Mobility in soil

Not known.

12.5 Results of PBT and vPvB assessment

This product does not contain any substances classified as PBT or vPvB.

12.6 Endocrine disrupting properties

128-37-0 (Under evaluation) (<0.1%)

12.7 Other adverse effects

Not known.

SECTION 13: DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods**

Dispose of contents/ container in accordance with the local/ regional/ national/ international regulations.

Must not be disposed of together with household garbage. Dispose at suitable refuse site. Do not allow to enter drains, sewers or watercourses. Empty containers may retain some product residues and hence be potentially hazardous.

13.2 Additional Information

Disposal should be in accordance with local, state or national legislation.

SECTION 14: TRANSPORT INFORMATION**14.1 UN number or ID number**

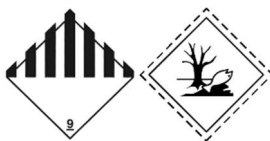
UN No. 3082

14.2 UN proper shipping name

UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Contains: dibenzoyl peroxide)

14.3 Transport hazard class(es)

ADR/RID	
ADR/RID Class	9
IMDG	
IMDG Class	9
ICAO/IATA	
ICAO/IATA Class	9
Labels	
Labels	9

ESTECM II PLUS PASTE B**14.4 Packing group**

Packing group

III

14.5 Environmental hazards

Environmental hazards

ADR/RID: Environmentally Hazardous

IMDG: Marine Pollutant

14.6 Special precautions for user

Special precautions for user

Not known.

14.7 Maritime transport in bulk according to IMO instruments

No information available

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

European Regulations - Authorisations and/or Restrictions On Use

Candidate List of Substances of Very High Concern for Authorisation	Not listed
REACH: ANNEX XIV list of substances subject to authorisation	Not listed
REACH: Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	Not listed
Community Rolling Action Plan (CoRAP)	(1-methylethylidene)bis (4,1-phenyleneoxy- 2,1-ethanediyl) bismethacrylate; (41637-38-1), silicon dioxide (7631-86-9), 2,6-di-tert-butyl-p-cresol (128-37-0)
Regulation (EU) N° 2019/1021 of the European Parliament and of the Council on persistent organic pollutants	Not listed
Regulation (EC) N° 2024/590 on substances that deplete the ozone layer	Not listed
Regulation (EU) N° 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals	Not listed
Directive 93/42/EEC	This product is a medical device as defined in Directive 93/42/EEC (MDD), which is invasive or used in direct physical contact with the human body, and therefore is exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5). Although not required, the product is classified and labelled according to the CLP regulation.

National regulations

Other

Not known.

15.2 Chemical Safety Assessment

A REACH chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

The following sections contain revisions or new statements:

This is the first issue.

Date of Issue :

01-09-2025

Revision (EN):

1

LEGEND

Hazard Pictogram(s)



GHS07



GHS09

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Hazard classification	<p>GHS08: GHS: Health hazard Org. Perox. B : Organic peroxide, Category B Acute Tox. 4 : Acute toxicity, Category 4 Skin Irrit. 2 : Skin corrosion/irritation, Category 2 Skin Sens. 1 : Skin sensitization, Category 1 Skin Sens. 1B : Skin sensitization, Category 1B Eye Irrit. 2 : Serious eye damage/irritation, Category 2 STOT SE 3 : Specific target organ toxicity — single exposure, Category 3 STOT RE 2 : Specific target organ toxicity — repeated exposure, Category 2 Aquatic Acute 1 : Hazardous to the aquatic environment, Acute, Category 1 Aquatic Chronic 1 : Hazardous to the aquatic environment, Chronic, Category 1 Aquatic Chronic 2 : Hazardous to the aquatic environment, Chronic, Category 2 Aquatic Chronic 3 : Hazardous to the aquatic environment, Chronic, Category 3</p>
Hazard Statement(s)	<p>H241: Heating may cause a fire or explosion. H302: Harmful if swallowed. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. H335: May cause respiratory irritation. H373: May cause damage to organs through prolonged or repeated exposure. 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. H412: Harmful to aquatic life with long lasting effects.</p>
Precautionary Statement(s)	<p>P261: Avoid breathing vapours. P264: Wash hands and exposed skin thoroughly after handling. P272: Contaminated work clothing should not be allowed out of the workplace. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P302+P352: IF ON SKIN: Wash with plenty of water. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P321: Specific treatment (see Medical Advice on this label). P332+P313: If skin irritation occurs: Get medical advice/attention. P333+P313: If skin irritation or rash occurs: Get medical advice/attention. P337+P313: If eye irritation persists: Get medical advice/attention. P362+P364: Take off contaminated clothing and wash it before reuse. P391: Collect spillage. P501: Dispose of contents in accordance with local, state or national legislation.</p>
Acronyms	<p>ADN : European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways ADR : European Agreement concerning the International Carriage of Dangerous Goods by Road ATE : Acute Toxicity Estimate CAS : Chemical Abstracts Service CLP : Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures DNEL : Derived No Effect Level EC : European Community EINECS : European Inventory of Existing Commercial Chemical Substances IATA : International Air Transport Association IBC : Intermediate Bulk Container ICAO : International Civil Aviation Organization IMDG : International Maritime Dangerous Goods LTEL : Long term exposure limit PBT : Persistent, Bioaccumulative and Toxic PNEC : Predicted No Effect Concentration REACH : Registration, Evaluation, Authorisation and Restriction of Chemicals RID : Regulations concerning the International Carriage of Dangerous Goods by Rail STEL : Short term exposure limit STOT : Specific Target Organ Toxicity UN : United Nations vPvB : very Persistent and very Bioaccumulative Regulation (EC) No. 1272/2008 (CLP)</p>
Key literature references and sources for data used to compile the SDS	

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Training Advice

Ensure operatives are trained to minimise exposure. Only trained personnel should use this material.

Disclaimers

The information which is contained in this document is based on available data. However, as such has been obtained from various sources, including independent laboratories, it is given without warranty or representation that is complete, accurate and can be relied upon. Tokuyama Dental Corp. has not attempted to conceal in any way the deleterious aspects of the product listed herein, but makes no warranty as to such.