

K965091

KURARAY CO., LTD.

1-12-39, Umeda, Kita-ku, Osaka 530, Japan

[TEETHMATE F-1, Kuraray]

MAR 27 1997

510(K) SUMMARY

1. Submitter

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- 5) Contact person : Yoshinori Nagase
Dental Material Department
Medical Product Division
- 6) Date : December 3, 1996

2. Representing (Subsidiary of Kuraray Co.,Ltd.)

- 1) Name : Kuraray America Inc.
- 2) Address : 30th Fl. Metlife Building, 200 Park Avenue, New York, NY 10166
- 3) Telephone : (212) 986-2230
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- 5) Contact person : Koji Fujita
President

3. Name of device

- 1) Proprietary Name : TEETHMATE F-1
- 2) Common/Usual Name : Pit and fissure sealant
- 3) Classification Name : Pit and fissure sealant and conditioner

4. Similar Products

Following similar products are sold in US market.

- 1) TEETHMATE-F by Kuraray Co.,Ltd.
- 2) DELTON PLUS by Dentsply Ash
- 3) WHITE SEALANT LC by 3M Company
- 4) FLURO SHIELD by Dentsply
- 5) FLURO BOND by ORMCO
- 6) HELIOSEAL by Vivadent(USA)

5. Description for the premarket notification

This product is classified into the pit and fissure sealant and conditioner, CFR 21 Section 872.3765, because it is a device composed of resin, such as polymethyl methacrylate, intended for use primary in young children to seal pit and fissure depressions in the biting surfaces of teeth to prevent cavities.

This product is similar and substantially equivalent in design, composition and function to the similar products which are identified in the paragraph 4 of this summary; all of which are safe, effective and beneficial.

6. Statement of the intended use

This device is used as a sealing material for pit and fissure. This intended use is same to that of similar products which are identified in the paragraph 4.

7. Statement of the technological characteristics

This device is developed as a simplified material on handling of Kuraray's TEETHMATE-F which was permitted to be marketed by registration of its 510(k) number K910424. The sealant resin of this device is a single-liquid type which is improved from the two-liquids type of TEETHMATE-F.

The chemical substances in the sealant resin other than TMDPO and HEMA are used in TEETHMATE-F. HEMA is used in the resin tooth bonding agent, C.F.R. section 872.3200, CLEARFIL LINER BOND 2 which was permitted to be marketed by registration of its 510(k) number K943170. TMDPO is used as a light-curing catalyst.

8. Summary of toxicity study

The ingredients in TEETHMATE F-1 other than TMDPO have been already used in Kuraray's dental materials allowed to be sold in US market. Therefore the biocompatibility of TMDPO the new ingredient TMDPO was evaluated its acute toxicity(LD 50), subacute toxicity and genotoxicity(Ames test).

The amount of leaching TMDPO from cured resin into distilled water and the acute toxicity of extracted fluid were evaluated.

These results suggest that TEETHMATE F-1 is a safe dental device.

8-1 Biological evaluation of TMDPO

8-1-1 Acute toxicity of TMDPO

- 1) Tested by : Kuraray Co., Ltd.
- 2) Animal : Mouse
- 3) Dosing Route : Oral
- 4) Dosing period : 10 days
- 5) Results : LD50 ; over 4,000 mg/kg

8-1-2 Subacute toxicity test

- 1) Tested by : The Kitasato Institute
- 2) Animal : Rat
- 3) Dosing Route : Oral (13mg/kg/day)
- 4) Dosing period : 25 days (5 days/week, 5 weeks)
- 5) Results : Negative

8-1-3 Genotoxicity test (Ames test)

- 1) Tested by : The Kitasato Institute
- 2) Results : Negative

Bacterial species	Genotoxicity	
	Directs test	Metabolic activity test
Escherichia coli WP2 uvrA	Negative	Negative
Salmonella typhimurium TA100	Negative	Negative
Salmonella typhimurium TA1535	Negative	Negative
Salmonella typhimurium TA98	Negative	Negative
Salmonella typhimurium TA1537	Negative	Negative

8-2 Leachables

8-2-1 Amount of TMDPO leached from cured resin

The amount of leaching TMDPO cured resin was evaluated in Kuraray Co., Ltd.

- 1) Sample : Cured resin 10mm ϕ \times 5mm
- 2) Extraction media : Distilled water
- 3) Method : Two pieces of cured resin were immersed into 20ml of distilled water and stored at 37°C or 50°C for 24 hours. The amount of leached TMDPO in water was measured using high pressure liquid chromatography
- 4) Results : Less than identification limit (0.04ppm) for both conditions.

8-2-2 Acute toxicity of Leachables

The acute toxicity of extraction fluid was evaluated in Kuraray CO.,LTD.

- 1) Sample : Cylindrical specimens, 3mm ϕ \times 3mm, of cured resin.
- 2) Extraction media : Distilled water
- 3) Animal : ICR mice
- 4) Route of administration : Around 44 specimens were immersed into distilled water, in the ratio of 10ml/1g-specimen, and stored at 85°C for one hour. The extraction fluid was administrate amount was 20 ml/kg-mouse. After 7 days, weight change of each mouse was obtained.
- 5) Result : The leachables from cured resin into water did not affect weight of mouse and no mouse died.