# Polytetrafluoroethylene Coating as a Suppository Mold Releasing Agent

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**Abstract** ☐ The release quality of suppository molds with either smooth or damaged polytetrafluoroethylene coated or uncoated cavity surfaces was compared using four different suppository bases. The release of suppositories from damaged molds was improved by coating the damaged cavity surfaces with polytetrafluoroethylene. Such a coating did not appreciably improve the release characteristics of new molds.

**Keyphrases** ☐ Polytetrafluoroethylene coating—suppository mold ☐ Suppository molds—suppository releasing agent

The fusion or melting-casting process is a popular method in the preparation of suppositories (1). However, sticking of the suppositories to the cavity surface can become a problem, particularly with worn or damaged molds. To obviate this problem, some authorities (2, 3) recommend coating the cavity surfaces of the mold with a lubricant such as mineral oil or green soap tincture. Obviously such a step requires time and is inconvenient. Lubricants used in this manner may also be deposited as a thin film on the surface of the suppository. It would seem best to avoid the use of lubricants entirely.

Similar problems of sticking in industrial molds have been prevented or reduced by using polytetrafluoroethylene[1] (4, 5), an inert plastic homopolymer. Polytetrafluoroethylene has the advantage of imparting a nonstick finish to the mold. This study, therefore, was undertaken to evaluate polytetrafluoroethylene as a mold releasing agent in the fusion method of molding suppositories.

## EXPERIMENTAL

**Materials**—The four molds used in this study were constructed of nickel-plated brass, having outside dimensions of 14.7 × 3 × 3.7 cm. and weighing 1261 g. each. They were of the divided type, aligned by two affixed pins and secured by two thumbscrews. Each mold contained six Wellcombe-shaped cavities having a capacity of 2 g. each. Two of the molds were new and their surfaces were smooth and polished. Two of the molds were badly damaged by severe scratches and chemical erosion. One new mold and one damaged mold were custom coated[2] with polytetrafluoroethylene.

The following suppository bases were used: (*a*) theobroma oil BP,[3] (*b*) suppository base II,[4] (*c*) glycerinated gelatin USP,[5] and (*d*) polyethylene glycol containing polyethylene glycol 1000,[6] 50%, and polyethylene glycol 4000,[6] 50%.

**Procedure**—The theobroma oil and suppository base II were melted and maintained molten, using a constant-temperature

[1] Teflon, E. I. du Pont de Nemours, Inc., Wilmington, Del.
[2] Custom coating applied by Plastic Coatings Ltd., Christchurch 1, New Zealand.
[3] Kempthorne Prosser and Co., Dunedin, New Zealand.
[4] A base composed of special, hardened, fatty alcohols and fats, marketed by Henkel International GMBH, Dusseldorf, Germany.
[5] The gelatin and glycerin used in this base were supplied by Kempthorne Prosser and Co., Dunedin, New Zealand.
[6] Union Carbide Corp., New York, N. Y.

**Table I**—Suppository Release from Polytetrafluoroethylene Coated and Uncoated Molds Using Various Bases

| Time Before Unmolding, min. | Condition of Mold[a] | Number of Suppositories Released from Molds[b]: Theobroma Oil | Suppository Base II | Glycerinated Gelatin | Polyethylene Glycol |
|---|---|---|---|---|---|
| 1 | N | 0 | 6 | 17 | 21 |
| | NP | 0 | 3 | 20 | 25 |
| | DP | 0 | 5 | 19 | 28 |
| | D | 0 | 0 | 8 | 12 |
| 2 | N | 2 | 12 | 29 | 25 |
| | NP | 0 | 12 | 39 | 29 |
| | DP | 1 | 13 | 39 | 38 |
| | D | 0 | 9 | 25 | 21 |
| 3 | N | 18 | 27 | 41 | 44 |
| | NP | 10 | 26 | 44 | 37 |
| | DP | 8 | 24 | 48 | 40 |
| | D | 4 | 15 | 20 | 32 |
| 4 | N | 23 | 42 | 46 | 51 |
| | NP | 14 | 40 | 49 | 52 |
| | DP | 15 | 36 | 50 | 53 |
| | D | 9 | 22 | 47 | 45 |
| 6 | N | 45 | 43 | 56 | 60 |
| | NP | 41 | 44 | 50 | 60 |
| | DP | 42 | 42 | 48 | 60 |
| | D | 25 | 27 | 44 | 60 |
| 8 | N | 55 | 56 | 60 | 60 |
| | NP | 45 | 51 | 59 | 60 |
| | DP | 44 | 51 | 58 | 57 |
| | D | 32 | 45 | 52 | 60 |
| 10 | N | 57 | 54 | 60 | 56 |
| | NP | 54 | 55 | 60 | 60 |
| | DP | 56 | 53 | 60 | 60 |
| | D | 36 | 47 | 42 | 58 |
| 12 | N | 60 | 57 | 59 | 60 |
| | NP | 60 | 60 | 60 | 60 |
| | DP | 59 | 60 | 60 | 60 |
| | D | 42 | 48 | 43 | 56 |

[a] Key: N, new mold with smooth polished cavity surfaces; NP, new mold with polytetrafluoroethylene-coated cavity surfaces; DP, damaged mold with polytetrafluoroethylene-coated cavity surfaces; D, damaged mold with scratched and eroded cavity surfaces. [b] For each time period, 10 lots containing six suppositories were formed for each of the possible suppository base–mold surface combinations. Each figure represents the quantity of perfectly formed suppositories released from the mold (60 suppositories maximum possible for each figure).

water bath,[7] at a temperature of 36.5 ± 0.5°. The polyethylene glycol base was similarly prepared and used at a temperature of 54.5 ± 0.5°. Glycerinated gelatin base was prepared according to the USP (6) method and maintained molten with the water bath at a temperature of 46.5 ± 0.5°. Each base was prepared and used as a single batch throughout the study.

For each time period (Table I), 10 lots containing six suppositories were formed for each of the possible suppository base mold surface combinations. The molten base was removed from the water bath and poured continuously to form each lot. After pouring, each lot of suppositories was allowed to solidify at room temperature, 17 ± 3°, for the designated time. At the end of the time period, the suppositories were removed from the mold, and the quantity of perfectly formed suppositories released from the mold was counted. After use, the molds were allowed to stand and equilibrate with room temperature before being used again.

[7] Constant-temperature water bath, type SB 3, manufactured by Grant Instruments (Cambridge) Ltd., Barrington, Cambridge, England.

**Table II**—Total Suppositories Released from Each Type Mold

| Suppository Base | New Mold, Uncoated | New Mold, Polytetrafluoroethylene Coated | Damaged Mold, Polytetrafluoroethylene Coated | Damaged Mold, Uncoated |
|---|---|---|---|---|
| Theobroma oil | 260 | 224 | 225 | 148 |
| Suppository base II | 301 | 291 | 284 | 213 |
| Glycerinated gelatin | 368 | 381 | 382 | 281 |
| Polyethylene glycol | 377 | 383 | 396 | 344 |
| Total | 1306 | 1279 | 1287 | 986 |
| % of maximum possible yield[a] | 68.0 | 66.6 | 67.0 | 51.4 |

[a] Maximum possible yield was 1920 suppositories.

## RESULTS AND DISCUSSION

Polytetrafluoroethylene was most effective in improving the release of suppositories composed of a fatty base and had little effect on the release of polyethylene glycol suppositories after the first 6 min. (Table I). Coating the molds with polytetrafluoroethylene did not decrease appreciably the time required for the molds to stand before removing the suppositories (Table I). As indicated in Table II, there was little difference in the number of suppositories released from polytetrafluoroethylene-coated molds *versus* the new mold with smooth cavity surfaces. However, the release qualities of the damaged mold that had been coated with polytetrafluoroethylene appeared to be very much improved and approximated that of the new molds (Table II). With the assumption that 12 min. is adequate for complete solidification of the four bases tested, the experimental results indicate an increase of approximately 20%[8] in the yield of suppositories from damaged molds that were polytetrafluoroethylene coated. According to these results, badly damaged molds could be restored by coating their surfaces with polytetrafluoroethylene. However, there would be little advantage in polytetrafluoroethylene coating new molds. The cost of the coating is relatively inexpensive and substantially less than buying a new mold. The coating is easily damaged and, as with new molds, the surfaces should be handled carefully.

[8] Calculated using data from the 12-min. time period, Table I, as follows: damaged molds (D) yield 42+48+43+56 = 189 suppositories, damaged molds polytetrafluoroethylene coated (DP) yield 59+60+60+60 = 239; 239−189 = 50 suppositories; 50/239 = 20.5%.

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