

Statement regarding FDA 21 CFR §175.105 – *Adhesives*

Product Safety & Regulatory Compliance

FDA 21 CFR §175.105 - *Adhesives*

The overall regulatory status of a pressure sensitive label used in food packaging is determined by the regulatory status of each individual substance that comprises the label that is reasonably expected to migrate to food. Individual substances expected to migrate to food should be covered by one of the following:

- a regulation listed in Title 21 Code of Federal Regulations
- a prior sanctioned letter
- meeting the criteria for Generally Recognized as Safe (GRAS) status (including but not limited to a GRAS regulation or GRAS notice)
- a Threshold of Regulation (TOR) exemption request
- or an effective Food Contact Notification (FCN).

UPM Raflatac has surveyed suppliers of components used to formulate the following adhesives and verified compliance with the requirements of 21 CFR 175.105 – *Adhesives*. The adhesives that meet the requirements of 21 CFR 175.105 – *Adhesives* are listed below:

RP31, RP36TX, RP37, RP45, RP48AT, RP51, RP54, RP74, RP75, RP76, RP77, RP78, RP88, RP500WD, RS30, RH01, RH03, RH04FG, RHC4, RH09, RH9X, RH15, RH23, RH25, RH70, RR05, RR10, RR12, RR19, RR20, RR22, RR28, RS32, RD809, RW85C, RW110F, RC18, SP34, XS01 and XR13.

Note that 21 CFR 175.105 (a)(2) states that for a complying adhesive:

The adhesive is either separated from the food by a functional barrier or used subject to the following additional limitations:

- In dry foods.* The quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice.
- In fatty and aqueous foods.* (a) The quantity of adhesive that contacts packaged fatty and aqueous foods shall not exceed the trace amount at seams and at the edge exposure between packaging laminates that may occur within the limits of good manufacturing practice.

It is the label end user's responsibility to determine if its intended end use of UPM Raflatac's products complies with 21 CFR 175.105 (a)(2).

Compliance with 21 CFR 175.105 does not mean that an adhesive is suitable for direct food contact. 21 CFR 175.125 addresses the requirements for pressure sensitive adhesives that may be safely used as the food contact surface of labels and/or tapes applied to food.

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Depending on the part of the label that becomes the food contact surface or on other factors that may lead to chemical migration from the label to food, other sections of 21 CFR may apply to pressure sensitive labels used in food packaging, including, but not limited to:

- 21 CFR 176 - Paper and Paperboard Components
- 21 CFR 177 – Polymers

It is the label end user's responsibility to determine if its intended end use of UPM Raflatac's products complies with the applicable regulatory requirements for food packaging applications, including the label. UPM Raflatac's sole warranty is that its products meet the requirements of 21 CFR 175.105 (a)(2).

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