

(b) (4)

ASSESSMENT REPORT – (b) (4)

**REGULATORY REVIEW ON COMPLIANCE
ACCORDING TO FDA OF A RESIN AND A
MASTERBATCH - SWEDISH MATCH**

(b) (4)

Container Components, Primary Container/Closure Composition (Can/Lid),
Primary Container/Closure Regulatory Compliance Assessment Report

(b) (4)

(b) (4)

25-05-2018

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Dear (b) (6)

Hereby we present to you the results of the assessment study, which was carried out by your request

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The general conditions of delivery of (b) (4), are applicable. These conditions are an integral part of all research carried out and the services and consultations provided; where appropriate, expanded upon by agreements specific to the client. This report applies only to the sample(s) tested. If information about the measurement uncertainty of a method is required, this can be provided on request.

We trust that this information will meet your approval.

Yours sincerely,

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25-05-2018

1. Introduction

Swedish Match has requested confirmation regarding compliance according to FDA food contact legislation of a polypropylene resin and a color masterbatch.

This resin and masterbatch are intended (b) (4)

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(b) (4), on behalf of Swedish Match, has conducted a regulatory review of the formulation for use in food contact applications. (b) (4) reviewed the components by supplier documentation and formed a conclusion based on applicable US FDA regulations.

2. Regulatory review on compliance according to FDA

(b) (4) has performed a regulatory review of the available documentation and assessed the content for accordance with the applicable FDA food contact regulations, see table 1. The documentation has been checked for compliance with CFR (Code of federal regulations) in accordance with permitted use of approved materials to 'food packaging' in general and specific for 21 CFR Parts 174 to 186.

Table 1 : Overview documentation

DOCUMENT	ISSUED BY	DATE DOCUMENT	PRODUCT	FDA COMPLIANCE
Declaration of Compliance to food contact regulations	(b) (4)	(b) (4)	(b) (4) (b) (4)	<p>The supplier states compliance with: FDA, CFR Title 21, § 177.1520(a)(3)(i)(c)(1), (b) and (c)3.1a Olefin polymers.</p> <p>Test samples made from this product fulfilled the extraction requirements according to FDA CFR 21 §177.1520(c) as defined for the type of polymer described above. Therefore this product may be used in contact with all food types as described in table 1 of FDA CFR 21 § 176.170(c), under conditions of use C through G as described in table 2 of CFR 21 § 176.176.170(c). The product is not intended for use in packing or articles holding food during cooking.</p>
Declaration of Compliance	(b) (4)	23.10.2017	(b) (4) (b) (4)	<p>The supplier states that the components are specifically approved under CFR Title 21 as follows:</p> <p>(b) (4) 21 CFR 178.3297</p> <p>(b) (4) 21 CFR 21 177.1520</p>

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(b) (4) cannot be held responsible for incomplete information provided by the supplier.

3. Conclusion

On behalf of Swedish Match Intertek conducted a regulatory assessment to check compliance with food contact regulations according to FDA of a polypropylene resin and a masterbatch (b) (4) (b) (4).

Based on the regulatory evaluation of supplier information and compositional statements, it was determined that both the resin of (b) (4) and the masterbatch of (b) (4) are approved materials for food packaging and are in accordance with respectively 21CFR §177.1520 for polyolefins and §178.3297 on Colorants for polymers

The colorant used in the masterbatch may be safely used as colorant, without limitations, in the manufacture of articles or components of articles intended for use in packaging holding food.

Both resin and masterbatch are FDA compliant.

4. Appendix

Appendix I: (b) (4), Declaration of Compliance to food contact regulations

Appendix II: (b) (4) Declaration of Compliance

(b) (4)

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Appendix I - (b) (4) Declaration of Compliance to food contact regulations

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Appendix II - (b) (4) Declaration of Compliance

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Corrections

- Title:
Regulatory review on compliance according to FDA of a resin and a Masterbatch – Swedish Match
Should be:
Regulatory review on compliance according to FDA of a Polypropylene resin and a color Masterbatch – Swedish Match
- (b) (4)
- 3. Conclusions
Based on the regulatory evaluation of supplier information and compositional statements, it was determined that both the resin of (b) (4) and the masterbatch of (b) (4) are approved materials for food packaging and are in accordance with respectively 21CFR §177.1520 for polyolefins and §178.3297 on Colorants for polymers

Should be:

Based on the regulatory evaluation of supplier information and compositional statements, it was determined that both the resin of (b) (4) and the color masterbatch of (b) (4) are approved materials for food packaging and are in accordance with 21CFR §177.1520 for polyolefins and §178.3297 on Colorants for polymers, respectively.