

DECLARATION OF COMPLIANCE FOR FOOD CONTACT MATERIALS

Packaging Material Description

Product Ref. "Tear Tapes" – EzeeRip/EzeeTear Products (printed, pigmented red & transparent)

	Silicone Release Layer
	Transparent/pigmented MOPP Film
	Printing Inks (if applicable)
	Water Based Acrylic Dispersion Adhesive

1. Intended food contact

The regulatory assessment was based on food contact being made only with the silicone release layer, with the MOPP film acting as a barrier to the printing ink and adhesive layers.

The approved conditions of use for MOPP-based tear tapes are as follows:

"Any conditions that include heating up to 70 °C for up to 2 hours, or up to 100 °C for up to 15 minutes, which are followed by long term room or refrigerated temperature storage in acidic foods and all aqueous and alcoholic foods and milk products with a pH \geq 4.5 and fatty foods**"

*Please note the above statement applies in full to tear tapes manufactured by Bagla Group's India based operations.

2. Regulatory Status:

EzeeRip/EzeeTear products are certified to be compliant with the following regulations, when applied as intended with the adhesive surface in contact with the packaging film.

- The revised European Framework Regulation 1935/2004.
- EC Regulation 2023/2006 for Good Manufacturing Practices
- EC Regulation 10/2011* plus amendments
- Japan ministry of Health and Welfare Notice No. 370 and its amendment part 3 section D
- FDA CFR Volume 21 (170-199)
- Council of Europe Resolution AP(2005)2 Packaging Inks
- Nestle Guidance Note on Packaging Inks
- Swiss Ordinance 817.023.21
- EuPIA Guidelines on Printing Inks applied to the non-food contact surface of food packaging materials and articles.

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*Organoleptic properties have been conducted in accordance with article 3 of EC Regulation 1935/2004, but additional assessments are currently being undertaken by Bagla independent 3rd party service providers to refresh the data. Once completed this DoC will be updated.

For the EzeeRip/EzeeTear pigmented red products only, the tape has been submitted to the CFIA and Health Canada for their approval.

3. Overall Migration:

PROPERTIES	UNITS	VALUE	TEST CONDITIONS
Overall Migration	mg/dm ²	<10	
Simulant B (3% acetic acid)	mg/dm ²	3.8	10 days at 40°C
Simulant C (10% ethanol)	mg/dm ²	2.0	10 days at 40°C
Simulant D (Olive Oil)	mg/dm ²	10.1*	10 days at 40°C

*As specified in EC Directive 2002/72/EC with an allowed reduction factor applied

The overall migration results for EzeeRip/EzeeTear are within the limit specified in EC Directive 2002/72/EC as amended, after applying an allowed tolerance (reduction factor). The EzeeRip/EzeeTear products can therefore be used safely for all food types under the following conditions.

1. Any period at temperature up to 40°C
2. Periods of up to 2 hours at temperatures up to 70°C
3. Periods up to 15 minutes at temperatures up to 100°C as specified in EC directive 97/48/EC

4. Specific Migration:

Specific migration limits only apply to the adhesive in its liquid state prior to processing by Bagla Group. The processing steps involve thoroughly drying the adhesive through the coating line (the Bagla Group coating process).

Compliance with specific restrictions mentioned in the EU Regulation No. 10/2011 of 14th

January 2011 on plastic materials & articles intended to come into contact with food, & amendments thereof, has been ensured. This includes the following restrictions regarding starting monomers & additives

2-methyl-2H-isothiazol-3-one CAS No. 2682-20-4	FCM No. 451	SML 0.5 mg/kg
Acrylic Acid CAS No. 79-10-7	FCM No. 147	SML(T) 6 mg/kg
Vinyl Acetate CAS No. 108-05-4	FCM No. 231	SML 12 mg/kg
Hydroxypropyl acrylate CAS No. 25584-83-2	FCM No. 385	SML 0.05 mg/kg
Methyl Methacrylate CAS No. 80-62-6	FCM No. 156	SML(T) 6 mg/kg
2-ethylhexyl acrylate CAS No. 103-11-7	FCM No. 206	SML 0.05 mg/kg

FCM-No. Unique identification number of substance within EC Regulation 10/2011

SML Specific migration limit in food or food simulant

SML(T) Specific migration limit in food or food simulant from respective substance

5. Mathematical Modeling:

Past assessment via independent 3rd party service providers have confirmed that EzeeRip/EzeeTear products are intended to make direct food contact (with silicone surface of the tape) for food products that include dried fruit, cracker biscuits, flour, frozen foods, cheese bread & biscuits under all storage times at frozen conditions. Further mathematical modelings, under elevated temperatures conditions are underway.

Mathematical modeling (an accepted tool to examine migration of substances from food contact materials) was conducted.

- The tear tape was modeled against contact with a fatty food such as cheese
- The molecular weight of a worst case migratory substrate in the adhesive is low. A molecular weight of 100 Daltons was used as the worst case scenario.
- 6 dm² of tear tape in contact with 1kg of food to represent worst case scenario

In conclusion the modeling has predicted <10µg/kg (10 ppb) of a very migratory substance of molecular weight 100 Daltons if present in the adhesive at 100 mg/kg would migrate through printed tear tape into an extractive fatty food such as cheese when completely packaged in tear tape 6dm²/kg during 100 days contact.

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The conclusions have been drawn through three methods of assessment as follows:

- Mathematical modeling worst case scenario
- Overall migration testing
- 100% migration calculation (Keller & Heckman LLP)

6. Dual Use Additives:

Based upon information supplied by our raw material suppliers, no dual use additives have been identified.

7. EzeeRip/EzeeTear products do not contain:

EzeeRip/EzeeTear products do not contain any of the following:

- CMR (carcinogens, mutagens and repro-toxins), PBT (persistent, bioaccumulative and toxic substances) and vPvB (very persistent very bioaccumulative substances.)
- Melamine 1,3,5-triazine-2,4,6-triamine (CAS No. 108-78-1).
- Any form of phthalates, natural rubber, PVC (poly vinyl chloride) or PVC Resins.
- Substances of very high concern or banned substances not permitted for packaging designed for food contact. In accordance with the Candidate List published by REACH latest edition.
- UV initiators, including benzophenone (CAS No.119-61-9) and 4-methylbenzophenone (CAS No.134-84-9), Isopropyl Thioxanthone (ITX) (CAS No. 5495-84 2 Isomer & 83846-86-0 4 Isomer)
- Bisphenol A Diglycidyl Ether (BADGE) Bisphenol F Diglycidyl Ether (BFDGE) or Novolac Glycidyl Ethers (NOGE)
- Brominated flame retardants
- Genetically modified organisms (GMO) or products containing GMO
- Ozone depleting substances according to Montreal Protocol
- Perfluoro-octanoic acid (PFOA) or perfluoro-octane sulfonate (PFOS)

The presence of the above substances within the finished product is not expected, but they have not been confirmed by analytical testing. Trace impurities cannot be fully excluded.

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8. Heavy Metals Status:

EzeeRip/EzeeTear products are compliant with the following:

- 94/62 EC Packaging and Packaging Waste directive The Packaging (Essential Requirements) Regulation 1998 heavy metals in packaging.
- RoHS Directive 2011/65 EU Annex II
- US CONEG directive

9. Allergen Status:

- Bagla Group does not process or intentionally add allergens, including milk, eggs, peanuts, tree nuts, fish, shellfish, soy and wheat derivatives during the manufacturing process

10. BSE/TSE:

Throughout the plastics conversion industry, certain low-level additives which are based on fatty acids/esters/alcohols that are derived from animal fats (tallows) are in widespread use and are generally considered as essential for plastic film manufacture. The following points must be noted:

- The substances are approved for food contact use
- Regulation EC No. 99/2001 plus amendments assure the specified risk materials are removed prior to production of the materials of animal origin
- The production of these additives is subject to very severe processing conditions that meet or exceed the recommendations for complete inactivation of BSE/TSE agents by use of high temperature processing

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Disclaimer:

This certificate covers the composition of Bagla EzeeRip/EzeeTear products. The customer/packer is responsible for ensuring that the finished food package complies with applicable restrictions in the food itself, under actual conditions of use.

Bagla is currently reviewing organoleptic properties with the emphasis on article 3 of EC Regulation 1935/2004.

This certificate is valid from the date specified below. The certificate will be replaced if a change of material composition occurs or when the relevant legislation is modified. These changes may require a new evaluation of the products performance & regulatory compliance status.

Ramashankar Kanojia
Quality Manager
Issue date – 18th May 2023