Declaration of Compliance for Food Contact (DoC)

We have completed the testing and compliance work for substances in Hostaphan® RSVI for a broad range of use conditions and food types. Thus, repeating migration testing or calculations for substances in Hostaphan® RSVI will not be necessary under the use conditions confirmed here.

What customers should do to ensure that their use of Hostaphan® RSVI complies with food contact regulations is:

a) Confirm that the use conditions and types of food described in section A.5. for Europe and section B for the USA cover the intended use.

b) Ensure that operations fulfil the good manufacturing practice requirements set out in Regulation (EC) 2023/2006.

c) Ensure that batch tracing links to our 10-character roll numbers, which are given in plain text and barcode on the labels supplied with each of the rolls. Other numbers are not suitable for rapid tracing!

d) Apply appropriate labelling to the product, “for food” or the wineglass and fork symbol.

This DoC only covers food contact regulations. Customers should also confirm that Hostaphan ® RSVI is technically suitable for their product design, process and use.

Product name:	Hostaphan® RSVI
Thickness range:	no restriction
"Type of product" for food contact use[1]:	"final plastic material"[2]
Polymer type (main component):	polyethylene terephthalate (PET)
Product form:	biaxially oriented PET film (boPET film)

Date and validity of this DoC

This DoC has been issued on 2 August 2021 and replaces all previous DoCs for Hostaphan® RSVI issued for Europe and the USA. It is valid only when signed by a Mitsubishi official, either manually or electronically, and will remain valid until 31 December 2023, unless:

- It has been withdrawn or replaced by an updated DoC, or
- Your company has not purchased Hostaphan® RSVI for a period of 12 months (or longer) after 2 August 2021, in which case this DoC will no longer be valid for new deliveries. On resuming purchases after such an interruption, a new DoC must be requested to ensure that up-to-date information is available.

Within an ongoing business, we will inform you of any changes in the composition of Hostaphan® RSVI which are relevant to food legislation or changes in legislation which affect the regulatory status of Hostaphan® RSVI by sending an update to the recipient named on this DoC, usually by e-mail.

2. Compliance with applicable regulations

Hostaphan® RSVI complies with the applicable requirements of EU "Framework Regulation" for food contact materials, (EC) 1935/2004[3], the "Food Contact Plastics Regulation" (EU) 10/2011 and the "Good Manufacturing Practice Regulation" (EC) 2023/2006, as well as the German LFGB and *Bedarfsgegenständeverordnung* as follows:

The monomers and additives used for Hostaphan® RSVI are authorized under Regulation (EU) 10/2011 (as amended by (EU) 321/2011, 1282/2011, 1183/2012, 202/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37, 2019/1338, and 2020/1245). Risk assessment of all other components of Hostaphan® RSVI, including intentionally added components, such as catalysts, and non-intentionally added substances ("NIAS"), such as reaction and degradation products, according to §19 of (EU) 10/2011 has been performed. Thus, the composition of Hostaphan® RSVI complies with the legal requirements throughout the European Economic Area (EU, Iceland, Liechtenstein, Norway, and Northern Ireland). Hostaphan® RSVI also fulfils the corresponding requirements in Switzerland and in Great Britain. The PET complies with the current requirements of BfR (German Federal Institute for Risk Assessment) Recommendation XVII, Polyterephthalic acid diolesters.

Hostaphan® RSVI complies with the overall migration limit, 10 mg/dm² under the most extreme standardized conditions, *i.e.:*

Simulant	*Food type*	*Test designation*	*Time and temperature*
A – 10 vol.-% ethanol	Aqueous (hydrophilic)	OM 6	4 h at reflux
B – 3 wt.-% acetic acid	Acidic (pH <4.5)	OM 6	4 h at 100° C
D2 – vegetable oil	Fatty (lipophilic)	OM 7	2 h at 175° C

Choice of simulants: According to (EU) 10/2011, Annex III point 4 overall migration testing in simulants A, B and D2 demonstrates compliance for all types of food.

Sensory testing with water and fat shows that Hostaphan® RSVI complies with §3(1c) of (EC) 1935/2004.

3. Substances subject to restrictions

The following substances or substance groups subject to SMLs can be present in Hostaphan® RSVI or could be given off if it were hydrolyzed:

Confidential				
Substance (group)	*FCM Substance No.*	*CAS-No.*	*Limit (SML)*	*Results**
terephthalic acid	785	100-21-0	7.5 mg/kg food	✓
ethylene glycol and **diethylene glycol**	227 and 263 (group 2)	107-21-1 and 111-46-6	30 mg/kg food (group limit)	✓

[1] See chapter 3.1 of the "Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain" for product type definitions.

[2] Hostaphan® RSVI can form a final plastic material alone or in combination with other finished components

[3] Articles 3, 11(5), 15 and 17 are applicable.

Confidential				
Substance (group)	*FCM Substance No.*	*CAS-No.*	*Limit (SML)*	*Results**
manganese acetate	None (Annex II number 1 of 10/2011)	2180-18-9	0.6 mg/kg food (expressed as manganese)	✓
zinc acetate	None (Annex II number 1 of 10/2011)	557-34-6 or 5970-45-6	5 mg/kg food (expressed as zinc)	✓
acetaldehyde	128	75-07-0	6 mg/kg food (expressed as acetaldehyde)	♦

You may only share this confidential information with customers, institutes and enforcement authorities for the purpose of assessing compliance of Hostaphan® RSVI and products containing it.[4]

**Explanation of symbols in the "Results" column:*

✓	The migration of substances with this mark is <u>not detectable</u> in our tests because the substances are chemically bound, the amounts of the substances in the film are far below the SML (*e.g.* residual monomers), and/or the substances are not mobile in the plastic (*e.g.* salts). These substances can only be set free under conditions that embrittle or destroy the film (hydrolysis under extreme heat, such as melting, or chemical attack).
♦	Acetaldehyde is present in Hostaphan® RSVI in very small amounts. It is the main decomposition product of polyethylene terephthalate. Acetaldehyde is also present in many foods as a natural component (e.g. in fruits, coffee, cheese). It is not dangerous in low concentrations. Based on its toxicological properties, a specific migration limit (SML) of 6 mg acetaldehyde per kg food has been set in the EU. Measurements indicate acetaldehyde amounts in Hostaphan® RSVI are well below 20 ppm. Taking into account the EU cube and assuming a total migration, the detected amount of acetaldehyde in Hostaphan® RSVI is more than a factor of 100 below the limit value

Thus, for normal film applications no further testing of specific migration is needed for Hostaphan® RSVI

4. "Dual use" additives

E551 and E650 are used in Hostaphan ® RSVI. These additives <u>do not migrate</u> out of Hostaphan ® RSVI at all, so they cannot cause technical effects or non-compliance of the foodstuffs. The heat sealable side of Hostaphan® RSVI may also contain E470b, the amount of which (<25 mg/dm²) will not adversely impact any EU food additive limits.

5. Permissible use conditions and specific migration test conditions

Our migration testing and calculations confirm that Hostaphan® RSVI may be used:

- In single use articles such as food packaging, as well as repeated use articles,
- For direct contact with all kinds of food, except for ethanol concentrations >50 vol.-%[5]
- For long term storage at room temperature (and below, including frozen storage),
- For sterilization, heating and cooking in microwave and conventional ovens at temperatures up to 175° C for 2 hours and
- At surface-volume ratios up to 30 dm²/kg food (5 times more than the "EU cube")[6].

Hostaphan® RSVI complies with the applicable specific migration limits under these conditions:

<u>Test conditions to confirm specific migration compliance according to (EU) 10/2011, Appendix V</u>
(New conditions of the 6th amendment, (EU) 2016/1416, mandatory as of 14 September 2017)

[4] Other substances of Annex II (EU) 10/2011 not listed in the table above are not intentionally added in Hostaphan® RSVI and could only be present in trace quantities that are ubiquitous in the environment and that meet the restrictions specified in Table 1 of Annex II of (EU) 10/2011.

5 High concentrations of ethanol swell PET, causing physical changes, such as softening, and changes in dimensions and appearance. Therefore PET is not recommended for use with very high ethanol concentrations, even if it were to pass a migration test.

[6] Surface-volume ratios higher than the „EU cube" were obtained by dividing each SML by the total amount of the substance in the product or the detection limit in its migration test. The lowest value is given.

test conditions		*applicable to*	
simulant	*time and temperature*	*food types*	*contact conditions*
A – 10 vol.-% ethanol	8 hours at 100°C, then 10 days at 60° C	hydrophilic (aqueous, alcoholic)	Up to 2 hours sterilization, (re-)heating, cooking or baking at up to 175 ° C and long term (>6 month) storage at room temperature and below
B – 3 wt.-% acetic acid	8 hours at 100° C, then 10 days at 60° C	acidic (pH < 4.5)	
D2 – vegetable oil	2 hours at 175° C, then 10 days at 60° C	lipophilic (fatty)	

Notes:

Choice of simulants: According to (EU) 10/2011, Annex V point 2.1.2, testing in simulants A, B and D2 demonstrates compliance for all types of food.

Heating and test conditions: For compliance, it does not matter how the heat is applied; microwave and conventional means are equivalent. In non-pressurized conditions such as in the microwave, only fatty foods can reach temperatures above 100° C.

Old test conditions according to EU Directives 82/711/EEC and 85/572/EEC: May no longer be used.

6. "Functional barrier" status

Hostaphan® RSVI does not require a functional barrier. Both sides are permissible for direct contact with food.

B. Food contact use in the USA (FDA approval)

We confirm that Hostaphan® RSVI complies with both the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., and applicable indirect food additive regulations found in 21 CFR § 177.1630, provided it is used subject to limitations found in 21 CFR § 177.1630 and in accordance with good manufacturing practices (defined in 21 CFR § 174.5). The film may be used in contact with all types of food under all conditions of use that are technically suitable for PET film and listed in 21 CFR § 177.1630, including oven baking or oven cooking at temperatures above 250° F, as specified in 21 CFR § 177.1630 (h).

C. Frequently asked questions about other regulations and certain substances

Hostaphan® RSVI does not contain post-consumer recyclate or "active or intelligent" components, so Regulations (EC) 282/2008 and 450/2009 are not applicable.

We confirm that the heavy metals cadmium, mercury, lead and chromium(VI) as such and their compounds are not used in the production of Hostaphan® RSVI. The sum of these heavy metals from possible contaminations is below 100 ppm (DIN 38 406) and complies with Article 11 of EU Directive 94/62/EC (Packaging and packaging waste) as well as with the CONEG Legislation in the USA. Hostaphan® RSVI also complies with the recoverability requirements set forth in Directive 94/62/EC.

The allergens for which Annex IIIa of Directive 2000/13/EC and Annex II of Regulation (EU) 1169/2011 require special food labelling are not used in the production of Hostaphan® RSVI. Any potential cross-contamination can also be ruled out, because they are not used in any of our other products.

The formulation of Hostaphan® RSVI contains no substances that are derived from "bisphenol A" (2,2-Bis(4-hydroxy-phenyl)¬propane), such as polycarbonate, "BADGE" (bisphenol A diglycidyl ether) or related compounds ("BFDGE" and "NOGE"), azodicarbonamide, vinyl chloride, perfluorooctylsulphonate ("PFOS"), perfluorooctanoic acid („PFOA"), other perfluoroalkyl substances („PFAS") or 2,4,4´-trichloro-2´-hydroxydiphenyl ether (triclosan). Consequently, none of the following legislation is (or was) relevant: Directives 78/142/EEC, 80/766/EEC, 81/432/EEC, 2004/1/EC and 2011/8/EU, Regulation 1895/2005, 17th amendment of the German *Bedarfsgegenständeverordnung*.

The formulation of Hostaphan® RSVI contains no primary aromatic amines listed in entry 43 to appendix 8 of Annex XVII to Regulation (EC) 1907/2006 or substances that could release those primary aromatic amines.

No plasticizing additives such as "phthalates" (esters of *ortho*-phthalic acid) or others are used in the formulation of Hostaphan® RSVI. Further, the formulation does not include benzophenone, alkyl phenols such as nonyl or octyl phenol, or derivatives thereof.

Hostaphan® RSVI is not a "nanomaterial" as defined in Commission Recommendation 2011/696/EU and is thus not subject to reporting to the French ANSES agency. Similarly, no reports are required for Hostaphan® RSVI to the Belgian or Danish nanomaterial registries.

Under the REACH Regulation (1907/2006), Hostaphan® RSVI is an "article". We confirm that it was manufactured in accordance with applicable REACH requirements and that it does not contain substances listed on the SVHC candidate

list of 08 July 2021 in amounts above 0.1 weight-%. Accordingly, Article 33 of the regulation does not require any special communication about substances in Hostaphan® RSVI along the supply chain or to consumers. It is not necessary to request updates every time the SVHC candidate list is changed. In the unlikely event that Hostaphan® RSVI is affected by such a change, we will inform you.

Hostaphan® RSVI is not subject to labelling as a hazardous chemical or mixture according to 67/548/EEC, 1999/45/EC and 1272/2008 (GHS Regulation). It is not classified as hazardous to water according to German regulations (no "WGK"). The formulation contains no substances forbidden or restricted by Annex XVII of REACH and 76/769/EEC or subject to authorisation by Annex XIV of REACH. As waste, Hostaphan® RSVI does not form materials that require monitoring according to Directives 91/689/EEC and 91/156/EEC, *i.e.* it is not hazardous waste.

D. General remarks on this DoC

We have confirmed that Hostaphan® RSVI complies with the legal requirements of regulations applicable to food contact materials. It is the responsibility of the user to test the technical suitability of our products for the intended product design, process and use. We recommend a practical test. Consequently we accept no liability for losses arising from the inadequate suitability of our products for your product design or process or for the inadequate suitability of your design for a particular food.

This DoC is intended for your company only and replaces all previous Declarations of Compliance for Food Contact for Europe and the USA. It is only valid for original Hostaphan® RSVI from Mitsubishi that is sold as “Hostaphan® RSVI”. This DoC may not be used for products from other manufacturers. We forbid you to copy or plagiarize the wording of this DoC to apply it to any product that is not Hostaphan® RSVI or does not contain Hostaphan® RSVI.