Polyplastics

POLYPLASTICS CO.,LTD.
JR SHINAGAWA EAST BLDG. 13F
18-1, KONAN 2-CHOME
MINATO-KU, TOKYO, 108-8280 JAPAN
TEL: 81 3 6711 8605 FAX: 81 3 6711 8616

Status as of May 9, 2019

Declaration of plastic food contact regulations

Product Name (Plastic pellets):

DURACON® POM M90-57 WK2001, M270-57 WK2001

1. The United States of America

Regarding US Food and Drug Administration (FDA), the above mentioned product complies with the Code of Federal Regulation, Title21, section 177.2470 for Polyoxymethylene copolymer. The finished articles from the above mentioned product shall not be in contact with foods containing more than 15 percent alcohol.

2. European union

The monomers used for the manufacturing of the above mentioned product and the additives used are listed in (EU)No10/2011 from January 14, 2011 and the amendments until the above status date, which are specific measures within the meaning of Article 5(1) of Regulation (EC) No 1935/2004.

Restriction exists as follows;

FCM substance No.	CAS No.	Substance Name	Specific migration limit (SML)
98	50-00-0	Formaldehyde	15 mg/kg
255	110-88-3	Trioxane	5 mg/kg
680	36443-68-2	triethyleneglycol bis[3- (3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]	9 mg/kg

The above mentioned product is considered applicable for repeated use only. Restrictions on the above table and the overall migration for plastics materials and articles have to be checked on the finished part by the manufacturer or seller in accordance with the above regulations.

Polyplastics

POLYPLASTICS CO.,LTD.
JR SHINAGAWA EAST BLDG. 13F
18-1, KONAN 2-CHOME
MINATO-KU, TOKYO, 108-8280 JAPAN
TEL: 81 3 6711 8605 FAX: 81 3 6711 8616

Good Manufacturing Practice, (EC) No. 2023/2006;
A constant product quality is assured through systems which control and document as required for Food Contact Good Manufacturing Practice by provisions of EU Regulation 2023/2006.

Dual use additives;
Restriction has to be ensured of the following substances for dual use additives, under the Regulation (EU)No10/2011 and the amendments.
Chemical names of the substances: Calcium stearate (CAS No. 15942-23-0), and Adipic acid (CAS No. 124-04-9)

Disclaimer:
Please be aware that final compliance with the end article made out of the above mentioned product lies in the responsibility of the producer of the final product regarding all applicable legal requirements of food contact regulations.

Sincerely,
Polyplastics Co., Ltd.

Yoichi Kurokawa, Chief
Quality Assurance Department

VINK PLAST

DECLARATION OF COMPLIANCE FOR SEMI-FINISHED PRODUCTS INTENDED TO COME INTO CONTACT WITH FOOD

Date of issue: 20. June 2024 [1)]

Vink Plast ApS hereby declare that:

Ertacetal C POM-C blue 50 FCM (POM-C) round rods and plates and finished parts machined from these products by Vink Plast ApS [2)]:

European Union

- Comply with the requirements of the articles 3, 11(5), 15 and 17 of the regulation (EC) no. 1935/2004
- Comply with the relevant requirements in Regulation (EU) 10/2011 as amended up to and inclusive the commission Regulation (EU) no. 2023/1627
- Are manufactured and handled according to good manufacturing practice (GMP) as set out in the (EC) 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.
- Comply with declaration 681/2020/DK

Based on the migration tests performed on the products according to Regulation (EU) 10/2011 as amended, the overall migration as well as the specific migration does not exceed the legal limits set out in Regulation (EU) 10/2011, when used as specified below.

Specification on the intended use of the products:

- Type(s) of food intended to come into repeated contact with the material:
  - **All types of food.**
- Type(s) of food not intended to come into repeated contact with the material:
  - **Not applicable**
- Time and temperature of treatment and storage when in contact with the food:
  - Overall migration tests run under the standardized testing conditions in
    - OM3 in 10 % ethanol (v/v) and 3 % acetic acid (w/v)
    - OM5 in Vegetable oil
  - Specific migration tests run in
    - 3 % acetic acid (2 h, 70 °C)
    - 10 % ethanol (2 h, 70 °C)
    - Vegetable oil (1 h at 121 °C) [3)]
  - Visible migration tests run according to the analytical method describes in the Appendix of European Resolution AP (89)1, "On the use of colorants in plastic materials coming into contact with food," dated September 13 1989, under III.1.
- Ratio of food contact surface area to volume (S/V) used to establish the compliance of the Products:
  - S/V = 6 dm^2/kg

Vink Plast ApS.
Kristrup Engvej 9
DK-8960 Randers SØ
Tlf. +45 89 11 01 00
E-mail: info@vink.dk
Web www.vink.dk
CVR 12559976

The following substances, subject to restrictions under Regulation EU 10/2011 as amended, are used in the products:

Chemical name of the substances	Restriction
Trioxane (CAS no. 110-88-3)	SML = 5 mg/kg
Formaldehyde (CAS no. 50-00-0)	SML(T) = 15 mg/kg
1.3-Dioxolane (CAS no. 646-06-0)	SML = 5 mg/kg
Triethyeneglycol bis (3-(3-terbutyl-4hydroxy-5-methylphenyl) propionate) (CAS no. 36443-68-2)	SML = 9 mg/kg
2,4,6-triamino-1,3,5-triazine (CAS no. 108-78-1)	SML = 2,5 mg/kg
2,5-bis (5-tert-butyl-2-benzoaxzolyl)thiophene (CAS no. 7128-64-5)	SML = 0.6 mg/kg
Ethanol, 2,2-iminobis-N-C-12-18-alkyl derivatives	SML(T) = 1.2 mg/kg
1,1,1-Trimethyllolpropan (CAS no. 77-99-6)	SML = 6 mg/kg
Zinc	SML = 5 mg/kg
Aluminium	SML = 1 mg/kg
Copper	SML = 5 mg/kg
Proprietary substances [4)]	

The following substances, identified as dual use additives under Regulation (EU) 10/2011 as amended, are used in the products:

Chemical name of the substance
Calcium stearate
Aluminium E173
Silicium dioxide E551
Magnesium silicate
Properity substances [4)]

A risk assessment of the Non-Listed Substances (NLS), such as catlysts and Non-Intentionally Added Substances (NIAS), such as reaction and degradation products has been performed in accordance with Article 3 of the Framework Regulation ((EU) 1935/2004) and article 19 of the Plastic Regulation ((EU) 10/2011) based on the conditions mentioned above.

United States

We hereby provide the following information based on the compliance atatus of the raw materials used at present by the producer for the manufacture of the stock shapes mentioned above, with respect to their composition as set out the compliance status of the stock shapes mentioned above, with respect to their composition, as set out in the regulations that apply in the United States of America /FDA) for plastic materials and articles intended to come into contact with foodstuffs:

- Ertacetal C POM-C blue 50 FCM complies with the compositional requirements of the FDA regulations 21 CFR § 177.2470 "Polyoxymethylene copolymer," 21 CFR § 178.3297 "Colorants for Polymers," as well as with those of other applicable FDA regulations.
  Based on their composition, Ertacetal C POM-C FCM blue 50 rods and plates may basically be used for the manufacture of articles or components of articles intended for repeated food-contact use with all types of food types I to IX, excluding alcoholic beverages that exceed 15 percent alcohol by volume and infant formula and breast milk, under conditions of use A to H where use temperature does not exceed 121 °C (250 °F) as defined in tables 1 and 2 in 21 CFR 176.170(c), respectively.

Japan

Based on the compliance status of the raw material used at present by the producer for the manufacture of stock shapes mentioned above, with respect to their composition, as set out by the Japan's Ministry of Health, Labour & Welfare (MHLW) in the Official Notificaton (Notification no. 196 of 2020) of 28 April 2020 for utensils, containers and packaging intended to come into contact with foodstuffs:

Vink Plast ApS.
Kristrup Engvej 9
DK-8960 Randers SØ
Tlf. +45 89 11 01 00
E-mail: info@vink.dk
Web www.vink.dk
CVR 12559976

- Ertacetal C POM-C FCM blue 50 complies with the compositional requirements of the 'Base polymers(Plastics)' and 'Additives' Japan food contact positive lists.
  Based on their composition, Ertacetal C POM-C FCM blue 50 stock shapes may basically be used for the manufacture of articles or components of articles intended for food-contact use with all food types, under maximum temperature conditions II.

It remains the responsibility of the customer putting the plastic article manufactured from the products into the intended use, to assess the final suitability of the plastics material for the intended food contact application; i.e. checking if the physical properties of the plastics material make it suitable for the intended application, checking compliances of the finished plastic article with the relevant migration limits, checking for possible influence of the plastics material on the composition and/or organoleptic properties of the contacting foodstuff, etc.

Notes:

[1] This declaration expires in case of regulatory or compositional changes which require reevaluation. Please always contact Vink Plast' customer service for latest version. For information about available dimensions, please contact Vink Plast' customer service.

[2] Reguation (EC) no. 1935/2004 of the European Parliament and the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC – Article 16.

[3] Specific migration tests in vegetable oil (1 h, 121 °C) under the standardized testing conditions OM5 being replaced by tests in isooctane (2h, 60 °C) and 95 % ethanol (4h, 60 °C) and MPPO (1 h, 121 °C) being replaced by tests in isooctane (2 h, 60 °C), 95 % ethanol (4h, 60 °C) and MPPO (1 h, 121 °C) in accordance with Directive 82/711EEC as vegetable oil is technically not feasible with the used methods of analysis.

[4] Substances subject to restrictions under Regulation EU 10/2011 as amended are used in the products. Upon request, the identity of these substances can be disclosed to third parties (e.g. test laboratories) under the terms of a Non-Disclosure Agreement.

Jan Busk

QHSE- & CSR-Manager
Vink Plast ApS.

Morten Grue Jakobsen

Business Unit Director
Vink Plast ApS.

Vink Plast ApS.
Kristrup Engvej 9
DK-8960 Randers SØ
Tlf. +45 89 11 01 00
E-mail: info@vink.dk
Web www.vink.dk
CVR 12559976

VINK PLAST

DECLARATION OF COMPLIANCE FOR SEMI-FINISHED PRODUCTS INTENDED TO COME INTO CONTACT WITH FOOD

Date of issue: 7. June 2024 [1)]

Vink Plast ApS hereby declare that:

Ertalyte TX PETP FCM grey (PET) round rods and plates and finished parts machined from these products by Vink Plast ApS [2)]:

European Union

- Comply with the requirements of the articles 3, 11(5), 15 and 17 of the regulation (EC) no. 1935/2004
- Comply with the relevant requirements in Regulation (EU) 10/2011 as amended up to and inclusive the commission Regulation (EU) no. 2023/1627
- Are manufactured and handled according to good manufacturing practice (GMP) as set out in the (EC) 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.
- Comply with declaration 681/2020/DK

Based on the migration tests performed on the products according to Regulation (EU) 10/2011 as amended, the overall migration as well as the specific migration does not exceed the legal limits set out in Regulation (EU) 10/2011, when used as specified below.

Specification on the intended use of the products:

- Type(s) of food intended to come into repeated contact with the material:
  - **All types of food.**
- Type(s) of food not intended to come into repeated contact with the material:
  - **Not applicable**
- Time and temperature of treatment and storage when in contact with the food:
  - Overall migration tests run under the standardized testing conditions in
    - OM2 in 10 % ethanol (v/v) and 3 % acetic acid (w/v)
    - OM5 in vegetable oil
  - Specific migration tests run in
    - 3 % acetic acid (10 days, 40 °C)
    - 10 % ethanol (10 days, 40 °C)
    - Vegetable oil (1 hour at 121 °C)
  - Visible migration tests run according to the analytical method described in the Appendix of European Resolution AP (89)1, "On the use of colorants in plastic materials coming into contact with food," dated September 13, 1989, under III.1.
- Ratio of food contact surface area to volume (S/V) used to establish the compliance of the Products:
  - S/V = 6 dm^2/kg

The following substances, subject to restrictions under Regulation EU 10/2011 as amended, is used in the products:

Chemical name of the substances	Restriction
Ethyleneglycol (CAS no. 000107-21-1)	SML(T) = 30 mg/kg
Diethyleneglycol (CAS no. 0000111-46-6)	SML(T) = 30 mg/kg
Terephthalic acid (CAS no. 0000100-21-0)	SML(T) = 7.5 mg/kg
Isophthalic acid (CAS no. 121-91-5)	SML(T) = 5 mg/kg
Antimony trioxide (CAS no. 1309-64-4)	SML = 0,04 mg/kg expressed as antimony
Acetaldehyde (CAS no. 75-07-0)	SML(T) = 6 mg/kg
Tetrafluorethylene (CAS no. 116-14-3)	SML = 0,05 mg/kg
Aluminium	SML = 1 mg/kg

Vink Plast ApS.
Kristrup Engvej 9
DK-8960 Randers SØ
Tlf. +45 89 11 01 00
E-mail: info@vink.dk
Web www.vink.dk
CVR 12559976

Gadolinium	SML = 0,05 mg/kg
Terbium	SML = 0,05 g/kg
Nickel	SML = 0,02 mg/kg
Mercury	SML = ND
Manganese	SML = 0,6 mg/kg
Lithium	SML = 0,6 mg/kg
Lead	SML = ND
Lanthanium	SML = 0,05 mg/kg
Iron	SML = 48 mg/kg
Europium	SML = 0,05 mg/kg
Copper	SML = 5 mg/kg
Chronium	SML = ND
Cadmium	SML = ND
Barium	SML = 1 mg/kg
Arsenic	SML = ND
Zinc	SML = 5 mg/kg
Proprietary substances [3)]	

The following substances, identified as dual use additives under Regulation (EU) 10/2011 as amended, are used in the products:

Chemical name of the substances
Phosphoric acd (CAS no. 7664-38-2)
Silicon dioxide (E551)
Dimethyl polysiloxane (E900)

A risk assessment of the Non-Listed Substances (NLS), such as catlysts and Non-Intentionally Added Substances (NIAS), such as reaction and degradation products has been performed in accordance with Article 3 of the Framework Regulation ((EU) 1935/2004) and article 19 of the Plastic Regulation ((EU) 10/2011) based on the conditions mentioned above.

United States

We hereby provide the following information on the compliance status of the raw materials used at present by the producer of the stock shapes mentioned above, with respect to their composition as set out in the regulations that apply in the United States of America (FDA) for plastic materials and articles intended to come into contact with foodstuffs:

- Ertalyte TX PETP natural FCM complies with the requirements of the FDA regulations 21 CFR § 177.1630 "Polyethylene phthalate polymers," and 21 CFR § 178.3297 "Colorants for polymers," as well as with those of other applicable FDA regulations.
  Based on their composition, Ertalyte TX PETP FCM stock shapes may basically be used for the manufacture of articles or components of articles intended for repeated food-contact use with all food types I to IX under conditions of use E to G as defined in tables 1 and 2 in 21 CFR 176.170(c), respectively.

Japan

We hereby provide the following information on the compliance status of the producer for the manufacture of stock shapes mentioned above, with respect to their composition, as set out by the Japan's Ministry of Health, Labour & Welfare (MHLW) in the Official Notificaton (Notification no. 196 of 2020) of 28 April 2020 for utensils, containers and packaging intended to come into contact with foodstuffs:

- ErtalyteTX PETP FCM complies with the compositional requirements of the 'Base polymers(Plastics)' and 'Additives' Japan food contact positive lists.
  Based on their composition, Ertalyte TX PETP FCM natural stock shapes may basically be used for the manufacture of articles or components of articles intended for food-contact use with all food types, under maximum temperature conditions III.

Vink Plast ApS.
Kristrup Engvej 9
DK-8960 Randers SØ
Tlf. +45 89 11 01 00
E-mail: info@vink.dk
Web www.vink.dk
CVR 12559976

It remains the responsibility of the customer putting the plastic article manufactured from the products into the intended use, to assess the final suitability of the plastics material for the intended food contact application; i.e. checking if the physical properties of the plastics material make it suitable for the intended application, checking compliances of the finished plastic article with the relevant migration limits, checking for possible influence of the plastics material on the composition and/or organoleptic properties of the contacting foodstuff, etc.

Notes:

[1)] This declaration expires 5 years after its date of issus or in case of regulatory or compositional changes which require reevaluation. Please always contact Vink Plast' customer service for latest version. For information about available dimensions, please contact Vink Plast' customer service.

[2)] Reguation (EC) no. 1935/2004 of the European Parliament and the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC – Article 16.

[3)] Substances subject to restrictions under Regulation EU 10/2011 as amended are used in the products. Upon request, the identity of these substances can be disclosed to third parties (e.g. test laboratories) under the terms of a Non-Disclosure Agreement.

Jan Busk

QHSE- & CSR-Manager
Vink Plast ApS.

Morten Grue Jakobsen

Business Unit Director
Vink Plast ApS.

Vink Plast ApS.
Kristrup Engvej 9
DK-8960 Randers SØ
Tlf. +45 89 11 01 00
E-mail: info@vink.dk
Web www.vink.dk
CVR 12559976

VINK PLAST

DECLARATION OF COMPLIANCE FOR SEMI-FINISHED PRODUCTS INTENDED TO COME INTO CONTACT WITH FOOD

Date of issue: 31. May 2024 [1)]

Vink Plast ApS hereby declare that:

Ertalyte PETP FCM natural (PET) round rods, plates and tubes and finished parts machined from these products by Vink Plast ApS [2)]:

European Union and China

- Comply with the requirements of the articles 3, 11(5), 15 and 17 of the regulation (EC) no. 1935/2004
- Comply with the relevant requirements in Regulation (EU) 10/2011 as amended up to and inclusive the commission Regulation (EU) no. 2023/1627
- Comply with the relevant requirements of GB 9685-2016 and GB 4806.7-2016 and their relevant announcements
- Are manufactured and handled according to good manufacturing practice (GMP) as set out in the (EC) 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.
- Are manufactured according to Good Manufacturing Practice (GMP) as set out in GB 31603-2015
- Comply with declaration 681/2020/DK

Based on the migration tests performed on the products according to Regulation (EU) 10/2011 as amended, GB 4806.7-2016, GB 5009.156-2016 and GB 31604.1-2015, the sensory index, the overall migration, potassium permanganate consumption, heavy metal fraction as well as the specific migration does not exceed the legal limits set out in Regulation (EU) 10/2011 and GB 4806.7-2016, when used as specified below.

Specification on the intended use of the products:

- Type(s) of food intended to come into repeated contact with the material:
  - **All types of food.**
- Type(s) of food not intended to come into repeated contact with the material:
  - **Not applicable**
- Time and temperature of treatment and storage when in contact with the food:
  - Overall migration tests run under the standardized testing conditions in
    - 3 % acetic acid (10 days, 40 °C)
    - 4 % acetic acid (10 days, 40 °C)
    - 10 % ethanol (10 days, 40 °C)
    - Vegetable oil (1 h at 121 °C)
  - Specific migration tests run in
    - 3 % acetic acid (10 days, 40 °C)
    - 4 % acetic acid (10 days, 40 °C)
    - 10 % ethanol (10 days, 40 °C)
    - Vegetable oil (1 h at 121 °C)

- Ratio of food contact surface area to volume (S/V) used to establish the compliance of the Products:
  - S/V = 6 dm^2/kg

The results of the overall migration test are expressed in the table below:

10 % ethanol (v/v)	3 % acetic acid (w/v)	4 % acetic acid (w/v)	Vegetable oil
0,6 mg/dm^2	0,5 mg/dm^2	0,5 mg/dm^2	1,1 mg/dm^2

Vink Plast ApS.
Kristrup Engvej 9
DK-8960 Randers SØ
Tlf. +45 89 11 01 00
E-mail: info@vink.dk
Web www.vink.dk
CVR 12559976

The following substances, subject to restrictions under Regulation EU 10/2011 as amended, is used in the products:

Chemical name of the substances	Restriction
Ethyleneglycol (CAS no. 000107-21-1)	SML(T) = 30 mg/kg
Diethyleneglycol (CAS no. 0000111-46-6)	SML(T) = 30 mg/kg
Terephthalic acid (CAS no. 0000100-21-0)	SML(T) = 7.5 mg/kg
Isophthalic acid (CAS no. 121-91-5)	SML(T) = 5 mg/kg
Acetaldehyde (CAS no. 75-07-0)	SML(T) = 6 mg/kg
Antimony trioxide (CAS no. 1309-64-4)	SML = 0,04 mg/kg (Antimony)
Aluminium	SML = 1 mg/kg
Iron	SML = 48 mg/kg
Proprietary substances [3)]	

The following substances, identified as dual use additive under Regulation (EU) 10/2011 as amended, are used in the products:

Chemical name of the substance
Phosphoric acid
Proprietary substances [3)]

A risk assessment of the Non-Listed Substances (NLS), such as catlysts and Non-Intentionally Added Substances (NIAS), such as reaction and degradation products has been performed in accordance with Article 3 of the Framework Regulation ((EU) 1935/2004) and article 19 of the Plastic Regulation ((EU) 10/2011) based on the conditions mentioned above.

United States

We hereby provide the following information on the compliance status of the producer of the stock shapes mentioned above, as set out in the regulations that apply in the United States of America /FDA) for plastic materials and articles intended to come into contact with foodstuffs:

- Ertalyte PETP natural FCM complies with the requirements of the FDA regulations 21 CFR § 177.1630 "Polyethylene phthalate polymers."
  Ertalyte PETP natural FCM stock shapes may basically be used for the manufacture of articles or components of articles intended for applications specified under 21 CPR § 177.1630 (f), (g) and (h).

Japan

We hereby provide the following information on the compliance status of the producer for the manufacture of stock shapes mentioned above, with respect to their composition, as set out by the Japan's Ministry of Health, Labour & Welfare (MHLW) in the Official Notificaton (Notification no. 196 of 2020) of 28 April 2020 for utensils, containers and packaging intended to come into contact with foodstuffs:

- Ertalyte PETP FCM natural complies with the compositional requirements of the 'Base polymers(Plastics)' and 'Additives' Japan food contact positive lists.
  Based on their composition, Ertalyte PETP FCM natural stock shapes may basically be used for the manufacture of articles or components of articles intended for food-contact use with all food types, under maximum temperature conditions III.

It remains the responsibility of the customer putting the plastic article manufactured from the products into the intended use, to assess the final suitability of the plastics material for the intended food contact application; i.e. checking if the physical properties of the plastics material make it suitable for the intended application, checking compliances of the

Vink Plast ApS.
Kristrup Engvej 9
DK-8960 Randers SØ
Tlf. +45 89 11 01 00
E-mail: info@vink.dk
Web www.vink.dk
CVR 12559976

finished plastic article with the relevant migration limits, checking for possible influence of the plastics material on the composition and/or organoleptic properties of the contacting foodstuff, etc.

Notes:

[1] This declaration expires in case of regulatory or compositional changes which require reevaluation. Please always contact Vink Plast' customer service for latest version. For information about available dimensions, please contact Vink Plast' customer service.

[2] Reguation (EC) no. 1935/2004 of the European Parliament and the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC – Article 16.

[3] Substances subject to restrictions under Regulation EU 10/2011 as amended are used in the products. Upon request, the identity of these substances can be disclosed to third parties (e.g. test laboratories) under the terms of a Non-Disclosure Agreement.

Jan Busk

QHSE- & CSR-Manager
Vink Plast ApS.

Morten Grue Jakobsen

Business Unit Director
Vink Plast ApS.

Vink Plast ApS.
Kristrup Engvej 9
DK-8960 Randers SØ
Tlf. +45 89 11 01 00
E-mail: info@vink.dk
Web www.vink.dk
CVR 12559976