# Test Report No.: 70.431.21.13207.01

## Date: 2021-06-17

| | |
|---|---|
| **Applicant:** | TAIZHOU ARK INTERNATIONAL TRADE CO., LTD |
| **Address:** | E801 XINTAI SQUARE,NO.168 GUANGCHANG SOUTH ROAD,JIAOJIAN G ECONOMIC DEVELOPMENT ZONE,TAIZHOU CITY,ZHEJIANG,CHINA |
| **Product Name:** | PEEK Products(PEEK rod) |
| **Supplier:** | Taizhou Ark International Trade Co., Ltd |
| **Manufacturer:** | Taizhou Ark International Trade Co., Ltd |
| **Country of Origin:** | China |
| **Receipt Date of Sample:** | 2021-06-02 |
| **Date of Testing:** | 2021-06-03 to 2021-06-17 |
| **Sample Submitted:** | The sample(s) was (were) submitted by applicant and identified. |
| **Test Result:** | Refer to the data listed in following pages |

| Test Item | Conclusion |
|---|---|
| 1. **EU-Commission Regulation (EU) 2020/1245 amending Regulation (EU) No 10/2011 and its amendments - Overall Migration** | **Pass** |
| 2. **EU- Commission Regulation (EU) 2020/1245 amending Regulation (EU) No 10/2011 and its amendments -Specific Migration of Primary Aromatic Amine** | **Pass** |
| 3. **EU- Commission Regulation (EU) 2020/1245 amending Regulation (EU) No 10/2011 and its amendments -Specific Migration of Primary Aromatic Amine (29)** | **Pass** |
| 4. **EU- Commission Regulation (EU) 2020/1245 amending Regulation (EU) No 10/2011 and its amendments -Specific Migration of Heavy Metals** | **Pass** |
| 5. **EU- Commission Regulation (EU) 2020/1245 amending Regulation (EU) No 10/2011 and its amendments - Specific migration of 1,4-dichlorobenzene** | **Pass** |

Remarks: 1. MDL = Method Detection Limit
2. ND = Not Detected (<MDL)
3. <= Less than
4. 1 mg/kg = 1 ppm = 0.0001%
5. The migration results in this report were tested and expressed based on repeated use articles
6. The testing approach, the testing methods, and the reported results in this report demonstrate compliance or non-compliance to the client's requirements which were mutually agreed at the contract review and stipulated in the quotation. The testing approach, the testing methods, and the reported results may not or only partially fulfil the associated requirements of the applicable regulations.

Greater China

**TÜV SÜD Certification and Testing (China) Co., Ltd. Shanghai Branch**
**Testing Center**

**Prepared by:**

Jenny Yao
Technical Engineer

**Authorized by:**

Sawyer Tang
Technical Manager

Note:
(1) The TÜV SÜD Certification and Testing (China) Co., Ltd. "General Terms & Conditions" applied.
Any use for advertising purposes must be granted in writing. This technical report may only be quoted in full. This report is the result of a single examination of the object in question and is not generally applicable evaluation of the quality of other products in regular production.
For further details, please see "Testing and certification regulation", chapter A-3.4
For full version, please visit: EN : https://www.tuvsud.cn/zh-cn/resource/terms-and-conditions---en ; SCN: https://www.tuvsud.cn/zh-cn/terms-and-conditions ; TCN: https://www.tuvsud.com/zh-tw/terms-and-conditions
(2) The results relate only to the Items tested.
(3) The test report shall not be reproduced except in full without the written approval of the laboratory
(4) Disclaimer Measurement Uncertainty:
Unless otherwise agreed upon, Pass or Fail verdicts are given based on the measured values without any considerations of measurement uncertainties. Please note, every test method has a measurement uncertainty which has been evaluated by the laboratory according to ISO/IEC 17025 requirements. By taking measurement uncertainties into account it might happen that measured values can neither be assessed as Pass nor as Fail.

Greater China

**Description of Tested Subject:**

| Sample | Description | Photo |
|---|---|---|
| A | PEEK rod |  |
| 001 | Beige yellow PEEK |  |

**Test Result(s):**

1. **EU-Commission Regulation (EU) 2020/1245 amending Regulation (EU) No 10/2011 and its amendments – Overall Migration**
   - With reference to EN1186-1:2002 for selection of test methods; EN1186-3:2002 aqueous food simulants by total immersion method; EN1186-14:2002 substitute test;
   - Sample 001 Migration ratio: 100ml/0.76dm$^2$

| Simulant(s) Used | Test Condition | Overall Migration Result(s) [mg/dm$^2$] | | | Maximum Permissible Limit [mg/dm$^2$] | Conclusion |
|---|---|---|---|---|---|---|
| | | 001 1st Migration | 001 2nd Migration | 001 3rd Migration | | |
| 3% Acetic acid | 100°C for 4 hours | 4.7 | <3.0 | <3.0 | 10 | **Pass** |
| 10% Ethanol | 100°C for 4 hours | 5.4 | 4.1 | 3.7 | 10 | **Pass** |
| 95% Ethanol | 60°C for 6 hours | 7.4 | 6.3 | 5.9 | 10 | **Pass** |
| Isooctane | 60°C for 4 hours | <3.0 | <3.0 | <3.0 | 10 | **Pass** |

2. **EU- Commission Regulation (EU) 2020/1245 amending Regulation (EU) No 10/2011 and its amendments - Specific Migration of Primary Aromatic Amine**
   - With reference to EN 13130-1:2004.
   - Test condition: 3% Acetic acid, 100°C for 2 hours
   - Sample 001 Migration ratio: 80ml/0.76dm$^2$

| Test Item(s) | Result(s) [mg/kg] | Method Detection Limit [mg/kg] | Maximum Permissible Limit [mg/kg] | Conclusion |
|---|---|---|---|---|
| | 001 | | | |
| Specific migration of primary aromatic amines – 1st Migration | ND | 0.01 | ND | **Pass** |
| Specific migration of primary aromatic amines – 2nd Migration | ND | 0.01 | ND | **Pass** |
| Specific migration of primary aromatic amines – 3rd Migration | ND | 0.01 | ND | **Pass** |

**3. EU- Commission Regulation (EU) 2020/1245 amending Regulation (EU) No 10/2011 and its amendments - Specific Migration of Primary Aromatic Amine (29)**

- With reference to EN 13130-1:2004.
- Test condition: 3% Acetic acid, 100°C for 2 hours
- Sample 001 Migration ratio: 80ml/0.76dm$^2$

| No. | Prohibited Amines | CAS No. | MDL [mg/kg] | Limit [mg/kg] | Result(s) [mg/kg] | | |
|---|---|---|---|---|---|---|---|
| | | | | | 001 1st Migration | 001 2nd Migration | 001 3rd Migration |
| 1 | 4-Aminobiphenyl | 92-67-1 | 0.002 | 0.002 | ND | ND | ND |
| 2 | 4,4'-Benzidine | 92-87-5 | 0.002 | 0.002 | ND | ND | ND |
| 3 | 4-Chloro-2-methylaniline | 95-69-2 | 0.002 | 0.002 | ND | ND | ND |
| 4 | 2-Naphthylamine | 91-59-8 | 0.002 | 0.002 | ND | ND | ND |
| 5 | o-Aminoazotoluene | 97-56-3 | 0.002 | 0.002 | ND | ND | ND |
| 6 | 5-Nitro-o-toluidine | 99-55-8 | 0.002 | 0.002 | ND | ND | ND |
| 7 | 4-Chloroaniline | 106-47-8 | 0.002 | 0.002 | ND | ND | ND |
| 8 | 4-Methoxy-1,3-phenylenediamine | 615-05-4 | 0.002 | 0.002 | ND | ND | ND |
| 9 | Bis-(4-aminophenyl) methane | 101-77-9 | 0.002 | 0.002 | ND | ND | ND |
| 10 | 3,3'-Dichlorobenzidine | 91-94-1 | 0.002 | 0.002 | ND | ND | ND |
| 11 | 3,3'-Dimethoxybenzidine | 119-90-4 | 0.002 | 0.002 | ND | ND | ND |
| 12 | o-Tolidine | 119-93-7 | 0.002 | 0.002 | ND | ND | ND |
| 13 | 3,3'-Dimethyl-4,4'-diaminadiphenylmethane | 838-88-0 | 0.002 | 0.002 | ND | ND | ND |
| 14 | 2-Methoxy-5-methylaniline | 120-71-8 | 0.002 | 0.002 | ND | ND | ND |
| 15 | 4,4'-Methylene bis(o-chloroaniline) | 101-14-4 | 0.002 | 0.002 | ND | ND | ND |
| 16 | 4,4'-Oxydianiline | 101-80-4 | 0.002 | 0.002 | ND | ND | ND |
| 17 | 4,4'-Thiodianiline | 139-65-1 | 0.002 | 0.002 | ND | ND | ND |
| 18 | o-Toluidine | 95-53-4 | 0.002 | 0.002 | ND | ND | ND |
| 19 | 2,4-Diaminotoluene | 95-80-7 | 0.002 | 0.002 | ND | ND | ND |
| 20 | 2,4,5-Trimethylaniline | 137-17-7 | 0.002 | 0.002 | ND | ND | ND |
| 21 | o-Anisidine | 90-04-0 | 0.002 | 0.002 | ND | ND | ND |
| 22 | 4-Amino-azobenzene | 60-09-3 | 0.002 | 0.002 | ND | ND | ND |
| 23 | 1,3-Phenylenediamine | 108-45-2 | 0.002 | 0.002 | ND | ND | ND |
| 24 | 2,4-Dimethylaniline | 95-68-1 | 0.002 | 0.002 | ND | ND | ND |
| 25 | 2,6-Dimethylaniline | 87-62-7 | 0.002 | 0.002 | ND | ND | ND |
| 26 | Aniline | 62-53-3 | 0.002 | 0.002 | ND | ND | ND |
| 27 | 1,4-Phenylenediamine | 106-50-3 | 0.002 | 0.002 | ND | ND | ND |
| 28 | 1,5-Diaminonaphthalene | 2243-62-1 | 0.002 | 0.002 | ND | ND | ND |
| 29 | 2,6-toluenediamine | 823-40-5 | 0.002 | 0.002 | ND | ND | ND |
| **Conclusion** | | | | | **Pass** | **Pass** | **Pass** |

**4. EU- Commission Regulation (EU) 2020/1245 amending Regulation (EU) No 10/2011 and its amendments - Specific Migration of Heavy Metals**

- With reference to EN 13130-1:2004, determination by ICP-MS.
- Test condition: 3% Acetic acid, 100°C for 2 hours
- Sample 001 Migration ratio: 100ml/0.76dm$^2$

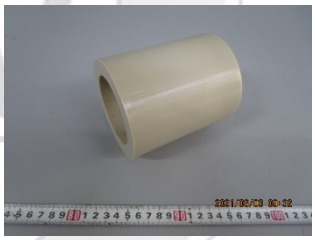
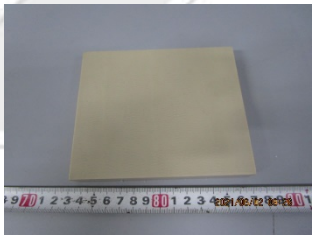
| Test Item(s) | MDL [mg/kg] | Result(s) [mg/kg] | | | Limit [mg/kg] | Conclusion |
|---|---|---|---|---|---|---|
| | | 001 1st Migration | 001 2nd Migration | 001 3rd Migration | | |
| Iron (Fe) | 1.0 | ND | ND | ND | 48 | **Pass** |
| Zinc (Zn) | 1.0 | ND | ND | ND | 5 | **Pass** |
| Copper (Cu) | 0.5 | ND | ND | ND | 5 | **Pass** |
| Manganese (Mn) | 0.05 | ND | ND | ND | 0.6 | **Pass** |
| Cobalt (Co) | 0.05 | ND | ND | ND | 0.05 | **Pass** |
| Barium (Ba) | 0.1 | ND | ND | ND | 1 | **Pass** |
| Lithium (Li) | 0.1 | ND | ND | ND | 0.6 | **Pass** |
| Aluminium (Al) | 0.1 | ND | ND | ND | 1 | **Pass** |
| Nickel (Ni) | 0.01 | ND | ND | ND | 0.02 | **Pass** |
| Antimony (Sb) | 0.01 | ND | ND | ND | 0.04 | **Pass** |
| Arsenic (As) | 0.01 | ND | ND | ND | 0.01 | **Pass** |
| Cadmium (Cd) | 0.002 | ND | ND | ND | 0.002 | **Pass** |
| Chromium (Cr) | 0.01 | ND | ND | ND | 0.01 | **Pass** |
| Lead (Pb) | 0.01 | ND | ND | ND | 0.01 | **Pass** |
| Mercury (Hg) | 0.01 | ND | ND | ND | 0.01 | **Pass** |
| Europium | 0.01 | ND | ND | ND | Sum 0.05 | **Pass** |
| Gadolinium | 0.01 | ND | ND | ND | | **Pass** |
| Lanthanum | 0.01 | ND | ND | ND | | **Pass** |
| Terbium | 0.01 | ND | ND | ND | | **Pass** |

**5. EU- Commission Regulation (EU) 2020/1245 amending Regulation (EU) No 10/2011 and its amendments - Specific migration of 1,4-dichlorobenzene**

- With reference to EN 13130-1:2004.
- Test condition: 3% Acetic acid, 100°C for 2 hours
- Sample 001 Migration ratio: 6dm²/L

| Test Item(s) | Result(s) [mg/kg] | Maximum Permissible Limit [mg/kg] | Conclusion |
|---|---|---|---|
| | 001 | | |
| Specific migration of 1,4-dichlorobenzene– 1st Migration | <5 | 12 | **Pass** |
| Specific migration of 1,4-dichlorobenzene– 2st Migration | <5 | 12 | **Pass** |
| Specific migration of 1,4-dichlorobenzene– 3st Migration | <5 | 12 | **Pass** |

**Annex:**
Reference submitted samples photo:

| Description | Photo |
|---|---|
| PEEK tube |  |
| PEEK sheet |  |

-End of Test Report-