

0.403 ±0.015

"H"

 $\phi 1.464 \pm 0.012$ 

"T"

 $\phi 1.370 \pm 0.012$ 

"E"

 $\phi 1.490 \pm 0.012$ 

"S"

0.046 ±0.015

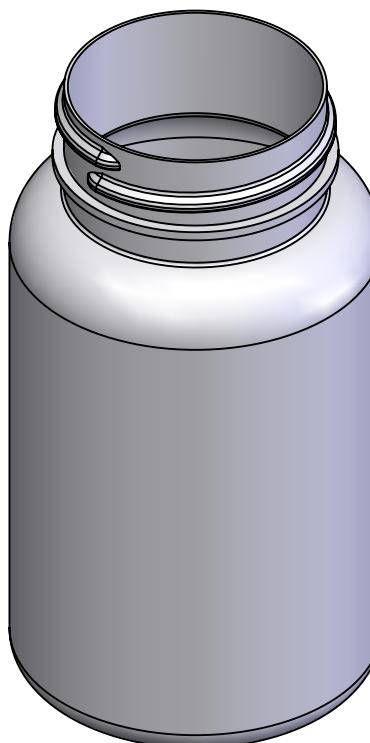
2.46  
Label Panel

3.609 ±0.040

R0.16

 $\phi 1.938 \pm 0.030$ 

R0.34


**SPECIFICATION  
NECK FINISH  
38SP400**

KEY	MAX	MIN
T	1.476	1.452
E	1.382	1.358
H	0.418	0.388
S	0.061	0.031

**PROPRIETARY AND CONFIDENTIAL**

THIS DOCUMENT IS THE EXCLUSIVE PROPERTY OF TIM PLASTICS, INC. THE INFORMATION CONTAINED HEREIN, AND ANY MODEL CONTAINER OR OTHER ARTICLE RECEIVED, IS PROPRIETARY AND CONFIDENTIAL AND MUST ONLY BE USED FOR THE PURPOSE FOR WHICH IT WAS DISCLOSED. THE HOLDER WILL NOT DISCLOSE TO A THIRD PARTY, UPON COMPLETION OF USE OR BY REQUEST. THIS MATERIAL IS TO BE RETURNED TO TIM PLASTICS, INC. THIS DOCUMENT IS NO LONGER A CONTROLLED DOCUMENT WITHIN TIM PLASTICS, INC. DO NOT ASSUME THAT THIS DRAWING IS CURRENT.

Rev.	Description	By	Date	ECR
A	Original Release	AS	1/14/2010	N/A
B	3D Model, format, min. wall thick.	SM	11/21/2017	N/A

**Notes/Comments:**

1. Min. wall thickness: 0.012 inches
2. Dimensions are nominal (millimeters/inches).
3. This drawing represents the bottle 72 hours after time of manufacture. (Storage at nominal conditions)
4. The dimensional tolerances applied to the Overall Height of the container are to be applied to all height dimensions.
5. The dimensional tolerances applied to the major diameter or width of the container are to be applied to all diameter, width and thickness dimensions.
6. The actual weight will vary based on the actual production weight of the preforms
7. Fill levels are based on room temperature water
8. Tim Plastics, Inc. assumes no responsibility for fit, function or form of closures, accessories and/or shelf life and compatibility of intended contents with this bottle.
9. The customer is responsible to determine the suitability of the intended use of this product and to keep it in a suitable environment (cool and dry) during transportation, storage and handling

**CONFIDENTIAL**
**Volume & Weight Information**
**Capacity Specification**

Fill Line Capacity (Approximate):	Overflow Capacity:	Process/Preform:
120	ml	142.0 ±3.0 ml
Material: PET	Container Target Weight: 19.0 ±2.0 gm	Neck Finish: 38SP400

**Drawing Information**

Date: 11/21/2017	Drawn By: SM	Customer:
Scale: SCALE: 1:1	Checked By: AS	

Title: **120cc Round Bottle**

Drawing Type: **Product Drawing**

Drawing Number: **A 3001121** Rev. **B**

 **Tim Plastics, Inc.**  
97 N. Leslie Rd.  
North East, MD 21901



P.O. Box V  
97 N. Leslie Rd  
North East, MD 21901  
410-287-6944

# Regulatory Status PET

All PET bottles and jars manufactured by Tim Plastics, Inc. are produced in the United States using good manufacturing practices. Products are manufactured using the following resin:

## **Nanya Plastics Corporation Tairilin Chip AA20**

AA20 compositionally complies with 21 C.F.R. § 177.1630 ("Polyethylene phthalate polymers") for contact with all food types under Conditions of Use A ("High temperature heat-sterilized (e.g. over 212°F)") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use"). Provided the appropriate end tests of Section 177.1630 are met, such use may properly be said to comply fully with the Federal Food, Drug, and Cosmetic Act and all applicable food additive regulations and Food Contact Notifications, Including 21 C.F.R. § 174.5 ("General provisions applicable to indirect food additives").

## **EU 10/2011**

AA20 complies with the safety requirements of Article 3.1.a) of the EU Framework Regulation (Regulation (EC) No. 1935/2004, as amended), as well as the Plastics Regulation (Regulation (EU) No. 10/2011, as amended), when used in contact with all types of food under high temperature applications, including conditions as severe as retort conditions (2 hours at 121°C) and oven cooking applications (2 hours at 175°C), as well as long-term storage (greater than 6 months) at room temperature and below.

## **US Pharmacopeia**

Tairilin PET resin AA20 has passed all physical and chemical tests for PET as indicated by USP Standard 661 for plastics containers

## **Food Allergens**

Tairilin PET resins do not contain allergenic ingredients such as tree nuts, peanut products, soybean products, egg products, milk products, fish, shellfish, wheat products, sunflower seeds, poppy seeds, sesame seeds, or sulfites.

## **Genetically Modified Organisms**

Genetically modified organisms are not used in the formulation or manufacture of Tairilin PET resins.

## **Latex**

To the best of our knowledge, the materials used, manufactured and processed for Tairilin PET resins do not contain natural rubber or dry natural rubber.

## **Ozone Depleting Substances**

Materials listed in the Clean Air Act Amendments of 1990 (Class I CFC's, Class II HCFC's and the solvents, carbon tetrachloride and 1,1,1-trichloroethane) are not used in the manufacture of Tairilin PET resins.

## **Heavy Metals CONEG / Toxics in Packaging**

These resins comply with the package requirements for heavy metals as set forth by the Coalition of Northeast Governors (CONEG), the California Toxics in Packaging act and the Article 11 of the EU Directive 94/62/EC. Lead, cadmium, mercury, and hexavalent chromium are not used in the formulation or manufacture of Tairilin PET resins. The sum of incidental (non-intentionally added) concentrations of these heavy metals in Tairilin PET resins do not exceed 100 parts per million by weight.

## **EU Restrictions of Hazardous Substances (RoHS) Directive 2002/95/EC**

These resins meet the safety and regulatory requirements for certification under this standard. Nan Ya Plastics Corporation does not intentionally add lead, cadmium, mercury, or hexavalent chromium, deca-BDE or polybrominated biphenols during the manufacture of Tairilin PET resins.

## **California Proposition 65**

Substances listed in California Proposition 65 (8/11/2023) are not utilized in the formulation of the 1AA20 except for Ethylene Glycol (Ethylene Glycol is a required feedstock for the production of PET); however, Ethylene Glycol is expected to be fully reacted into PET.

## **REACH and Substances of Very High Concern**

AA20 does not contain any chemicals listed as Substances of Very High Concern (6/14/2023) greater than the 0.1 wt% requirement for reporting.

Pentabromodiphenyl Ether and Octabromodiphenyl Ether

Pentabromodiphenyl Ether and Octabromodiphenyl Ether are not used in the formulation or the manufacture of Tairilin PET resins. To the best of our knowledge, this product is in compliance with EU Directives 2003/11/EC and 76/769/EEC.

## **Phthalates and Bisphenol A (BPA)**

Phthalates (DEHP, DBP, BBP, DINP, DIDP, DNOP) or Bisphenol A are not used in the formulation or the manufacture of Tairilin PET resins.

## **Glycidyl Ethers (Badge, BFDGE, NOGE)**

Bisphenol A Diglycidyl ether (BADGE), Bisphenol F diglycidyl ether (BFGDE) and Novolac glycidyl ether (NOGE) are not used in the formulation or manufacture of Tairilin PET resin.

## **Butylated Hydroxytoluene (BHT) & Butylated Hydroxyanisole (BHA)**

Butylated Hydroxytoluene (BHT) & Butylated Hydroxyanisole (BHA) are not used in the formulation or manufacture of Tairilin PET resins.

## **Organotin Compounds**

Organotin compounds are not used in the formulation or manufacture of Tairilin PET resins.

## **Perfluorinated Chemicals**

Perfluorinated chemicals, specifically perfluorooctanoic acid (PFOA) or PFAs are not used in the formulation or manufacture of Tairilin PET resins.

## **Animal Derived Materials**

No materials derived from animals are used in the formulation or manufacture of Tairilin PET resins. These resins meet both European Union and U.S. Food and Drug Administration standards for being free from contamination with Transmissible Spongiform Encephalopathy (TSE) agents.

## **Sustainability**

All Tim Plastics PET bottles can be recycled as all polyester resins.

## **N-Nitrosamines**

The PET resin used by Tim Plastics does not utilize N-nitrosamines or their reagents in the formulation and therefore do not expect N-nitrosamines to be present in the resin. This includes the N-nitrosamines NDMA, NDEA, NMBA/BMSA, DIPNA/NDIPA/NDIA, EIPNA/NIPEA/NIEA, NDBA, NDPA, NMEA and the reagents Dimethylamine, Diethylamine, N-methyl-4-amino butyric acid, Diisopropylamine, N,N-diisopropylethel amine, Dibutylamine, Dipropylamine, and N-ethylmethylamine.

## **Melamine**

Tim Plastics' products are not formulated with melamine compounds and they are not expected to be present.

## **Radiological Statement**

Tim Plastics' products are not formulated with any components that contain harmful levels of radiation contamination.

## **Residual Solvents**

Tim Plastics' products are not formulated with any residual solvents and they are not expected to be present.

## **Debarment and Conviction Statement**

Pursuant to Section 306(k) of the Federal Food and Drug Cosmetic Act, as amended by the Generic Drug Enforcement Act of 1992, Tim Plastics, Inc. hereby certifies to the best of it's knowledge, that it does not and will not use, in any capacity, the services of any principal employee debarred under subsection (a) or (b) of the Generic Drug Enforcement Act.

## **California Transparency in Supply Chains Act of 2010**

Tim Plastics' relationships with suppliers are based on lawful, efficient, and fair practices. We expect our suppliers to obey the laws that require them to treat workers fairly, provide a safe and healthy work environment, and protect environmental quality. All of the raw materials and packaging components used in Tim's production are sourced from within the United States.

## **National Organic Program**

We hereby certify that we do not use, add, or treat any of our packaging with any type of synthetic fungicides, preservatives, or fumigants in accordance with USDA NOP (National Organic Program) 205.272.

This information is based on the current formulation for this product as dated by this memo. Materials were not used to replace the regulated

chemicals present in a quantity or manner that creates a hazard as great or greater than the hazard created by the regulated chemicals.

Tim Plastics maintains certification letters on file from the material manufacturers. Unless specifically mentioned, Tim Plastics does not use any recycled post-consumer content in any of our products.

Tim Plastics does not add any synthetic fungicides, preservatives, or fumigants to the resin used for the manufacturing of the bottles.

### **Disclaimer**

In determining the acceptability of this product we recommend you consult the Regulation for complete details. This information is based on data collected by Tim Plastics and is believed to be correct.

### **Emergency Contact Information:**

**Phone - 410-287-6944      Fax - 410-287-6945**



## FDA DECLARATION OF COMPLIANCE

Customer: **TIM PLASTICS**  
Product Code: **CC10176625FD**  
Product Name: **AMBER CONC 2**  
Certificate Date: **10 NOV 2021**

It is hereby declared based on supplier information and/or own evaluation that the product AMBER CONC 2 is a material that may be lawfully used in the manufacture of plastic articles that will contact food, subject to the restrictions provided below, in compliance with the Federal Food, Drug, and Cosmetic Act, and all applicable regulations of the U.S. Food and Drug Administration (FDA) as outlined in Title 21 Code of Federal Regulations.

Applicable sections of 21 CFR are identified below for the intended end use article as identified by your company:

170.39 177.1630 178.2010 178.3280 178.3297 178.3400 K&H OPINION LETTER

### Applicable Restrictions (if any)

May be used at levels not to exceed 0.50% by weight.

The finished articles are to contact foods only under FDA's Conditions of Use E,F,G as described on the FDA website:  
<http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/ucm109358.htm>

The finished articles are to contact only the following food types as defined on the website given above:  
I,VI-A,VI-B,VIII. The safety of usage of the material in contact with infant formula, its ingredients, and breast milk has not been evaluated.

Polymer Types permitted:  
PET

For use in PET only

A higher use level may be permitted for some food types. Please contact your local representative if you need to discuss your requirements in more detail.

Additional food types, use levels, polymer types or conditions of use may be cleared with different restrictions. Please contact your local representative if you need to discuss your requirements in more detail.

### General Conditions

The present certificate does not warrant against modifications of AMBER CONC 2 resulting from its processing or from the addition of other products, nor against any inadequate use and/or storage of AMBER CONC 2 or the materials and articles containing it.

It is the responsibility of the manufacturer of the finished food-contact article to ensure that all materials used in the production of the finished article have an appropriate regulatory status and are suitably pure (in accordance with 21 CFR 174.5) for the intended use and region of sale.

Extraction, migration, and NIAS testing, and organoleptic tests are the responsibility of the end-use manufacturer and are not part of our routine quality control.

The use of this product manufactured by Avient Corporation or its subsidiaries and affiliates (Avient) in medical devices and drug packaging applications is not covered by the above or any other general regulation. It is the responsibility of the device or package manufacturer to establish safety with the FDA or other authorities through the submission of individual applications on the device or drug.

## **FDA DECLARATION OF COMPLIANCE**

Avient does not control the conditions under which the products are used by the end-use manufacturer. Therefore, Avient does not warrant that the products meet all national regulatory requirements. It is the responsibility of the finished article manufacturer to ensure that all restrictions, including but not limited to food contact and organoleptic requirements, are met by the finished article and that such article is fully compliant with all the relevant national regulations.

The information provided pursuant to current regulations is valid as of the date of this letter and from one-year following its issuance or until changes of the cited regulations become effective whichever comes earlier. Avient makes no representations or warranties as to the accuracy of the information contained or referenced as of any other date. This certificate applies to the product manufactured in North America.

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