



September 14, 2015

Sean Lykins
High Performance Alloys
1985 E 500 N
Windfall, IN 46076

Dear Mr. Lykins:

This is in response to your letter dated May 28, 2015, regarding a stainless steel alloy for use as food contact surfaces of equipment.

The stainless steel in your submission has the following composition:

Composition

	% Min	% Max
Carbon	0.060	0.080
Manganese	7.50	8.50
Phosphorus		0.040
Sulfur		0.030
Silicon	3.70	4.20
Chromium	16.00	17.00
Nickel	8.00	8.50
Molybdenum		0.75
Copper		0.75
Nitrogen	0.10	0.18
Titanium		0.050
Aluminum		0.020
Boron		0.0015
Columbium		0.10
Tin		0.050
Vanadium		0.20
Tungsten		0.15

As you are aware, proposed uses of metals for contact with food are reviewed on a case-by-case basis. In order for a metal to be used in contact with food under the Federal Food, Drug, and Cosmetic Act, it must have pre-market approval for that use [*an effective food contact substance notification (FCN)*^[1] or *threshold of regulation exemption*^[2]. *There are no metals listed in the Code of Federal Regulations*

^[1] Under section 409(h)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348 (h)(2)(C)) an is only effective for the manufacturer or supplier identified in the notification. All persons who purchase a food contact substance manufactured or supplied by a manufacturer or supplier identified in an effective notification may rely on that notification to legally market or use the food contact substance for the use that is the subject of the notification, consistent with any limitations in that notification.

^[2] <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm081833.htm>

(CFR)] or be exempt from the requirement as either generally recognized as safe for the intended use by experts qualified by training and experience to make that determination, prior-sanctioned by a letter before 1958 from FDA or USDA offering no objection to that specific use.

In the past, we have reviewed stainless steels with compositions as described in your submission. We believe this alloy is expected to be highly resistant to abrasion and corrosion that there is little or no likelihood that components of these materials would migrate to food in significant amounts. Therefore, we have no objection to the use of the stainless steel as described in your submission for use as food contact surfaces of equipment.

Below are the criteria for authorized stainless steels for use as utensils and food contact surfaces of equipment:

As you are aware, not all stainless steels are authorized to be used in contact with food.

Stainless steel is classified by its: 1) formulation (iron alloy plus metallic element[s] such as chromium, nickel, manganese); 2) series/type (wrought or cast grade series or type number such as AISI Series 300, Type 304; 3) surface finish (polish level, grit designation such as No. 4, 150 grit); and, 4) gage (thickness and weight such as Gage # 24).

Formulation: Stainless steel with a minimum chromium content of 16% is acceptable for food contact.

Grade Type: Wrought grades of stainless steel are identified by American Iron and Steel Institute (AISI) series and number/letter designations. For example, AISI grades sometimes used in the manufacture of the food contact surfaces of equipment include Type Numbers 303, 304, and 316. Stainless steel in AISI Series 200 and 300 contain the proper formulation, and, if they also have an appropriate surface finish, are acceptable for food contact surfaces of equipment.

The 200 series is not commonly used due to expense, but may be preferred for damp more corrosive environments. Grade Types 302 and 304 are generally considered to be "all purpose" since they are exceptionally durable, have high tensile strength, and are very ductile. Type 304 contains less carbon making it more corrosion resistant and more expensive. Type 316 with its 10-14% nickel content has high creep strength and the highest level of corrosion resistance.

Within AISI Series 400, only Types 430 and above contain the proper formulation and are acceptable. (These Types are often used for their resistance to heat scaling at high temperatures.) Lower 400 series types contain only about 10.5 percent chromium and are, therefore, unacceptable.

Surface Finishes: Surface finishes are generally categorized as "unpolished" or "polished." Examples of unpolished Stainless steel include No. 1, No. 2D, and No. 2B. Polished Stainless steels are designated by numbers 3, 4, 6, and 7. These numbers are based on their "grit" value. The higher the grit value the smoother the finish. For example, No. 3 Stainless steel has a 100 grit surface finish, No. 4 a 150 grit surface, etc. Generally, a No. 3 finish is acceptable for food equipment. However, a No. 4 finish is usually specified for dairy equipment.

Gage: The thickness and weight of a stainless steel is designated by its U. S. Standard Gage Numbers. Gage number may range from 8 to 30. No gage number is specified for general use, rather, the appropriate gage for Stainless steel is application specific.

Stainless steel Grade Type 304 is considered to be "all purpose" since it is exceptionally durable, has high tensile strength, and is very ductile. Type 304 contains less carbon than some of the other stainless grades

used in food equipment, making it more corrosion resistant. If it has a surface finish of No. 3 (100 grit) or greater, Type 304 would meet American National Standards Institute (ANSI) specifications for "materials" used for food contact surfaces in the manufacture of food equipment.

It is up to the manufacturer to choose the standard or test that is the most appropriate for their stainless steel to assure compliance.

Further, the 2013 U.S. Public Health Service (FDA Food Code), in Chapter 4, subpart 101.11 Characteristics, states that materials used in the construction of food contact surfaces of equipment may not allow the migration of deleterious substances or impart colors, odors, or tastes to food and under normal conditions, shall be safe, durable, corrosion resistant, and nonabsorbent, sufficient in weight and thickness to withstand repeated warewashing, finished to have a smooth, easily cleanable surface and resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition. In addition, the Food Code in Chapter 4, subpart 201.11 specifies that equipment shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions. All materials are subject to current good manufacturing practices as outlined in Title 21 of the Code of Federal Regulations (CFR), Part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food and more specifically 21 CFR 110.40, *Equipment and Utensils*.

Sincerely yours,

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