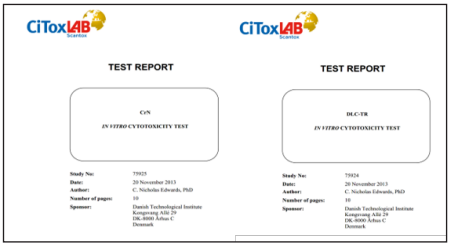
DANISH TECHNOLOGICAL INSTITUTE

FDA

Recognition of the Tribology Center's coatings

In collaboration with the renowned U.S. Food and Drug Administration (FDA), which is responsible for the approval of food and medical-contact materials, the Tribology Center at the Danish Technological Institute has reviewed the center's commercial chromium nitride coatings – the CrN family – and the diamond-like low-friction coatings, the so-called DLCs.

The FDA sees no issues with using the Tribology Centre's coatings **CrN-SD, CrN-SS**, and **CrN-HP**, as well as **DLC-TR** and **DLC-Si,** for repeated and/or continuous contact with food.


CiToxLAB Scantox

TEST REPORT

CrN

IN VITRO CYTOTOXICITY TEST

CiToxLAB Scantox

TEST REPORT

DLC-TR

IN VITRO CYTOTOXICITY TEST

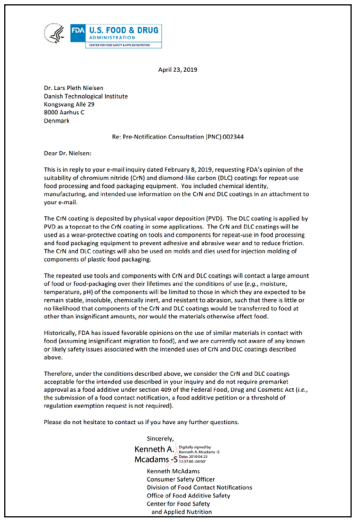
Test reports for in vitro-cytotoxicity.

The FDA also accepts use in injection molding or other forming processes - for example, on tools for the manufacture of plastic, metal and paper packaging for food products.

The evaluation was conducted by the Food Contact Notification division in accordance with *Section 409 of the Federal Food, Drug, and Cosmetic Act*.

Of course, the official endorsement is not surprising. The Tribology Center's DLC and chromium nitride coatings have been successfully used on equipment and tools for the manufacture of medicine, medical devices, food processing equipment, and packaging, among other things. For many years, these coatings have also been used by a wide range of the largest pharmaceutical and food producers both inside and outside Denmark.

Despite the long and positive experience with these coatings and ongoing toxicity studies, it is, of course, still satisfying to have also received the FDA's official approval. The fact is that more and more customers are requesting FDA approval for contact materials used in food production – and the Center now has the FDA's official recognition for industrial use.


U.S. FOOD & DRUG ADMINISTRATION

April 23, 2019

Dr. Lars Pløth Nielsen
Danish Technological Institute
Kongsvang Allé 29
8000 Aarhus C
Denmark

Re: Pre-Notification Consultation (PNC) 002344

Dear Dr. Nielsen:

This is in reply to your e-mail inquiry dated February 8, 2019, requesting FDA's opinion of the suitability of chromium nitride (CrN) and diamond-like carbon (DLC) coatings for repeat-use food processing and food packaging equipment. You included chemical identity, manufacturing, and intended use information on the CrN and DLC coatings in an attachment to your e-mail.

The CrN coating is deposited by physical vapor deposition (PVD). The DLC coating is applied by PVD as a topcoat to the CrN coating in some applications. The CrN and DLC coatings will be used as a wear-protective coating on tools and components for repeat-use in food processing and food packaging equipment to prevent adhesive and abrasive wear and to reduce friction. The CrN and DLC coatings will also be used on molds and dies used for injection molding of components of plastic food packaging.

The repeated use tools and components with CrN and DLC coatings will contact a large amount of food or food-packaging over their lifetimes and the conditions of use (e.g., moisture, temperature, pH) of the components will be limited to those in which they are expected to be remain stable, insoluble, chemically inert, and resistant to abrasion, such that there is little or no likelihood that components of the CrN and DLC coatings would be transferred to food at other than insignificant amounts, nor would the materials otherwise affect food.

Historically, FDA has issued favorable opinions on the use of similar materials in contact with food (assuming insignificant migration to food), and we are currently not aware of any known or likely safety issues associated with the intended uses of CrN and DLC coatings described above.

Therefore, under the conditions described above, we consider the CrN and DLC coatings acceptable for the intended use described in your inquiry and do not require premarket approval as a food additive under section 409 of the Federal Food, Drug and Cosmetic Act (i.e., the submission of a food contact notification, a food additive petition or a threshold of regulation exemption request is not required).

Please do not hesitate to contact us if you have any further questions.

Sincerely,

Kenneth A. Mcadams -S

Kenneth McAdams
Consumer Safety Officer
Division of Food Contact Notifications
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

Documentation for FDA acceptance.

If you have any questions or need further clarification regarding the use of our coatings on equipment for food processing and packaging production, we are, of course, always at your disposal.

For more information, contact

Tribology Center
Kongsvang Allé 29
DK-8000 Aarhus C

Tel. +45 72 20 15 99
Mail: tribo@teknologisk.dk
www.dti.dk/tribo

DANISH TECHNOLOGICAL INSTITUTE

TOXICITY-TESTED COATINGS

Toxicity-tested coatings: CrN-SD, CrN-SS, CrN-HP, DLC-TR og Grafit-TR

Conclusion: Non-toxic

When materials and coatings come into direct contact with cells or living tissue, it is important to quantify the material's cytotoxicity. This is especially crucial when materials and coatings are used in the production of, for example, medical devices, medical accessories, and implants. However, it is also highly significant when the coatings are used in components and devices that come into direct contact with food or are involved in food processing.

The cytotoxicity of several of the commercially available coatings from the Tribology Center has been tested in accordance with ISO 10993-5, in compliance with the OECD principle of good laboratory practice. The toxicity was quantified using mammalian L929 connective tissue stem cells from mice.

The test was designed according to the methods in the ISO 10993-5 standard for elution testing and the US Pharmacopeia: <87> Biological reactivity test in vitro (elution test), with the exception that triplicate cultures were used for each sample.

The extract of the test specimen was prepared in accordance with part 12 of the ISO 10993 standard. The requirements for determining the cytotoxicity of a medical device were followed as specified in part 1 of the ISO 10993 standard.

RESULT

Coating type	Quality		
	Undiluted extraction	Diluted extraction	Conclusion
Diamond-like carbon, DLC-TR	0	0	**Non-toxic**
Grafit-TR	0	0	**Non-toxic**
CrN-SD, CrN-SS, CrN-HP	0	0	**Non-toxic**

Toxicity quality was assessed based on undiluted and diluted (1 part extract + 3 parts fresh cell culture medium) extracts obtained by exposure to 6 cm² of coating per ml of extraction medium (HAM F12 with 10% fetal calf serum and 50 µg/ml gentamicin).

For more information, contact

Tribology Center
Kongsvang Allé 29
DK-8000 Aarhus C

Tlf. +45 72 20 15 99
Mail: tribo@teknologisk.dk
www.dti.dk/tribo