



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Dutch Committee for Safety Assessment of Food Contact Materials

CBVV

Opinion

on an application for authorisation under the Dutch
Commodities Act Decree on packaging and consumer
articles for

Chromium nitride

CAS Number: 24094-93-7 or 12053-27-9

**Submitting applicant: Keller and Heckman LLP,
on behalf of IKEA of Sweden AB**

CBVV-S1031-D0043

Adopted

17 March 2022

1. Introduction

Before a substance is authorised to be used in food contact materials (FCM) and is included in a positive list, an opinion on its safety is required. This is laid down in Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food¹, and implemented in the Dutch Commodities Act Decree on packaging and consumer articles (Warenwetbesluit verpakkingen en gebruiksartikelen)² and its corresponding Regulation (Warenwetregeling verpakkingen en gebruiksartikelen)³. In case industry seeks authorisation for a substance that is not yet on a positive list and which is used in a material for which so far no harmonized EU legislation applies, it may submit an application for authorisation to the Dutch Committee for Safety Assessment of Food Contact Materials (CBVV) for its evaluation. Such an application may also be submitted for a modification of a current entry on a positive list. The CBVV will carry out an assessment of the risks related to the intended use of the substance and deliver a scientific opinion.

In this case, the CBVV received an application from IKEA of Sweden AB, requesting the evaluation of the substance chromium nitride (CAS No 24094-93-7 or 12053-27-9) for inclusion in Chapter X (Coatings), subsection a (macromolecular compounds) of section 9 (Other solvent-free materials) of Part A of the Annex to the Commodities Act Regulation on packaging and consumer articles.

2. Data and methodologies

2.1 Data

The applicant has submitted a dossier in support of their application for the authorisation of chromium nitride in chromium nitride-based coatings obtained by Physical Vapor Deposition (PVD)

Data submitted and used for the evaluation are:

Non-toxicological data and information

- Chemical identity
- Physical and chemical properties
- Manufacturing process
- Intended use
- Existing authorisation(s)
- Migration of the substance
- Residual content of the substance

Toxicological data were not provided (see section 3.2).

¹ Regulation (EC) No 1935/2004 of the European parliament and of 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. OJ L 338, 13.11.2004, p. 4-17.

² Besluit van 30 mei 2005, houdende vaststelling van het Warenwetbesluit verpakkingen en gebruiksartikelen in verband met Verordening (EG) nr. 1935/2004 van het Europees Parlement en de Raad van de Europese Unie van 27 oktober 2004 inzake materialen en voorwerpen bestemd om met levensmiddelen in contact te komen en houdende intrekking van de richtlijnen 80/590/EEG en 89/109/EEG (PbEU L 338) (Warenwetbesluit verpakkingen en gebruiksartikelen). Staatsblad van het Koninkrijk der Nederlanden, 2005, 420.

³ Regeling van de Minister van Volksgezondheid, Welzijn [en Sport] van 14 maart 2014, kenmerk 328583-117560-VGP, houdende vaststelling van de Warenwetregeling verpakkingen en gebruiksartikelen die in contact komen met levensmiddelen (Warenwetregeling verpakkingen en gebruiksartikelen). Staatscourant, 2014, 8531.

2.2 Methodologies

The assessment was conducted in line with the principles laid down in Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. This Regulation underlines that applicants may consult the Guidelines of the Scientific Committee on Food (SCF) for the presentation of an application for safety assessment of a substance to be used in FCM prior to its authorisation (European Commission, 2001), including the corresponding data requirements. The dossier that the applicant submitted for evaluation was in line with the SCF guidelines (European Commission, 2001) and the Note for Guidance of the European Food Safety Authority (EFSA) for the preparation of an application for the safety assessment of a substance to be used in plastic FCM (EFSA CEF Panel, 2021).

The methodology is based on the characterisation of the substance that is the subject of the request for safety assessment prior to authorisation, its impurities and reaction and degradation products, the evaluation of the exposure to those substances through migration and the definition of minimum sets of toxicity data required for safety assessment.

To establish the safety from ingestion of migrating substances, the toxicological data indicating the potential hazard and the likely human exposure data need to be combined. Exposure is estimated from studies on migration into food or food simulants and considering that a person may consume daily up to 1 kg of food in contact with the relevant FCM.

As a general rule, the greater the exposure through migration, the more toxicological data is required for the safety assessment of a substance. Currently there are three tiers with different thresholds triggering the need for more toxicological information as follows:

- a) In case of high migration (i.e. 5–60 mg/kg food), an extensive data set is needed.
- b) In case of migration between 0.05 and 5 mg/kg food, a reduced data set may suffice.
- c) In case of low migration (i.e. < 0.05 mg/kg food), only a limited data set is needed.

More detailed information on the required data is available in the SCF guidelines (European Commission, 2001) and the EFSA Scientific Committee recommendations on genotoxicity testing strategies applicable to food and feed safety assessment (EFSA Scientific Committee, 2011).

3. Assessment

The substance has not been evaluated in the past by the SCF or EFSA, and it is not listed in the Dutch Commodities Act Regulation on packaging and consumer articles. The Regulation does however have listings for several other chromium-containing compounds (in chapters I, II, IV, V, VI, IX and XI), with an SML of 0.1 mg/kg (as chromium).

The purpose of the present application is to get authorisation for the use of chromium nitride in the manufacture of a coating layer obtained using PVD. The finished PVD coating is intended to be used as a protective, non-stick coating on metal substrates, like pans, and on repeated-use FCM, including cookware and bakeware. Finished articles produced

with the PVD coating based on chromium nitride may be used in contact with all food types, under all conditions of use.

3.1 Non-toxicological data

3.1.2 Identity of the substance

Chromium nitride is an interstitial alloy that cannot be represented by a discrete chemical structure and/or definable molecular weight. It consists of lattice structure containing chromium (Cr) and nitrogen (N) atoms in varying concentrations. The finished chromium nitride-based PVD coating is 100% pure and has been demonstrated not to contain hexavalent chromium. The finished coating is cited as Cr₂N (representing the coating with a chromium content in the highest range) or CrN (coating representing the lowest chromium content range).

The PVD coating technology used in the manufacture of the final chromium nitride-based coating is briefly described in the dossier. It is based on magnetron sputtering. Sputtering is a plasma-based deposition process in which energetic ions are accelerated from a source towards a target. The vacuum chamber of the PVD coating machine is filled with an inert gas, such as argon. By applying a high voltage, a glow discharge is created, resulting in acceleration of ions from the source to the target surface. An additional gas such as nitrogen is used, which will react with the ejected material (reactive sputtering).

3.1.2 Physical and chemical properties

Chromium nitride is an inert material that as such is very stable and not reactive. It will not decompose or dissolve, and it is not susceptible to hydrolysis.

3.1.3 Migration data

Specific migration of total chromium from two PVD coatings (Cr₂N and CrN) on pans has been determined in 3% acetic acid as a worst-case food-simulating solvent, under repeated use conditions (testing 3 successive times for 2 hours at 100°C). The specific migration of chromium was found to be very low to not detectable, and decreased from the first to the third test. All migration values were found to be far below the restriction set for chromium (SML = 0.1 mg/kg) in several chapters of the Dutch Commodities Act Regulation on packaging and consumer articles.

It is argued in the dossier that the migration of nitride, if any, will be limited, in view of the very low migration observed for chromium in the first of three successive tests only. In case any release of nitride ions would occur, these would immediately become protonated in 3% acetic acid solution to form ammonia. Ammonia is listed in the Plastics Regulation⁴ without a restriction.

3.2 Toxicological data

No toxicological data were provided in the dossier for chromium (including hexavalent chromium) or nitride. The Committee considered that justified in this case, given that:

- the specific migration of chromium was shown to be far below the restriction set for chromium (SML = 0.1 mg/kg) in several chapters of the Dutch Commodities Act Regulation on packaging and consumer articles;

⁴ Commission Regulation (EC) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L 12, 15.1.2011, p. 1-89.

- hexavalent chromium was shown to be undetectable in the chromium nitride when applied as a coating;
- the migration of nitride, if any, will be in the form of ammonia and for ammonia no restriction is needed.

4. Conclusions

Based on the data submitted, the CBVV concluded that the substance chromium nitride does not raise a safety concern for the consumer under the intended and tested conditions of use in the manufacture of a coating layer obtained using PVD (Physical Vapor Deposition). To CBVV's opinion, the substance can be included in part A of the Annex to the Commodities Act Regulation on packaging and consumer articles as follows:

Chapter	Section	Subsection
X. Coatings	9. Other solvent-free materials	a. macromolecular compounds

CAS No	Name	SML mg/kg	Restrictions and specifications
24094-93-7 or 12053-27-0	Chromium nitride, in chromium nitride-based coatings obtained by Physical Vapor Deposition (PVD)	0.1	as chromium

In Dutch:

Hoofdstuk	Paragraaf	Subparagraaf
X. Deklagen	9. Overige oplosmiddelvrije materialen	a. macromoleculaire verbindingen

CAS Nr	Naam	SML mg/kg	Restricties en specificaties
24094-93-7 of 12053-27-0	Chroomnitride, in chroomnitride-gebaseerde deklagen verkregen door 'Physical Vapor Deposition' (PVD)	0,1	als chroom

Documentation provided to CBVV

Dossier. April 2021. Submitted by Keller and Heckmann LLP, on behalf of IKEA of Sweden AB.

References

EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2021. Note for Guidance for the preparation of an application for the

safety assessment of a substance to be used in plastic Food Contact Materials (update 2021). EFSA Journal 2008, 6(7):21r, 41 pp. <https://doi.org/10.2903/j.efsa.2008.21r>

EFSA Scientific Committee, 2011. Scientific Opinion on genotoxicity testing strategies applicable to food and feed safety assessment. EFSA Journal 2011;9(9):2379, 69 pp. <https://doi.org/10.2903/j.efsa.2011.2379>

European Commission, 2001. Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation. Available online: https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out82_en.pdf

Abbreviations

CAS	chemical abstracts service
EFSA	European Food Safety Authority
FCM	food contact materials
PVD	Physical Vapor Deposition
SCF	Scientific Committee on Food
SML	specific migration limit