

Ministry of Public Health,
Welfare and Sport

Regulation of the State Secretary for Health, Welfare and Sport of 2025, reference number WJZ;
amending the Commodities Act Regulation on packaging and consumer articles in relation to adding substances to Part A of the Annex

The State Secretary for Health, Welfare and Sport,

Having regard to articles 3 (1) (a) and (4) (1) of the Commodities Act Regulation on packaging and consumer articles;

Decision:

Article I

Chapter X of Part A of the Annex to the Commodities Act Regulation on packaging and consumer products is amended as follows:

1. Section 3(a) is amended as follows:

- a. 'adipic acid dihydrazide, CAS 1071-93-8; to be used only as cross linker in acrylic copolymers with keto side groups in coatings on plastics and not in direct contact with food;' is replaced by 'adipic acid dihydrazide, CAS 1071-93-8; not to be used in coatings in direct contact with acidic foods;'.
b. The following substance is inserted before the substance 'styrenesulfonic acid and the ammonium, potassium and sodium salts':

Reaction products of propyleneimine with 1,6-diisocyanato-hexane homopolymer, blocked with butyl glycidyl ether and monomethoxy polyethylene glycol, CAS 2416007-57-1;

2. In Section 7(c), after 'epoxy polymers, in accordance with Chapter XII and Chapter IV, Section 2.2g.1;', the following substance with associated data is inserted:

reaction products of propyleneimine with 1,6-diisocyanato-hexane homopolymer, blocked with butyl glycidyl ether and monomethoxy polyethylene glycol, CAS 2416007-57-1;

3. Section 12.3 is amended as follows:

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a. The substance 'di-isobutyl phthalate' with associated data is replaced by:
adipic acid dihydrazide: 5

b. After 'quaternary ammonium compounds, total: 0.5', the following substance with corresponding entries is inserted:

reaction products of propyleneimine with 1,6-diisocyanato-hexane homopolymer, blocked with butyl glycidyl ether and monomethoxy polyethylene glycol, CAS 2416007-57-1:	0.05
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Article II

This order enters into force on the day following the date of its publication in the Government Gazette.

This order and explanatory memo will be published in the Government Gazette.

The State Secretary for Health, Welfare and Sport,

Explanatory Memo

I. General

1. Introduction

The purpose of this order is to add new substances to Part A of the Annex to the Commodities Act Regulation on packaging and consumer articles that have been requested by interested parties and assessed by the Dutch Committee for Safety Assessment of Food Contact Materials (hereinafter: NCbvv). The NCbvv carries out the risk assessments for national authorisations under the Commodities Act Decree on packaging and consumer articles on behalf of the State Secretary for Health, Welfare and Sport.

Based on risk assessments carried out, the NCbvv advised that certain substances could be authorised and under what conditions this could happen. NCbvv assessments are made public by default. To this end, the relevant assessments on the website of the National Institute for Public Health and the Environment (www.rivm.nl) are published.

2. Consultation

The draft of this order was submitted to the participants in the Regular Consultation on the Commodities Act¹. This consultation did not give rise to any comments.

3. Notification

The draft version of this order has been reported to the European Commission under article 5 (1) of Directive (EU) 2015/1535². Notification to the European Commission is required, as Article I of this order contains technical provisions as defined by Directive (EU) 2015/1535. In response to this notification **to be specified**

4. Consequences for regulatory burden and financial impact

This order does not impact the administrative burden on citizens and businesses. There is no information cost. There are no compliance costs. The business community has submitted applications for the authorisation of certain substances in packaging and consumer articles. This order provides, among other things, for the addition (and expansion of conditions) of substances to various chapters of part A of the annex to the Commodities Act Regulation on packaging and consumer articles. By adding these substances, the business community can use these substances. This will have a positive impact on business.

The Dutch Advisory Board on Regulatory Burden (ATR) did not select the file for a formal opinion since – with the exception of minor one-off information costs – it is not expected to have any substantial consequences for the regulatory burden.

¹ Representatives of industry and commerce, consumers, relevant ministries and the Dutch Food and Consumer Product Safety Authority (NVWA) participate in the ROW.

² Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 concerning an information procedure on technical provisions and rules regarding the services of the information society (codification) (PbEU 2015, L 241).

5. Enforceability and feasibility

The draft of this order was submitted to the Dutch Food and Consumer Product Safety Authority (hereinafter: NVWA) to assess the possible consequences for enforceability and feasibility . The NVWA has concluded that the order is enforceable, practicable and fraud-proof. A textual suggestion from the NVWA has been adopted. The NVWA has also requested to specify more clearly which reaction products are concerned (instead of mentioning a single CAS number). In consultation with the NVWA and NCbvv, it was decided not to change the indication of the reaction products. The future authorisation of substances will consider how to avoid possible confusion.

The development costs reported by the NVWA are taken into account in the broader assessment of the tasks to be carried out by the NVWA.

II. Explanatory notes for individual articles

Article I

Substantive amendments based on dossier assessments by the NCbvv

One substance is added to Chapter X (coatings) of Part A of the Annex to the Commodities Act Regulation on packaging and consumer articles (hereinafter: WVG). In addition, the conditions of use of one substance are amended. To this end, applicants who have applied for authorisation of this substance have submitted a dossier. The evaluation of the dossiers leads to the inclusion of this substance with corresponding restrictions or to the adaptation of the listed restriction.

In Chapter X (coatings), Section 3(a) (monomers) of Part A of the Annex to the WVG, the following adaptations are made on the basis of assessments by the NCbvv:

- One substance (group) is added (reaction products of propyleneimine with 1,6-diisocyanato-hexane homopolymer, blocked with butyl glycidyl ether and monomethoxy polyethylene glycol), to be used as a binder for coatings.
- The conditions of use of one substance (adipic acid dihydrazide) are expanded.

Article II

This article governs the entry into force of the order. The entry into force is not associated with the fixed change moments, but - given the positive business effects - enters into force as soon as possible.

The State Secretary for Health, Welfare and Sport,