

TECHNICAL DATA SHEETEffective date: 01.2020
Rev.0**Lipbalm tube, white, 6 ml**

CONFORMITY DECLARATION**FOOD APPROVALS****European Union****Regulation 1935/2004/EC**

This grade meets the relevant requirements of Regulation 1935/2004/EC, so far applicable for plastic raw materials, used for articles or components of articles intended to come into contact with food. This grade is a plastic raw material for which specific measures are adopted as foreseen in article 5 of Regulation 1935/2004/EC. For plastic materials and articles, specific measures are adopted through Regulation 10/2011/EC as amended (see below).

Regulation 10/2011/EC

The monomers and additives used to manufacture this grade are listed in Regulation 10/2011/EC including amendments 1282/2011/EC, 1183/2012/EC, 202/2014/EC & 174/2015/EC, relating to plastic materials and articles intended to come into contact with foodstuffs. This grade contains one or more components which are regulated with a specific migration limit. The identity of this/these component(s) can be disclosed for testing purposes upon special request and under maintaining secrecy.

For full compliance an overall migration limit of 60 mg/kg resp. 10 mg/dm² and specific migration limits apply to the final article intended to come in contact with food, which shall be measured from the finished food contact article by using real food or appropriate food simulants at the time/temperature conditions as applicable, according to the rules as specified in Directives 82/711/EC (as amended) and 85/572/EC. It is the responsibility of the convertor to check and confirm that the final article meets both the technical and regulatory requirements of the application.

United States of America

The base resin in this grade meets the FDA (Food and Drug Administration) requirements contained in the Code of Federal Regulations in 21 CFR 177.1520 (a) (1) (i) and (c) (1.1a). According to information received from all of our suppliers, all other ingredients used in this grade meet the requirements of their respective FDA regulations and 21 CFR 177.1520 (b). This grade meets the FDA criteria in 21 CFR 177.1520 for food contact applications listed under conditions of use A through H in 21 CFR 176.170 (c), Table 2., and can be used in contact with all food types as listed in 21 CFR 176.170 (c), Table 1.

Chemical Inventories

All ingredients in this grade are in compliance with the following chemical inventories:

United States : Toxic Substances Control Act Inventory (TSCA)

Canada : Domestic Substances List (DSL) – Non Domestic Substances List (NSDL)

Europe : European Inventory of Existing Commercial Chemical Substances (EINECS)

European List of Notified Chemical Substances (ELINCS)

Australia : Australian Inventory of Chemical Substances (AICS)

Korea : Korean Existing Chemicals List (ECL)

Japan: Japanese Existing and New Chemical Substances (ENCS)

12 (b) This grade has no special requirements under US TSCA (e.g. consent orders, test rules, requirements, etc.)

European Pharmacopoeia (EP)

This product has not been tested for E.P.

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This product has not been tested for USP.

Drug Master File (DMF)

This product is not listed in a DMF

Bovine Spongiform Encephalopathy (BSE) / Transmissible Spongiform Encephalopathy (TSE) / Animal Derived Material

From information received from our suppliers we know that one additive in this grade can be derived from materials (tallow) of animal (mainly ovine and bovine) origin. Tallow derivatives, used for the production of plastic materials, undergo a series of (thermal and chemical) process steps in which they are subjected to severe conditions. These conditions are more stringent as those described as "rigorous processes" by CPMP (Committee on Proprietary Medicinal Products) in the "note for guidance on minimizing the risk of transmitting TSE via medicinal products" dated 21st of September 1999. The process conditions also far exceed the requirements in annex II of the European directive 99/534/EC and 2000/6/EC.

To the best of our knowledge, these treatments ensure complete inactivation of any agents present in the tallow derivatives to be used in plastics materials. We therefore can state that this grade is considered safe to use with respect to BSE and TSE transmissions.

Toys (EN 71-3)

This grade meets the requirements of the European Standard EN 71 "Safety of Toys", Part 3 (1994): "Migration of certain elements". None of the substances mentioned in EN 71-3 are intentionally introduced as additives or used during the manufacturing of the above-mentioned grade.

Phthalates in toys and childcare articles (Directive 2005/84/EC)

The phthalates listed in the Annex of Directive 2005/84/EC are not intentionally added in the manufacture of or the formulation of this grade in a concentration above the given limits.

Phthalate Free

Phthalates are not intentionally used in the manufacture or the formulation of this grade.

REACH (Regulation 1907/2006/EC)

The substances, which are contained in this grade, and require registration, have been (pre-)registered by Ducor Petrochemicals B.V., or by our upstream suppliers. This grade does not contain the substances listed on the current Substances of Very High Concern (SVHC) candidate list, issued by the European Chemicals Agency (17-12-2015), in a concentration above 0.1% (w/w).

Packaging and packing waste (Directive 94/62/EC)

The chemical composition of this product meets the relevant requirements of Directive 92/62/EC (as amended) on packaging and packaging waste. The sum of the concentration Cd, Cr (VI), Hg and Pb in this product does not exceed 100 ppm. This grade can be recycled according to Directive 94/62/EC requirements.

Heavy metals (Directive 2000/53/EC)

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The chemical composition of this product meets the relevant requirements of Directive 2000/53/EC (as amended) on the end-of-life of vehicles (ELV). The concentration of Cr (VI), Hg, and Pb in this product does not exceed 0.1 wt.%, and the concentration of Cd does not exceed 0.01 wt.%

Restrictions on the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EC)**- ROHS**

The chemical composition of this product meets the relevant requirements of Directive 2011/65/EC (repealing Directive 2002/95/EC) on Restriction of the use of certain Hazardous Substances in electrical and electronic equipment - RoHS. The concentration of Cr (VI), Hg, Pb, PBB, and PBDE in this product does not exceed 0.1 wt.%, and the concentration of Cd does not exceed 0.01 wt.%.

Waste Electrical & Electronic Equipment (Directive 2002/96/EC) - WEEE

No ingredients are intentionally used in the manufacturing of or the formulation of this grade, which are subject to the selective waste requirements of Annex II of Directive 2002/96/EC on the waste of electrical & electronic Equipment - WEEE.

Coalition of Northeastern Governors (CONEG)

The chemical composition of this product meets the relevant CONEG requirements as described in the "Toxics in Packaging" Model legislation, rev. 2004 (USA) on packaging and packaging components. The sum of the concentration Cd, Cr (VI), Hg and Pb in this product does not exceed 100 ppm.

SWITZERLAND "VOC-LENKUNGSABGABE"

This product contains less than 3% VOC's of the substances in the positive lists of the above Regulations.

Composting – CEN Standard prEN 13432

This raw material is not suitable for composting.

Energy Recovery – CEN Standard prEN 13431

The calorific gain from this raw material in an energy recovery process is 24 MJ/Kg.

Absence of substances and chemicals

None the following substances are intentionally used in the manufacturing of or the formulation this grade.

Acrylamide

Allergens (as defined in Directive 2003/89/EC - Annex IIIa)

Antimony, Arsenic, Beryllium, Bismuth

Aromatic Amines (restricted in Directive 2002/61/EC)

Asbestos

Azocolorants (restricted in Directive 2002/61/EC)

Biocides (Pesticides, Herbicides, Insecticides)

Bisphenol A and its compounds (e.g. NOGE, BFDGE, BADGE)

Bisphenol S

Brominated flame retardants (e.g. PBB, PBDE)

Cadmium, Chromium (VI), Lead, Mercury

Chlorinated hydrocarbons, Chlorinated Paraffins (C10-C13)

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Cobalt (II) chloride hexahydrate
Conflict minerals (as defined in the U.S. Federal Law "Dodd-Frank Wall Street Reform and Customer Protection Act"),
i.e.: Tin, Tungsten (or Wolfram), Tantalum, Gold
Dioxines and furanes
Dimethyl fumate (DMF)
2-EHA, Ethoxyquin, ITX, Thiuram
Formaldehyde
Genetically modified organisms (GMO)
Gold, Indium, Nickel, Palladium
Melamine
Nanoparticles (i.e. TiO₂ nanoparticles, Silver nanoparticles, Carbon-nanotubes)
Natural rubbers, Latex
Octyl- or Nonylphenols or -phenoethoxylates, Tris nonylphenol phoshite (TNPP)
Ozone depleting substances (CFC's, HCFC's, Halons, CCl₄, Trichloroethane, HBFC's)
Phthalates (DBP, DEHP, DIBP, BBP)
Tert-butyl-4-hydroxyanisole (BHA) and 2,6-di-tert-butyl-p-cresol (BHT)
Triclosan
Organotin compounds
Pentachlorophenol (PCP)
Perfluorinated tensides - PFT (e.g. PFOA, PFOS)
Plasticisers (e.g. Adipates, Epoxidised Soya Bean Oil (ESBO))
Polychlorinated Bi- or Terphenyls (PCB/PCT)
Polycyclic aromatic hydrocarbons (PAH)
Radioactive substances
Selenium, Silver, Tellurium, Thorium
Semicarbazide
Silicones
UV-hardeners (e.g. ITX, Titanyl-acetylacetone)
Vinylchloride, Vinylidenechloride, PVC or PVDC
The absence of these substances has not been checked by tests. The information provided in this document applies to the product mentioned above as it leaves the production facility of Ducor Petrochemicals B.V., and does not cover any additive, pigment, or any other third party material, subsequently included by the convertor.

1. General requirements

We confirm that the materials and articles we supplied are suitable for cosmetic packaging according to Article 1 (Purpose and subjectmatter) of Regulation (EC) 1223/2009. The materials and articles supplied comply with the requirements of the general following legal regulations (in each case including all amendments and in the version that is valid at the date of issue of this certificate):

- Regulation (EC) No. 1935/2004
- Regulation (EC) No. 2023/2006 amended by Regulation (EC) No 282/2008
- German Food and Feed Code (LFGB) as of 22.08.2011
- German Commodity Ordinance as of 23.12.1997

2. Plastics

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The plastic materials and articles we supply, are manufactured from raw material complying with the Plastics Regulation (EU) 10/2011 (replaces the Commission Directive 2002/72/EC) and if applicable with the German Bedarfsgegenständeverordnung (BedGgStV) as of 23.12.1997 including all amendments and in the version that is valid at the date of issue of this certificate. Additional testing to confirm compliance of the packaging materials in case of food contact with the Plastics Regulation have not been conducted. If the usage of the packaging material in terms of the Plastics Regulation is intended an evaluation of adherence to and compliance with the relevant regulations is recommended.

3. Heavy metals

The requirements of Directive 94/62/EC (amendments 2004/12/EC and 2013/2/EC included) are met regarding heavy metals.

4. Substances of Very High Concern / REACH Regulation

Supplier herewith confirms

- the products, delivered by us, are goods as defined by REACH regulation (section 3 no. 3)
- under normal or reasonably foreseeable conditions of use, no substances are released (section 7 no. 1)
- the product does not contain any substances of very high concern (section 59 no. 1) in concentrations of more than 0.1% (w/w).
- the product does not contain any substances subject to authorisation as defined by REACH Annex XIV.

We certify, that during manufacturing of our products we do not use in our processes or intentionally incorporate into our products any chemicals restricted by the REACH Regulation 1907/2006/EC and their subsequent amendments and that we had not been notified by our suppliers about the incorporation or presence of these specific substances, compounds or combinations. However, we have to rely on the information provided by our suppliers that concerning regulated chemicals the applicable limits are not exceeded as we do not analyze for these specific substances or compounds.

In case there will be any changes on the above mentioned information, especially regarding to Reach substances of very high concern, we will immediately inform you actively in the future and thus attend our duty to supply information and to give information to our customers according to REACH section 33. This applies also for new knowledge gained on our products.

The relevant parts of the EG regulation ref. 1907/2006 - REACH are known to us and we confirm obligatorily the legally conformant implementation in our company.

5. Other Information

As a packaging manufacturer and non-distributor, we do not carry out any migration testing and are not responsible to do so. The OML/SML values determined by the manufacturer of the raw materials are communicated through passing the manufacturers documents. This declaration of conformity does not release the user of the packaging from their duties to implement requirements which are part of their area of responsibility. This declaration does not release the user of the packaging from carrying out the corresponding durability tests with their fillers. Please do not hesitate to contact us for any questions.

