

PIGMENTO MINERAL COSMETICO AZUL

REGULACION

The product can be used in compliance with the following legislations (unless stated otherwise):

Electrical and Electronic equipment

RoHS Directive

Directive 2011/65/EU (recast) and its amendments on the restrictions of use of certain hazardous substances in electrical and electronic equipment. Directive 2015/863 expanded and replaced Annex II (restricted substances list) to this Directive. The latest amendments to RoHS are Directive (EU) 2017/2102 and many other delegated Directives.

WEEE Directive

Directive 2012/19/EU (recast) repealing Directive 2002/96/EC. The purpose of this Directive is the prevention of electrical and electronic waste, by promoting reuse, recycling and recovery of such wastes. Last amendment: Directive (EU) 2018/849.

End Life of Vehicles

Directive 2000/53/EC on end life of vehicles, as last amended by Delegated Directive (EU) 2023/544. This Directive lays down measures aiming at the prevention and reduction of waste from vehicles, in quantity and the harmfulness for the environment.

General Packaging

Europe

Directive 94/62/EC, as last amended by Directive (EU) 2018/852, on packaging and packaging waste: all packaging placed on the Market within the European Community must comply with concentration levels of heavy metals. The sum of concentration levels of lead, cadmium, mercury and chromium (VI) present in packaging shall not exceed 100 ppm by weight.

United States – CONEG

The Coalition of Northeastern Governors aims to reduce the use of heavy metals (lead, mercury, cadmium and hexavalent chromium) in packaging.

Cosmetic Packaging

Regulation (EC) 1223/2009 (recast) on cosmetic products that establishes new requirements for cosmetic packaging: "information related to the purity and stability of packaging is compulsory". Food Contact approved colorants are considered suitable for such application. Last amendment: Regulation (EU) 2022/2195.

Toys

Europe

Directive 2009/48/EC, as last amended by Directive (EU) 2021/903, lays down migration limits for certain elements in toys or components of toys which, due to their accessibility, function, volume or mass, may pose a hazard due to sucking, licking, swallowing or prolonged contact with skin when used as specified in the first subparagraph of Article 10(2). According to this directive, test of the toys is compulsory before placing toys on the market.

EN 71 Part 3: 2019 + A1: 2021 defines the requirements and test methods for the migration of certain elements from different categories of Toys or Toy materials. Once our pigment, INORPLAST ULTRA 582 Ultramarine Blue, is included in a plastic matrix or in a coating applied on the Toy, its components do not migrate. Hence, INORPLAST ULTRA 582 Ultramarine Blue can be used to coloring plastic Toys and to formulate coatings/paints intended to color Toys (Category III, scraped-off toy materials).

United States

ASTM F963-17, Standard Consumer Safety Specification for Toy Safety. This version became mandatory by the US CPSC (Consumer Product Safety Commission) rule on February 28, 2018.

Pigment Food Contact legislation

Europe

Resolution AP (89) I: "Use of colorants in plastic materials coming into contact with food".

France: French Positive List; "Circulaire No. 176" and amendments, on pigments and colorants intended for use in plastic materials and packaging. (Brochure No. 1227 of the JORF). Ultramarines are listed.

Germany: BfR IX Recommendation (June 2019): "Farbmittel zum Einfärben von Kunststoffen und anderen Polymeren für Bedarfsgegenstände" (Colorants for the coloration of plastics and other polymers for materials and articles).

Italy: "Decreto Ministeriale della Sanità 21 Marzo 1973, concernente la Disciplina igienica degli imballaggi, recipienti, utensili destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale". Updated on April 2019 ("GU nº 84 - Decreto 7 Febbraio 2019, nº 30")

Belgium: «Arrête Royal du 11 Mai 1992 concernant les matériaux et objets destinés à entrer en contact avec les denrées alimentaires», as last amended by «Arrête Royal du 29 Avril 2020». Publication: 25.05.2020 «Moniteur Belge».

Netherlands: “Warenwetregeling verpakkingen en gebruiksartikelen” (Commodities Act on packaging and consumer articles coming into contact with foodstuffs), as amended effective July 1, 2022. Chapter XI, “Kleurstoffen en pigmenten”, lays down the purity requirements for colorants and pigments used in food contact materials.

Spain: “Real Decreto” 847/2011 of 17 June 2011. Annex II fixes the purity requirements for colorants used in food contact applications.

United States

FDA 21 CFR compliance

§178.3297 (Colorants for Polymers)

§177.2600 (Colorants in Rubber Articles intended for repeated Use)

§177.1210 (Closures with sealing gaskets for food containers)

§175.300 (Resinous and polymeric coatings)

China

Chinese Hygienic Standard GB9685-2016 “Uses of Additives for food contact materials and articles”. This standard entered into force on 19 October 2017. Ultramarine Blue is approved as C.I. Pigment Blue 29 for use in paper, rubber, coatings and in the following plastics: PE, PP, PS, AS, ABS, PA, PET, PC, PVC, PVDC and UP, dosage as necessary. (FCA number: 0474)

Switzerland

The Swiss Ordinance, SR 817.023.21, on materials and articles in contact with food, version of 1 October 2022. INORPLAST ULTRA 582 Ultramarine Blue complies with the purity criteria for pigments defined in Annex 2 and C.I. Pigment Blue 29 is listed on Part A of Annex 10, as an evaluated substance to be used in printing inks for food contact packaging.

Mercosur

“Resolución GMC nº 15/10” on colorants in plastic materials intended to come into contact with foodstuffs.

Brazil-Anvisa

“Resolução - RDC nº 52/2010” with regard colorants in plastic materials for contact with foodstuffs.

Other EU Food Contact Legislation

Regulation (EU) 10/2011, and its amendment (Regulation (EU) 2020/1245), on plastic materials and articles intended to come into contact with food. Annex II give Specific Migration Limits (SML) for elements which must not be exceeded. Migration data available upon request.

INORPLAST ULTRA 582 Ultramarine Blue does not contain dual-use additives or aromatic amines.

European Framework Regulation (EC) 1935/2004 regulates materials and articles intended to come into contact with food. Tests are compulsory for the downstream users.

Regulated Substances

Animal and Plant origin

Genetically Modified Organisms (GMO) No

Animal-Derived Ingredients No

Plant-Derived Ingredients No

Biocides, Regulation (EU) 528/2012 No

Conflict Minerals

No substances controlled by legislation of “Dodd-Frank Wall Street Reform and Consumer Protection Act”. The so-called Conflict minerals currently include columbite-tantalite (coltan: niobium, tantalum), cassiterite (tin), wolframite (tungsten), gold and their derivatives.

EU Nanomaterials

No nanoparticles present in an unbound state, aggregated or agglomerated, with more than 50% of the particles in the size range of 1-100 nm.

GADSL

No substances listed and reportable according to the GADSL (Global Automotive Declarable Substances List). Latest GADSL update: February 1, 2023 (version:1.0).

Organic Compounds

No Volatile Organic Compounds (VOCs) or Semi Volatile Organic Compounds (SVOCs) present.

No Primary Aromatic Amines (PAAs) present. INORPLAST ULTRA 582 Ultramarine Blue is not an azo dye/colorant.

Persistent Organic Pollutants (POPs)

No chemicals restricted by the EU Recast Regulation 2019/1021 on persistent organic pollutants, as last amended by Regulation (EU) 2022/2400 and 2023/866.

PFAS

No fluorinated or perfluorinated organic substances (PFAS, PFOS, PFOA...) have been added to this product.

Proposition 65

Not listed as substance on the Californian Safe Drinking Water and Toxic Enforcement Act of 1986. The current proposition list is dated on April 21, 2023.

SVHC

No substances present identified by ECHA as Substances of Very High Concern (SVHC) above the threshold value of 0.1%. The Candidate List now contains 235 substances. Last updated June 14, 2023.

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Global Chemical Inventories

EINECS – Europe	Listed
TSCA – USA (Active notification)	Listed (Active)
DSL/NDSL – Canada	Listed (DSL)
AICS/AICC – Australia	Listed
NZIoC – New Zealand	Listed
IECSC – China	Listed
KECL – Korea	Listed
MITI/ENCS – Japan	Listed
TCSI – Taiwan	Listed
PICCS – Philippines	Listed
NCI - Vietnam	Listed

Additional Product Information

EU REACH:	compliant
REACH registration number (only EU):	SDS section 1 or 3
Classification:	SDS section 2 and 3
German water hazard class:	SDS section 15
International regulatory information:	SDS section 15
Shelf life:	5 years (minimum)

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