

Product Safety Information

Evonik Operations GmbH

Product Name: AEROXIDE® Alu C
 Chemical Name: Aluminium oxide
 CAS-No.: 1344-28-1,
 Customs Tariff Number: 281820

How to find specific information in this document

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Regulations China

Domain	Legal Record	Registration	Remarks
Food contact additive	NHFPC Year 2016 No.5	No registration necessary	Plastic: dosage as necessary; Coating: 17 %; Ink: 2%; Paper: 2%; Rubber: 2%

Regulations Europe

Domain	Legal Record	Registration	Remarks
Food contact articles	CoE Resolution AP 2002 (1), paper and boards, V4 – 12.02.2009	Ref.-No.: 34720 - Aluminium oxide	A. List 1 of Additives
Food contact articles	CoE Resolution AP 2004 (1), coatings, V3 - 12.02.2009	Ref.-No.: 34720 - Aluminium oxide	C. List 1 of additives
Food contact articles	CoE Resolution AP 2004 (4), rubber products, V1 - 10.06.2004	Ref.-No.: 34720 - Aluminium oxide	Appendix 1 - Index list of additives
Food contact articles	CoE Resolution AP 2004 (5), silicones, V1 - 10.06.2004	Ref.-No.: 34720 - Aluminium oxide	List 1 - No. 3. Additives
Food contact articles	Regulation (EU) 10/2011	FCM substance No.: 418 Ref.-No.: 34720 - Aluminium oxide	Annex I, Substances The above mentioned product is not in line with the requirements of regulation (EU) 10/2011, because the required nano specification is not available.

Regulations Germany

Domain	Legal Record	Registration	Remarks
Food contact articles	BfR recommendations: XXI, XXXVI/1, XLIV	CAS-No.: 1344-28-1 - Aluminium oxide	Purity criteria acc. to BfR recommendation LII are met

Regulations Japan

Domain	Legal Record	Registration	Remarks
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Regulations Japan

Domain	Legal Record	Registration	Remarks
Food contact articles	Japan's positive list for plastic as Food Contact Materials, Section 1, Table 2 - Additives	Reference number: 292, serial number: 617, substance: aluminium oxide	Please consider the distinction limit for the use of synthetic resins, special notes and other limitations.

Composition / substances

Above mentioned product is a single substance and not a mixture.

Purity Criteria

This product meets specific purity criteria (e.g. for heavy metals) and can therefore be used in regulated applications. The purity criteria were determined from mean values of arbitrarily selected samples. The data provided are therefore representative values and do not represent specifications. The analysis of these purity criteria is not part of our routine standard quality and production control.

Safety of toys – directive 2009/48/EG, EN 71-3

Concerning the qualification for above mentioned application please visit the chapters 'Heavy metals' and 'Substance declaration'.

Allergens

This product is a pure substance. During the production process we do not intentionally use or add any ingredients usually mentioned to be allergens

- according to EU-Directive 2000/13/EC and amendments
- according Regulation (EU) No 1169/2011 - Food information to consumers
- according the Brazilian resolution RDC No. 26 – requirements for labeling of main foods that cause food allergies
- according to the ALBA-list: Cereals containing gluten (e.g. Wheat, Rye, Barley, Oat, Spelt, Kamut), Maize, Crustaceans, Molluscs, Egg, Fish, Milk, Lactose, Ox, Pig, Hen/Chicken, Peanuts, Soybeans, Almonds, Hazelnut, Walnut, Cashew nut, Pecan nut, Brazil nut, Pistachio, Macadamia nut, Queensland nut, Celery, Mustard, Sesame, Lupines, Leguminous plants, Cinnamon, Vanilla, Coriander, Cocoa, Sulphur dioxide, Sulphites, Yeast, Glutamate (E620 – E625), Benzoic acid (E210 – E219) Azo-colorants/pigments
- Pine, Chestnuts
- Other additives, preservatives, flavors/fragrances or natural latex.

Since testing of these substances is not part of our standard routine quality control and production testing procedures, we therefore cannot warrant or guarantee the absence of these substances in this product.

GMO

In the production process of this product we do not use any Genetically Modified Organisms (GMOs). This product is non-GMO, it does not contain any GMO and has not been in contact with any GMO. Therefore Regulations (EC) No. 1829/2003 (as amended) and No. 1830/2003 (as amended) are not applicable.

Origin - TSE/BSE and Materials of animal or plant origin

This product is chemically produced. In the production process we do not use any raw material of animal or plant origin (as mentioned in EMEA/410/01, current version). In our manufacturing facilities we generally do not use any material of animal or plant origin. Our product is not contaminated with any animal- or plant-based material when it leaves the manufacturing sites and warehouses of the manufacturing company.

Information on REACH / Substances of Very High Concern (SVHC)

According to Regulation (EU) 1907/2006 (REACH) substances of very high concern (SVHC) must be mentioned in the safety data sheet (SDS) when the content is above the threshold limit of 0.1% w/w. Please visit the current safety data sheet for more information regarding this issue.

Please use the following e-mail address to order the current SDS: sds-hu@evonik.com

Information on REACH / PBT- and vPvB - substances

This product is not a PBT, vPvB substance as per the criteria of the REACH Regulation.

Information on REACH / Annex XIV or Annex XVII

This product is not a substance and does not contain any substances subject to authorization and/or restriction according to Annex XIV or Annex XVII of the REACH Regulation (EC) No. 1907/2006, respectively. However, testing of these substances is not part of our standard routine quality control and production testing procedures.

RoHS and WEEE Directives

This product fulfils the limitations and requirements of the EU-Directives 2011/65/EU (RoHS), 2012/19/EU (WEEE) and amendments. It is chemically produced. In the production process we do not use or intentionally add the following substances:

pentabromodiphenylether, octabromodiphenylether, lead, cadmium, chromium (total), mercury, polybrominated biphenyls (PBBs), polybrominated diphenylethers (PBDE), Di(2-ethylhexyl)phthalate (DEHP), Butylbenzylphthalate (BBP), Dibutylphthalate (DBP), Diisobutylphthalate (DIBP), chlorinated organic compounds, such as PCB, PCN, CP, mirex, organic tin compounds, asbestos, azo compounds, polyvinyl chloride (PVC) and PVC-blends.

The analysis on above mentioned substances is not part of our standard quality and production analyses. Therefore, we cannot warrant or guarantee the absence or level of these substances to any specific limit or threshold value.

EuPIA exclusion policy for printing inks

During the production process of this product we do not intentionally use or add any substance from the EuPIA exclusion policy for printing inks. Since testing of these substances is not part of our standard routine quality control and production testing procedures, we therefore cannot warrant or guarantee the absence of these substances in this product.

California List of Chemicals, Proposition 65 (USA)

In the production process of this product we do not intentionally use or add any of the substances on the California list of chemicals (USA), Proposition 65, in the current published version. The analysis on above mentioned substances is not part of our standard quality and production analyses. Therefore, we cannot warrant or guarantee the absence or level of these substances to any specific limit or threshold value.

Oeko-Tex Standard 100

For limit values please visit the chapters "Heavy metals" and "Substance declaration".

C.M.R. classified substances

The following EU-Directives are since 2008 no longer in force:

2003/34/EC, 2003/36/EC and 76/769/EEC (“restrictions of dangerous substances and preparations”). This class of substances is now regulated under REACH-SVHC.

End-of life vehicles

This product fulfils the limitations and requirements of the EU Directive 2000/53/EC. For limit values, please visit the chapters “Heavy metals” and “Substance declaration”.

Volatile Organic Compounds (VOC´s)

Volatile Organic Compounds are not used or intentionally added during production process of this product. To the best of our knowledge this product does not contain any Volatile Organic Compounds. The analysis on above mentioned substances is not part of our standard quality and production analyses. Therefore, we cannot warrant or guarantee the absence or level of these substances to any specific limit or threshold value.

“Substance declaration”

During the production process of this product we do not intentionally use or add any of the following substances: Aromatic amines according to EU Directive 2002/61/EC.

Volatile aromatic hydrocarbons, alkylphenol-ethoxylates, glycol ethers, isothiazolinone compounds, formaldehyde or formaldehyde donators as mentioned in Commission Directive 2002/739/EC.

2,2-bis(4-hydroxyphenyl)propane, bis(2,3-epoxypropyl) ether (BADGE), bis(hydroxyphenyl)methane, bis(2,3-epoxypropyl)ethers (BFDGE) and novolac glycidyl ethers (NOGE) as mentioned in Regulation (EC) No 1895/2005.

Substances mentioned in the “VDA-List of Substances to be Declared” version 2005, in the IMDS International list of reportable substances (ILRS-list), in 2005 replaced by GADSL, version 2019 or its subsequent revision, respectively.

Polychlorinated biphenyls (PCB), polychlorinated naphthalenes (PCN), polychlorinated terphenyls (PCT), pentachlorophenol (PCP) and PCP-salts, chlorinated paraffins (CP), Mirex (perchlorodecone), polycyclic aromatic hydrocarbons (PAHs), polybrominated biphenyls (PBB), polybrominated terphenyls (PBT), polybrominated diphenylethers (PBDE), tetrabromobisphenol-A-bis-(2,3-dibromopropylether) (TBBP-A-bis), organic tin compounds, asbestos, azo dye, polyvinyl chloride (PVC) and PVC-blends, latex, ozone depleting substances, phthalates, cyanides, radioactive materials, pesticides, biocides.

Substances listed in Sony’s Technical Standards “SS-00259” 15th edition 2017.

Perfluorooctane sulfonates (PFOS) and Perfluorooctanoic acid (PFOA) as described in EC-Directive 2006/122/EC.

Melamine

Any kind of Bisphenol

Dimethylfumarat (DMF)

Asbestos

DEHP (diethylhexyl phthalate) and DINP (diisononyl phthalate) or any other phthalates

The analysis on above mentioned substances is not part of our standard quality and production analyses. Therefore, we cannot warrant or guarantee the absence or level of these substances to any specific limit or threshold value.

Registration Status

The above mentioned product is registered in the following inventories:

Australia	AICS (Australian Inventory of Chemical Substances)	registered
Canada	DSL (Domestic Substance List)	registered
China	IECSC (Inventory of Existing Chemical Substances in China)	registered
Europe	REACH (Registration, Evaluation, Authorisation and Restrictions of Chemicals)	registered (01-2119529248-35)
Europe	EC (European Community)	registered (215-691-6)
Japan	ENCS (Existing and New Chemical Substances)	registered
Korea	KECI (Korea Existing Chemicals Inventory)	registered
New Zealand	NZIoC (New Zealand Inventory of Chemicals)	registered
Philippines	PICCS (Philippine Inventory of Chemicals and Chemical Substances)	registered
Taiwan	TCSI (Chemical Substances Nomination and Notification)	registered
USA	TSCA (Toxic Substances Control Act)	registered

The following information is available in our Safety Data Sheet (SDS):

Hazard Identification, Composition/Information on Ingredients, REACH-Registration number (if available), (SVHC) Substances of high concern (if applicable), First Aid, Fire Fighting Measures, Accidental Release Measures, Handling and Storage, Exposure Control/Personal Protection, Physical and Chemical Properties, Stability and Reactivity, Toxicological and Ecological Information, Disposal Considerations, Risk Information (e.g. Transportation, Labeling, Risk Phrases). The Water Hazard Class (WGK) is only in the German version of the safety data sheet available. Please, pay attention to the national edition of the SDS!

The following e-mail address should be used in order to request the SDS: sds-hu@evonik.com

Heavy metals and other metal traces

In the production process of this product we do not intentionally use or add any heavy metal constituents. The overall content of these elements, in their entirety, lies below 100 ppm and is therefore in line with the limits set by the EU Packaging Directive 94/62/EU.

It is also compliant with the requirements of the Coalition of Northeastern Governors (CONEG) model legislation limiting heavy metals (January 1994).

Heavy metals

Substance	Concentration
Cadmium (Cd)	≤ 2 ppm
Chromium, total (Cr)	≤ 10 ppm
Mercury (Hg)	≤ 1 ppm
Lead (Pb)	≤ 5 ppm

Other metal-traces

Substance	Concentration
Arsenic (As)	≤ 5 ppm
Antimony (Sb)	≤ 5 ppm
Selenium (Se)	≤ 5 ppm
Barium (Ba)	≤ 1 ppm
Zinc (Zn)	≤ 15 ppm
Iron (Fe)	≤ 30 ppm
Copper (Cu)	≤ 10 ppm

Nickel (Ni)

≤ 20 ppm

(The analysis for heavy metals or other metals traces is not part of our standard quality and production analyses. The limits given represent typical values from arbitrarily selected samples, but do not represent any specifications)

Disclaimer

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Legend

BfR:	Bundesinstitut für Risikobewertung
CAS:	Chemical Abstract Services Register Number
CoE:	Council of Europe
CONEG:	Coalition of Northeastern Governors
CosIng	European Commission database for information on cosmetic substances and ingredients
FDA:	Food and Drug Administration
FSMA	Food safety modernisation act
INCI:	International Nomenclature Cosmetic Ingredients
JHOSPA:	Japan Hygienic Olefin and Styrene Plastics Association
PBT:	Persistent, Bioaccumulative, Toxic
PCPC	Personal Care Products Council
SAS:	Synthetic Amorphous Silicon dioxide, Synthetic Amorphous Silica
vPvB:	very Persistent, very Bioaccumulative