Evonik Operations GmbH
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Germany

Product Safety Information

VISIOMER® THFMA

1. Conformity with legislation for contact with foodstuffs

1.1. Europe

1.1.1. Regulation (EU) No 10/2011 and Regulation (EC) No 1935/2004

VISIOMER® THFMA is not listed with respect to its monomer in Regulation (EU) No 10/2011 on plastics materials and articles intended to come into contact with food and its amendments, implementing Regulation (EC) No 1935/2004 for plastics.

1.1.2. Framework Resolution ResAP (2004)1

VISIOMER® THFMA is not listed with respect to its monomer in Council of Europe Framework Resolution ResAP (2004)1 on coatings intended to come into contact with foodstuffs.

1.1.3. Commission Regulation (EC) No 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food

Below listed substances mentioned in Commission Regulation (EC) No 1895/2005 are not intentionally used during the manufacturing process of VISIOMER® THFMA.

Substance	CAS-No.
2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (BADGE)	1675-54-3
Bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers (BFDGE)	39817-09-9
Novolac glycidyl ethers (NOGE)	-

VISIOMER® THFMA is made of raw materials of technical purity. The occurrence of above listed substances can be excluded, except negligible amounts on the level of natural/ technical impurities. Please notice that VISIOMER® THFMA is not routinely analysed for those substances listed above.

1.1.4. Regulation (EU) No 1169/2011 on the provision of food information to consumers

Allergens as mentioned in Annex II - Substances or Products Causing Allergies or Intolerances of Regulation (EU) No 1169/2011 and its amendments are not intentionally used during the manufacturing process of VISIOMER® THFMA.

VISIOMER® THFMA is made of raw materials of technical purity. The occurrence of allergens listed in Annex II of Regulation (EU) No 1169/2011 and its amendments can

be excluded, except negligible amounts on the level of natural/ technical impurities. Please notice that VISIOMER® THFMA is not routinely analysed for those allergens listed in Annex II of Regulation (EU) No 1169/2011 and its amendments.

1.1.5. Swiss Ordinance SR 817.023.21

VISIOMER® THFMA is not listed with respect to its monomer in the Swiss Ordinance Schweizer Bedarfsgegenstände – Verordnung SR 817.023.21 on materials and articles in contact with food in Annex 2 (plastic materials) (version from 01 December 2019) and Annex 10 (packaging inks) (version from 01 December 2020).

1.2. The USA

1.2.1. Food and Drug Administration (FDA), Code of Federal Regulation (CFR), 21

VISIOMER® THFMA does not comply with respect to its monomer with the food contact regulations in the USA (Food and Drug Administration (FDA), Code of Federal Regulation (CFR), 21).

1.3. China

1.3.1. Chinese National Standard GB 9685-2016 for uses of additives in food contact materials and products

VISIOMER® THFMA is not listed as an additive in the Chinese National Standard GB 9685-2016.

2. Additional Regulations

2.1. General

VISIOMER® THFMA is made of raw materials of technical purity. The occurrence of substances that are not intentionally used in the manufacturing process (see subsections 2.2 – 2.10 of current document) can be excluded, except negligible amounts on the level of natural/ technical impurities. Please notice that VISIOMER® THFMA is not routinely analysed for those substances.

2.2. Directive 94/62/EC on packaging and packaging waste

Substances mentioned in Directive 94/62/EC and its amendments (lead, mercury, cadmium and their compounds, and chromium (VI) compounds) are not intentionally used in our recipes to produce VISIOMER® THFMA.

2.3. Directive 2011/65/EU on the restriction of certain hazardous substances in electrical and electronic equipment (RoHS)

Below listed substances and heavy metals listed in Directive 2011/65/EU and its amendments are not intentionally used in our recipes during the manufacturing process of VISIOMER® THFMA.

Substance	Maximum concentration values tolerated by weight in homogeneous material
Lead	0,1 %
Mercury	0,1 %
Cadmium	0,01 %
Hexavalent chromium	0,1 %
Polybrominated biphenyls (PBB)	0,1 %
Polybrominated diphenyl ethers (PBDE)	0,1 %
Bis(2-ethylhexyl) phthalate (DEHP)	0,1 %
Butyl benzyl phthalate (BBP)	0,1 %
Dibutyl phthalate (DBP)	0,1 %
Diisobutyl phthalate (DIBP)	0,1 %

2.4. EN 71-3:2019 + A1:2021 (Safety of toys - Part 3: Migration of certain elements)

Metals listed in EN 71-3:2019+A1:2021, table 2, under 4.2 (aluminium, antimony, arsenic, barium, boron, cadmium, chromium (III and VI), cobalt, copper, lead, manganese, mercury, nickel, selenium, strontium, tin, organotin compounds and zinc) are not intentionally used during the manufacturing process of VISIOMER® THFMA or their concentrations are below migration limits as mentioned in EN 71-3:2019+A1:2021, table 2, under 4.2 for category III of toy materials.

2.5. Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Below listed substances mentioned in Annex XVII – Restrictions of the REACH Regulation are not intentionally used during the manufacturing process of VISIOMER® THFMA.

- Toluene (Pos. 48)
- Polycyclic aromatic hydrocarbons (PAHs) (Pos. 50);
- Phthalates (Pos. 51, 52);
- Bisphenol A (Pos. 66);
- C9–C14 linear and/or branched perfluorocarboxylic acids (C9–C14 PFCAs), their salts and C9–C14 PFCAs–related substances including their salts and precursors (Pos. 68)

2.6. Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Biocidal products authorised according to Regulation (EU) No 528/2012 and its amendments are not intentionally used to produce VISIOMER® THFMA.

2.7. Regulation (EC) No 1005/2009 on substances that deplete the ozone layer and the Clean Air Act

Ozone depleting substances mentioned in Regulation (EC) No 1005/2009 as well as substances listed as Class I and Class II in section 602 of the Clean Air Act (adoption of "The Montreal Protocol on Substances that Deplete the Ozone Layer" into legislation) are not intentionally used during the manufacturing process of VISIOMER® THFMA.

2.8. Regulation (EU) No 2019/1021 on persistent organic pollutants

Substances as listed in Annex I and/or III of the Regulation (EU) No 2019/1021 are not intentionally used during the manufacturing process of VISIOMER® THFMA.

2.9. California Proposition 65

Please refer to the US Safety Data Sheet, Section 15 Regulatory Information, State Regulations.

2.10. Certain restricted substances

2.10.1. Substances of Genetically Modified Organisms (GMO) Origin

Substances of GMO (Genetically Modified Organisms) origin are not intentionally used during the manufacturing process of VISIOMER® THFMA.

2.10.2. BSE / TSE risk

The substances of animal origin are not intentionally used during the manufacturing process of VISIOMER® THFMA.

2.10.3. Halal/Kosher Certification

Up to now VISIOMER® THFMA is neither Kosher, nor Halal certified.

2.10.4. Bisphenol F and Bisphenol S

Below listed substances are not intentionally used during the manufacturing process of VISIOMER® THFMA.

Substance	CAS-No.
Bis-(hydroxylphenyl)methane (Bisphenol F)	1333-16-0
4,4'-Bis(4-hydroxyphenyl)sulfone (Sulphonylbisphenol, Bisphenol S)	80-09-1

2.10.5. Nanoparticles

Nanomaterials (according to the definition from Commission Recommendation on the definition of nanomaterial (10.06.2022, C(2022) 3689)) are not intentionally used during the manufacturing process of VISIOMER® THFMA.

2.10.6. Alkylphenol ethoxylates

Alkylphenol ethoxylates (APEO) are not intentionally used during the manufacturing process of VISIOMER® THFMA.

3. Inventory Information

3.1. REACH

VISIOMER® THFMA purchased from Evonik Operations GmbH is in compliance with REACH in case this product is manufactured within the EU or imported into the EU by Evonik Operations GmbH. If so, all REACH relevant monomers and substances contained in this product are either registered by Evonik or by our suppliers or are exempted from REACH Registration. Please be aware that various exemptions are defined in REACH which can be relevant for our products (natural materials, polymers, production or imports < 1 t/y and more). As a result, no registration number may be listed in the SDS even for REACH compliant products.

Please note that in case you are the EU importer of this product you may be obliged to register the product or its ingredients. In this case please contact us for clarification.

3.2. Substances of Very High Concern (SVHC)

Please refer to Section 3 of the current EU Safety Data Sheet where Evonik Operations GmbH lists Substance of Very High Concern (SVHC) and other hazardous ingredients in its products. The European Chemicals Agency (ECHA) publishes and regularly updates a list of SVHC (Candidate List). REACH obliges producers and importers to inform their customers if their products contain more than 0,1 % of a substance on the Candidate List. Evonik Operations GmbH continuously monitors the Candidate List and updates the EU Safety Data Sheets of affected products to include new SVHC. To fulfill REACH communication requirements, Evonik Operations GmbH provides updated EU Safety Data Sheets to all recorded customers who purchased affected products within the 12 months preceding the update of the EU Safety Data Sheet. Evonik Operations GmbH encourages downstream users to ensure compliance with the requirements for communication and notification of the REACH legislation.

3.3. International Inventories

Please refer to the Safety Data Sheet, Chapter 15. Regulatory Information, Status of Registration.

For technical enquiries, please contact:

E-mail: visiomer@evonik.com
Date: 17. January 2023

Information mentioned in this document is based on the current legislation and is updated periodically to include new amendments. In the case of uncertainty we recommend to consult our technical service.

Finished food contact materials or articles containing this product as a component, need to comply inter alia with Overall Migration Limit (OML) requirements – as specified in above mentioned standards such as Regulation (EU) No 10/2011, Chinese Regulations GB 9685-2016, GB 4806.6-2016, GB 4806.10-2016, Swiss Ordnance SR 817.023.21. Verification of compliance with migration limits (OML and SML) should be carried out in accordance with the rules laid down there. We would like to point out that it is the sole responsibility of the manufacturer of the final material or article to assure the compliance with the OML requirements under actual and foreseeable conditions of use, and to check it on a regular basis. The manufacturer of food contact materials or articles, containing this product as a component, must in particular ascertain that these finished materials or articles meet the general regulatory requirement that they do not endanger human health, or bring about an unacceptable change in the composition of the food or deterioration in the organoleptic characteristics thereof.

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