Declaration of Compliance
Holcosil LSR White 281.9747

Version: 2 : 30/04/2024

This product is a Liquid Silicone Rubber preparation, and the composition of this preparation is considered proprietary knowledge of HOLLAND COLOURS Europe BV. Additional information about hazardous components can be found in the Safety Data Sheets in case of presence above the reportable concentration limits pursuant to the applicable relevant legislation.

This preparation is not to be used to colour food or beverage.

In case the colouring preparation is to be used in food contact applications, it is the responsibility of both the manufacturers of finished food contact articles as well as the industrial food packers to make sure that these articles in their actual use are in compliance with the relevant food contact regulations. Note that only the final finished food contact article can be assessed for compliance, not the individual ingredients.
Thus, it is of the utmost importance to test and assess the performance of our colouring preparation in the actual compound being used.

HOLLAND COLOURS Europe B.V. formulates with carefully selected ingredients that meet below mentioned regulatory compliance. The suitability of the coloring preparation must be established by performing relevant migration test(s) on the final article.
This document provides information enabling customers to do their compliance assessment according to the relevant regulations, which may include migration testing.

1. Applicable legislation and purity confirmation

Since this preparation contains one or more Liquid Silicone Rubbers, we would like to point out that COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011, as amended, does not regulate silicone oil based and/or silicone rubber based binders, as is stated in Article 2 (Scope), item 2:

> This Regulation shall not apply to the following materials and articles which are placed on the EU market and are intended to be covered by other specific measures:
> (a) ion exchange resins;
> (b) rubber;
> (c) silicones.

Nevertheless, in order to inform downstream users accordingly, HOLLAND COLOURS provides relevant information regarding impurities and reportable substances that arise from the formulation including, but not limited to, the silicone.

A. European legislation

Material group	Legislation
COLOURANTS & PIGMENTS **Country:** Europe - CoE AP(89)1 **Status: Compliant**	Council of Europe Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food.
GENERAL **Country:** Europe - Directive 94/62/EC Packaging and packaging waste. **Status: Compliant**	Directive 94/62/EC sets out the EU's rules on managing packaging and packaging waste.

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Country: Europe - Framework Regulation (EC) No 1935/2004 (amended by 2019/1381) **Status: Compliant**	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. (Amended by REGULATION (EC) No 2019/1381). Stating compliance with the Framework Regulation not only covers the safety aspects set out in Article 3(1)(a), but also covers: GMP (Article 3), labelling requirements (Article 15) and Traceability (Article 17).
Country: Europe - GMP Regulation (EC) No 2023/2006 **Status: Compliant**	COMMISSION REGULATION (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food
PLASTICS **Country:** Europe - 10/2011 up to 2023/1627 **Status: Not applicable**	COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. Amended up to Commission Regulation (EU) 2023/1627 of 10 August 2023 **Remark:** This preparation is developed for use in Liquid Silicone Rubber.

B. Member State legislation and non-European legislation

Intentionally added substances not subject to listing in Annex I according to Article 6 of Regulation (EU) No 10/2011, and other components made from non-plastic materials, are either risk assessed in accordance with Article 3 of Regulation (EC) No 1935/2004 or comply with the requirements of the legislation listed below.

National legislation in EU Member States	
Material group	**Legislation**
COLOURANTS & PIGMENTS **Country:** France - Circulaire 176 **Status: Compliant**	Circulaire 176 dated 2.12.1959, published in the Journal Officiel of 30.12.1959 incl. amendments, positive list and purity criteria for colorants. (Brochure 1227)
Country: Germany - BfR IX Colorants (As of 01.06.2019) **Status: Compliant**	BfR Recommendation IX Colorants for Plastics and other Polymers Used in Commodities. (As of 01.06.2019)
Country: Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten (26 april 2022) **Status: Compliant**	Regeling van de Minister van Volksgezondheid, Welzijn van 14 maart 2014, kenmerk 328583-117560-VGP, houdende vaststelling van de Warenwetregeling verpakkingen en gebruiksartikelen die in contact komen met levensmiddelen (Warenwetregeling verpakkingen en gebruiksartikelen), geamendeerd tot aan regeling van de Minister van Volksgezondheid, Welzijn en Sport van 26 april 2022, 3348384-1027396-VG Hoofdstuk XI –Kleurstoffen en pigmenten
SILICONES **Country:** Germany - BfR XV. Silicones (As of 01.02.2023) **Status: Compliant**	BfR Recommendations XV. Silicones (As of 01.02.2023)

Legislation for countries outside the EU	
Material group	**Legislation**
COLOURANTS & PIGMENTS **Country** United States - § 178.3297 **Status: Compliant**	U.S. Food and Drug Administration CFR - Code of Federal Regulations Title 21 § 178.3297- Colorants for polymers
GENERAL **Country** United States - Title 21: Food and Drugs PART 174—INDIRECT FOOD ADDITIVES: GENERAL §174.5 General provisions	§174.5 General provisions applicable to indirect food additives. Regulations prescribing conditions under which food additive substances may be safely used predicate usage under conditions of good manufacturing practice. Specifications of use (FDA 21 CFR 176.170) : [01, 02, 03, 04.A, 04.B, 05, 06.A, 06.B, 06.C, 07.A,

Status: Compliant	07.B, 08, 09] (FDA FCN) : [A, B, C, D, E, F, G, H] Maximum concentration: 40,000 % **Remark:** This preparation is developed for use in Liquid Silicone Rubber.
RUBBERS **Country** United States - § 177.2600 **Status: Compliant**	TITLE 21--FOOD AND DRUGS CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED) PART 177 INDIRECT FOOD ADDITIVES: POLYMERS Subpart C--Substances for Use Only as Components of Articles Intended for Repeated Use § 177.2600 - Rubber articles intended for repeated use.

C. Non-intentionally added substances

Non-intentionally added substances in plastics, according to Article 6(4a) of Regulation (EU) No 10/2011, and in non-plastic materials, are risk assessed in accordance with Article 3 of Regulation (EC) No 1935/2004. Adequate information on non-intentionally added substances can be found in section 2A of this document.

D. Organoleptic properties

We have not determined whether a material or final article that is produced with this Product will induce an unacceptable change in the composition of the food or will cause deterioration of the organoleptic properties of the food. It is the responsibility of the downstream user to perform these tests.

2. Limits, restrictions and compositional specifications

A. Limits and restrictions of non-listed substances

Europe - Framework Regulation (EC) No 1935/2004 (amended by 2019/1381) GENERAL		
1,1,1-Trimethylolpropane	CAS number: 77-99-6 Reference number: -	Fat-reduction factor: unknown
Maximum concentration: 0,280 % **Restrictions and specifications** **SML:** 4,2 mg/kg **Remark:**	**Maximum Use Level:** n/a **Notes:** 1,1,1-Trimethylolpropane present in this product, has been self-classified as a reproductive toxicant (Rep. Tox. Cat. 2)" with GHS hazard statements H361f and H361d by the EU REACH TMP industry consortium. Based on an updated risk assessment a more conservative SML of 4.2 mg/kg-food is recommended.	

Europe - Framework Regulation (EC) No 1935/2004 (amended by 2019/1381) GENERAL		
Cyclohexasiloxane, dodecamethyl-	CAS number: 540-97-6 Reference number: -	Fat-reduction factor: unknown
Maximum concentration: < 49,700 ppm **Restrictions and specifications** **SML:** 60 mg/kg	**Maximum Use Level:** n/a **SML(T) Remark:** sSML based on CES opinion on D4 D5 and D6 NOEL/NOAEL	

	Notes: SVHC substance	
Remark:		

Europe - Framework Regulation (EC) No 1935/2004 (amended by 2019/1381) GENERAL		
Cyclopentasiloxane, decamethyl-	CAS number: 541-02-6 Reference number: -	Fat-reduction factor: unknown
Maximum concentration: < 49,700 ppm **Restrictions and specifications** **SML:** 60 mg/kg	**Maximum Use Level:** n/a **SML(T) Remark:** sSML based on CES opinion on D4 D5 and D6 NOEL/NOAEL **Notes:** SVHC substance	
Remark:		

Europe - Framework Regulation (EC) No 1935/2004 (amended by 2019/1381) GENERAL		
Octamethylcyclotetrasiloxane	CAS number: 556-67-2 Reference number: -	Fat-reduction factor: unknown
Maximum concentration: < 49,700 ppm **Restrictions and specifications** **SML:** 60 mg/kg	**Maximum Use Level:** n/a **SML(T) Remark:** sSML based on CES opinion on D4 D5 and D6 NOEL/NOAEL **Notes:** SVHC substance	
Remark:		

B. Substances with limits and restrictions as listed in Regulation (EU) No 10/2011

Substance identification	Restrictions and specifications	Maximum concentration
FCM: 141 **EEC ref:** 13380, 25600, 94960 **CAS:** 0000077-99-6 ***1,1,1-trimethylolpropane***	**SML:** 6 mg/kg **FRF:** no **Compliance Notes:**	0,280 %

C. Limits and restrictions as listed in Regulation (EU) No 10/2011, Annex II, Metals

Name / Element	Restriction	Maximum concentration
Aluminium	**SML:** 1 mg/kg	< 1,741 %
Antimony	**SML:** 0,04 mg/kg	< 0,515 ppm
Arsenic	**SML:** 0,01 mg/kg	< 0,509 ppm
Barium	**SML:** 1 mg/kg	< 1,650 ppm

Cadmium	**SML:** 0,002 mg/kg	< 0,053 ppm
Chromium	**SML:** (1) 0,01 mg/kg (2) 3,6 mg/kg	< 1,580 ppm
Cobalt	**SML:** 0,05 mg/kg	0,050 ppm
Copper	**SML:** 5 mg/kg	< 0,418 ppm
Europium	**SML:** 0,05 mg/kg	0,250 ppm
Gadolinium	**SML:** 0,05 mg/kg	0,250 ppm
Iron	**SML:** 48 mg/kg	< 21,500 ppm
Lanthanum	**SML:** 0,05 mg/kg	0,250 ppm
Lead	**SML:** 0,01 mg/kg	< 6,015 ppm
Lithium	**SML:** 0,6 mg/kg	1,500 ppm
Manganese	**SML:** 0,6 mg/kg	0,350 ppm
Mercury	**SML:** 0,01 mg/kg	< 0,008 ppm
Nickel	**SML:** 0,02 mg/kg	< 0,659 ppm
Terbium	**SML:** 0,05 mg/kg	0,250 ppm
Zinc	**SML:** 5 mg/kg	< 5,030 ppm

D. Limits and restrictions as listed in Regulation (EC) No 10/2011, Annex II, Primary Aromatic Amines

This Product may contain Primary Aromatic Amines according to Annex II: NO

3. Dual Use Additive(s)

A substance is defined as a "Dual Use Additive" if the chemical identity of the plastic additive matches that of an authorized food additive or flavoring, regardless of its purity or whether or not the substance is subject to a restriction in food and/or in the plastic. In the case of salts it is the salt that matters, not the authorized acid, phenol or alcohol.

Number (E or FL)	Name	Maximum concentration
E 551	Silicon dioxide	0,450 %

The purity of the Dual Use Additives used in this Product respect the purity criteria set out in Annex I of Regulation (EU) No 10/2011.

4. Specifications for use

Specifications of use as regards of type or types of food

None

Specifications for use as regards of time and temperature of treatment and storage of food

None

Any other limitations of use

Compliant with the provisions within Regulation (EU) No 10/2011 for infants and young children: NOT SPECIFIED
Compliant with the provisions within Regulation (EU) No 10/2011 for repeated-use articles: NOT SPECIFIED
A surface/volume ratio expressed in dm² FCM/kg food of: NOT SPECIFIED

Significant decimals
The concentrations listed in this document are automatically calculated by our software tool and do not reflect the actual amount of significant decimals.

Legend
FCM = Food Contact Material number, from Annex I, 10/2011
FRF = Fat Reduction Factor, under 10/2011
NIAS = Non Intentionally Added Substance
PAA = Primary Aromatic Amine
SML = Specific Migration Limit, under 10/2011
SML(T) = Total SML for group substances, under 10/2011
QM = Maximal Quantity of substance present in finished product

Food types and Conditions of Use of USA Food Contact Regulation

USA 21 CFR 176,170 Table 1 - Types of Raw and Processed Foods	
01	Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
02	Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
03	Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
04 A	Dairy products and modifications: Water-in-oil emulsions, high- or low-fat.
04 B	Dairy products and modifications: Oil-in-water emulsions, high- or low-fat.
05	Low-moisture fats and oil.
06 A	Beverages: Containing up to 8 percent of alcohol.
06 B	Beverages: Nonalcoholic.
06 C	Beverages: Containing more than 8 percent alcohol.
07 A	Bakery products other than those included under Types 8 or 9 of this table: Moist bakery products with surface containing free fat or oil.
07 B	Bakery products other than those included under Types 8 or 9 of this table: Moist bakery products with surface containing no free fat or oil.
08	Dry solids with the surface containing no free fat or oil (no end test required).
09	Dry solids with the surface containing free fat or oil.

USA 21 CFR 176,170 Table 2 - Conditions of Use - Time and Temperature	
A	High temperature, heat sterilized or retorted
B	Boiling water, sterilized
C	Hot filled or pasteurized above 66 °C (150 °F)
D	Hot filled or pasteurized below 66 °C (150 °F)
E	Room temperature filled and stored

F	Refrigerated storage
G	Frozen storage
H	Frozen or refrigerated storage - ready prepared foods intended to be reheated in container at time of use
I	Irradiation
J	Cooking at temperatures exceeding 121 °C (250 °F)

* Substances marked with a single asterisk in this document are reportable substances with variable concentrations due to variations in supply source. The maximum concentration is shown.

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For Notice:

Note that only the final finished food contact article can be assessed for compliance, not the individual components. This document has been prepared and issued on the basis of information provided by our raw material suppliers and our knowledge and expertise of currently applicable laws and regulations. The recipient is advised to regularly request updates hereof. This document replaces all previous ones relating to this subject. The information in this document holds for the material as it leaves its production facilities and does not apply to any additive, pigment etc. subsequently added by the converter or to any change in the composition of the product as a result of further processing, adding additives, or otherwise.

Disclaimer:

HOLLAND COLOURS Europe BV does not control the conditions under which its products are stored or used. Therefore HOLLAND COLOURS Europe BV is not in a position to warrant suitability for a specific purpose or that their customers' products meet FDA or other regulatory requirements. Statements regarding the absence of certain substances are based on knowledge of materials and processes, not on direct analytical data. It is the responsibility of both the manufacturers of finished food contact articles as well as the industrial food packers to make sure that these articles in their actual use are in compliance with the imposed migration limits and to ensure that any proprietary rights and existing laws and legislations are observed.

HOLLAND COLOURS Europe BV
EU Product Stewardship 30/04/2024