Amylomer™ Care Fusion

Technical Data Sheet

1.	**INFORMATION OF INGREDIENT**	
1.1	Trade Name	Amylomer™ Care Fusion
1.2	Legal Manufacturer	Gräfe Chemie GmbH Deichstraße 48-50 D-20459 Hamburg, Germany Tel.: +49 - (0)40 – 7602638 E-Mail: info@graefe-naturchemie.de
1.3	Manufacturing Site	Ursa-Chemie GmbH

2.	**PRODUCT DESCRIPTION**		
2.1	Raw Material category/ function	Hair/Skin Conditioning; Antistatic	
2.2	Ingredients according to INCI	Water (US)/Aqua (EU); Hydroxypropyl Oxidized Starch PG Trimonium Chloride; Starch Hydroxypropyltrimonium Chloride; Sodium Lactate; Sodium Chloride; Urea; Lactic Acid; Glycerin, Levulinic Acid, p-Anisic Acid	
2.2.1	**Composition (INCI)**		
	Components	**Source**	**Percentage [%]**
	Water/Aqua		> 50
	Hydroxypropyl Oxidized Starch PG Trimonium Chloride	vegetable/synthetic	10 - 25
	Starch Hydroxypropyltrimonium Chloride	vegetable/synthetic	5 - 10
	Sodium Lactate	vegetable/organic	> 1 - 5
	Sodium Chloride	synthetic	> 1 - 5
	Urea	synthetic	> 1 - 5
	Lactic Acid	vegetable/organic	> 1 - 5
	Glycerin	vegetable	> 0,1 - 1
	Levulinic Acid	vegetable	> 0,1 - 1
	p-Anisic Acid	synthetic	> 0,1 - 1
2.3	Registration Status	Europe: registered in EU-Inventory US: CTFA-registered	

3.	**MANUFACTURING INFORMATION**	
3.1	**Plant Origin of starting material**	**Origin**
	Hydroxypropyl Oxidized Starch PG Trimonium Chloride	Potato Starch
	Starch Hydroxypropyltrimonium Chloride	Potato Starch
	Lactic Acid / Sodium Lactate	Fermentation
	Glycerin	Zea Mays
	Levulinic Acid	Corn

3.2	Description of manufacturing process
	Amylomer® Care Fusion is manufactured by blending aqueous solutions of Hydroxypropyl Oxidized Starch PG Trimonium Chloride and Starch Hydroxypropyltrimonium Chloride The aqueous solution of Hydroxypropyl Oxidized Starch PG Trimonium Chloride is manufactured by reaction of Hydroxypropyl Starch with quaternization agent. The aqueous solution of Starch Hydroxypropyltrimonium Chloride is manufactured by reaction of Potato Starch with quaternization agent. Irridiation: Neither Amylomer™ Care Fusion nor any of the raw materials used have been submitted to any irradiation with with γ-rays. Amylomer™ Care Fusion is produced in the absence of any animal derived material of any type. Based on the information on the manufacturing process and production site no contamination with BSE/ TSE risk materials is to be expected. Origin of plant based materials (dominant origin of constituents): potato CITES: Amylomer™ Care Fusion not based on raw materials from species listed in CITES appendices.

4.	Specification	
4.1	Active matter / Dry substance Density [g/ml] pH DIN 19268 Viscosity (Brookfield, LVT)	20,5 – 24,5 % (30-34 % total solids) 1,12 ± 0,01 g/ml ~ 4,3-6,0 100-1000 mPa*s

5.	Microbiological Specification	
5.1	Total Plate Count (KBE/g) Challenge test according to Pharm Eur. 2003, 5.1.3	< 10 passed

6.	Impurities	
6.1	1,4-Dioxan	Not to be expected
6.1.2	Ethylenoxide	Not to be expected
6.1.3	Residual Solvent	Not to be expected
6.1.4	Monomers	Not to be expected
6.1.5	Free Amines	Not to be expected
6.1.6	Nitrosamines	Not to be expected
6.1.7	Pesticides	Not detectable (detection limit 0,1 ppm)
6.1.8	Polyaromatic Hydrocarbons	No data available
6.1.9	Other Impurities	Aflatoxine B1, B2, G1, G2: not detectable (detection limit 4 µg/kg)
6.1.10	Formaldehyde	Not to be expected
6.1.11	Heavy Metals	max 20 ppm (each < 1ppm As, Cd, Co, Cr, Hg, Ni, Pb, Sb)
6.1.12	Polyfluorinated Alkyl Substances (PFAS)	Not to be expected
6.1.13	GMO status	GMO-free

7.	Shelf life / storage Conditions
7.1	24 months after production (unopened original packaging)

8.	Regulatory Status			
8.1	HS-Code EU-CN-Code		350510 35051050	
8.2	Regulatory status (chemical regulations) Europa			
	Components	**Reach Status**	**CAS.No**	**EINECS / EC No.**
	Water/Aqua	Exempt (Annex IV)	7732-18-5	231-791-2
	Hydroxypropyl Oxidized Starch PG Trimonium Chloride	Exempt (Polymer)	222021-85-4	Polymer
	Starch Hydroxypropyl Trimonium Chloride	Exempt (Polymer)	56780-58-6	Polymer
	Sodium Lactate	Exempt (Annex V, no. 5)	72-17-3 867-56-1	200-772-0 212-762-3
	Sodium Chloride	Exempt (Annex V, no. 5)	7647-14-5	231-598-3
	Lactic Acid	01-2119474164-39	79-33-4	201-196-2
	Urea	01-2119463277-33	57-13-6	200-315-5
	Glycerin	Exempt	56-81-5	200-289-5
	Levulinic Acid	01-2120116230-78	123-76-2	204-649-2
	p-Anisic Acid	01-2120758802-49	100-09-4	202-818-5

9.	TOXICOLOGY	
9.1	Acute Oral Toxicity	>2000 mg/kg (derived from Cyctotoxicity test)
9.2	Acute Dermal Toxicity	Not expected
9.3	Skin Irritation	Not irritating (OECD 439)
9.4	Eye Irritation	Not irritating (OECD 437, 20% Solution)
9.5	Skin Sensitization	No incidents of skin sensitization reported, OECD 442 D and E in progress
9.6	Genotoxicity (e.g. Ames-Test) Mutagenicity, Cancerogenity, Teratogenity	Not mutagenic (Ames Test)
9.7	Percutaneous Permeation	As the product is a polymer, no percutaneous penetration is expected
9.8	Subchronic Toxicity tests	No data available
9.9	Teratogenicity	No data available
9.10	Toxicokinetics	No data available
9.11	Additional Toxicitytests	No data available
9.12	Phototoxicity	No data available
9.13	Photosensitization	No data available
9.14	Inhalative Toxicity	No data available

10.	HUMAN EXPERIENCE	
10.1	Human Dermal Irritation	So far no incidents of skin irritation have been reported when used within the recommended limits
10.2	Human Sensitization	So far no incidents of skin sensitization have been reported when used within the recommended limits

11.	**ECOTOXICOLOGICAL DATA**	
11.1	Biodegradability (OECD 302)	Inherently biodegradable
11.2	Aquatic Toxicity (OECD 201, Alge)	EC_{50} (72h, Desmodesmus subspicatus) >100 mg/L
11.3	Water Endangering Class	1 (self-classification based on AwSV)
11.4	Bioaccumulation Potential	No data available
11.5	Other Information	None

12.	**DERMATOLOGICAL ANALYSIS**	Certificated with „excellent“

13.	**INDEX ISO 16128-1 & -2:2017 for natural ingredients**				
	Natural substance content calculation	Natural content	natural origin content	organic content	organic origin content
	Formulation components including formulation water	0,00 %	90,40 %	-/-	-/-

14.	**SAFETY DATA SHEET**	see attachment: sd37237_Amylomer Care Fusion