#### Section 1: General Form:

This questionnaire is intended to help in the technical approval and qualification of potential suppliers. As such, the prompt and accurate completion of all sections will facilitate this process and the data on the form is treated as critical base data for safety and regulatory work. All information will be treated as confidential.

If the information being requested is either unavailable or not applicable, please indicate and explain.

#### A. Material /Supplier Identification:

#### Trade Name: lubrajel\* oil free

\*lubrajel is a registered trademark of United-Guardian, Inc lubrajel is a registered trademark of United-Guardian, Inc

#### Color Index Number (if applicable): NA

Manufacturer Name (if different from Supplier): Refer COA.

Supplier Name: Ashland

#### Contact Name: Global Quality and Regulatory Customer Request Team – Personal Care & Household

Title: Analyst

Phone: NA

Manufacturer's Plant Address (Address where material is manufactured): Refer to CoA

**Country of Origin: USA** 

#### Section 1: General Form

**B.** Composition & Material Identification:

Total target contents of the components should sum up to 100%. List all intentionally-added constituents in this table. Please be noted the data here is critical base data for safety and regulatory work.

**\* Definition of Function:** 

Key Ingredients - defined as chemicals intended to function in finished products.

Carryover Ingredients – defined as chemicals intentionally added to material to maintain its quality or stability, such as preservative, anti-oxidant, UV filter, that does not function in finished product formula.

#	Constituent name	CAS#	EINECS# /	Min	Target	Max	Constituent	Feedstock Origin
	( Approved INCI name)		ELINCS#	(W %)	(W %)	(W %)	Function	
1	Glycerin	56-81-5	200-289-5	36.5%	40.55	44.6%	Solvent	Plant
2	Water (Aqua)	7732-18-5	231-791-2	50.8 %	56.4	62%	Solvent	Mineral
3	Glyceryl Acrylate*/Acrylic Acid	9003-01-4	Exempt	1.07%	1.19	1.31%	Key Ingredient	Combination
4	Copolymer			0	0.60	0.600/		~
4	PVM/MA Copolymer	9011-16-9	Exempt	0.56 %	0.62	0.68%	Key Ingredient	Synthetic
5							Select	Select
6							Select	Select
7							Select	Select
8							Select	Select
9							Select	Select

General Comments: \*Mix of vegetables consisting primarily of palm, palm kernel, coconut, (Cocos nucifera and Elaeis guineensis) and soybean (Glycine max). If you selected the Feedstock Origin "Bovine" or "Animal-other", please attach TSE certification.

GRAS (Generally Recognized as Safe)?

Yes 🕅 No

 $\neg$  Yes  $\Box$  No 7 Yes 🕅 No

If you select the Feedstock Origin "Other", please explain:

## Is the material a polymer according to the definition (Cefic) Select

Yes No

 $\Box$  Yes  $\boxtimes$  No

 $\Box$  Yes  $\boxtimes$  No

Please note if the material is a polymer a detailed impurity profile should be provided in following table G.

#### C. Certifications:

Kosher Certification

Is the material Food Grade?

USP?

Other? (Please describe and/or attach)

#### LOI Declaration:

Do you certify that all the lots you supply will comply with all the answers until further notice from you? 🛛 Yes 🗌 No **Comments/Notes:** 

Halal Certification

EU Pharmacopeia?

Section 1: General Form

## Section 1: General Form

D. Global Inventory Status: In the table below, please describe the inventory status of each constituent.	Please add in the Inventory Number or choose
the Inventory Status in each field below:	

#	Constituent name	US	Canada	Australia	China	Ja	ipan	Korea	Philippines
	( Approved INCI name)	TSCA	Inventory	AIIC	IECSC	ENCS	JCIA	ECL	PICCS
1	Glycerin	Listed	DSL	Listed	Listed	Listed	Select	Listed	Listed
2	Water	Listed	Listed	Listed	Listed	Listed	Select	Listed	Listed
3	Glyceryl Acrylate*/Acrylic Acid Copolymer	Listed	Listed	Listed	Listed	Listed	Select	Listed	Listed
4	PVM/MA Copolymer	Listed	Listed	Listed	Listed	Listed	Select	Listed	Listed
5		Listed	Listed	Listed	Listed	Listed	Select	Listed	Listed
6		Listed	Listed	Listed	Listed	Listed	Select	Listed	Listed
7		Select	Select	Select	Select	Select	Select	Select	Select
8		Select	Select	Select	Select	Select	Select	Select	Select
9		Select	Select	Select	Select	Select	Select	Select	Select
10		Select	Select	Select	Select	Select	Select	Select	Select

**General Comments/Notes:** \*Mix of vegetables consisting primarily of palm, palm kernel, coconut, (Cocos nucifera and Elaeis guineensis) and soybean (Glycine max).

#### **E. Impurity Profile:**

Impurities/Residues/Catalysts/Monomers/By-Products An impurity is any chemical substance that is unintentionally present. List all impurities (regardless of amount).	CAS #	Max Level in RM	% or ppm or ppb	Comments
Acrylic Acid	79-10-7	<5	ppm	Residual monomer
Methyl Vinyl Ether	107-25-5	0.5	ppm	Residual impurity
Maleic Acid	110-16-7	5	ppm	Residual Impurity
Refer to Residual Solvent Statement				
Refer to Heavy metal statement				
Refer to Sales specifications				

# **Section 2:** Regulatory Status:

**Instructions:** Provide any known restrictions on this material for use in cosmetic products: For example, restrictions relating to UV Filters, colorants or preservatives or other restrictions noted in Annex III of the Cosmetic regulation, CIR. or Canadian Hot List

#### A. Restrictions:

Country	Restriction
	(% and approved use if any)
US	Glycerin, Glyceryl Acrylate/Acrylic Acid Copolymer and PVM/MA Copolymer - CIR Reviewed
Canada	Manufacturers of oral and leave-on products containing glycerin must ensure the raw material used is within the specifications of an accepted pharmacopoeia with respect to diethylene glycol (DEG) impurities (e.g. Glycerin Official Monograph in the most current edition of the USP).
EU	_
Australia	-
China	Glycerin, Aqua, Glyceryl Acrylate/Acrylic Acid Copolymer and PVM/MA Copolymer – Listed in IECIC CFDA 2021
Japan	_
Korea	-
Other:	-

#### **B.** Compliance:

Compliance with Regulations:	Yes or	Description
	No?	
Are any of the ingredients a known Carcinogen, Mutagen or Reproductive	No	Refer to CMR statement
Toxicant as defined under European Regulation (EC) No. 1272/2008?		
Does the raw material as supplied contain any ingredients or impurities	Select	Refer to REACH letter and
identified on the Substances of Very High Concern List under the REACH		positioning letter on SVHC.
(NUMBER)		
Are all of the ingredients compliant with the European Regulation (EC) No	Yes	
1272/2008 on classification, labelling and packaging of substances and		
mixtures?		
Are all of the ingredients in compliance with the European Cosmetic	Yes	
Regulation (EC) No. 1223/2009?		
Are any of the ingredients or impurities listed by California Proposition 65?	No	Please refer to section 15 of US
		SDS
Are any of the ingredients declarable under the California Safe Cosmetics	Select	
Act (SB 484)?		
Are any of the ingredients or impurities found to be Carcinogenic by NTP?	No	Refer to section 11 of US SDS
Are any of the ingredients or impurities found to be Carcinogenic by IARC?	No	Refer to section 11 of US SDS

# \*\*Please attach the REACH status and summary (including any components that may require authorization) for the material.

Animal Testing:	Yes or No?	Description
Are you in compliance with the European Cosmetic Regulation (EC) No. 1223/2009 prohibiting animal testing after a certain date?	Yes	
Has your company conducted or commissioned any animal testing on this raw material, or are you aware of any such animal testing conducted by a third party? Please specify most recent testing date.	Select	Refer to animal testing statement
If testing was conducted post September 11, 2004, please specify date; describe purpose and endpoints for the test(s).	Refer to animal testing statement	

Volatile Organic Content	Description
Are any of this material's ingredients classified as a VOC?	No
Total Raw Material VOC content in % (wt/wt) HVOC	
MVOC	
LVOC	
VOC Exempt?	

# Section 3: Physical Chemical Properties

A. Physical Form:

The material is supplied as Liquid:

Please refer to section 9 of SDS for physical and chemical properties

# Section 4. Human Safety

#### Please supply robust summaries of the tests performed as an attachment.

The testing identified here was completed on the material as it is supplied. Select If the answer is "no," please explain.

Please specify when *in vitro* models are used.

A. Testing Summary
--------------------

Test	Protocol	Date	Result
Acute Oral Toxicity			
Sub chronic Toxicity (28 / 90 day test)			
Dermal Irritation			
Dermal Sensitization			
Dermal Absorption			
Mucous Membrane Irritation (Eye)			
Mutagenicity (Ames)			
Genotoxicity			
Carcinogenicity			
Inhalation Toxicity			
Reproductive Toxicity			
Comedogenicity			
Photo-irritation			
Photo-toxicity			
Photosensitization			
Other:			

General Comments/Notes: <u>Refer to SDS</u>. *Data on above mentioned endpoints may be available in* <u>toxicology summary</u>.

#### **B. Materials of Concern:**

Material(s) of Concern	CAS#	ALL SOURCES: Total Inclusion Level %	Added Ingredient Contribution Inclusion Level %	<i>Natural Source Contribution</i> Inclusion Level %
Refer to the Impurity Profile section				

# C. Declarable Allergens:

Regulated Allergens	CAS#	Does not contain	ALL SOURCES Total Inclusion Level %	Added Ingredient Contribution Inclusion Level %	<i>Natural Source Contribution</i> Inclusion Level %
Alpha-Isomethyl Ionone	127-51-5	$\square$			
Amyl cinnamal	122-40-7	$\square$			
Amyl cinnamyl alcohol	101-85-9	$\square$			
Anise alcohol	105-13-5	$\square$			
Benzyl alcohol	100-51-6	$\square$			
Benzyl benzoate	120-51-4	$\square$			
Benzyl cinnamate	103-41-3	$\square$			
Benzyl salicylate	118-58-1	$\square$			
Butylphenyl methylpropional	80-54-6	$\square$			
Cinnamal	104-55-2	$\square$			
Cinnamyl alcohol	104-54-1	$\square$			
Citral	5392-40-5	$\square$			
Citronellol	106-22-9				
Coumarin	91-64-5				
Eugenol	97-53-0				
Isoeugenol	97-54-1				
Evernia Furfuracea (Treemoss) Extract	90028-67-4				
Evernia Prunastri (Oakmoss) Extract	90028-68-5				
Farnesol	4602-84-0	$\square$			
Geraniol	106-24-1	$\square$			
Hexyl cinnamal	101-86-0	$\square$			
Hydroxycitronellal	107-75-5	$\square$			
Hydroxyisihexyl 3-	31906-04-4	$\square$			
cyclohexene carboxaldehyde					
(Lyral)					
Limonene	5989-27-5	$\square$			
Linalool	78-70-6	$\square$			
Methyl 2-octynoate	111-12-6	$\boxtimes$			

## Section 5. Environmental Impact.

**Please supply robust summaries of the tests performed as an attachment.** The testing identified here was completed on the material as it is supplied. Select If the answer is "no," please explain. <u>Refer to SDS. Data on below</u> endpoints may be available in toxicology summary.

Endpoint Endpoint	Protocol	Date	Result
Aquatic Toxicity			
Short-term toxicity testing on Daphnia*			
Long-term toxicity testing on Daphnia			
Growth inhibition study on algae			
Short-term toxicity testing on fish*			
Long-term toxicity testing on fish (OECD 210, OECD 212 or OECD 215)			
Activated sludge respiration inhibition testing			
Nitrification inhibition testing			
Degradation			
Biodegradability Study			
Simulation testing on ultimate degradation in surface water			
Soil simulation testing			
Sediment simulation testing			
Aerobic rate of biodegradation (please specify media)			
Anaerobic rate of biodegradation (please specify media)			
Hydrolysis as a function of pH			
Identification of degradation products			
Fate & Behavior in the Environment			
Life cycle analysis (LCA)			
Adsorption/desorption screening study			
Bioconcentration in an aquatic species			
Effects on Organisms			
Short-term toxicity testing on earthworms*			
Long-term toxicity testing on earthworms			
Long-term toxicity testing on soil invertebrates other than earthworms			
Effects on soil microorganisms			
Short-term toxicity testing to plants*			
Long-term toxicity testing to plants			
Long-term toxicity testing to sediment organisms			
Long-term or reproductive toxicity testing to birds			

Section 5: Environmental Impact

#### Section 6: Plant Derived:

**Please attach a manufacturing flow chart specifying mode of isolation or extraction.** For materials that have identified plant or combination feedstock origin or contain more than one plant species please fill out one for each species identified.

Please specify plant species: Glycerin: Mix of vegetables consisting primarily of palm, palm kernel, coconut, (Cocos nucifera and Elaeis guineensis) and soybean (Glycine max).

Please specify plant part(s) used to make this material: Glycerin: palm kernel and seeds.

Extract % Solids %

If a marker compound is included, or available please identify and specify level.

Please specify Phylogenetic name:

Genetically modified? Yes 🗌 No🛛 Not Applicable 🗌 Unknown 🗌

#### If the INCI name includes the phylogenic name of the plant, please answer the following questions:

- 1. Is your Raw Material included in the IFRA guidelines? Yes 🗌 No🖂
- 2. If 'Yes', does the Raw Material meet the IFRA guidelines? Yes 🗌 No
- 3. If 'Yes', please specify the amendment:
- 4. Revision Date:
- 5. Was the plant / botanical /fragrance screened for pesticides? Yes 🗌 No
- 6. If 'Yes', what are the pesticide residue levels?
- 7. Do the pesticide residues present meet the European Pharmacoposia Guidelines? Yes 🗌 No
- 8. Does the Raw Material contain any denatured alcohol? Yes 🗌 No🖂
- 9. If "Yes", please specify the denaturant(s):

#### Does the botanical contain, by addition or as a processing aid, any of the following nut/seed products?

Materials of Concern	Does Not Contain	All Sources Total Inclusion Level %	Added Ingredient Contribution Inclusion Level %	Natural Source Contribution Inclusion Level %
Tree Nuts	$\square$			
Almonds	$\square$			
Brazil nuts	$\square$			
Cashews	$\square$			
Chestnuts	$\square$			
Cobnuts	$\square$			
Hazelnuts (Filberts)	$\square$			
Macadamia nuts	$\square$			
Pecans	$\square$			
Pistachio nuts	$\square$			
Shea nuts	$\square$			
Seed products, oils or	$\square$			
derivatives				
Peanuts				
Sesame seed	$\square$			
Sunflower seed	$\square$			
Cotton seed	$\square$			
Canola (Rapeseed)	$\square$			
Other (please specify and describe)				Soybean

## Section 7: TSE Certification:

The information captured here is intended to collect details on components that are derived from internal organs or connective tissues of animals.

	<b>I P A</b>	Identify Animal	Identify Source	Age of	Country of	BSE Country
	Ingredient	Species	Organs	Animal	Origin	Status GBR#
1	Not-applicable	Select				
	"Product is made only from					
	Non-animal derived					
	ingredients "					
2		Select				
3		Select				
4		Select				
5		Select				
6		Select				
7		Select				
8		Select				
9		Select				
10		Select				

\*\* Category rating based on the EU Commission scientific steering committee (SCC) Regulation 999/2001-Geographical Risk of Spongiform Encephalopathy (GBR) Adopted on January 11, 2002. Updated on October 31 2007. As noted on the <u>EFSA website</u>.

*NOTE*: Level I--Highly Unlikely, Level II--Unlikely but Not Excluded, Level III--Likely but Not Confirmed or Confirmed at a Lower Level, Level IV--Confirmed at a Higher Level

## **Certification of Isolation Method:**

The material described in the table above is certified to be classified as a Category 3 under <u>Regulation (EC) No</u> <u>1774/2002</u>. As such the material shall be compliant with Articles 6 & 7 including:

(b) processed in a processing plant approved in accordance with Article 13 using any of processing methods 1 to 5, in which case the resulting material shall be permanently marked, where technically possible with smell, in accordance with Annex VI, Chapter I, and disposed of as waste either by incineration or by co-incineration in an incineration or co-incineration plant approved in accordance with Article 12 or in a landfill approved under Directive 1999/31/EC;

(c) processed in a processing plant approved in accordance with Article 17;

(d) transformed in a technical plant approved in accordance with Article 18;

and suitable for its intended use.

Shilpa Maria Name of Certifying Person

Analyst Title

March 2, 2022 Date

Section 5: Environmental Impact