

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758

## PEARL SURFACE Z

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	15.12.2023	11311154-00001	Date of first issue: 15.12.2023

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : PEARL SURFACE Z

Product code : S870-Z

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-  
stance/Mixture : Dental material

Recommended restrictions  
on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : Kuraray Europe GmbH  
Philipp-Reis-Str. 4  
65795 Hattersheim am Main

Telephone : +49 (0)69 305 35 835

E-mail address of person  
responsible for the SDS : dental.eu@kuraray.com

#### 1.4 Emergency telephone number

(UK) 0 800 680 0425 Code:334674

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK  
SI 2019/720, and UK SI 2020/1567)**

Not a hazardous substance or mixture.

#### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI  
2019/720, and UK SI 2020/1567)**

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

EUH210 Safety data sheet available on request.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758

## PEARL SURFACE Z

Version      Revision Date:      SDS Number:      Date of last issue: -  
1.0          15.12.2023          11311154-00001      Date of first issue: 15.12.2023

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### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Substances with a workplace exposure limit :			
Silicon carbide	409-21-2 206-991-8		>= 50 - < 70

For explanation of abbreviations see section 16.

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## SECTION 4: First aid measures

### 4.1 Description of first aid measures

- Protection of first-aiders : No special precautions are necessary for first aid responders.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.
- In case of skin contact : Wash with water and soap as a precaution.  
Get medical attention if symptoms occur.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.

### 4.2 Most important symptoms and effects, both acute and delayed

None known.

### 4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758

## PEARL SURFACE Z

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	15.12.2023	11311154-00001	Date of first issue: 15.12.2023

---

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

#### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

#### 5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758

## PEARL SURFACE Z

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	15.12.2023	11311154-00001	Date of first issue: 15.12.2023

employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

### 7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.
- Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents

### 7.3 Specific end use(s)

- Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Silicon carbide	409-21-2	TWA (inhalable dust)	10 mg/m <sup>3</sup>	GB EH40
		TWA (Respirable dust)	4 mg/m <sup>3</sup>	GB EH40

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758

## PEARL SURFACE Z

Version 1.0      Revision Date: 15.12.2023      SDS Number: 11311154-00001      Date of last issue: -  
Date of first issue: 15.12.2023

### Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
Silicon carbide	Workers	Inhalation	Acute systemic effects	94 mg/m <sup>3</sup>
	Consumers	Inhalation	Acute systemic effects	23 mg/m <sup>3</sup>
	Consumers	Skin contact	Acute systemic effects	200 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	13 mg/kg bw/day
Stearic acid	Workers	Inhalation	Long-term systemic effects	17.63 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	10 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	4.348 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	5 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	2.5 mg/kg bw/day
(Z)-Octadec-9-enol	Workers	Inhalation	Long-term systemic effects	389 mg/m <sup>3</sup>
	Workers	Inhalation	Long-term local effects	219.5 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	110 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	96 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	55 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	55 mg/kg bw/day

### Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Petrolatum	Oral (Secondary Poisoning)	9.33 mg/kg food
(Z)-Octadec-9-enol	Sewage treatment plant	1 mg/l
	Fresh water sediment	89 mg/kg dry weight (d.w.)
	Marine sediment	8.9 mg/kg dry weight (d.w.)
	Soil	17.7 mg/kg dry weight (d.w.)

## 8.2 Exposure controls

### Engineering measures

Ensure adequate ventilation, especially in confined areas.  
Minimize workplace exposure concentrations.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758

## PEARL SURFACE Z

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	15.12.2023	11311154-00001	Date of first issue: 15.12.2023

---

### Personal protective equipment

- Eye/face protection : Wear the following personal protective equipment:  
Safety glasses  
Equipment should conform to BS EN 166
- Hand protection
- Remarks : Wash hands before breaks and at the end of workday.
- Skin and body protection : Skin should be washed after contact.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Equipment should conform to BS EN 14387
- Filter type : Combined particulates and organic vapour type (A-P)
- 

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- Appearance : Wax like
- Colour : grey
- Odour : odourless
- Odour Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available
- Flash point : Not applicable
- Evaporation rate : Not applicable
- Flammability (solid, gas) : Not classified as a flammability hazard
- Upper explosion limit / Upper flammability limit : Not applicable
- Lower explosion limit / Lower flammability limit : Not applicable
- Vapour pressure : Not applicable
- Relative vapour density : Not applicable

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758

## PEARL SURFACE Z

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	15.12.2023	11311154-00001	Date of first issue: 15.12.2023

---

Density	:	2.6 g/cm <sup>3</sup>
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

### 9.2 Other information

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Information on likely routes of exposure : Skin contact  
Ingestion  
Eye contact

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758

## PEARL SURFACE Z

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	15.12.2023	11311154-00001	Date of first issue: 15.12.2023

---

### Acute toxicity

Not classified based on available information.

### Components:

#### Silicon carbide:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 423
Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal toxicity

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Silicon carbide:

Species	:	Rat
Result	:	No skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Silicon carbide:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative
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### Carcinogenicity

Not classified based on available information.

### Components:

#### Silicon carbide:

Species	:	Rat
Application Route	:	Intraperitoneal injection



# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758

## PEARL SURFACE Z

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	15.12.2023	11311154-00001	Date of first issue: 15.12.2023

---

Exposure time : 40 weeks  
Result : negative

### Reproductive toxicity

Not classified based on available information.

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Components:

#### Silicon carbide:

Assessment : No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.

### Repeated dose toxicity

### Components:

#### Silicon carbide:

Species : Rat  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 50 hrs

### Aspiration toxicity

Not classified based on available information.

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## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

#### Silicon carbide:

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC:  $\geq 100$  mg/l  
Exposure time: 22 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

No data available

### 12.4 Mobility in soil

No data available

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758

## PEARL SURFACE Z

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	15.12.2023	11311154-00001	Date of first issue: 15.12.2023

---

### 12.5 Results of PBT and vPvB assessment

**Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

**Product:**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 12.7 Other adverse effects

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

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## SECTION 14: Transport information

### 14.1 UN number

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

### 14.2 UN proper shipping name

ADN : Not regulated as a dangerous good

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758

## PEARL SURFACE Z

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	15.12.2023	11311154-00001	Date of first issue: 15.12.2023

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**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA** : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

**ADN** : Not regulated as a dangerous good

**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA** : Not regulated as a dangerous good

### 14.4 Packing group

**ADN** : Not regulated as a dangerous good

**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA (Cargo)** : Not regulated as a dangerous good

**IATA (Passenger)** : Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

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## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Not applicable

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation : Not applicable

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

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# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758

## PEARL SURFACE Z

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	15.12.2023	11311154-00001	Date of first issue: 15.12.2023

---

UK REACH List of substances subject to authorisation : Not applicable  
(Annex XIV)

GB Export and import of hazardous chemicals - Prior : Not applicable  
Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)  
Not applicable

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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### SECTION 16: Other information

Other information : Items where changes have been made to the previous version  
are highlighted in the body of this document by two vertical  
lines.

#### Full text of other abbreviations

GB EH40 : UK. EH40 WEL - Workplace Exposure Limits  
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet;

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758

## PEARL SURFACE Z

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	15.12.2023	11311154-00001	Date of first issue: 15.12.2023

---

SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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