Date of issue: 29/04/16 Version: 1.2 Revised: 20/03/17

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: Ana Etching Gel

REACH registration numbers:

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

Identified use(s): Etching of enamel and dentin

1.3. Details of the supplier of the safety data sheet

Adress: Directa AB

Box 723

SE-194 27 UPPLANDS VÄSBY

SWEDEN

Telephone: +46-8-506 505 75 E-mail: info@directadental.com

1.4. Emergency telephone number: +46-8-33 12 31 (Swedish Poisons Information Centre)

2. Hazards identification

2.1. Classification of the substance or mixture

Classification: Skin Corr. 1B; H314

HEALTH

Causes severe skin burns and eye damage.

ENVIRONMENT

The product does not contain any substances classified as hazardous for the environment.

FIRE

The product is not flammable.

2.2. Label elements

Hazard pictogram(s):

Signal word(s): Danger

Hazard statement(s): H314

Causes severe skin burns and eye damage.

Precautionary statement(s): P260, P264, P280, P301+P330+P331, P303+P361+P353, P363, P310,

P305+P351+P338, P405, P501

Do not breathe mist/spray.

Wash the hands thoroughly after handling.

Wear protective gloves/ protective clothing/eye protection/face protection.

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.

Date of issue: 29/04/16 Version: 1.2 Revised: 20/03/17

Wash contaminated clothing before reuse.

Immediately call a POISON CENTER or doctor.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Store locked up.

Dispose of contents/container in accordance with local regulations.

Contains: Phosphoric acid 37%

2.3. Other hazards

PBT/vPvB: Not relevant.

3. Composition/information on ingredients

3.2. Mixtures

Classification of substances according to CLP, 1272/2008/EC

Hazardous substances	Content, %	CAS No	EC No	Hazard class(es)/	Hazard statements
				Category code(s)	
Phosphoric acid, 37% ¹	37.0	7664-38-2	231-633-2	Skin Corr. 1B	H314

Other substances

Silicon dioxide 4.7 7631-86-9 231-545-4 NC NC

Hazard statements, full text; H314 = Causes severe skin burns and eye damage, NC = not classified.

Note 1. Specific concentration limits apply: classified as H314 in an amount exceeding 25 %.

4. First aid measures

4.1. Description of first aid measures

Inhalation

Move affected person to fresh air at once. Place unconscious person on their side in the recovery position and ensure breathing can take place. When breathing is difficult, properly trained personnel may assist affected person by administering oxygen. Call a physician or poison center.

Skin contact

Remove all contaminated clothing immediately. Wash off with plenty of water. Chemical burns must be treated by a physician.

Contact with eyes

Irrigate thoroughly with eyewash solution or clean water, holding the eyelids apart, for at least 15 minutes. If discomfort persists, obtain medical attention. Remove contact lenses, if present and easy to do. Get medical attention if symptoms are severe or persist after washing.

Ingestion

Not relevant.

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

Inhalation

Inhalation of fumes may cause respiratory tract irritation, coughing and breathing problems. May cause damage to lungs in high concentrations.

Skin contact

This product is corrosive. May cause serious chemical burns to the skin. Pain.

Date of issue: 29/04/16 Version: 1.2 Revised: 20/03/17

Contact with eyes

Causes serious eye damage. Conjunctivitis, irritation, tearing. Pain. Profuse watering of the eyes.

Ingestion

Not relevant.

4.3 Indication of any immediate medical attention and special treatment needed

As a general rule, and in all cases of doubt or when symptoms persist, always seek medical attention. Never give anything by mouth to an unconscious person.

5. Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Small fires: Extinguish with carbon dioxide or dry powder.

Larger fires: Extinguish with foam, carbon dioxide or dry powder.

Unsuitable extinguishing media:

Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special hazards arising from the substance or mixture

Flammable hydrogen gas may be formed in contact with metals (i.e. iron, zinc). Also risk of formation of poisonous and flammable gas (phosphine).

5.3. Advice for firefighters

Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes. Follow precautions for safe handling described in this safety data sheet.

6.2. Environmental precautions

Prevent liquid from entering sewers, watercourses, underground or low areas. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

6.3. Methods and material for containment and cleaning up

Contain spillage with sand, earth or other suitable non-combustible material. Absorb in vermiculite, dry sand or earth and place into containers. Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.

6.4 Reference to other sections

For personal protection, see section 8.

For waste disposal, see section 13.

Date of issue: 29/04/16 Version: 1.2 Revised: 20/03/17

7. Handling and storage

7.1. Precautions for safe handling

7.1.1 Safety handling advice:

Do not eat, drink or smoke when using this product. Eye wash facilities and emergency shower must be available when handling this product. Good personal hygiene procedures should be implemented. Take off contaminated clothing and wash it before reuse. Wash promptly with soap and water if skin becomes contaminated.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures for safe storage:

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Keep away from oxidising substances, metals and strong bases.

7.3. Specific end use(s)

The product is to be used as an etching of enamel and dentin lubricant in clinical dentistry. Direct contact should be prevented due to risk of severe skin burns and eye damage.

8. Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit value (EH40/2005 WELs, United Kingdom (UK), 12/2011)

Phosphoric acid STEL: 2 mg/m³ (15 minutes)

TWA: 1 mg/m³ (8 hours)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Provide adequate ventilation. Provide access to washing facilities incl. soap, skin cleanser and fatty cream.

8.2.2. Individual protection measures, such as personal protective equipment

Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

a) Eye/face protection

Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible. The following protection should be worn: Chemical splash goggles.

b) Skin protection

Wear protective gloves. Viton and nitrile rubber gloves are recommended. Frequent change is advisable. Other types of gloves can be recommended by the glove supplier.

c) Respiratory protection

If ventilation is inadequate, suitable respiratory protection must be worn. Seek advice from supervisor on the company's respiratory protection standards. Respiratory protection complying with an approved standard should be worn if a risk assessment indicates inhalation of contaminants is possible.

Date of issue: 29/04/16 Version: 1.2 Revised: 20/03/17

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Blue gel
Odour	Odourless
Odour threshold	Not determined
рН	1.6
Melting point/freezing point	Not determined
Boiling point / range	Not determined
Flash point	Not determined
Evaporation rate (BuAc = 1)	Not determined
Flammability (solid, gas)	Not determined
Explosion limits	Not determined
Vapour pressure	Not determined
Vapour density (air = 1)	Not determined
Relative density	1200 kg/m³ at 20°C
Solubility - water	Completely miscible
Partition coefficient: n-octanol/water	Not determined
Auto-ignition temperature	Not determined
Decomposition temperature	Not determined
Viscosity	Not determined
Explosive properties	Not applicable
Oxidising properties	Non-oxidising

9.2. Other information

Not available.

10. Stability and reactivity

10.1. Reactivity

The product contains a strong acid that reacts exothermically with water evolving high heat.

10.2. Chemical stability

The product is stable under recommended storage and handling conditions (see section 7).

10.3. Possibility of hazardous reactions

No specific hazardous reactions are expected to occur.

10.4. Conditions to avoid

Avoid heat, flames and other sources of ignition.

10.5. Incompatible materials

Keep away from the following materials to prevent strong exothermic reactions: oxidisers, strong alkalis and strong acids.

10.6. Hazardous decomposition products

Flammable hydrogen gas may be formed in contact with metals (i.e. iron, zinc). Also risk of formation of poisonous and flammable gas (phosphine).

Date of issue: 29/04/16 Version: 1.2 Revised: 20/03/17

11. Toxicological information

11.1. Information on toxicological effects

Symptoms related to the physical, chemical and toxicological characteristics Inhalation

Inhalation of fumes may cause respiratory tract irritation, coughing and breathing problems. May cause damage to lungs in high concentrations.

Skin contact

This product is corrosive. May cause serious chemical burns to the skin. Pain.

Contact with eyes

Causes serious eye damage. Conjunctivitis, irritation, tearing. Pain. Profuse watering of the eyes.

Ingestion

Not relevant.

11.1.2. Mixtures

11.1.2.1. The relevant effects, for which information shall be provided, are:

Phosphoric acid

Relevant hazard class	Effective dose/ concentration	Species	Method	Result
Acute oral toxicity	LD50: 1530 mg/kg	Rat		Not classified
Acute dermal toxicity	LD50: 2740 mg/kg	Rabbit		Not classified
Acute toxicity inhalation	n/a			Not classified
Skin corrosion/irritation	n/a			H314 (Causes severe skin burns and eye damage)
Serious eye damage/ irritation	n/a			H318 (Causes serious eye damage)
Respiratory or skin sensitisation	n/a			Not classified
Germ cell mutagenicity	n/a			Negative (not mutagenic)
Carcinogenicity	n/a			Negative (not carcinogenic)
Reproductive toxicity	n/a			Negative (not toxic for reproduction)
Specific organ toxicity – single exposure	n/a			Not classified
Specific organ toxicity – repeated exposure	n/a			Not classified
Aspiration hazard	n/a			Not classified

12. Ecological information

12.1. Toxicity

Phosphoric acid

Relevant hazard class	Effect	Species	Exposure time	Result
Acute toxicity, fish	LC50	Lepomis macrochirus	96h	3-3.25 mg/L

Date of issue: 29/04/16 Version: 1.2 Revised: 20/03/17

Acute toxicity,	NOEC	Daphnia magna	48h	56 mg/L
Daphnia				
Acute toxicity,	EC50	Desmodesmus	72h	> 100 mg/L
algae		subspicatus		

12.2. Persistence and degradability

Phosphoric acid

Criteria for biodegradability not applicable to inorganic substances.

12.3. Bioaccumulative potential

Phosphoric acid

Not expected to have the potential for bioaccumulation in aquatic organisms.

12.4. Mobility in soil

The product is water soluble and may be adsorbed to soil particles.

12.5. Results of PBT and vPvB assessment

None of the substances in this product fulfil the criteria for being regarded as PBT or vPvB substances.

12.6. Other adverse effects

No other adverse effects are observed.

13. Disposal considerations

13.1. Waste treatment methods

Chemical residues, including contaminated containers, are generally classified as hazardous waste, and as such are covered by regulations which vary according to location. Contact your local waste disposal authority for advice, or pass to a licensed chemical disposal company.

14. Transport information

14.1. UN number: UN1805

14.2. UN proper shipping name: Phosphoric acid solution

14.3. Transport hazard class(es): 8

14.4. Packing group: III

14.5. Environmental hazards: Not applicable

14.6. Special precautions for user: Sea (EmS): F-A, S-B

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packaging of substances and mixtures (CLP), amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, with amendments.

Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Date of issue: 29/04/16 Version: 1.2 Revised: 20/03/17

The Control of Substances Hazardous to Health Regulations (COSHH) 2002 (S.I. 2002 No. 2677) with amendments.

EH40/2005, Workplace exposure limits 2005, with amendments.

The List of Wastes (England) (Amendment) Regulations 2005 (S.I. 2005 No 895) with amendments.

15.2. Chemical Safety Assessment

The supplier has not performed a Chemical Safety Assessment of this mixture.

16. Other information

The following sections have been amended since the last version of the safety data sheet (dated 29/04/16):

Section 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16

Key literature references and sources for data: Safety Data Sheet, Ana Etching Gel, Directa AB, 29/04/16.

- End of safety data sheet -