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## SAFETY DATA SHEET

Complies with REACH (EC) Regulation no. 1907/2006 and no. 453/2010

<b>SPRAYGEN</b>	Internal Code	<b>CE12</b>
Medical device of Class IIb Directive 93/42/EEC - Mark CE	Revision n°	00
	Date	30-03-2017

### 1. IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND OF THE COMPANY/ UNDERTAKING

#### 1.1 PRODUCT IDENTIFIER

**SPRAYGEN**

#### 1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

- Professional use
- Disinfectant for surgical medical devices

#### 1.3 INFORMATION ON THE SUPPLIER OF THE SAFETY DATA SHEET

**Pharma Trade Company s.r.l.**

Street  
Nationality plate/ZIP code/city  
Telephone no.  
Fax  
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**Torazza, 115/21**  
**IT - 20861 - Brugherio (MB)**  
**+39 039 2142186**  
**+39 039 2872944**  
**[info@pharmatrade.it](mailto:info@pharmatrade.it)**

#### 1.4 EMERGENCY TELEPHONE NUMBER

**045.6103594 or Poison-control centre of Pavia**  
(Centro Antiveleni di Pavia) **Tel. +39.0382.24444**  
**Poison-control centre Polyclinic Careggi**  
**Firenze** (Centro Antiveleni Azienda Ospedaliera Careggi Firenze) -  
**Tel. +39.055.7947819 Operating 24/7**

### 2. HAZARDS IDENTIFICATION

#### 2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

**In accordance with 67/548/EEC directives, 1999/45/EC and s.m.i. and with CLP Regulations.**

The product under normal conditions of storage and use is irritating to the eyes, easily inflammable and inhalation of its vapours may cause drowsiness and dizziness.

#### 2.2 LABEL ELEMENTS (GHS Classification)

**Warning:** Danger

**Pictograms:** GHS02 - GHS07



#### **Hazardous components to be reported on the label**

Chlorhexidine digluconate

Isopropyl alcohol

#### **Hazard statements**

H225: Highly flammable liquid and vapour

H412: Harmful to aquatic life with long lasting effects

H320: Causes eye irritation

H336: May cause drowsiness or dizziness.

#### **Precautionary statements**

P210: Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P233: Keep container tightly closed.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338: IN CASE OF CONTACT WITH EYES: rinse cautiously with water for several minutes. Remove contact lenses if it is easy to do. Continue rinsing.

## 2.2 OTHER HAZARDS

No data available.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 SUBSTANCES

No substance meets the criteria set out in Annex II Part A of the REACH regulations (EC) no.1907/2006.

### 3.2 MIXTURES

Identification	Ingredients	Classification	% p/p
CAS: 18472-51-0 EINECS: 242-354-0	Chlorhexidine digluconate	GHS07, GHS09, Dgr H: 302-410	0,05
CAS: 68424-85-1 EINECS: 270-325-2	Benzalkonium chloride	GHS05, GHS07, GHS09, Dgr H: 302-312-314-400	0,04
CAS: 7173-51-5 EINECS: 230-525-2	Didecyltrimethylammonium chloride	----- H: ----	0,06
CAS: 64-17-5 EINECS: 200-578-6	Ethyl alcohol	GHS02 H: 225	31,50
CAS: 67-63-0 EINECS: 200-661-7	Isopropyl alcohol	GHS02, GHS07, Dgr H: 225-319-336	31,00

Please refer to section 16 for complete text of the phrases H.

## 4. FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor. NEVER swallow anything to a person who has lost consciousness.

### 4.1 DESCRIPTION OF FIRST AID MEASURES

**In case of ingestion:** Do not give anything to an unconscious person. Rinse out mouth with water. Consult a doctor.

**In case of exposure by inhalation:** in case of inhalation, take the person to fresh air. If not breathing, give artificial respiration. Consult a doctor.

**In case of splashes or contact with skin:** remove contaminated clothing immediately, wash affected body parts with plenty of water and soap. If redness or irritation persists send the injured person to the emergency room.

**In case of splashes or contact with eyes:** intervene immediately; wash abundantly with running water for at least 15 minutes, keeping the eyelid well away from the eye. Immediately send the injured person to an eye specialist. Do not treat the eye with ointments or oils.

### 4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

No delayed effects are known because of its exposure.

### 4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

In case of ingestion and inhalation it is necessary to consult a doctor immediately.

## 5. FIREFIGHTING MEASURES

### 5.1 EXTINGUISHING MEDIA

*Suitable extinguishing media:* water spray, foam, resistant alcohol, dry chemicals or carbon dioxide.

*Unsuitable extinguishing media:* none.

Intervening with water, preferably fractional, from a safe distance and upwind. Cool down the containers exposed to the fire and the surrounding area. Do not take place reclamation operations, clearing or recovery until the entire area has been completely cooled down. In case of decomposition, highlighted by formation of smokes and the overheating of the containers, it is essential to cool down with water.

### 5.2 SPECIAL HAZARDS ARISING FROM THE MIXTURE

The main decomposition products: carbon oxides and nitrogen oxides.

### 5.3 RECOMMENDATIONS PER FOR FIREFIGHTERS

In the event of fire, if necessary, wear respiratory protection devices with independent air supply.

## 6. ACCIDENTAL RELEASE MEASURES

### 6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Use respiratory protection. Avoid breathing vapours/mist/gas. Provide adequate ventilation. Evacuate staff to safety areas.

### 6.2 ENVIRONMENTAL PRECAUTIONS

Avoid spills or additional leaks, if this can be done without danger.

### 6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Impregnate with inert absorbent material and dispose of as waste (see section 13). Store in suitable and closed containers for disposal. Follow the recommendations of paragraph 13.

### 6.4 REFERENCE TO OTHER SECTIONS

Please refer to sections 8 and 13.

## 7. HANDLING AND STORAGE

### 7.1 PRECAUTIONS FOR SAFE HANDLING

Apply legislation on occupational safety and hygiene. Use the personal protective equipment describe in section 8. Avoid contact with eyes and skin. Do not inhale vapours or mists.

### 7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Prohibit access to unauthorized persons. Store the product:

- in compliance with local/National regulations;
- in original and closed containers.

### 7.3 SPECIFIC END USES

The solution is dedicated exclusively as a disinfectant of surgical medical devices.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 CONTROL PARAMETERS

#### ISOPROPYL ALCOHOL

400 ppm (980 mg/m<sup>3</sup>) OSHA TWA

500 ppm (1230 mg/m<sup>3</sup>) OSHA STEL (vacated by 58 FR 35338, June 30, 1993)

400 ppm ACGIH TWA

500 ppm ACGIH STEL

400 ppm (980 mg/m<sup>3</sup>) NIOSH recommended TWA 10 hour(s)

500 ppm (1225 mg/m<sup>3</sup>) NIOSH recommended STEL

500 mg/m<sup>3</sup> (200 ml/m<sup>3</sup>) DFG MAK (peak limitation category-II, 1)

400 ppm (999 mg/m<sup>3</sup>) UK OES TWA

500 ppm (1250 mg/m<sup>3</sup>) UK OES STEL

#### ETHYL ALCOHOL

TLV units: ACGIH-TLV 1000 ppm (TWA)

PEL units: OSHA-PEL 1000 ppm (TWA)

### 8.2 EXPOSURE CONTROLS

#### Hand protection (protective gloves)

Handle with gloves.

#### Eye/ face protection

Not applicable.

#### Skin protection

Complete protective clothing resistant to chemicals.

#### Respiratory protection

Not applicable.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

FEATURE	UdM	VALUE
Form	--	Clear liquid
Odour	--	Typical alcoholic
Olfactory threshold	--	No data available
pH	U of pH	6,0 - 8,0 U of pH
Boiling point/boiling range	°C	No data available
Flash point Closed-Cup ASTM D3278	°C	< 21 °C
flammability DIN 51 794	°C	No data available
Explosive properties	--	Does not present explosive properties
Oxidizing properties	--	No data available
Steam pressure	--	No data available
Relative density UNI EN ISO 12185-00	d <sub>20/20</sub>	0,880 ± 0,010
Water solubility	--	Miscible
Fat solubility	--	Partially miscible
Partition coefficient (n-Octane/water)	logP <sub>ow</sub>	No data available
Viscosity at 20 °C ISO UNI EN 3104	mPa*s	No data available
Vapour density	air = 1	No data available
Evaporation rate		No data available
VOC content %	%	61,5 w/w

## 9.2 OTHER INFORMATION

FEATURE	UdM	VALUE
Autoflammability	°C	No data available
Melting point/range	°C	No data available

## 10. STABILITY AND REACTIVITY

### 10.1 REACTIVITY

No data available.

### 10.2 CHEMICAL STABILITY

The product is stable within the terms indicated on the label, under normal conditions of storage and use.

### 10.3 POSSIBILITY OF HAZARDOUS REACTIONS

Reactions with alkalis (basis). Exothermic reactions.

### 10.4 CONDITIONS TO AVOID

No data available.

### 10.5 INCOMPATIBLE MATERIALS

Strong acids, strong bases, strong oxidizing agents.

### 10.6 HAZARDOUS DECOMPOSITION PRODUCTS

The main products of combustion / decomposition: carbon dioxide, carbon monoxide and nitrogen oxides.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

#### 11.1.1. SUBSTANCES

#### CHLORHEXIDINE DIGLUCONATE 20% SOLUTION

DL<sub>50</sub> rat (oral): > 2000 mg/kg

#### **Respiratory or skin sensitization**

Maximisation Test – guinea pig - Causes sensitization. - OECD TG 406

#### **Germ cell mutagenicity**

No data available.

#### **Carcinogenicity**

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as known or expected carcinogen by IARC.

#### **Reproductive toxicity**

No data available.

#### **Specific target organ toxicity (STOT) – single exposure**

No data available.

#### **Specific target organ toxicity (STOT) - repeated exposure**

No data available.

#### **Aspiration hazard**

No data available.

#### **Potential health consequences**

**Inhalation:** May be harmful if inhaled. May cause irritation of the respiratory tract.

**Ingestion:** May be harmful if swallowed.

**Skin:** May be harmful if absorbed through the skin. May cause skin irritation.

**Eyes:** May cause eye irritation.

#### ISOPROPYL ALCOHOL

Acute Toxicity - Ingestion	LD <sub>50</sub> (lethal dose – rat)	5.045 mg/Kg
Acute Toxicity - Inhalation	LC <sub>50</sub> (rat - 8 h)	16.000 ppm
Acute Toxicity - skin	LD <sub>50</sub> (rabbit)	12.800 mg/kg
Irritant Power- eyes	Not determined	
Irritant Power - skin	Not determined	
“In vitro” Genotoxicity (Ames test)		Negative
Skin sensitization	Not determined	

#### ETHYL ALCOHOL

Acute Toxicity - Ingestion	LD <sub>50</sub> (lethal dose – rat)	7.060 mg/kg
Acute Toxicity - Inhalation	LC <sub>50</sub> (rat - 10 h)	20.000 ppm
Skin - rabbit – Irritating to the skin. - 24 h		
Eyes - rabbit – Light eye irritation - 24 h – Draize test		

#### **Respiratory or skin sensitization**

No data available.

#### **Germ cell mutagenicity**

No data available.

#### **Carcinogenicity**

Mouse-Oral: doubt oncogenic agent according to RTECS Liver: blood tumours : lymphomas including Hodgkin's disease. IARC: No component of this product present at levels greater than or equal to 0.1% is identified as known or expected carcinogen by IARC.

#### **Reproductive toxicity**

Reproduction toxicity - human - female - Oral: effects on newborns: Apgar index (for men only). Effects on newborns: pharmacodependence. No data available.

#### **Specific target organ toxicity (STOT) – single exposure**

Inhalation - May cause respiratory irritation.

#### **Specific target organ toxicity (STOT) - repeated exposure**

No data available.

#### **Aspiration hazard**

No data available.

#### **Potential health consequences**

**Inhalation:** May be harmful if inhaled. May cause irritation of the respiratory tract.

**Ingestion:** May be harmful if swallowed.

**Skin:** May be harmful if absorbed through the skin. May cause skin irritation.

**Eyes:** May cause eye irritation.

#### **Signs and symptoms of exposure**

Depression of the central nervous system, narcosis, cardiac lesions.

#### **BENZALCONIUM CHLORIDE SOLUTION 50%**

LD<sub>50</sub> - oral: Not available.

LC<sub>50</sub> - inhalation: Not available.

LD<sub>50</sub> - dermal: Not available.

Primary skin irritation: Corrosive to the skin and mucous membranes.

Primary irritation of the mucous membranes: Eyes: Strongly corrosive.

Supplementary statements: The product shows the following hazards according to the calculation method of the General EU Classification guidelines for dangerous preparations as issued in the latest version: Corrosive. If ingested, it causes strong corrosion of the oral cavity and pharynx with the risk of perforation of the esophagus and stomach.

#### **DIDECYLDIMETHYLAMMONIUM CHLORIDE**

Acute Toxicity - Ingestion DL<sub>50</sub> (lethal dose - rat) 238 mg/Kg (OECD TG 401)

Acute Toxicity - Inhalation CL<sub>50</sub> (rat) Not determined

Acute Toxicity - skin DL<sub>50</sub> (rabbit) 3.342 mg/kg

Irritant Power- eyes Not determined

Irritant Power - skin rabbit - 3 min. Irritant (OECD TG 404)

"In vitro" Genotoxicity Ames test, Salmonella typhimurium - Negative (OECD 471).

Chromosome aberration, CHO cells - Negative.

Gene mutation, CHO cells - Negative.

"In vivo" Genotoxicity In vivo chromosomal aberration, modality of application: Oral (rat)  
Negative (OECD 475).

#### **11.1.2. MIXTURE**

No information toxicological is available on the mixture.

#### **11.1.3. FURTHER INFORMATION**

No data available.

## **12. ECOLOGICAL INFORMATION**

### **12.1 TOXICITY**

#### **12.1.1. SUBSTANCES**

The product must be used according to good working practices, avoiding its dispersion into the environment. The ecotoxicity data of the individual components of the preparation are shown below

#### **CHLORHEXIDINE DIGLUCONATE 20% SOLUTION**

IC<sub>50</sub> (Algae): 0,01 < IC<sub>50</sub> ≤ 0,1 mg/l

EC<sub>50</sub> (Daphnia): 0,1 < EC<sub>50</sub> ≤ 1 mg/l

#### **ISOPROPYL ALCOHOL**

Itiotoxicity: LC<sub>50</sub> > 100 mg/l

Algae toxicity: LC<sub>50</sub> > 100 mg/l

Bacterial toxicity: LC<sub>50</sub> > 1000 mg/l

Aquatic invertebrates: LC<sub>50</sub> > 1000 mg/l

#### **ETHYL ALCOHOL**

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Ittiotoxicity: LC<sub>50</sub> - Oncorhynchus mykiss (rainbow trout) - 13.000 mg/l - 96 h

LC<sub>50</sub> - Oncorhynchus mykiss (rainbow trout) - 10.400 mg/l - 96 h

LC<sub>50</sub> - Pimephales promelas (American chub) - 15.300 mg/l - 96 h

LC<sub>50</sub> - Other fishes - 10.000 mg/l - 24 h

#### BENZALCONIUM CHLORIDE

Aquatic toxicity: the lowest known ecotoxicity (DL<sub>50</sub>, IC<sub>50</sub>, EC<sub>50</sub>) is 0,016 mg/l (from literary sources or from Stephan test). Daphnia, CE<sub>50</sub>: 0,016 mg/l.

#### DIDECYLDIMETHYLAMMONIUM CHLORIDE

Ittiotoxicity: LC<sub>50</sub> - Oncorhynchus mykiss (rainbow trout) - 1,0 mg/l - 96 h (OECD TG 203)

Chronic toxicity: NOEC - Brachydanio rerio (zebra fish) - 0,032 mg/l - 34 d (OECD 210)

Toxicity for Daphnia: EC<sub>50</sub> - Daphnia magna (large water flea) - 0,094 mg/l - 48 h (EPA-FIFRA)

NOEC - Daphnia magna (large water flea) - 0,010 mg/l - 34 d (OECD 211)

Algae toxicity: EC<sub>50</sub> - Selenastrum capricornutum (Algae chlorophyceae) - 0,026 mg/l - 96 h (OECD TG 201)

Bacterial toxicity: EC<sub>10</sub> Pseudomonas putida - 0,13 mg/l - 16 h (DIN 38412 parte 8)

EC<sub>50</sub> Activated sludge - 11 mg/l - 3 h (OECD 209)

#### **12.1.2. MIXTURE**

No aquatic toxicity information is available for the mixture.

### **12.2 PERSISTENCE AND DEGRADABILITY**

#### **12.2.1. SUBSTANCES**

##### CHLORHEXIDINE DIGLUCONATE 20% SOLUTION

The substance is slowly degradable.

##### ISOPROPYL ALCOHOL

Easily biodegradable. It involves a significant risk of reducing the oxygen content of the water.

##### ETHYL ALCOHOL

No data available.

##### BENZALCONIUM CHLORIDE

Easily biodegradable. The ingredient, as cationic surfactant, complies with the biodegradability criteria established by Regulation(EC) n. 648/2004 on detergents.

##### DIDECYLDIMETHYLAMMONIUM CHLORIDE

Abiotic degradation . Stable hydrolytically (EPA-FIFRA).

Biodegradation:

Modified strum test: 72% - Rapidly biodegradable – Duration of experiment: 28 d (OECD 301B)

CO<sub>2</sub> formation: 81%. Duration of experiment: 28 d (US-EPA)

Die-Away test: 93,3%. Duration of experiment: 28 d

OECD Confirmatory test: 91% - 24. Duration of experiment: 70 d (OECD 303 A)

Zahn-Wellens test: 87 - 94%. Duration of experiment: 28 d

The ingredient, as cationic surfactant, complies with the biodegradability criteria established by Regulation(EC) n. 648/2004 on detergents.

#### **12.2.2. MIXTURE**

No data available.

### **12.3 BIOACCUMULATIVE POTENTIAL**

#### **12.3.1. SUBSTANCES**

##### CHLORHEXIDINE DIGLUCONATE 20% SOLUTION

It is not considered to be bioaccumulable.

##### ISOPROPYL ALCOHOL

It doesn't give significant bioaccumulation phenomena.

##### ETHYL ALCOHOL

No data available.

##### BENZALCONIUM CHLORIDE

No data available.

##### DIDECYLDIMETHYLAMMONIUM CHLORIDE

Does not bioaccumulate: Bioconcentration factor (BCF): 81,00.

Species: Fish – Bluegill salt – Exposure time: 46 d (EPA-FIFRA).

#### **12.3.2. MIXTURE**

No data available.

### **12.4 MOBILITY IN SOIL**

#### **12.4.1. SUBSTANCES**

##### CHLORHEXIDINE DIGLUCONATE 20% SOLUTION

The substance is soluble in water and may diffuse into the aquatic environment.

##### ISOPROPYL ALCOHOL



No data available.

ETHYL ALCOHOL

No data available.

BENZALCONIUM CHLORIDE

No data available.

DIDECYLDIMETHYLAMMONIUM CHLORIDE

No data available.

#### **12.4.2. MIXTURE**

No data available.

#### **12.5 RESULTS OF PBT AND VPVB ASSESMENT**

No data available.

#### **12.6 OTHER ADVERSE EFFECTS**

No data available.

### **13. DISPOSAL CONSIDERATIONS**

Appropriate handling of the waste of the mixture and/or its container must be determined in accordance with the provisions of Directive 2008/98/EC.

#### **13.1 WASTE TREATMENT METHODS**

##### **Residues**

Residues must be handled and eliminate in accordance with the local and National regulations in force.

##### **Dirty empty packaging**

Empty and contaminated packaging must be disposed of according to the local and National regulations in force.

##### **Product**

Dispose of through sewage system.

**Waste codes (Decision 2001/573/EC, Directive 2006/12/EEC, Directive 94/31/EEC relating to hazardous waste):**

15 01 02 Plastic packaging.

18 01 07 Chemical substances other than those mentioned in 18 01 06

### **14. TRANSPORT INFORMATION**

Comply with the rules established by ADR for road transport (ADR 2010), RID for rail transport, IMDG for sea transport (IMDG 2011), ICAO/IATA for air transport (ICAO/IATA 2011).

#### **14.1 UN NUMBER**

1987

#### **14.2 UN SHIPPING NAME**

UN 1987: Alcoli N.A.S.

#### **14.3 HAZARD CLASSES RELATED TO TRANSPORT**

3

#### **14.4 PACKAGING GROUP**

III

#### **14.5 HAZARDS FOR THE ENVIRONMENT**

The solution is not dangerous for the environment.

#### **14.6 SPECIAL PRECAUTIONS FOR USERS**

ADR/RID	Class	Code	Number	Label	Identif.	LQ	Dispo.	EQ	Cat.	Tunnel
	3	F1	III	3	30	5 I	274	E	3	E
IMDG	Class	2° label	Number	LQ	Ems	Dispo.	EQ	Marine pollutant		
	3	-	III	5 I	F-A, S-B	274	E3	NO (NO)		
IATA	Class	2° label	Number							
	3	-	III							

#### **14.7 TRANSPORT DI BULK ACCORDING TO ANNEX II MARPOL 73/78 AND THE IBC CODE**

Not relevant.

### **15. REGULATORY INFORMATION**

#### **15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCES OR MIXTURE**

This safety data sheet complies with the provisions of Regulation (EC) No. 1907/2006 and Regulation No. 453/2010. The hazard classification of the mixture complies with Directive 1999/45/EC and Regulation (EC) No.1272/2008 (CLP Regulation).

#### **15.2 CHEMICAL SAFETY ASSESSMENT**

No chemical safety assessment has been performer for this mixture.

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## 16. OTHER INFORMATION

This complete sheet does not replace the technical information of use. The information contained in it is based on the state of our consciousness related to the product in question, on the date indicated. Users' attention is also drawn to the possible risks in case that a product is used for purposes other than those for which it is intended.

### FULL TEXT OF THE H-PHRASES DRAWN UP IN SECTION 3.

#### H-PHRASES

H225: Highly flammable liquid and vapour.

H302: Harmful if swallowed.

H312: Harmful in contact with skin.

H314: Causes severe skin burns and eye damage.

H319: Causes serious eye irritation.

H336: May causes drowsiness or dizziness.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

#### REVISIONS

00 30 March 2017      First issue

The information contained in this safety data sheet is based on our present knowledge and is supplied in compliance with the provisions of the EC Regulation no. 1907/2006 of 18.12.2006 (REACH). It is always the responsibility of the user to comply with the rules of hygiene, safety and environmental protection required by current legislation. The information contained in this sheet is to be understood as a description of the product characteristics for safety purposes. For any technical information refer to the Technical Data Sheet.