

Safety data sheet

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

1.1. Product identifier

Code: C400888/ C400887/ C401500/ C401520/ C203225/ C203226/ C203227/ C303230/ C203231/
C203232
Product name: SEPARATOR FOR GINGIFAST

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

Intended use: For professional use only. Isolator between two gingival surfaces.

1.3. Details of the supplier of the safety data sheet

Name: Zhermack S.p.a
Full address: Via Bovazecchino 100
District and Country: 45021 Badia Polesine (RO)
Italy

Tel. +39 0425-597611

Fax +39 0425-597689

e-mail address of the competent person

responsible for the Safety Data Sheet

msds@zhermack.com

1.4. Emergency telephone number

For urgent inquiries refer to

CAV Italia: Centro Antiveleni di Milano: 02 66101029; Centro Antiveleni di Pavia: 0382 24444; Centro Antiveleni di Bergamo: 800 883300; Centro Antiveleni di Firenze: 055 7947819; Centro Antiveleni di Roma: 06 3054343; Centro Antiveleni di Roma: 06 49978000; Centro Antiveleni di Napoli: 081 7472870

Servicio de Información Toxicológica (España): + 34 91 562 04 20 (24h/365 días)

Numéro ORFILA (INRS-France): + 33 (0)1 45 42 59 59 (24h/ 7 jours sur 7)

UK Emergency number: 844 892 0111 (24 hours)

Deutschland Notruf: BERLIN Tel.: 030/19240; HOMBURG Tel.: 06841/19240; BONN Tel.: 0228/19240; MAINZ Tel.: 06131/19240; ERFURT Tel.: 0361/730 730; MÜNCHEN Tel.: 089/19240; FREIBURG Tel.: 0761/19240; NÜRNBERG Tel.: 0911/398-2451; GÖTTINGEN

Tel.:0551/19 240

SECTION 2. Hazards identification.

2.1. Classification of the substance or mixture.

The product is classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of EC Regulation 1907/2006 and subsequent amendments. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Flammable liquid, category 2

H225

Highly flammable liquid and vapour.

Eye irritation, category 2

H319

Causes serious eye irritation.

Specific target organ toxicity - single exposure, category 3

H336

May cause drowsiness or dizziness.

2.2. Label elements.

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Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.



Signal words:

Danger

Hazard statements:

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
EUH066	Repeated exposure may cause skin dryness or cracking.

Precautionary statements:

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233	Keep container tightly closed.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves / eye protection / face protection.
P304+P340	IF INHALED: remove person to fresh air and keep comfortable for breathing.
P312	Call a POISON CENTER / doctor if you feel unwell.

Contains: ETHYL ACETATE

2.3. Other hazards.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

SECTION 3. Composition/information on ingredients.

3.1. Substances.

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Conc. %.	Classification 1272/2008 (CLP).
ETHYL ACETATE		
CAS. 141-78-6	70 - 90	Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336, EUH066
EC. 205-500-4		
INDEX. 607-022-00-5		
Reg. no. 01-2119475103-46-XXXX		

Note: Upper limit is not included into the range.

The full wording of hazard (H) phrases is given in section 16 of the sheet.

**C400888/ C400887/ C401500/ C401520/ C203225/ C203226/ C203227/
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EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

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

For symptoms and effects caused by the contained substances, see chap. 11.

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

Information not available.

SECTION 5. Firefighting measures.**5.1. Extinguishing media.****SUITABLE EXTINGUISHING EQUIPMENT**

Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.

UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2. Special hazards arising from the substance or mixture.**HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE**

Excess pressure may form in containers exposed to fire at a risk of explosion. Do not breathe combustion products.

5.3. Advice for firefighters.**GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures.

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Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions.

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up.

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Check incompatibility for container material in section 7. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections.

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage.**7.1. Precautions for safe handling.**

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Vapours may catch fire and an explosion may occur; vapour accumulation is therefore to be avoided by leaving windows and doors open and ensuring good cross ventilation. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. When performing transfer operations involving large containers, connect to an earthing system and wear antistatic footwear. Vigorous stirring and flow through the tubes and equipment may cause the formation and accumulation of electrostatic charges. In order to avoid the risk of fires and explosions, never use compressed air when handling. Open containers with caution as they may be pressurised. Do not eat, drink or smoke during use. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities.

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Store in a well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s).

Information not available.

SECTION 8. Exposure controls/personal protection.

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8.1. Control parameters.

Regulatory References:

AUS	Österreich	Grenzwerteverordnung 2011 - GKV 2011
BEL	Belgique	AR du 11/3/2002. La liste est mise à jour pour 2010
CHE	Suisse / Schweiz	Valeurs limites d'exposition aux postes de travail 2012. / Grenzwerte am Arbeitsplatz
CZE	Česká Republika	Nařízení vlády č. 361/2007 Sb. kterým se stanoví podmínky ochrany zdraví při práci
DEU	Deutschland	MAK-und BAT-Werte-Liste 2012
DNK	Danmark	Graensevaerdier per stoffer og materialer
ESP	España	INSHT - Límites de exposición profesional para agentes químicos en España 2015
FIN	Suomi	HTP-arvot 2012. Haitallisiksi tunnetut pitoisuudet - Sosiaali- ja terveystieteiden tutkimuskeskus julkaisuja 2012:5
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
GRB	United Kingdom	EH40/2005 Workplace exposure limits
IRL	Éire	Code of Practice Chemical Agent Regulations 2011
NLD	Nederland	Databank of the social and Economic Council of Netherlands (SER) Values, AF 2011:18
NOR	Norge	Veiledning om Administrative normer for forurensning i arbeidsatmosfære
POL	Polska	ROZPORZĄDZENIE MINISTRA PRACY I POLITYKI SPOŁECZNEJ z dnia 16 grudnia 2011r
SWE	Sverige	Occupational Exposure Limit Values, AF 2011:18
	TLV-ACGIH	ACGIH 2014

ETHYL ACETATE

Threshold Limit Value.

Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
MAK	AUS	1050	300	2100	600
VLEP	BEL	1461	400		
VEL	CHE	1400	400	2800	800
MAK	CHE	1400	400	2800	800
TLV	CZE	700		900	
AGW	DEU	1500	400	3000	800
MAK	DEU	1500	400	3000	800
TLV	DNK	540	150		
VLA	ESP	1460	400		
HTP	FIN	1100	300	1800	500
VLEP	FRA	1400	400		
WEL	GRB		200		400
OEL	IRL		200		400
OEL	NLD	550		1100	
TLV	NOR	550	150		
NDS	POL	200		600	
MAK	SWE	500	150	1100	300
TLV-ACGIH		1441	400		

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(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

8.2. Exposure controls.

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration. Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

HAND PROTECTION

Protect hands with category III work gloves (see standard EN 374).

Splash contact

Suitable material: nitrile-rubber.

Break through time recommended: 30-60 minutes.

Additional information: the selection of appropriate gloves not only depends on the material, but also on other quality characteristics, and may vary depending on the manufacturer. Please observe information from your glove supplier in terms of permeability and breakthrough time.

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

Consider the appropriateness of providing antistatic clothing in the case of working environments in which there is a risk of explosion.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS.

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties.**9.1. Information on basic physical and chemical properties.**

Appearance	fluid
Colour	opalescent
Odour	typical of solvent
Odour threshold.	Not available.
pH.	Not available.
Melting point / freezing point.	Not available.
Initial boiling point.	73 °C.

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Boiling range.	Not available.
Flash point.	< 21 °C.
Evaporation Rate	Not available.
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Relative density.	0,926 Kg/l
Solubility	Not available.
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.

9.2. Other information.

Information not available.

SECTION 10. Stability and reactivity.
10.1. Reactivity.

There are no particular risks of reaction with other substances in normal conditions of use.

ETHYL ACETATE: decomposes slowly into acetic acid and ethanol under the effect of light, air and water.

10.2. Chemical stability.

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions.

The vapours may also form explosive mixtures with the air.

ETHYL ACETATE: risk of explosion on contact with: metals, alkalis, hydrides, oleum, can react violently with: fluoride, strong oxidising agents, chlorosulfuric acid, potassium tert-butoxide. Forms explosive mixtures with the air.

10.4. Conditions to avoid.

Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition.

ETHYL ACETATE: avoid exposure to light, sources of heat and naked flames.

10.5. Incompatible materials.

ETHYL ACETATE: acids and bases, strong oxidising agents; aluminium and some plastics, nitrates and chlorosulphuric acid.

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In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

SECTION 11. Toxicological information.**11.1. Information on toxicological effects.**

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification. It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

Acute effects: stinging eyes. Symptoms may include: rubescence, edema, pain and lachrymation. Ingestion may cause health problems, including stomach pain and sting, nausea and sickness.

This product contains highly volatile substances, which may cause serious depression of the central nervous system (CNS) and have negative effects, such as drowsiness, dizziness, slow reflexes, narcosis.

This product may have a degreasing action on the skin, producing dryness and chapped skin after repeated exposure.

ETHYL ACETATE

LD50 (Oral).5620 mg/kg (rat, MSDS supplier).

LD50 (Dermal).> 18000 mg/kg (rabbit, MSDS supplier).

LC50 (Inhalation).45000 mg/m3 (mouse, 2h, MSDS supplier).

Irritation/Corrosion

Skin irritation: Can cause irritation and dermatitis (SDS supplier).

Eye irritation: No data available (SDS supplier). Irritant according to the harmonized classification (Annex VI, Reg. 1272/2008/EC).

Respiratory or skin Sensitization: No data available (SDS supplier).

STOT – Repeated exposure: Depression of central nervous system, may cause drowsiness or dizziness (MSDS supplier).

Genotoxicity: No data available (SDS supplier).

Carcinogenicity: Negative according to IARC classification (SDS supplier).

Toxicity to reproduction: No data available (SDS supplier).

Aspiration toxicity: No data available (SDS supplier).

SECTION 12. Ecological information.

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity.**ETHYL ACETATE**

EC50 - for Crustacea. 560 mg/l/48h (Daphnia magna, MSDS supplier).

EC50 - for Algae / Aquatic Plants. 1200 mg/l/72h (Selenastrum, MSDS supplier).

LC10 for Fish. 350 mg/l/96h (Oncorhynchus mykiss (rainbow trout), MSDS supplier).

12.2. Persistence and degradability.**ETHYL ACETATE**

Solubility in water. > 10000 mg/l

Rapidly biodegradable.

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ETHYL ACETATE

Partition coefficient: n-octanol/water.	0,68
BCF.	30

12.4. Mobility in soil.

Information not available.

12.5. Results of PBT and vPvB assessment.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects.

Information not available.

SECTION 13. Disposal considerations.**13.1. Waste treatment methods.**

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

Waste transportation may be subject to ADR restrictions.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information.**14.1. UN number.**

ADR / RID, IMDG, IATA:	1866
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14.2. UN proper shipping name.

ADR / RID:	RESIN SOLUTION
IMDG:	RESIN SOLUTION
IATA:	RESIN SOLUTION

14.3. Transport hazard class(es).

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ADR / RID: Class: 3 Label: 3

IMDG: Class: 3 Label: 3

IATA: Class: 3 Label: 3

**14.4. Packing group.**

ADR / RID, IMDG, IATA: II

14.5. Environmental hazards.

ADR / RID: NO

14.6. Special precautions for user.

ADR / RID:	HIN - Kemler: 33	Limited Quantities 5 L	Tunnel restriction code (D/E)
	Special Provision: 640C		
IMDG:	EMS: F-E, S-E,	Limited Quantities 5 L	
IATA:	Cargo:	Maximum quantity: 60 L	Packaging instructions: 364
	Pass.:	Maximum quantity: 5 L	Packaging instructions: 353
	Special Instructions:	A3	

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code.

Information not relevant.

SECTION 15. Regulatory information.**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.**Seveso category. 7bRestrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.Product
Point. 3 - 40Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

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Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None.

Substances subject to the Rotterdam Convention:

None.

Substances subject to the Stockholm Convention:

None.

Healthcare controls:

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

SECTION 16. Other information.

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Flam. Liq. 2	Flammable liquid, category 2
Eye Irrit. 2	Eye irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
EUH066	Repeated exposure may cause skin dryness or cracking.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006

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- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EU) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
 4. Regulation (EU) 2015/830 of the European Parliament
 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
- The Merck Index. - 10th Edition
 - Handling Chemical Safety
 - INRS - Fiche Toxicologique (toxicological sheet)
 - Patty - Industrial Hygiene and Toxicology
 - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
 - ECHA website

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:

The following sections were modified:

01 / 02 / 08 / 09 / 11 / 12 / 14.