Z	hermack S.p.a	Revision nr. 4 Dated 29/09/2016
C302070/ C3020	Printed on 03/10/2016	
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	Safety data sheet	
SECTION 1. Identification of the	substance/mixture and of the compan	y/undertaking.
1.1. Product identifier.		
Code:	C302070/ C302071/ C302075	
Product name.	HYDROGUM 5	
1.2. Relevant identified uses of the substand Intended use.For profession	<u>ce or mixture and uses advised against.</u> al use only. Alginate for dental impression.	
1.3. Details of the supplier of the safety data		
Name. Full address.	Zhermack S.p.a 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	
<u>1.4. Emergency telephone number.</u> For urgent inquiries refer to.	0039 0425597611	

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: Specific target organ toxicity - repeated exposure, category 2 H373

May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements.

The Regulation EC 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP), shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 1.5, letter d). Therefore the product is exempted from the CLP labeling requirements.

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

Hazard pictograms:

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~		
V		
Signal words:	Warning	
azard statements:		
H373	May cause damage to lungs through prolonged or repeated exposure. Route	of exposure: inhalation.
ecautionary statements		
-		
P260 P305+P351+P338	Do not breathe dust / fume / gas / mist / vapours / spray. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact	t lenses, if present and easy to do. Continue
D244	rinsing.	· · · · · , , · · · · · · · · · · · · ·
P314	Get medical advice / attention if you feel unwell.	
Contains:	CRISTOBALITE	
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%.

Classification of the mixture is based on the results of an in vitro assay conducted in accordance with the guidelines provided by OCSE (OECD Test Guideline 437 resp. EU Method B.47 – Bovine Corneal Opacity and Permeability (BCOP) Test Method) and GLP certified - Good Laboratory Practices. For more information refer to section 11.

SECTION 3. Composition/information on ingredients.

3.1. Substances.

Information not relevant.

3.2. Mixtures.

Contains:

ľ	Jontains.		
	Identification.		Classification 1272/2008 (CLP).
	CRISTOBALITE		
	CAS. 14464-46-1	1 ≤ x < 8	STOT RE 1 H372
	EC. 238-455-4		
	INDEX		
	DIPOTASSIUM HEXAFLUOTOTITANATE		
	CAS. 16919-27-0	1≤x< 3	Acute Tox. 4 H302, Eye Dam. 1 H318
	EC. 240-969-9		
	INDEX		
	Reg. no. 01-2119978268-20-XXXX		
	ISOPENTYL ACETATE		
	CAS. 123-92-2	$0 \le x < 0,2$	Flam. Liq. 3 H226, EUH066
	EC. 204-662-3		

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

SECTION 4. First aid measures.

4.1. Description of first aid measures.

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. Rinse skin with a shower immediately. Get medical advice/attention immediately. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately. INGESTION: Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

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

Specific information on symptoms and effects caused by the product are unknown. 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 The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray. UNSUITABLE EXTINGUISHING EQUIPMENT None in particular.

5.2. Special hazards arising from the substance or mixture.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products. The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

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).

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SECTION 6. Accidental release measures.

6.1. Personal precautions, protective equipment and emergency procedures.

If there are no contraindications, spray powder with water to prevent the formation of dust. 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 and place it in containers for recovery or disposal. If the product is flammable, use explosion-proof equipment. If there are no contraindications, use jets of water to eliminate product residues.

Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. 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.

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

7.2. Conditions for safe storage, including any incompatibilities.

Store only in the original container. Store the containers sealed, in a well ventilated place and dry place, away from direct sunlight (storage temperature: 5-27° C). Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s).

See section 1.2.

SECTION 8. Exposure controls/personal protection.

8.1. Control parameters.

Regulatory References:

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	C302070/ C	302071/ C302075 - HYDROGUM 5	Printed on 03/10/2016 Page n. 5/13
BEL DNK FRA HUN IRL ITA NLD	Belgique Danmark France Magyarország Éire Italia Nederland	AR du 11/3/2002. La liste est mise à jour pour 2010 Graensevaerdier per stoffer og materialer JORF n°0109 du 10 mai 2012 page 8773 texte n° 10 50/2011. (XII. 22.) NGM rendelet a munkahelyek kém Code of Practice Chemical Agent Regulations 2011 Decreto Legislativo 9 Aprile 2008, n.81 Databank of the social and Economic Concil of Nethe	iai biztonságáról
SWE	Sverige	AF 2011:18 Occupational Exposure Limit Values, AF 2011:18	

Sverige	Occupational Exposure Limit Values, AF 2011:18
OEL EU	Directive 2009/161/EU; Directive 2006/15/EC; Directiv

ACGIH 2016

Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC.

TLV-ACGIH

CRISTOBALITE						
Threshold Limit Value. Type	Country	TWA/8h		STEL/15min		
		mg/m3	ppm	mg/m3	ppm	
VLEP	BEL	0,05				RESP.
TLV	DNK	0,15				RESP.
VLEP	FRA	0,05				RESP.
AK	HUN	0,15				RESP.
OEL	IRL	0,1				RESP.
VLEP	ITA	0,05				(USA-NIOSH)
MAC	NLD	0,075				RESP.
MAK	SWE	0,05				RESP.
TLV-ACGIH		0,025				

DIPOTASSIUM HEXAFLUOTOTITANATE

Predicted no-effect concentration - PNEC.							
Normal value in fresh water Normal value in marine water Normal value for fresh water sediment Normal value for marine water sediment Normal value of STP microorganisms Normal value for the terrestrial compartment			0,131 0,131 24,45 4,89 1,51 19,1		mg/l mg/l mg/kg mg/kg mg/l mg/kg	/d	
Health - Derived no-effect level - DNEL / DMEL				, i		0.0	
Route of exposure	Effects on consumers. Acute local	Acute systemic	Chronic local	Chronic systemic	Effects on workers Acute local	Acute systemic	Chronic local
Inhalation.				,	VND	5,2 mg/m3	5,2 mg/m3

Skin.

EU

ISOPENTYL ACETATE STEL/15min Туре TWA/8h Country mg/m3 mg/m3 ppm ppm MAK SWE 500 100 800 150 INHAL. OEL EU 270 50 540 100 INHAL. Predicted no-effect concentration - PNEC. Normal value in fresh water 0,022 mg/l 0,0022 Normal value in marine water mg/l Normal value for fresh water sediment 17,87 mg/kg Normal value for marine water sediment Normal value for water, intermittent release Normal value of STP microorganisms 1,787 mg/kg 0,22 mg/l 30 mg/l

Chronic systemic

75 mg/kg

bw/d

VND

VND

5,2 mg/m3

75 mg/kg

bw/d

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Normal value for the terrestrial compartment	4,15		mg/kg		
Health - Derived no-effect level - DNEL / DMEL Effects on		Effects on			
Route of exposure Acute local Acute systemic C	Chronic local Chror		Acute systemic	Chronic local	Chronic systemic
Oral.	VND 1,47 r	ng/kg/d	·		,
Inhalation.	VND 5,1 m	g/m3		VND	20,8 mg/m3
Skin. V	VND 1,47 r	ng/kg/d		VND	2,85 mg/kg/d

Legend:

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

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

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.

Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).

HAND PROTECTION

In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374). Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.

SKIN PROTECTION

Wear category II 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.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

Use a type P filtering facemask (see standard EN 149) or equivalent device, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment.

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	powder
Colour	violet
Odour	mangustan
Odour threshold.	Not available.
pH.	Not applicable.
Melting point / freezing point.	Not available (Melting point). Not applicable (freezing point).
Initial boiling point.	Not applicable.
Boiling range.	Not applicable.
Flash point.	Not available.

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Evaporation Rate Flammability of solids and gases Lower inflammability limit. Upper inflammability limit. Lower explosive limit. Upper explosive limit. Vapour pressure. Vapour density Relative density. Solubility Partition coefficient: n-octanol/water Auto-ignition temperature. Decomposition temperature. Viscosity Explosive properties Oxidising properties

Not available. 0,2-0,5 g/cm3 partially soluble in water Not available. Not available. Not available. Not applicable. Not available. 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.

10.2. Chemical stability.

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

10.3. Possibility of hazardous reactions.

The powders are potentially explosive when mixed with air.

10.4. Conditions to avoid.

Avoid environmental dust build-up. Avoid moisture and high temperatures.

10.5. Incompatible materials.

Not known.

Not available.

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10.6. Hazardous decomposition products.

Not known.

SECTION 11. Toxicological information.

11.1. Information on toxicological effects.

ACUTE TOXICITY.

LC50 (Inhalation - vapours) of the mixture: Not classified (no significant component).

LC50 (Inhalation - mists / powders) of the mixture: Not classified (no significant component).

LD50 (Oral) of the mixture:12960,000 mg/kg

LD50 (Dermal) of the mixture: Not classified (no significant component).

SKIN CORROSION / IRRITATION.

Does not meet the classification criteria for this hazard class.

SERIOUS EYE DAMAGE / IRRITATION.

Does not meet the classification criteria for this hazard class (INTERNAL TEST (Bridging Principle) - Negative (OECD 437 resp. EU Method B.47, GLP, in vitro, study report 2014).

RESPIRATORY OR SKIN SENSITISATION.

Does not meet the classification criteria for this hazard class.

GERM CELL MUTAGENICITY. Does not meet the classification criteria for this hazard class.

CARCINOGENICITY

Does not meet the classification criteria for this hazard class.

REPRODUCTIVE TOXICITY. Does not meet the classification criteria for this hazard class.

STOT - SINGLE EXPOSURE.

Does not meet the classification criteria for this hazard class.

STOT - REPEATED EXPOSURE.

May cause damage to organs.

ASPIRATION HAZARD.

Does not meet the classification criteria for this hazard class.

CRISTOBALITE

LD50 (Oral).> 2000 mg/kg (OECD 401, rat, MSDS supplier) LC50 (Inhalation).> 2,6 mg/l (OECD 403, rat, MSDS supplier) Irritation/Corrosion Skin irritation: Not irritating (MSDS supplier). Eye irritation: Not irritating (MSDS supplier). Sensitization: Not sensitizing (MSDS supplier). Mutagenicity: No data available. Carcinogenicity: No data available.

Toxicity to reproduction: No data available.

STOT Repeated Exposure:

In 1997, IARC (the International Agency for Research on Cancer) concluded that crystalline silica inhaled from occupational sources can cause lung cancer in humans. However it pointed out that not all industrial circumstances, nor all crystalline silica types, were to be incriminated (IARC Monographs on the evaluation of the carcinogenic risks of chemicals to humans, Silica, silicates dust and organic fibres, 1997, Vol. 68, IARC, Lyon, France).

In June 2003, SCOEL (the EU Scientific Committee on Occupational Exposure Limits) concluded that the main effect in humans of the inhalation of respirable crystalline silica dust is silicosis. "

There is sufficient information to conclude that the relative risk of lung cancer is increased in persons with silicosis (and, apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefore preventing the onset of silicosis will also reduce the cancer risk..." (SCOEL SUM Doc 94-final, June 2003).

There is a body of evidence supporting the fact that increased cancer risk would not be limited to people already suffering from silicosis. According to the current state of the art, worker protection against silicosis can be consistently assured by respecting the existing regulatory occupational exposure limits. Occupational exposure to nuisance dust (total and respirable) and respirable crystalline silica should be monitored and controlled.

DIPOTASSIUM HEXAFLUOTOTITANATE Acute Toxicity Inhalation: No data available. Dermal: No data available. Irritation/Corrosion Skin irritation: Not irritating (OECD 404, in vivo, rabbit, MSDS supplier).

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Eye irritation: Corrosive (OECD 405, in vivo, rabbit, MSDS supplier). Skin sensitization: Not sensitising (OECD 406, GLP, Guinea pig maximisation test, MSDS supplier). STOT Repeated/single exposure: No data available. Genotoxicity in vitro: Negative (OECD 471, Test di Ames); Positive (OECD 487,476; chromosomic aberration) (MSDS supplier). Genotoxicity in vivo: Positive (OECD 474, rat, SDS supplier). Carcinogenicity: No data available. Toxicity to reproduction: No data available.

SECTION 12. Ecological information.

12.1. Toxicity.

 DIPOTASSIUM

 HEXAFLUOTOTITANATE

 LC50 - for Fish.

 172,4 mg/l/96h (OECD 203, Brachydanio rerio, SDS supplier).

 EC50 - for Crustacea.

 48,2 mg/l/48h (OECD 203, Daphnia magna, SDS supplier).

 EC50 - for Algae / Aquatic

 Plants.

12.2. Persistence and degradability.

CRISTOBALITE

NOT rapidly biodegradable.

DIPOTASSIUM HEXAFLUOTOTITANATE NOT rapidly biodegradable.

12.3. Bioaccumulative potential.

Information not available.

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.

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13.1. Waste treatment methods.

Reuse, when possible. Product residues should be considered special hazardous waste (HP 5). 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. CONTAMINATED PACKAGING

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

SECTION 14. Transport information.

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number.

Not applicable.

14.2. UN proper shipping name.

Not applicable.

14.3. Transport hazard class(es).

Not applicable.

14.4. Packing group.

Not applicable.

14.5. Environmental hazards.

Not applicable.

14.6. Special precautions for user.

Not applicable.

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14.7. Transport in bulk according to Annex II of Marpol 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 - Directive 2012/18/EC:

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

None.

Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisarion (Annex XIV REACH).

None.

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. 3	Flammable liquid, category 3
Acute Tox. 4	Acute toxicity, category 4
STOT RE 1	Specific target organ toxicity - repeated exposure, category 1
STOT RE 2	Specific target organ toxicity - repeated exposure, category 2

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Eye Dam. 1	Serious eye damage, category 1
Eye Irrit. 2	Eye irritation, category 2
H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
EUH066	Repeated exposure may cause skin dryness or cracking.
 CAS NUMBER: Chemical A CE50: Effective concentrati CE NUMBER: Identifier in E CLP: EC Regulation 1272/2 DNEL: Derived No Effect Li EmS: Emergency Schedule GHS: Globally Harmonized IATA DGR: International Ai IC50: International Maritime INDEX NUMBER: Identifier LC50: Lethal Concentration LD50: Lethal Concentration DD50: Lethal dose 50% OEL: Occupational Exposu PBT: Persistent bioaccumu PEC: Predicted environmer PEL: Predicted exposure le PNEC: Predicted no effect REACH: EC Regulation 199 RID: Regulation concerning TLV: Threshold Limit Value TLV CEILING: Concentration WAS TEL: Short-term exp TWA: Time-weighted avera VOC: Volatile organic Com vPvB: Very Persistent and 9 WGK: Water hazard classe GENERAL BIBLIOGRAPHY Regulation (EU) 1907/200 Regulation (EU) 1907/200 Regulation (EU) 1907/200 Regulation (EU) 1907/200 	ion (required to induce a 50% effect) ESIS (European archive of existing substances) 2008 evel 3 I System of classification and labeling of chemicals r Transport Association Dangerous Goods Regulation entration 50% ne Code for dangerous goods e Organization r in Annex VI of CLP 1 50% rre Level lative and toxic as REACH Regulation ntal Concentration 07/2006 g the international transport of dangerous goods by train on that should not be exceeded during any time of occupational exposure. bosure limit ge exposure limit pounds very Bioaccumulative as for REACH Regulation as (German).
 Regulation (EU) 487/2013 Regulation (EU) 944/2013 Regulation (EU) 944/2013 Regulation (EU) 605/2014 The Merck Index 10th Ed Handling Chemical Safety INRS - Fiche Toxicologique Patty - Industrial Hygiene a 	e (toxicological sheet)
	quired for this product under article 31 of Regulation 1907/2006/EC. een created on a voluntary basis.

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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 / 03 / 04 / 07 / 08 / 09 / 10 / 11 / 12 / 13 / 14 / 15 / 16.