Personal Protective Equipment

Safety Data Sheet & Test Report Document

Including:

- Face Masks
  - *KN95*
  - *Type 11R*
  - *3 Ply*
- Face Shields
- Hand Sanitiser
- Aprons

KN95 FACE MASKS

Our KN95 masks are currently tested to GB2626-2006 standards, demonstrating an effectiveness of filtering 95%+ of particles with a mass median diameter of 0.3 micro meters.

They are also tested to EN14683 - The EU standard for medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements.

EN14683 test reports are due imminently.

No.

CMA 201719002006

ilac-MRA

CNAS

中国认可
国际互认
检测
TESTING
CNAS L0153

2017(粤)质监认字039号

检 测 报 告

TEST REPORT

委托方 Commissioned by	
生产单位 Factory	
样品名称 Name of Sample	99_95A 折叠口罩/KN95 折叠口罩/Daily protective masks(Not Sterile)
型号规格 Type, Specification	99_95A
检测类别 Testing Purpose	委托检测 Commission

广东产品质量监督检验研究院

GUANGDONG TESTING INSTITUTE OF PRODUCT QUALITY SUPERVISION

No.

广 东 产 品 质 量 监 督 检 验 研 究 院

GUANGDONG TESTING INSTITUTE OF PRODUCT QUALITY SUPERVISION

检测报告

TEST REPORT

报告随机号 Security Code：

样品名称 Name of Sample	99_95A 折叠口罩/KN95 折叠口罩 /Daily protective masks(Not Sterile)		样品编号 Sample number	
	送样（√） Sending	抽样（/） sampling		
商标 Trade mark	---		型号规格 Type, Specification	99_95A
委托方 Commissioned by			检测类别 Testing Purpose	委托检测 Commission
委托方地址 Address of client			产品编号/批号 Product No. / batch No	---
生产单位 Factory			抽样单编号 Sampling list No	---
受检单位 Inspected unit			生产日期 Date of manufacture	---
抽样单位 Sampling unit	---		样品数量 Quantity of sample	35(个) 35（Piece）
抽样地点 Location of sampling	---		抽样基数 Basic quantity of sampling	---
抽样日期 Date of sampling	---		检验地点 Location of testing	本部实验室 Laboratory
收样日期 Date of receiving	2020 年 04 月 10 日		检验日期 Date of testing	2020 年 04 月 10 日～ 2020 年 04 月 20 日
检测依据 Testing reference	GB 2626-2006《呼吸防护用品 自吸过滤式防颗粒物呼吸器》 GB 2626-2006 Respiratory protective equipment. Non-powered air-purifying particle respirator			
判定依据 Judging reference	---			
检测结论 Remarks	见检测结果。 Test results are attached as below. （检验检测专用章） 签发日期：2020 年 04 月 20 日			
备注 Notes	报告中的“---”表示此项不适用，报告中“/”表示此项空白。 "--" in the report indicates that this item is not applicable, and "/" in the report indicates that this item is blank.			

批准： 审核： 主检：

No.

检 测 报 告
TEST REPORT

序号 No	检测项目[单位] Test items[Unit]	标准条款 Standard terms	标准要求 Standard requirements	检测结果 Result		单项结论 Conclusion	备注 Notes
1	过滤效率[%] Filtering efficiency[%]	5.3	KN95 ≥ 95.0	未预处理 Unpretreated	99.6	合格 Pass	/
					99.6		
					99.7		
					99.7		
					99.6		
					99.6		
					99.5		
					99.6		
					99.5		
					99.5		
				预处理 Pretreated	99.6		
					99.7		
					99.6		
					99.5		
					99.5		
			氯化钠颗粒物检测 Detection of NaCl particles 温度 Temperature: （25±5）℃ 湿度 Humidity: （30±10）%	实测温度 Measured temperature: （26）℃ 实测湿度 Measured Humidity: （35）%			
2	吸气阻力[Pa] Inhale resistance[Pa]	5.5	总吸气阻力≤350 Total inhale resistance≤350	未预处理 Unpretreated	153.2	合格 Pass	/
					160.1		
				预处理 Pretreated	156.7		
					158.9		
3	呼气阻力[Pa] Exhalation resistance[Pa]	5.5	总呼气阻力≤250 Total exhalation resistance≤250	未预处理 Unpretreated	129.2	合格 Pass	/
					138.4		
				预处理 Pretreated	131.5		
					134.5		

No.

检 测 报 告
TEST REPORT

序号 No	检测项目[单位] Test items[Unit]	标准条款 Standard terms	标准要求 Standard requirements	检测结果 Result		单项结论 Conclusion	备注 Notes
4	死腔[%] Dead cavity[%]	5.7	以吸入气中二氧化碳体积分数表示时，结果平均值应≤1 When expressed as the volume fraction of carbon dioxide in the inhaled air, the average value of the results should be ≤ 1	平均值 Average：1.0		合格 Pass	/
5	头带 Headband	5.9	随弃式面罩的每条头带、带扣及其他调节部件在承受 10N，持续时间 10s 的拉力时，不应出现滑脱或断裂 Each headband, buckle and other adjustment parts of the disposable mask should not slip or break when it bears a tensile force of 10N for 10s.	未预处理 Unpretreated	未出现滑脱、断裂 No slippage or fracture	合格 Pass	/
				预处理 Pretreated	未出现滑脱、断裂 No slippage or fracture		
6	可燃性 Flammability	5.13	暴露于火焰的各部件在从火焰移开后，不应燃烧；如果燃烧，续燃时间不应超过 5s After being removed from the flame, the parts exposed to the flame should not burn. If burning, the after burning time should not exceed 5s	未预处理 Unpretreated	未出现燃烧现象 Unburned	合格 Pass	/
					未出现燃烧现象 Unburned		
				预处理 Pretreated	未出现燃烧现象 Unburned		
					未出现燃烧现象 Unburned		

中凯检测
ZKT TEST

案件受理回执

2020 年 04 月 16 日收到客户案件申请，已受理，特发此回执，请妥协保管；

客户：

产品名称： KN95 折叠口罩

产品型号：99_95A；KN95

申请标准：TUV-CE EN149

若有其他疑问或者需要解决的内容，请提前准备相关文件资料。

深圳市中凯检测技术有限公司

2020-04-16

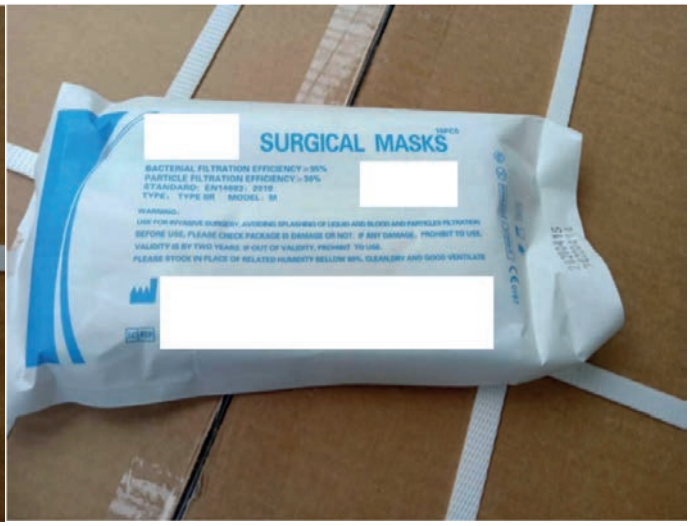
深圳市中凯检测技术有限公司/ Shenzhen ZKT Technology Co., Ltd.
地址：深圳市宝安区福海街道塘尾社区工业大道 6 号 B 栋 101（一层）中凯检测
1/F, No. 101, Building B, No. 6, Tangwei Community Industrial Avenue, Fuhai Street, Bao'an District, Shenzhen, China
Http://www.zkt-lab.com E-mail:zkt@zkt-lab.com Tel: 0086-400 000 9970

Type IIR FACE MASKS

Our Type IIR surgical face masks are tested to EN14683 - The EU standard for medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements.

The factory is also ISO 13485:2016 accredited - which specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

These masks are also CE Certified.



TEST REPORT

Sample Description	:	Surgical masks
Sample Quantity	:	50 pieces
Lot Number/Batch Code	:	
Specification	:	M
Size	:	/
Type of Mask	:	Type
Brand Name	:	IIR /

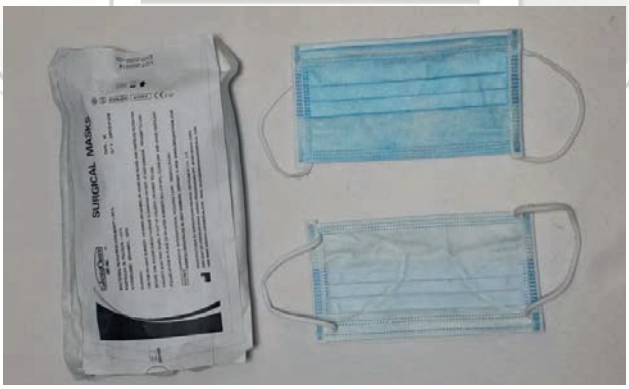
Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Standard	Judgement
1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass
2	Differential Pressure Test	EN 14683:2019+AC:2019(E) Annex C	Pass
3	Synthetic Blood Penetration Test	ISO 22609:2004	Pass
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E) Annex D	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
# = No comment;
N.D. = Not detected.

Photo of Samples



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Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.9% Specimen 2#: 99.9% Specimen 3#: 99.8% Specimen 4#: 99.8% Specimen 5#: 99.7%
2	Differential Pressure Test	25.3 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~13#: None seen
4	Microbial Cleanliness Test	Specimen 1#: 22 CFU/g Specimen 2#: 14 CFU/g Specimen 3#: 10 CFU/g Specimen 4#: 8 CFU/g Specimen 5#: 10 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of mask.

2. Sample description was given by client

Sample description : Surgical masks
Specification : M
Lot Number
Sample Receiving Date : 2020-03-28

3. Test Method

EN 14683:2019+AC:2019(E) Annex B

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 6538.
4.2 Peptone water.
4.3 Tryptic Soy Broth(TSB).
4.4 Tryptic Soy Agar(TSA).
4.5 Bacterial filtration efficiency test apparatus.
4.6 Six-stage viable particle Anderson sampler.
4.7 Flow meters.

5. Test specimen

5.1 As requested by client, take a total of 5 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
6.4 Perform a positive control run without a test specime to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.
  6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediaterly begin sampling the aerosol using the Anderson sampler.
  6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
  6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
  6.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen facing towards the bacterial challenge (test area: 77cm^2).
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control after completion of the sample set.
6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
6.9 Incubate agar plates at (37±2)°C for (20 to 52) h.
6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$BFE=(C-T) / C \times 100$$

T is the total plate count for the test specimen.

C is the mean of the total plate counts for the two positive controls.

8. Test results*

P Value / Stage Number	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	15	19	0	0	0	0	0	0
2	28	33	0	0	0	0	0	0
3	49	75	0	0	0	0	0	0
4	250	180	0	0	0	0	1	0
5	942	1036	0	0	1	3	2	5
6	426	874	0	1	2	1	1	2
Total (*T*), CFU	1710	2217	<1	1	3	4	4	7
Average (*C*), CFU	$2.0x10^3 = (P_A+P_B) / 2$							
BFE ,%				99.9	99.9	99.8	99.8	99.7
Requirements	≥ 98							
Remarks	*P* is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. *T* is the total of *P* value for the test specimen. *C* is the mean of the total of *P* value of the two positive controls.							

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Differential pressure Test

1.Purpose

The purpose of the test was to measure the differential pressure of masks.

2.Sample description was given by client

Sample description : Surgical masks
Specification : M
Lot Number
Sample Receiving Date : 2020-03-28

3.Test Method

EN 14683:2019+AC:2019(E) Annex C

4. Apparatus and materials

Differential pressure testing instrument

5.Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5) °C and (85±5)% relative humidity.

6. Procedure

6.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 L/min.
6.2 The pretreated specimen is placed across the orifice (total area 4.9cm^2, test area diameter 25mm) and clamped into place so as to minimize air leaks.
6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.
6.4 The differential pressure is read directly.
6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

Results:

Specimen	Test Results* (Pa/cm^2)	Average (Pa/cm^2)	Requirements	Judgement
1#	23.9	25.3	< 60	Pass
2#	28.8			
3#	23.3			
4#	25.7			
5#	24.6			

Synthetic Blood Penetration Test

1.Purpose

For evaluation of resistance of masks to penetration by a fixed volume of synthetic blood at a high velocity.

2.Sample description was given by client

Sample description	:	Surgical masks
Specification	:	M
Lot Number	:	
Sample Receiving Date	:	2020-03-28

3.Test Method

ISO 22609:2004

4.Apparatus and materials

4.1 Synthetic blood.
4.2 Tensiometer.
4.3 Synthetic blood penetration test apparatus;
4.4 Targeting plate.
4.5 Air pressure source.
4.6 Ruler.
4.7 Balance.
4.8 Controlled temperature and humidity chamber.

5.Test specimen

5.1 As requested by client, take a total of 13 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4h at (21±5)°C and (85±5) % relative humidity.

6.Procedure

6.1 Prepare the synthetic blood (40~44 mN/m) for the test.
6.2 Determine the density of the synthetic blood.
6.3 Fill the reservoir with new synthetic blood.
6.4 Position the test specimen 30.5 cm (12 in.) from the exit of the canula.
6.5 Set the reservoir pressure to the approximate pressure.
6.6 Place the targeting plate approximately 1 cm away from the mask.
6.7 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

6.8 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

6.9 Calculate the difference in weight of the two spurts. For a test fluid with a density of 1.003, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2% of the target.

Table 1 Target weight difference

Fluid Pressure (mmHg)	Weight difference for 1s difference in spurt duration (g)		
	Min.	Target	Max.
120	3.002	3.063	3.124

6.10 Adjust the reservoir pressure and repeat steps 6.7 to 6.9 until the weight difference is within the target range.

6.11 Record the weight difference for the spurts exiting the nozzle.

6.12 Record the pressure in the reservoir.

6.13 Set the valve time to 0.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.14 Set the valve time to 1.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.15 The difference in weight between the 0.5 s and 1.5 s spurts through the targeting plate shall be within +2 % ~ -5 % of the difference in weight from the nozzle.

6.16 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.

6.17 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 6.7 to 6.11).

6.18 For standard synthetic blood, the timer duration can be estimated using the formula:
(p is the density of the test fluid.) t = 0.5 + (2× p - g at 0.5 s) / (g at 1.5 s - g at 0.5 s).

6.19 Record the timer setting to use as the starting point for subsequent testing.

6.20 Mount a test specimen on the specimen holding fixture. If the mask contains pleats, spread the pleats out when mounting the mask onto the fixture to present a single layer of material as the target area.

6.21 Squirt the synthetic blood onto the test specimen for the calculated time. Ensure that the synthetic blood hits the target area of mask.

6.22 Inspect the inside surface for synthetic blood penetration within 10 s of squirting the synthetic blood against the target area.

6.23 Report the results (none / penetration) for each test specimen at the test pressure.

Results:

Specimen	Test Results*	Requirements	Judgement
1#	None Seen	Pass Pressure at 16.0 kPa (120mmHg)	Pass
2#	None Seen		Pass
3#	None Seen		Pass
4#	None Seen		Pass
5#	None Seen		Pass
6#	None Seen		Pass
7#	None Seen		Pass
8#	None Seen		Pass
9#	None Seen		Pass
10#	None Seen		Pass
11#	None Seen		Pass
12#	None Seen		Pass
13#	None Seen		Pass

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Microbial Cleanliness Test

1. Purpose

The purpose of the test was to measure microbial cleanliness of mask.

2. Sample description was given by client

Sample description : Surgical masks

Specification : M

Lot Number

Sample Receiving Date : 2020-03-28

3. Test Method

According to EN ISO 11737-1:2018 to determine the microbial cleanliness of mask material, and refer to the procedure as described in EN 14683:2019+AC:2019(E) Annex D

4. Apparatus and materials

4.1 Orbital shaker.
4.2 0.45 um filter.
4.3 Tryptic Soy Agar (TSA).
4.4 Sabouraud Dextrose Ager (SDA) with chloramphenicol.
4.5 Formula of Extraction Liquid: 1g/L peptone, 5g/L NaCl and 2g/L Tween 20.
4.6 Extraction apparatus.

5. Test specimen

5.1 As requested by client, take a total of 5 mask samples.
5.2 Mask samples for testing are provided in the original primary packaging.
5.3 Condition at (18 to 26)℃ and (45 to 65)% relative humidity during testing.

6. Procedure

6.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.
6.2 The mask is aseptically removed from the packaging and placed in a sterile 500 mL bottle containing 300 mL of extraction liquid.
6.3 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
6.4 After extracting, 100mL of the extraction liquid is filtered through a 0.45 um filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 mL aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDA for fungi enumeration.
6.5 The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively.
6.6 Calculate the colonies of each agar plate.

7. Calculation

For each test specimen calculate the microbial cleanliness as follows by counting the total colonies of the TSA and SDA plates.

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Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	19	3	22	According to EN ISO 11737-1:2018 the microbial cleanliness of the mask shall be ≤30 CFU/g tested.	Pass
2#	11	3	14		
3#	8	8	8		
4#	6	2	8		
5#	7	3	10		

Note:

1.*denotes this test was carried out by external laboratory assessed as competent.

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

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SUBJECT	**Physical & Microbiological Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	
CLIENT ADDRESS	
TEST PERIOD	28-Mar-2020~06-Apr-2020

Prepared By	**Authorized By**
Bella Xu	Leo liu
(Bella Xu) Report Drafter	(Leo Liu) Authorized Signatory

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TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Medical Devices

(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-03-24

Certificate Registration No.:

An audit was performed. Report No.:

This Certificate is valid until: 2023-01-31

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-03-24

Fuxiu Sheng

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TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate Registration No.:
Report No.:

Organization:

Scope:

Products:
Sterile Syringes for Single Use, Sterile Infusion Sets for Single Use (Sterile Infusion Sets with Needles, Sterile Bag Type Infusion Sets with Needles, Disposable Infusion Sets with Precision Filters, Disposable Precise Filter Light-resistant Infusion Sets, Disposable Flow Trimming Precision Filter Infusion Sets With Needles, Disposable Fluid Automatic Stopped Infusion Sets With Needles), Sterile Hypodermic Needles for Single Use, Sterile Intravenous Needles for Single Use, Disposable Blood Transfusion Sets, Disposable I.V. Catheters, Disposable Venous Blood Collection Needles, Disposable Nasal Oxygen Cannulas, Sterile Insulin Syringes for Single Use, Sterile Retraction Type Safety Syringes for Single Use, Disposable Safety Intravenous Catheters, Tracheal Tubes for Single Use, Breathing Tubes, Disposable Oxygen Masks, Disposable Stomach Tube Kits, Disposable Endotracheal Intubation Kits, Medical Laryngeal Masks, Anesthesia Masks, Heat and Moisture Exchangers

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2020-03-24

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate Registration No.:
Report No.:

Organization:

Scope:

Products:
Syringes for Fixed-Dose immunization with Retractable Needles, Disposable Heparin Caps, Disposable Urethral Catheter Kits, Disposable Drainage Bags, Disposable Medical Pads, Medical Caps, Surgical Masks, Disposable Suction Catheters, Disposable Spatula, Disposable Vaginal Dilators, Wound Plasters, Drainage Tubes for Single Use, Sterile Medical Cotton Balls, Sterile Medical Sheets, Sterile Cotton Swabs, Examination Gloves, Disposable Dressing Kits, Medical Absorbent Gauze Pieces, Medical Absorbent Gauze Pads, Disposable Medical Films, Positive Pressure Needle-Free Infusion Connectors, Medical Use Cotton Rolls, Medical Gauze Bandages, Medical Elastic Bandages, Oropharyngeal Airways, Disposable Sterile Dispensing Syringes, Disposable Delivery Kits, Medical Masks, Protectors for Transfusion Joint, Disposable Oral Irrigation Tubes

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2020-03-24

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Fuxiu Sheng

EC Declaration of Conformity

Manufacturer:
Address:
EC Representative:

Item Name: Surgical Masks
Specification: L, M, S
Classification: Is
We, the manufacturer, herewith declare that the products

meet the provisions of Directive 93/42/EEC which apply to them.

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body

DIRECTIVES

General applicable directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC OF 14 July 1993 concerning medical devices (MDD 93/42/EEC)

Standard Followed:
ISO9001 ISO13485 EN 14683-2019 MDD(92/42/EEC)

Notified body: TUV Rheinland LGA Products Gmbh Number 0197
(EC) Certificate(s):
Expire date of the Certificate: 22TH OCT.2021

3 PLY FACE MASKS

Our 3 PLY surgical face masks are tested to EN14683 - The EU standard for medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements.

The factory is also ISO 13485:2016 accredited - which specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements

These masks are also CE Certified.

Test Report

Applicant :

Address :

Description : Disposable Medical Mask

Date : March 20, 2020

Monotek Technical Service Company Limited

EST REPORT EN 14683	
Report reference No. ..... :	
Compiled by (+ signature)..... :	Tony Xiao
Approved by (+ signature) ..... :	Barry Zhou
Date of issue..... :	March 20, 2020
Contents ..... :	10
Testing laboratory ..... :	
Address..... :	
Testing location ..... :	
Applicant ..... :	
Address ..... :	
Test specification	
Standard ..... :	EN 14683:2005
Test procedure ..... :	Type test
Procedure deviation ..... :	N.A.
Non-standard test method ..... :	N.A.
Type of test object	
Description..... :	Disposable Medical Mask
Model..... :	
Trademark ..... :	
Manufacturer ..... :	Same as applicant
Address..... :	Same as applicant

Possible test case verdicts

- **test case does not apply to the test object.....: N (Not applicable)**
- test object does meet the requirement .....: P (Pass)
- test object does not meet the requirement .....: F (Fail)

Testing

Date of receipt of test item .....: Mar. 09, 2020

Date(s) of performance of test.....: Mar. 09, 2020 to Mar. 13, 2020

General remarks

The test results presented in this report relate only to the object tested.

This report shall not be reproduced except in full without the written approval of the testing laboratory.

Models OH01-00 and OH01-01 are same except for model name

Marking information

Model:
Type II
EN 14683
CE

EN 14683			
Clause	Requirement – Test	Result - Remark	Verdict
4.	Classification		N
	Classified into two types according to bacteria filtration efficiency and differential pressure and each type is further divided according to whether or not the masks are splash resistant	Type II	P
5	Requirements		P
5.1	General		P
5.1.1	Materials and construction		P
	The surgical mask shall not disintegrate, split or tear during intended use	checked and found compliance	P
5.1.2	Design		P
	The surgical mask shall have a means by which it can be fitted closely over the nose, mouth and chin of wearer and which ensures that the mask fits closely at the sides	checked and found compliance	P
5.2	Performance requirements		P
5.2.1	Bacterial filtration efficiency (BFE)		P
	When tested in accordance with Annex B, the bacterial filtration efficiency(BFE) of the surgical mask shall conform to the minimum value given for the relevant type in Table 1		P
	Table 1 — Performance requirements for surgical masks		--

Test	Type I	Type IR	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 95	≥ 98	≥ 98
Differential pressure (Pa)	< 29.4	< 49.0	< 29.4	< 49.0
Splash resistance pressure (mm Hg)	Not required	≥ 120	Not required	≥ 120

NOTE Type IR and Type IIR are splash resistant types.

5.2.2	Breathability		P

EN 14683			
Clause	Requirement – Test	Result - Remark	Verdict
	When tested in accordance with Annex C, the differential pressure of the surgical mask shall conform to the value given for the relevant type in Table 1 NOTE1 If the use of a respiratory protective device as surgical mask is required in an operating theatre and/or other medical settings, it might not fulfil the requirement with regard to differential as defined in this European Standard. In such cases NOTE 2 Differential Pressure is expressed in Pa 1 Pa equals 9,806 times pressure expressed in mm water		P
5.2.3	Splash resistance		N
	When tested in accordance with ASTM F1862, the resistance of the surgical mask to penetration of splashes of liquid shall conform to the minimum value given for the relevant type in Table 1.		N
6	Testing requirements		P
	Sample requirement		P
	Condition T:20±2°C RH: 65 2±%	T:21.5°C RH: 66%	P
7	Labelling and information		P
	Annex I & 13 of MDD(93/42/EEC) specified the information that to be provided on the packaging in which the surgical mask is supplied.	Checked and found comliance	P
	The following information shall be supplied in addition		P
	a) Number of the European standard	EN 14683	P
	b) Type of mask(as indicated in Table 1)	Type II	P
Annex A	Information for users		P
	Majority of nuclei are between 0.5um and 12 um in diameter		P
	Designed to protect the working environment and not the wearer.		P
	Specifies the performance requirements and gives a test method for a special class of surgical masks offering protection against splashes.		P
	Protection degree depends on a number of factors, such as the filtration capacity and efficiency of the material and the fit of mask on the wearer's face.		P
	The filtration capacity of mask materials can vary depending on the filter media.		P
	The need for large groups of test subjects and observations.		P

EN 14683			
Clause	Requirement – Test	Result - Remark	Verdict
	A further factor to be considered is the capacity of the mask to absorb moisture form the exhaled air and thereby to maintain its performance over a long period of time.		P
	The contamination risk resulting from hand contact with a used mask means that it is essential that the mask is taken off and disposed of when no longer worn over nose and mouth.		P
	In summary, to use an appropriate mask is an effective means to protect the working environment from droplet contamination from nose and throat during health care procedures.		P
Annex B	Method for intro determination of BFE		P
B.1	Principle		P
	A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber.		P
	The bacterial filtration efficiency of the mask is given by the number of colony forming units passing units passing through the surgical mask material expressed as a percentage of the number of colony forming units in the challenge asrosol.		P
B.2	Reagents and material		P
B2.1.1	Tryptic soy agar		P
B2.1.2	Tryptic soy broth		P
B2.1.3	Peptone water		P
B2.1.4	Culture of Staphylococcus aureaus ATCC 209, growing on tryptic soy agar slants		P
B.3.	Apparatus		P
B3.1	Six stage cascade impactor.		P
B3.2	Nebulizer		P
B3.3	Aerosol chamber		P
B3.4	Flow meter		P
B3.5	Pressure gauge		P
B3.6	Erlenmeyer flasks		P
B3.	Peristaltic or syringe pump		P
B3.	Vacuum pump		P
B.4	Test specimens		P
	Cut from complete mask		P
	Each one shall be min. 100mm by 100mm.		P
	The number is min. 5		P
	Specimens taken form areas representative to incorporate all/any variation in construction		P

EN 14683			
Clause	Requirement – Test	Result - Remark	Verdict
B.5	Preparation of bacterial challenge		P
	B.2.4 shall be inoculated into 30ml trypic soy broth in an Erienmyer flask and incubated with mild shaking at temperature of 37 ±2°C for 24 ±2 h		P
	The culture shall be diluted in peptone water to give a concentration of appro. $5x10^5$ cuf/ml.		P
	The bacterial challenege shall be maintained at 2200 ±500 cuf per test.		P
	The mean particle size in the bacterial challenge shall be maintained at 3 ±0.3 um		P
B.6	Procedure		P
B.6.1	Assemble the apparatus as shown in below figure.		P
B.6.2	Deliver the bacterial challenge to the nebulizer		P
B.6.3	Perform a positive control run without a test specimen.		P
B.6.4	Place fresh plates in the impactor, fix a test specimen in place and repeat the above procedure.		P
B.6.5	Repeat this procedure for each test specimen.		P
B.6.6	After the last test specimen has been tested, perform a further positive control run.		P
B.6.7	Perform a negative control run by passing air, through the cascade impactor for 2 min.		P
B.6.8	Incubate all the plates at 37± 2 °C for 48± 4h.		P
B.6.9	Calculate the mean particle size of the bacterial challenge aerosol in accordance with the instructions of the cascade impactor manufacturer.		P
8.7	Calculation of BFE		P
	Using the equation B=(C-T)/C X 100		P
	Where C is the mean of the total plate counts for the 2 positive control runs T is the total plate count for the test specimen		P
B.8	Test report		P
	The following information shall be given		P
	a) number and date of the standard.	EN 14683: 2005	P
	b) Dimension of the test specimens.	6cm x 6cm	P
	c) Which side of the test specimen was towards the challenge aerosol	Inner side	P
	d) Flow rate during testing	28.3L/min	P
	e) Mean of the total plate counts of the 2 positive controls.	$1.9X10^3$ CFU	P
	f) Mean plate count of the negative control	Less than 1CUF	P

EN 14683			
Clause	Requirement – Test	Result - Remark	Verdict
	g) BFE for each test specimen	BFE#1: 99.8 BFE#2: 99.8 BFE#3: 99.8	P
Annex C	Method of determination of breathability		P
C.1	Principle		P
C.2	Apparatus		P
C.2.1	Flow meter		P
C.2.2	Manometers M1 and M2		P
C.2.3	Electric vacuum pump		P
C.2.4	Valve		P
C.3	Test specimen		P
	Complete mask or cut from masks		P
	Each one shall be able to provide 5 different circular test areas of 2.5cm in diameter.		P
	The number of test specimens is 5.		P
C.4	Procedure		P
C4.1	Specimen placed across the 2.5cm diameter orifice and clamped so that the tested area will be in line and across the air flow		P
C.4.2	The pump is adjusted to 8l/min.		P
C.4.3	The manometers M1 and M2 are read and recoded.		P
C.4.4	Above carried out on 5 different areas of the mask and the readings averaged.		P
C.5	Calculation of differential pressure		P
	differential pressure		P
C.6.	Test report		P
	The following information shall be given		P
	number and date of the standard.	EN 14683:2005	P
	Flow rate during testing	24.8L/min	P
	Differential pressure for each test specimen	Sample1:22.0 Sample2:22.4 Sample3:22.8	P
Annex ZA	Clause of this standard addressing essential requirements or other provisions of EU directive 93/42 concerning medical devices.		P

EN 14683			
Clause	Requirement – Test	Result - Remark	Verdict
			--

Table ZA.1 — Correspondence between this European Standard and EU Directive 93/42/EEC Medical devices

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
5.1.1	1, 2, 3, 4, 7.1, 8.1	
5.1.2	1, 2, 3, 7.1, 8.1	
5.2.1	3, 8.1	
5.2.2	3, 8.1, 9.2	
5.2.3	3, 8.1	
6	3, 8.1	
7	13	

Photo 1

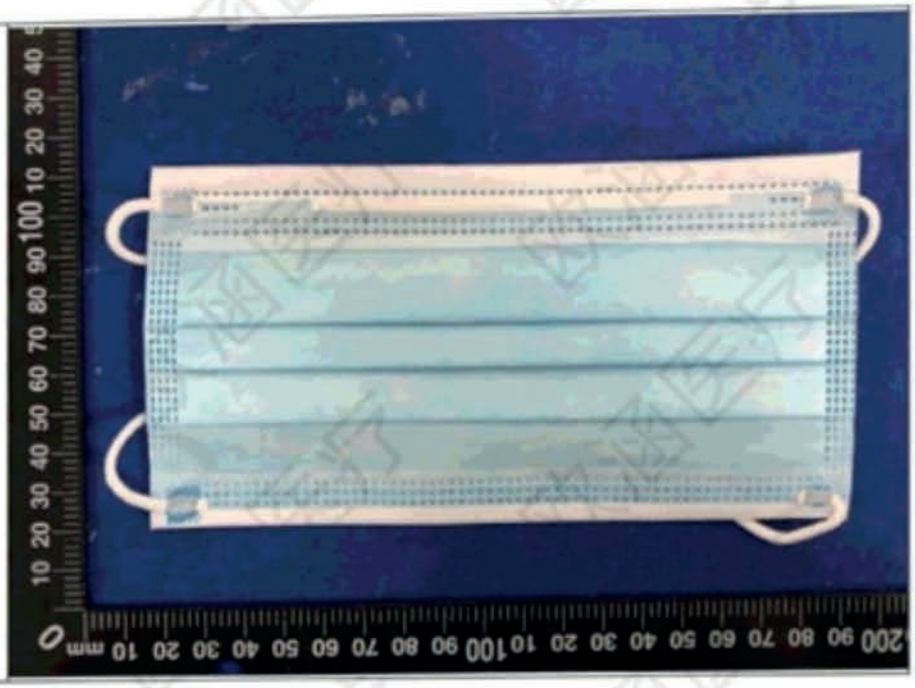
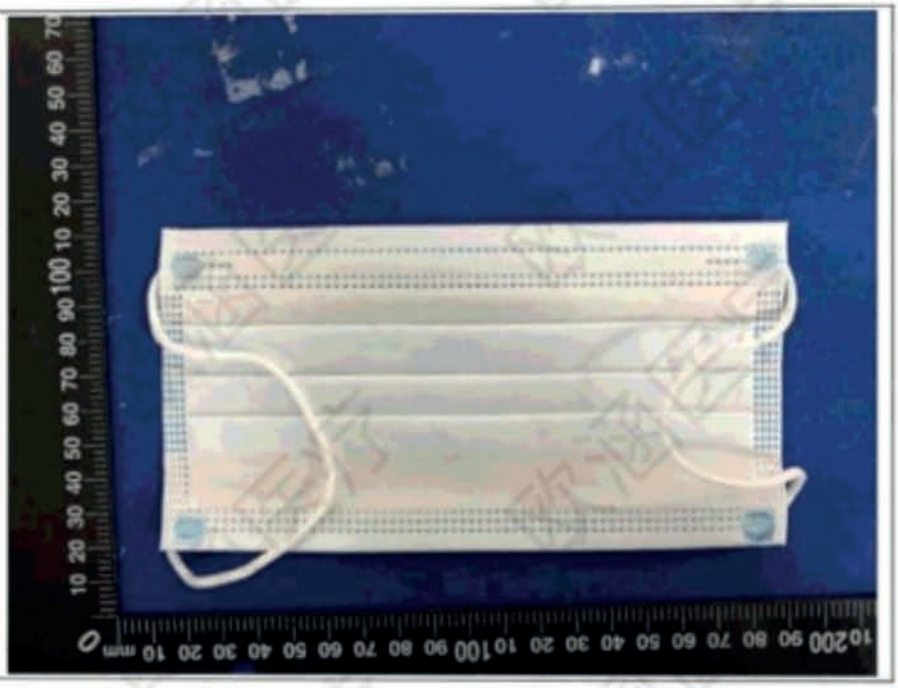


Photo 2



**** End of Report ****

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Medical Devices

(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-03-24

Certificate Registration No.:

An audit was performed. Report No.:

This Certificate is valid until: 2023-01-31

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-03-24

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety

CE Self – Declaration and ISO 13485 Certification

CE Declaration of Conformity CE

Manufacturer
Address No.

Product: Disposable Medical mask
Model: OH01-01

Applicable standard: EN14683:2019

We hereby declare under our sole responsibility that above mentioned products meets the provisions of the Medical Device Directive 93/42/EEC. All supporting documentation is retained under the premises of the manufacturer. The mention products bear the CE-Marking according to Medical Device Directive 93/42/EEC, and are in compliance with the essential requirements according to this directive.

The validity with the date of issue

Signed by:

Printed Name:

Position: CEO

Date:April 13,2020

Medical Device Management

CERTIFICATION EUROPE HONG KONG

Certificate of Registration

Certificate NO:

This is to Certify that the Medical Devices Industry Management System of

Has been audited to the following Medical Devices Industry Management System standard:

ISO13485:2016

This system is valid for the

Production and Sales of Disposable Medical Mask,

Medical Surgical Mask

Date of issue: Mar. 25, 2020 **Date of expiry: Mar. 24, 2023**

This certificate will not remain valid only if the certified organization accepts at least one surveillance audit annually within the validity period of the certificate in which the surveillance audit conforming mark is in the designated position on the certificate.

IAF UKAS

Issued by:

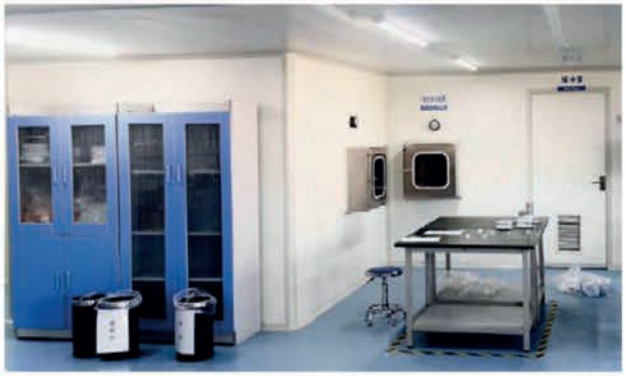
12months	24months

CERTIFICATION EUROPE(HONGKONG)LIMITED WWW.CCE-HK.COM

Q6: Is there any authorisation/mandatory certification that needs to be performed before the products are placed on the market?

Surgical/medical masks, examination gloves and some types of gowns (when supplied in non-sterile condition) are 'Class I Medical devices'. As such, they do not require the mandatory involvement of a notified body (third party testing body) prior to being placed on the market. The manufacturer must certify that the product complies with the applicable requirements. This regime is essentially one of self-certification. If such devices are supplied in a sterile condition they are however classified in a higher risk class and a conformity assessment by a Notified Body is required.

Photos of production line and Lab



FACE SHIELDS
(Blue & White Foam)

Our face shields comply with Regulation (EU) 2016/425 relating to personal protective equipment, and EU standard directive 86/686/EEC. EN 166/2002.

EN166 test reports are due imminently.

These face shields are also UK manufactured.

INTRODUCTION

PURPOSE & INTENDED AUDIENCE

Our Visors/Face shields have been designed in order to support the medical/healthcare/frontline worker sector during the Coronavirus Outbreak. They are intended to be worn by frontline staff for the protection against infectious disease and provide protection from projections of particulate matter in good visibility conditions

SPECIFICATION & FEATURES

Soft foam forehead band connected directly to face shield PVC protective

face shield

Fully adjustable PVC headband

Designed for use with additional PPE e.g. Facemasks

Product's technical features

PPE category 1 Disposable
face shield Adjustable
headband
Visor suitable for use with prescription lenses and protective masks Version: 1.0
Lens: Gloss clear PVC
Can be used for prolonged periods as it does not create distortion or fatigue Can be single use or reusable in less infectious circumstances
No colour distortion
Latex Free
Boxed in 250's Quick
Self Assembly

MANUFACTURING PROCESS

These visors are produced from the raw materials and die cut to shape.

OPERATING ENVIRONMENT

NHS hospitals, Care Homes and anywhere where there is a Coronavirus risk for frontline workers

Designed for the protection of the facial area and associated mucous membranes (eyes, nose, mouth) from splashes, sprays, and spatter of body fluids.

COMPLIANCE & STANDARDS

- Conforms to EU standard directive 86/686/EEC, EN 166/2002
- Regulation (EU) 2016/425 relating to personal protective equipment

PRODUCTION TIMESCALES

Approximately 120,000 can be produced and delivered per week

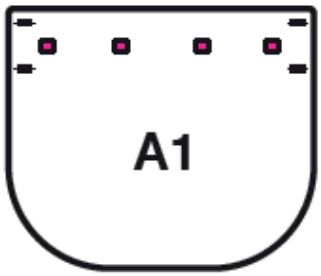
PRODUCT PHOTOGRAPHS

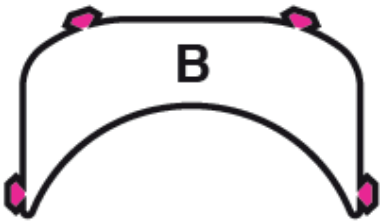
APPENDIX 1 – PRODUCT ASSEMBLY INSTRUCTIONS

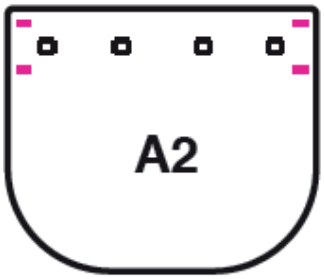
Face Shield Assembly

Step One

insert the highlighted rubber notches (B) into the visor slots (A1) and pull tabs through to secure.

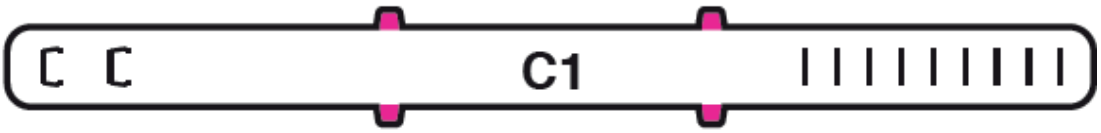






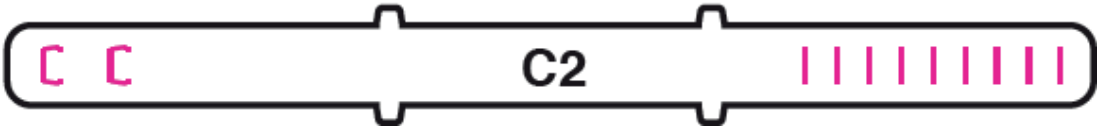
Step Two

Insert locking tabs highlighted (C1) in to either side of the visor (A2) and pull through to secure.



Step Three

Place strap round head and try for fit. Insert locking tabs (C2) to secure when comfortable.



Technical Data Sheet

Product name: ***PVC***

Description: high impact strength
suitable for screen printing, UV offset and inkjet-UV

Quality segment: Print film
Type: PVC
Color: 1-RG-Grey, crystal clear-000
Surface: Glossy / Glossy-00
Additional treatment: No additional treatment-00

Properties	***Standard***	***Unit***	***Values***
Thickness base film	DIN 53370 / ISO 4593	µm	80 ... 800
Tolerance of Thickness	DIN 53370 / ISO 4593	%	-10 ... 10 200 µm -7 ... 7 201 ... 400 µm -5 ... 5 401 ... 800 µm
Density	DIN EN ISO 1183-2	g/cm³	1,31 ... 1,35
Tensile strength, min.	DIN EN ISO 527 test speed V 50 mm/min, measured lengthwise, depending on thickness	MPa	45
Impact strength, min.	DIN EN ISO 8256 measured lengthwise	kJ/m²	550
VICAT-softening point	DIN EN ISO 306 method B/50	ºC	72 ... 76
Dimensional stability -longitudinal	DIN 53377 storage in oven at 140°C/10min	%	-10,0 ... 0,0 100 µm -7,0 ... 0,0 101 ... 200 µm -5,0 ... 0,0 201 ... 400 µm -4,0 ... 0,0 401 ... 800 µm
Dimensional stability -transverse	DIN 53377 storage in oven at 140°C/10min	%	-2,0 ... 2,0 80 ... 800 µm
Max. temperature load	without remaining change of si zes	ºC	55
Cold Break Temperature	DIN EN 1876-2 drop-hammer method	ºC	-30
Surface tension, min.	DIN ISO 8296 measured with test inks	mN/m	32 ... 36
Surface reflexion, 20°	DIN 67530; ASTM D-523 measuring angle 20°	GE	100 ... 130

Revision: 11/06.12.2018

Technical Data Sheet

Regulatory:

The product corresponds to:
- respective regulations and directives for food contact
- Packaging requirements for heavy metals
- Supplementary confirmations to the above-named points can be issued on request.

Storage conditions:

- Ideal storage conditions between 10 - 30°C (50 - 86°F)
- Ideal RH 40 - 70%
- Should not be stored in direct sunlight and avoid major thermal fluctuation
- Store in original packaging
- Before working up the films should be conditioned a minimum of 24 hours room temperature (15 - 30°C)
- recommended use of the material within one year of production date

Safety information for articles

acc. to the regulation REACH 1907/2006/EC

Polymer name: Rigid PVC Films
L, M or N, types 100 - 195 and 370 - 380

1.	**Substance/Preparation and Company Identification**	
	Polymer:	Rigid PVC films L, M or N types 100 to 195 and 370 to 380
	Company name:	
	Information about material/preparation:	
2.	**Composition/Information on Ingredients**	
	Chemical description:	Polyvinyl Chloride
	Dangerous components:	None
3.	**Hazard Identification**	
	Not applicable	
4.	**Emergency and First Aid Procedures (only necessary when handled without care)**	
	Inhalation:	If PVC decomposes due to overheating or in contact with fire: Remove affected persons to fresh air. In case of irritation of respiratory system or if feeling unwell after prolonged exposure, get medical attention.
	Skin contact:	If contact with hot (melt) product occurs: Wash with plenty of water, treat as for thermal burn.
	Eye contact:	After contact with hot (melt) product: Immediately flush eyes with water for several minutes at least, get medical attention.
	Ingestion:	To avoid mechanical irritation; get medical advice.
	Advises for the doctor:	After inhalation of decomposed products: Symptomatic treatment (decontamination, vital functions), if necessary action against irritations of the mucous membranes by HCl.

Safety information for articles

acc. to the regulation REACH 1907/2006/EC

5. Fire Fighting Procedures

Suitable extinguishing media:	Water spray, powder, carbon dioxide
Unsuitable extinguishing media:	None
Burning may release:	Carbon Dioxide (CO_2) Water vapour (H_2O) Hydrochloric gas (HCl) If the burning material cannot get enough air, release of carbon monoxide, soot, and other gases and vapors is possible.
Special protective equipment:	If necessary, use air-bottled or air circulating apparatus for fire fighters.
Further information:	PVC-U does not burn without a slave flame (self extinguishing). Observe local regulations when contaminated water and burning waste are removed.

6. Spill or Leak Procedures

Personal precautions:	Not applicable
Environmental precautions:	Not applicable
Methods of cleaning:	Pick up by mechanical means for disposal or reuse

7. Handling and Storage Precautions

Handling:	Avoid overheating the material, it decomposes to gaseous components (see also 5.). Thermal degradation does not occur at low temperatures, but becomes faster at higher temperatures.
Decomposition:	>150°C (long-term contact) >200°C (short-term contact/i.e., warm forming) It is advisable to install local exhaust ventilation in the vicinity of processing machines in all areas where melt or high temperature processing is carried out (Germany: observe TRGS 402).
Fire and Explosion Protection:	Take precautionary measures against static discharge (i.e., using proper grounding techniques) when handling rolls or sheets in dry rooms (especially to avoid harm to people). According to VDI 2263, page 1, paragraph 2.1.2.3 (dd May 1990), PVC is not dust explosive as delivered by
Storage:	Take precautionary measures to avoid fire hazard. Store in normal room conditions without direct exposure to sunlight.

made / revised: 31 / 01.03.2019
n

Safety information for articles

acc. to the regulation REACH 1907/2006/EC

8. Exposure Control/Personal Protection

Additional advice for design of machines:	See item 7
Components with limits to be observed (depending upon work station):	PVC is recognized as safe. However, it may contain trace amounts of: Vinylchloride monomer VCM, CAS-No. 75-01-4, EINECS-No. 2008310 MAK-Value: 2ppm (5 mg/m^3) (Germany as TRK-value acc. to TRGS 102) **For brand films, a VCM value of ≤ 0,5 ppm is guaranteed.**
Protection:	Given the special precautions mentioned under "7. Handling," these traces present no toxic risk to the processing personnel. Gloves should be worn when handling hot material. Safety glasses are normally recommended for all industrial workplaces when handling hot material.

9. Physical and Chemical Properties

Form:	Mono films
Color:	From clear to black as required
Smell:	Odorless under normal conditions, melt material has a specific odor know as "plastic."
Change of state:	Softening temperature (DIN EN ISO 306): 60-90°C Glass transition temperature: approx 80°C Ignition temperature: see point 7 Density (DIN EN ISO 1183-2): 1,25-1,60 g/cm^3
Solubility of PVC:	Soluble in: tetrahydrofurance and cyclohexanone Partly soluble in: different aromatic hydrocarbons Not soluble in: water, diluted acids and bases
Fire supporting properties:	PVC products are not easily combustible without a slave flame source

10. Stability and Reactivity

Conditions to avoid:	Thermal degradation by overheating (see 7.)

made / revised: 31 / 01.03.2019

Safety information for articles

acc. to the regulation REACH 1907/2006/EC

11. Information about Toxicity

PVC is recognized as safe and biologically inert.

certifies that its rigid films comply with the most recent package requirements for heavy metals of the Toxic Packaging Clearing House (TPCH, formerly CONEG) legislation and the latest March 9, 2005, requirements of the Directive 2013/2/EU amending the European Packaging Directive EU 94/62, as well as the Commission Decision of 2011/534/EU amending the Directive 2002/95/EC [RoHS-Reduction of Hazardous Substances] in their actual valid version.

12. Ecological Information

PVC is not soluble in water (WKG 0, by supplier self declaration); PVC is harmless in contacts with fish and bacteria. In a water treatement plant, PVC can be separated mechanically.

13. Disposal Considerations

guarantees the recycling of customers' material (=100% kp material). Recycling of printed or other used material is also possible, but this depends on the degree of impurities.

Uncontaminated material is normally used as material for recycling, but can also be treated as household or incineration waste in accordance with local regulations.

European Waste-Catalogue: code 200139 for plastics.

certifies that its rigid films comply to the European Packaging Directive EU 94/62, as well as its actual valid amendments.

14. Transport

No hazardous material according to transport regulations (ADR, RID, ADNR, IMDG, IATA).

15. Regulatory Information

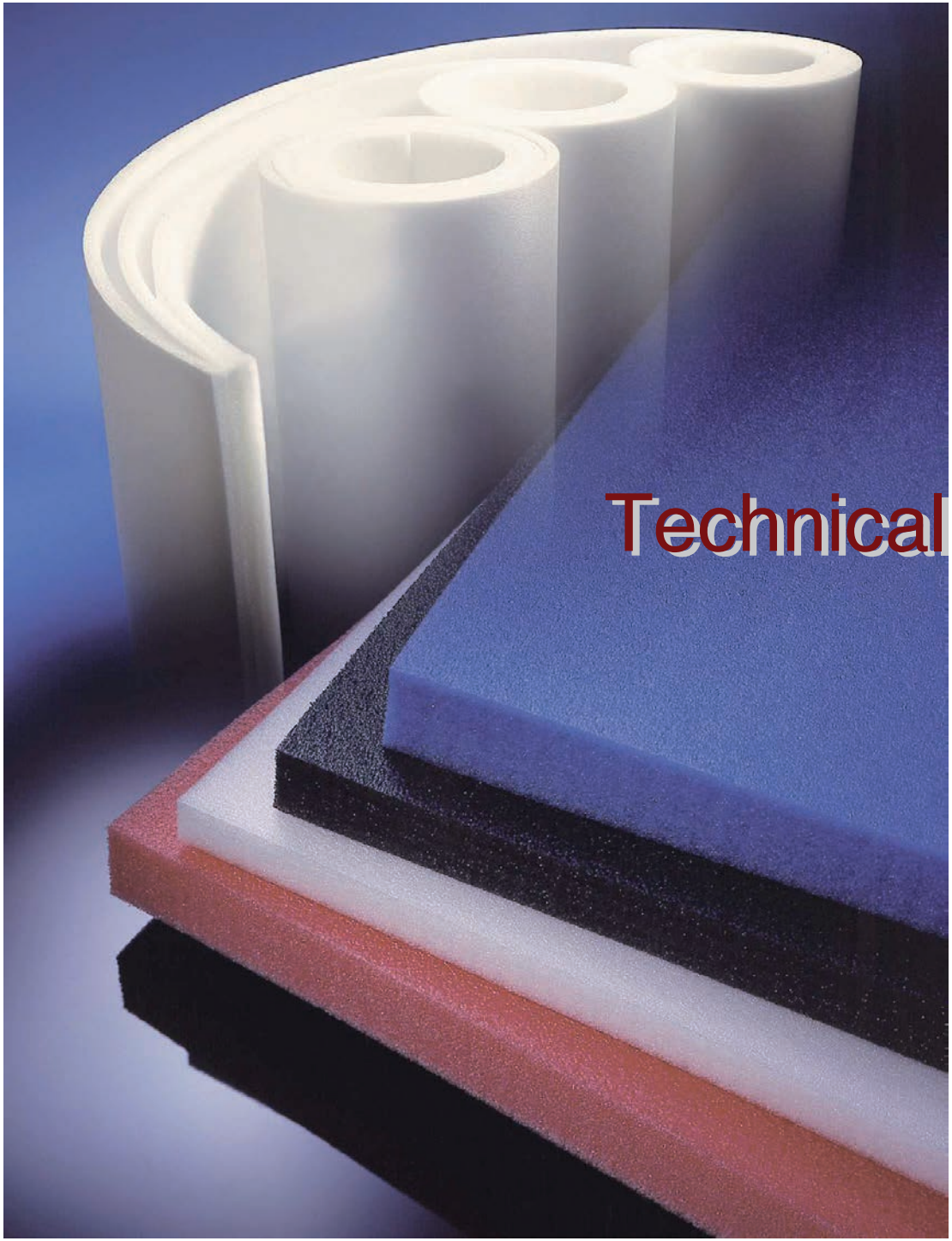
EEC labelling acc. Regulation (EC) 1272/2008 (Directive 67/548/EEC) as well as its actual valid amendments.	Not applicable
National legislation acc. to § 4a GefStoffV:	Not applicable NB: This means PVC films are not considered

16. Further Information

rigid films do not contain any Ozone depleting substances, including those listed in the 1990 Clean Air Act Amendments.

The information and recommendations contained herein are based upon present data believed to be correct. However, no guarantee or warranty of any kind expressed or implied is made with respect to the information contained herein.

made / revised: 31 / 01.03.2019



Laminated planks out of non-cross-linked closed cell PE foam

Technical & Safety Information

NORM	UNIT	TECHNICAL PROPERTIES			LD	MD	HD	UHD	ANTISTATIC MD
EN ISO 845	Kg/m³	**DENSITY**			23	28	35	65	28
EN ISO 3386/1	kPa	**COMPRESSIVE STRESS**	**1e impression**	- 25 % impression	50	55	45	80	55
				- 50 % impression	115	120	105	160	120
				- 70 % impression	240	250	230	325	250
			4e impression	- 25 % impression	25	35	20	60	35
				- 50 % impression	85	95	80	135	95
				- 70 % impression	210	230	205	320	230
EN ISO 1856	%	**COMPRESSION SET**	- 22 h/23°C/50 % after 24 h		< 20	< 20	< 20	< 20	< 20
ASTM D-3575-BB	%	**COMPRESSIVE CREEP**	1.0 psi / 168 h/ 23°C		< 10	< 10	< 10	-	< 10
ASTM D-3575-S	%	**THERMAL STABILITY**	24 h/70 °C		< 5	< 5	< 5	< 5	< 5
BS 4443/1/4		**CELL COUNT**	cells per 25 mm		+/- 25	+/- 25	+/- 25	+/- 23	+/- 25
IEC 61340-5-1	Ω	**SURFACE RESISTANCE**(1)	23 °C 50 % RH		-	-	-	-	$< 10^{11}$ Ω

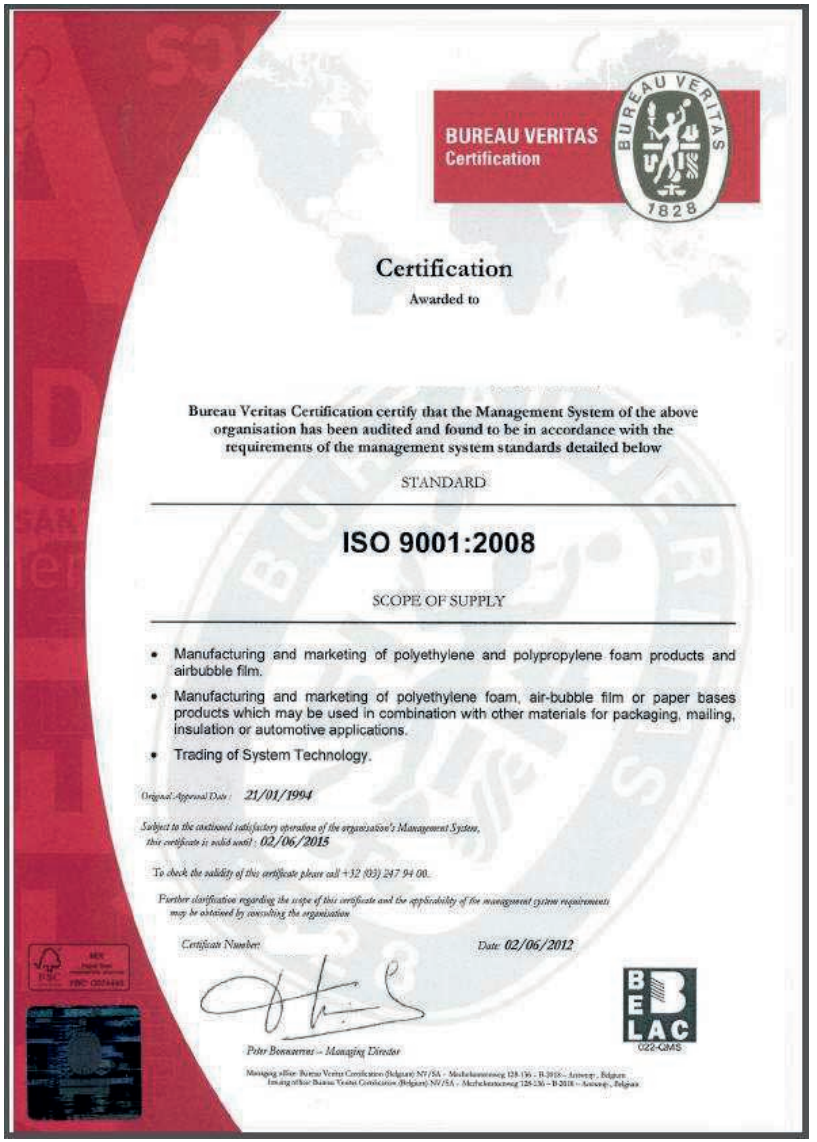
(1) The above mentioned antistatic characteristics are valid for 3 years after production date. antistatic contains amines.

The information above relies on our knowledge and experience and is assumed to be correct. We do not, however, accept any form of liability or give any guarantee.

General information

- - a closed cell non-cross-linked polyethylene foam - is made out of low density polyethylene (LDPE). LDPE is an organic product build up out of the same hydrocarbon bonds as wood, coal and other natural composites.
- is manufactured free from the ozone damaging fully halogenated Chlorofluorocarbons (CFC's) and partially halogenated Chlorofluorocarbons (HCFC's).
- is not cross-linked while extruded and can therefore be easily recycled and taken back into the raw material cycle for re-use.
- The temperature range lies between –40°C en +70°C.
- conforms to the European guidelines 2002/95/EC (WEEE), 2002/96/EC (RoHS) and 2003/11/EC and therefor contains no lead, cadmium, mercury, hexavalent chromium or polybrominated biphenyls (PBB) and polybrominated diphenylethers (PBDE) or any other product from the lists of these guidelines.
  also complies to the demands of the European decree nr. 98-638 and the European guideline 94/64/EC concerning packaging and packaging waste, and this in as far as the specific demands of the customer allow.
- When being incinerated, produces a high calorific value without emitting any harmful gases. Carbon dioxide and water vapour are released.
- has no influence on the quality of the ground water.

De productions and controles are carried out according to the predifined Procedures and Work Instructions of our Quality Management System



BUREAU VERITAS
Certification

Certification

Awarded to

Bureau Veritas Certification certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

STANDARD

ISO 9001:2008

SCOPE OF SUPPLY

- Manufacturing and marketing of polyethylene and polypropylene foam products and airbubble film.
- Manufacturing and marketing of polyethylene foam, air-bubble film or paper bases products which may be used in combination with other materials for packaging, mailing, insulation or automotive applications.
- Trading of System Technology.

Original Approval Date : 21/01/1994

Subject to the continued satisfactory operation of the organisation's Management System, this certificate is valid until : 02/06/2015

To check the validity of this certificate please call +32 (03) 247 94 00.

Further clarification regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation

Certificate Number: Date: 02/06/2012

Peter Bonnarens – Managing Director

BELAC 022-QMS

Safety Data Sheet

according to EC-Directive 2001/58/EC

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

PRODUCT NAME	
	Non-cross linked, closed celled Polyethylene foam
INTENDED USE	Packaging
SUPPLIER	
EMERGENCY TELEPHONE	

2. COMPOSITION / INFORMATION ON INGREDIENTS

NAME	Polyethylene
CAS NUMBER	CAS 026221-73-8

3. HAZARDS IDENTIFICATION

With proper use of the product, no harmful effects are known.

4. FIRST AID MEASURES

INHALATION	not applicable
CONTACT WITH THE SKIN	not applicable
CONTACT WITH THE EYES	not applicable
INGESTION	not applicable

5. FIRE-FIGHTING MEASURES

EXTINGUISHING MEDIA	- Water - Koolstofdioxide - Bluspoeder - Synthetische blusmiddelen
UNSUITABLE EXTINGUISHING MEDIA	not applicable
SPECIAL HAZARDS	none known
PROTECTIVE EQUIPMENT	res ademhalingsbescherming

6. ACCIDENTAL RELEASE MEASURES

CLEANING METHODS	Clean-up, remove.
ENVIRONMENTAL PRECAUTIONS	Keep out of reach of sewers, water drainage and surface water.
PERSONAL PRECAUTIONS	not applicable

Safety Data Sheet

according to EC-Directive 2001/58/EC

7. HANDLING AND STORAGE

HANDLING AND STORAGE	- Direct contact with open flames or excessive heat must be avoided. The product can contain traces of flammable gas and must be stored in a properly ventilated area. As for all foams, proper ventilation during transport and/or transformation is essential. - Heaping up of PE-particles is to be avoided. - Avoid statically electricity.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS	not applicable
PERSONAL PROTECTION	
- Respiration	none
- Hands	none
- Eyes	none
- Skin	none

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE	fast
ODOUR	odourless
COLOUR	white (without additives)
DENSITY (at 23°C)	25 - 35 kg/m³
VISCOSITY	not applicable
BOILING POINT/RANGE	not applicable
MELTING POINT/RANGE	100 - 140°C
FLASH POINT	> 360°C
FLAMMABILITY	> 400°C
AUTO-IGNITION TEMPERATURE	> 450°C
EXPLOSION LIMITS	not applicable
RELATIVE VAPOUR DENSITY (water = 1)	0,90 - 0,98
VAPOUR PRESSURE	not applicable
SOLUBILITY IN WATER	insoluble
SOLUBILITY IN ORGANICAL SOLVENTS	insoluble
pH VALUE	not applicable
OXIDIZING PROPERTIES	none
PARTITION COEFFICIENT (n-octanol / water)	not applicable

Safety Data Sheet

according to EC-Directive 2001/58/EC

10. STABILITY AND REACTIVITY

CONDITIONS TO AVOID	see 7. Handling and storage
PRODUCTS TO AVOID	none
DECOMPOSITION OF PRODUCTS	From the moment of combustion, the product produces a high calorific value without emitting any harmful gasses and releases carbon dioxide and water vapour.

11. TOXICOLOGICAL INFORMATION

With proper use of the product according to the valid instructions, no innocuous effects to the human health are currently known.

ACUTE TOXICITY

- Oral	not applicable
- Dermal	not applicable
- Inhalation	not applicable

12. ECOLOGICAL INFORMATION

The product has no influence on the quality of the groundwater.

The product is biodegradable when exposed to sunlight.

13. DISPOSAL INSTRUCTIONS

Removal of waste materials conform to the local and national regulations.

14. TRANSPORT INFORMATION

The product is not classified as a dangerous product with reference to the regulations of transport.

ADR/RID	not restricted
IMCO	not restricted
ICAO/IATA	not restricted
ADNR	not restricted

15. REGULATORY INFORMATION

The product is not subject to the regulation CE67/548/CEE, nor to the regulations of the concerned countries.

16. OTHER INFORMATION

The information and data given in this Safety Data Sheet are correct as far as known to us on the date of publication. This information is a guide for the manipulation, the use, the storage, the transport, the elimination and the dispersion of the product without risk. This information and data can not be used as a guarantee, nor as prove of quality, because the conditions in which the mentioned actions take place do not fall under our supervision. The given information concerns only the above mentioned product and does not need to be valid if used with other product(s) or in any other process than mentioned in this document. accepts no responsibility or liability for any loss or damage resulting from the use of this information or data.

Declaration Of Conformity

We:

Declare under our sole responsibility that the product:

Product:	Face Shield Visor
Type:	Multiple / Single Use
Batch or serial no:	N/A
Object:	*(colour Image)*

To which this declaration relates is in conformity with the following relevant Union harmonisation legislation:

- Regulation (EU) 2016/425 relating to personal protective equipment

And that the product is in conformity with the following standards and / or other normative documents:

- EU standard directive 86/686/EEC. EN 166/2002

Place and date of issue (of this document)

Signed by or for the manufacturer

Director
Signed by.

Date:- 6th April 2020

INTRODUCTION

PURPOSE & INTENDED AUDIENCE

Our Visors/Face shields have been designed in order to support the medical/healthcare/frontline worker sector during the Coronavirus Outbreak. They are intended to be worn by frontline staff for the protection against infectious disease and provide protection from projections of particulate matter in good visibility conditions

SPECIFICATION & FEATURES

Soft foam forehead band connected directly to face shield PVC protective

face shield

Fully adjustable PVC headband

Designed for use with additional PPE e.g. Facemasks

Product's technical features

PPE category 1 Disposable
face shield Adjustable
headband
Visor suitable for use with prescription lenses and protective masks Version: 1.0
Lens: Gloss clear PVC
Can be used for prolonged periods as it does not create distortion or fatigue Can be single use or reusable in less infectious circumstances
No colour distortion
Latex Free
Boxed in 250’s Quick
Self Assembly

MANUFACTURING PROCESS

These visors are produced from the raw materials and die cut to shape.

OPERATING ENVIRONMENT

NHS hospitals, Care Homes and anywhere where there is a Coronavirus risk for frontline workers

Designed for the protection of the facial area and associated mucous membranes (eyes, nose, mouth) from splashes, sprays, and spatter of body fluids.

COMPLIANCE & STANDARDS

- Conforms to EU standard directive 86/686/EEC, EN 166/2002
- Regulation (EU) 2016/425 relating to personal protective equipment

PRODUCTION TIMESCALES

Approximately 120,000 can be produced and delivered per week

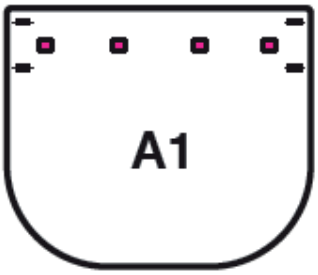
PRODUCT PHOTOGRAPHS

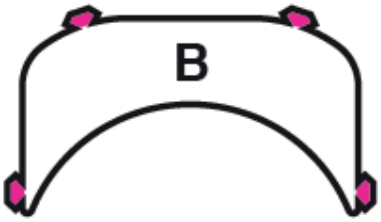
APPENDIX 1 – PRODUCT ASSEMBLY INSTRUCTIONS

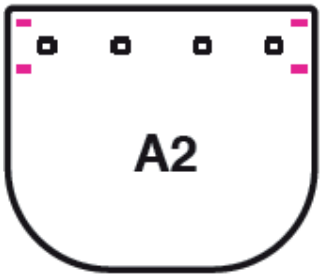
Face Shield Assembly

Step One

insert the highlighted rubber notches (B) into the visor slots (A1) and pull tabs through to secure.

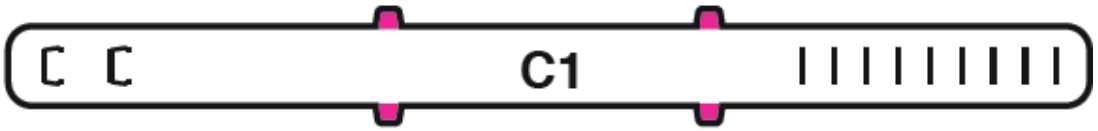






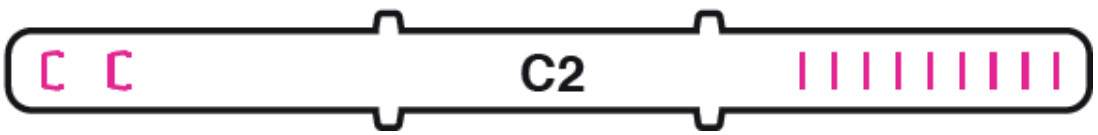
Step Two

Insert locking tabs highlighted (C1) in to either side of the visor (A2) and pull through to secure.



Step Three

Place strap round head and try for fit. Insert locking tabs (C2) to secure when comfortable.



Technical Data Sheet

Product name: ***PVC***

Description: high impact strength
suitable for screen printing, UV offset and inkjet-UV

Quality segment: Print film
Type: PVC
Color: 1-RG-Grey, crystal clear-000
Surface: Glossy / Glossy-00
Additional treatment: No additional treatment-00

Properties	***Standard***	***Unit***	***Values***
Thickness base film	DIN 53370 / ISO 4593	µm	80 ... 800
Tolerance of Thickness	DIN 53370 / ISO 4593	%	-10 ... 10 200 µm -7 ... 7 201 ... 400 µm -5 ... 5 401 ... 800 µm
Density	DIN EN ISO 1183-2	g/cm³	1,31 ... 1,35
Tensile strength, min.	DIN EN ISO 527 test speed V 50 mm/min, measured lengthwise, depending on thickness	MPa	45
Impact strength, min.	DIN EN ISO 8256 measured lengthwise	kJ/m²	550
VICAT-softening point	DIN EN ISO 306 method B/50	ºC	72 ... 76
Dimensional stability -longitudinal	DIN 53377 storage in oven at 140°C/10min	%	-10,0 ... 0,0 100 µm -7,0 ... 0,0 101 ... 200 µm -5,0 ... 0,0 201 ... 400 µm -4,0 ... 0,0 401 ... 800 µm
Dimensional stability -transverse	DIN 53377 storage in oven at 140°C/10min	%	-2,0 ... 2,0 80 ... 800 µm
Max. temperature load	without remaining change of si zes	ºC	55
Cold Break Temperature	DIN EN 1876-2 drop-hammer method	ºC	-30
Surface tension, min.	DIN ISO 8296 measured with test inks	mN/m	32 ... 36
Surface reflexion, 20°	DIN 67530; ASTM D-523 measuring angle 20°	GE	100 ... 130

Revision: 11/06.12.2018

Technical Data Sheet

Regulatory:

The product corresponds to:
- respective regulations and directives for food contact
- Packaging requirements for heavy metals
- Supplementary confirmations to the above-named points can be issued on request.

Storage conditions:

- Ideal storage conditions between 10 - 30°C (50 - 86°F)
- Ideal RH 40 - 70%
- Should not be stored in direct sunlight and avoid major thermal fluctuation
- Store in original packaging
- Before working up the films should be conditioned a minimum of 24 hours room temperature (15 - 30°C)
- recommended use of the material within one year of production date

Safety information for articles

acc. to the regulation REACH 1907/2006/EC

Polymer name: Rigid PVC Films
L, M or N, types 100 - 195 and 370 - 380

1.	**Substance/Preparation and Company Identification**	
	Polymer:	Rigid PVC films L, M or N types 100 to 195 and 370 to 380
	Company name:	
	Information about material/preparation:	
2.	**Composition/Information on Ingredients**	
	Chemical description:	Polyvinyl Chloride
	Dangerous components:	None
3.	**Hazard Identification**	
	Not applicable	
4.	**Emergency and First Aid Procedures (only necessary when handled without care)**	
	Inhalation:	If PVC decomposes due to overheating or in contact with fire: Remove affected persons to fresh air. In case of irritation of respiratory system or if feeling unwell after prolonged exposure, get medical attention.
	Skin contact:	If contact with hot (melt) product occurs: Wash with plenty of water, treat as for thermal burn.
	Eye contact:	After contact with hot (melt) product: Immediately flush eyes with water for several minutes at least, get medical attention.
	Ingestion:	To avoid mechanical irritation; get medical advice.
	Advises for the doctor:	After inhalation of decomposed products: Symptomatic treatment (decontamination, vital functions), if necessary action against irritations of the mucous membranes by HCl.

made / revised: 31 / 01.03.2019

Safety information for articles

acc. to the regulation REACH 1907/2006/EC

5. Fire Fighting Procedures

Suitable extinguishing media:	Water spray, powder, carbon dioxide
Unsuitable extinguishing media:	None
Burning may release:	Carbon Dioxide (CO_2) Water vapour (H_2O) Hydrochloric gas (HCl) If the burning material cannot get enough air, release of carbon monoxide, soot, and other gases and vapors is possible.
Special protective equipment:	If necessary, use air-bottled or air circulating apparatus for fire fighters.
Further information:	PVC-U does not burn without a slave flame (self extinguishing). Observe local regulations when contaminated water and burning waste are removed.

6. Spill or Leak Procedures

Personal precautions:	Not applicable
Environmental precautions:	Not applicable
Methods of cleaning:	Pick up by mechanical means for disposal or reuse

7. Handling and Storage Precautions

Handling:	Avoid overheating the material, it decomposes to gaseous components (see also 5.). Thermal degradation does not occur at low temperatures, but becomes faster at higher temperatures.
Decomposition:	>150°C (long-term contact) >200°C (short-term contact/i.e., warm forming) It is advisable to install local exhaust ventilation in the vicinity of processing machines in all areas where melt or high temperature processing is carried out (Germany: observe TRGS 402).
Fire and Explosion Protection:	Take precautionary measures against static discharge (i.e., using proper grounding techniques) when handling rolls or sheets in dry rooms (especially to avoid harm to people). According to VDI 2263, page 1, paragraph 2.1.2.3 (dd May 1990), PVC is not dust explosive as delivered by
Storage:	Take precautionary measures to avoid fire hazard. Store in normal room conditions without direct exposure to sunlight.

made / revised: 31 / 01.03.2019

Safety information for articles

acc. to the regulation REACH 1907/2006/EC

8. Exposure Control/Personal Protection

Additional advice for design of machines:	See item 7
Components with limits to be observed (depending upon work station):	PVC is recognized as safe. However, it may contain trace amounts of: Vinylchloride monomer VCM, CAS-No. 75-01-4, EINECS-No. 2008310 MAK-Value: 2ppm (5 mg/m^3) (Germany as TRK-value acc. to TRGS 102) **For brand films, a VCM value of ≤ 0,5 ppm is guaranteed.**
Protection:	Given the special precautions mentioned under “7. Handling,” these traces present no toxic risk to the processing personnel. Gloves should be worn when handling hot material. Safet glasses are normally recommended for all industrial workplaces when handling hot material.

9. Physical and Chemical Properties

Form:	Mono films
Color:	From clear to black as required
Smell:	Odorless under normal conditions, melt material has a specific odor know as “plastic.”
Change of state:	Softening temperature (DIN EN ISO 306): 60-90°C Glass transition temperature: approx 80°C Ignition temperature: see point 7 Density (DIN EN ISO 1183-2): 1,25-1,60 g/cm^3
Solubility of PVC:	Soluble in: tetrahydrofurance and cyclohexanone Partly soluble in: different aromatic hydrocarbons Not soluble in: water, diluted acids and bases
Fire supporting properties:	PVC products are not easily combustible without a slave flame source

10. Stability and Reactivity

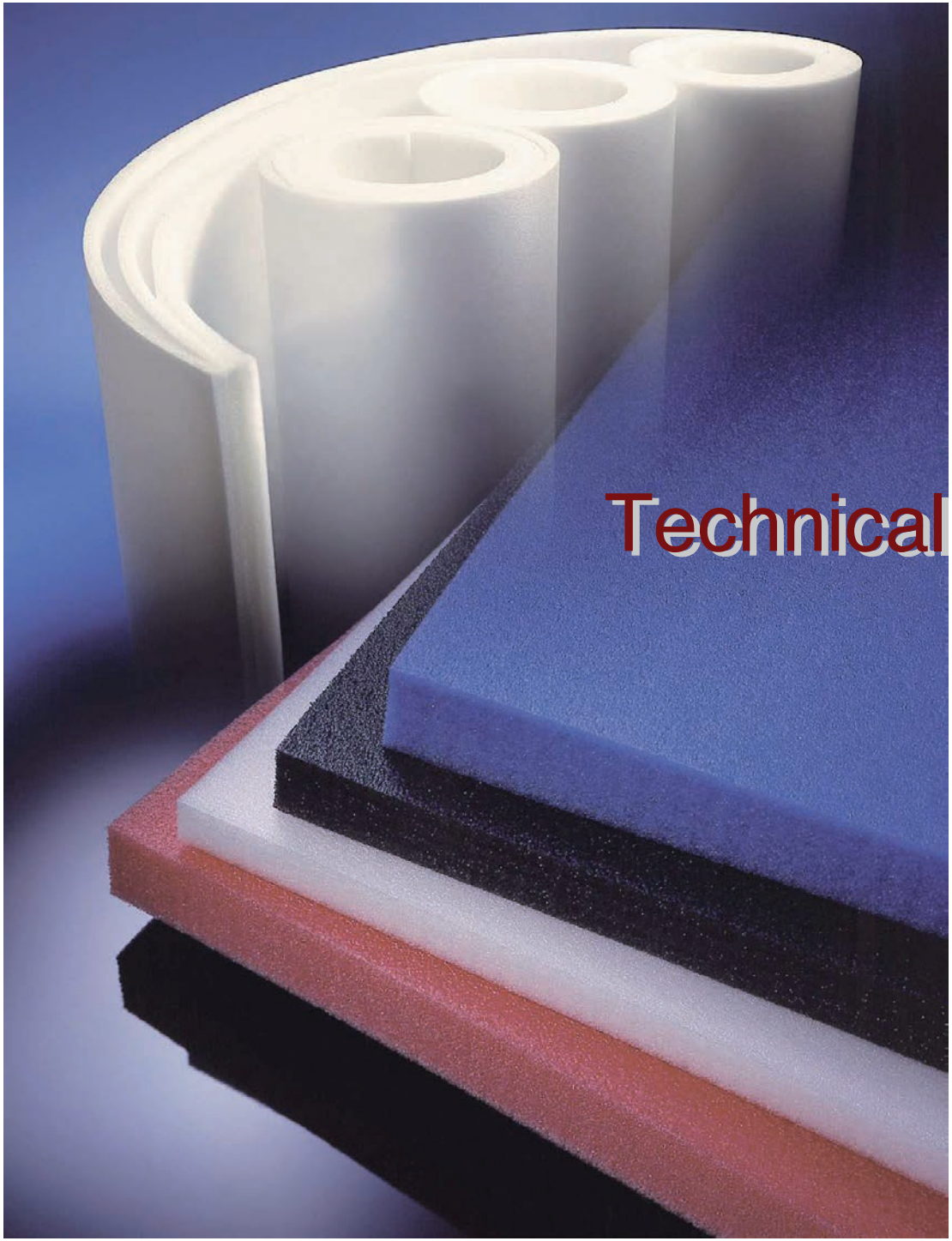
Conditions to avoid:	Thermal degradation by overheating (see 7.)

Safety information for articles

acc. to the regulation REACH 1907/2006/EC

11.	**Information about Toxicity** PVC is recognized as safe and biologically inert. certifies that its rigid films comply with the most recent package requirements for heavy metals of the Toxic Packaging Clearing House (TPCH, formerly CONEG) legislation and the latest March 9, 2005, requirements of the Directive 2013/2/EU amending the European Packaging Directive EU 94/62, as well as the Commission Decision of 2011/534/EU amending the Directive 2002/95/EC [RoHS-Reduction of Hazardous Substances] in their actual valid version.
12.	**Ecological Information** PVC is not soluble in water (WKG 0, by supplier self declaration); PVC is harmless in contacts with fish and bacteria. In a water treatement plant, PVC can be separated mechanically.
13.	**Disposal Considerations** guarantees the recycling of customers' material (=100% kp material). Recycling of printed or other used material is also possible, but this depends on the degree of impurities. Uncontaminated material is normally used as material for recycling, but can also be treated as household or incineration waste in accordance with local regulations. European Waste-Catalogue: code 200139 for plastics. certifies that its rigid films comply to the European Packaging Directive EU 94/62, as well as its actual valid amendments.
14.	**Transport** No hazardous material according to transport regulations (ADR, RID, ADNR, IMDG, IATA).
15.	**Regulatory Information** EEC labelling acc. Regulation (EC) 1272/2008 (Directive 67/548/EEC) as well as its actual valid amendments. — Not applicable National legislation acc. to § 4a GefStoffV: — Not applicable NB: This means PVC films are not considered
16.	**Further Information** rigid films do not contain any Ozone depleting substances, including those listed in the 1990 Clean Air Act Amendments. The information and recommendations contained herein are based upon present data believed to be correct. However, no guarantee or warranty of any kind expressed or implied is made with respect to the information contained herein.

made / revised: 31 / 01.03.2019



Laminated planks out of non-cross-linked closed cell PE foam

Technical & Safety Information

Laminated planks out of non-cross-linked closed cell PE foam

NORM	UNIT	TECHNICAL PROPERTIES			LD	MD	HD	UHD	ANTISTATIC MD
EN ISO 845	Kg/m³	**DENSITY**			23	28	35	65	28
EN ISO 3386/1	kPa	**COMPRESSIVE STRESS**	**1e impression**	- 25 % impression	50	55	45	80	55
				- 50 % impression	115	120	105	160	120
				- 70 % impression	240	250	230	325	250
			4e impression	- 25 % impression	25	35	20	60	35
				- 50 % impression	85	95	80	135	95
				- 70 % impression	210	230	205	320	230
EN ISO 1856	%	**COMPRESSION SET**	- 22 h/23°C/50 % after 24 h		< 20	< 20	< 20	< 20	< 20
ASTM D-3575-BB	%	**COMPRESSIVE CREEP**	1.0 psi / 168 h/ 23°C		< 10	< 10	< 10	-	< 10
ASTM D-3575-S	%	**THERMAL STABILITY**	24 h/70 °C		< 5	< 5	< 5	< 5	< 5
BS 4443/1/4		**CELL COUNT**	cells per 25 mm		+/- 25	+/- 25	+/- 25	+/- 23	+/- 25
IEC 61340-5-1	Ω	**SURFACE RESISTANCE**(1)	23 °C 50 % RH		-	-	-	-	< 10^{11} Ω

(1) The above mentioned antistatic characteristics are valid for 3 years after production date. antistatic contains amines.

The information above relies on our knowledge and experience and is assumed to be correct. We do not, however, accept any form of liability or give any guarantee.

General information

- - a closed cell non-cross-linked polyethylene foam - is made out of low density polyethylene (LDPE). LDPE is an organic product build up out of the same hydrocarbon bonds as wood, coal and other natural composites.

- is manufactured free from the ozone damaging fully halogenated Chlorofluorocarbons (CFC's) and partially halogenated Chlorofluorocarbons (HCFC's).

- is not cross-linked while extruded and can therefore be easily recycled and taken back into the raw material cycle for re-use.

- The temperature range lies between –40°C en +70°C.

- conforms to the European guidelines 2002/95/EC (WEEE), 2002/96/EC (RoHS) and 2003/11/EC and therefor contains no lead, cadmium, mercury, hexavalent chromium or polybrominated biphenyls (PBB) and polybrominated diphenylethers (PBDE) or any other product from the lists of these guidelines.
  also complies to the demands of the European decree nr. 98-638 and the European guideline 94/64/EC concerning packaging and packaging waste, and this in as far as the specific demands of the customer allow.

- When being incinerated, produces a high calorific value without emitting any harmful gases. Carbon dioxide and water vapour are released.

- has no influence on the quality of the ground water.

LDPE

De productions and controles are carried out according to the predifined Procedures and Work Instructions of our Quality Management System

BUREAU VERITAS
Certification

Certification

Awarded to

Bureau Veritas Certification certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

STANDARD

ISO 9001:2008

SCOPE OF SUPPLY

- Manufacturing and marketing of polyethylene and polypropylene foam products and airbubble film.
- Manufacturing and marketing of polyethylene foam, air-bubble film or paper bases products which may be used in combination with other materials for packaging, mailing, insulation or automotive applications.
- Trading of System Technology.

Original Approval Date : 21/01/1994

Subject to the continued satisfactory operation of the organisation's Management System, this certificate is valid until : 02/06/2015

To check the validity of this certificate please call +32 (03) 247 94 00.

Further clarification regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation

Certificate Number: Date: 02/06/2012

Peter Bonnarens – Managing Director

BELAC 022-QMS

Pregis

Safety Data Sheet

according to EC-Directive 2001/58/EC

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

PRODUCT NAME	Non-cross linked, closed celled Polyethylene foam
INTENDED USE	Packaging
SUPPLIER	
EMERGENCY TELEPHONE	

2. COMPOSITION / INFORMATION ON INGREDIENTS

NAME	Polyethylene
CAS NUMBER	CAS 026221-73-8

3. HAZARDS IDENTIFICATION

With proper use of the product, no harmful effects are known.

4. FIRST AID MEASURES

INHALATION	not applicable
CONTACT WITH THE SKIN	not applicable
CONTACT WITH THE EYES	not applicable
INGESTION	not applicable

5. FIRE-FIGHTING MEASURES

EXTINGUISHING MEDIA	- Water - Koolstofdioxide - Bluspoeder - Synthetische blusmiddelen
UNSUITABLE EXTINGUISHING MEDIA	not applicable
SPECIAL HAZARDS	none known
PROTECTIVE EQUIPMENT	res ademhalingsbescherming

6. ACCIDENTAL RELEASE MEASURES

CLEANING METHODS	Clean-up, remove.
ENVIRONMENTAL PRECAUTIONS	Keep out of reach of sewers, water drainage and surface water.
PERSONAL PRECAUTIONS	not applicable

Safety Data Sheet

according to EC-Directive 2001/58/EC

7. HANDLING AND STORAGE

HANDLING AND STORAGE	- Direct contact with open flames or excessive heat must be avoided. The product can contain traces of flammable gas and must be stored in a properly ventilated area. As for all foams, proper ventilation during transport and/or transformation is essential. - Heaping up of PE-particles is to be avoided. - Avoid statically electricity.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS	not applicable
PERSONAL PROTECTION	
- Respiration	none
- Hands	none
- Eyes	none
- Skin	none

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE	fast
ODOUR	odourless
COLOUR	white (without additives)
DENSITY (at 23°C)	25 - 35 kg/m³
VISCOSITY	not applicable
BOILING POINT/RANGE	not applicable
MELTING POINT/RANGE	100 - 140°C
FLASH POINT	> 360°C
FLAMMABILITY	> 400°C
AUTO-IGNITION TEMPERATURE	> 450°C
EXPLOSION LIMITS	not applicable
RELATIVE VAPOUR DENSITY (water = 1)	0,90 - 0,98
VAPOUR PRESSURE	not applicable
SOLUBILITY IN WATER	insoluble
SOLUBILITY IN ORGANICAL SOLVENTS	insoluble
pH VALUE	not applicable
OXIDIZING PROPERTIES	none
PARTITION COEFFICIENT (n-octanol / water)	not applicable

Safety Data Sheet

according to EC-Directive 2001/58/EC

10. STABILITY AND REACTIVITY

CONDITIONS TO AVOID	see 7. Handling and storage
PRODUCTS TO AVOID	none
DECOMPOSITION OF PRODUCTS	From the moment of combustion, the product produces a high calorific value without emitting any harmful gasses and releases carbon dioxide and water vapour.

11. TOXICOLOGICAL INFORMATION

With proper use of the product according to the valid instructions, no innocuous effects to the human health are currently known.

ACUTE TOXICITY

- Oral	not applicable
- Dermal	not applicable
- Inhalation	not applicable

12. ECOLOGICAL INFORMATION

The product has no influence on the quality of the groundwater.

The product is biodegradable when exposed to sunlight.

13. DISPOSAL INSTRUCTIONS

Removal of waste materials conform to the local and national regulations.

14. TRANSPORT INFORMATION

The product is not classified as a dangerous product with reference to the regulations of transport.

ADR/RID	not restricted
IMCO	not restricted
ICAO/IATA	not restricted
ADNR	not restricted

15. REGULATORY INFORMATION

The product is not subject to the regulation CE67/548/CEE, nor to the regulations of the concerned countries.

16. OTHER INFORMATION

The information and data given in this Safety Data Sheet are correct as far as known to us on the date of publication. This information is a guide for the manipulation, the use, the storage, the transport, the elimination and the dispersion of the product without risk. This information and data can not be used as a guarantee, nor as prove of quality, because the conditions in which the mentioned actions take place do not fall under our supervision. The given information concerns only the above mentioned product and does not need to be valid if used with other product(s) or in any other process than mentioned in this document. accepts no responsibility or liability for any loss or damage resulting from the use of this information or data.

Declaration Of Conformity

We:

Declare under our sole responsibility that the product:

Product:	Face Shield Visor
Type:	Multiple / Single Use
Batch or serial no:	N/A
Object:	*(colour Image)*

To which this declaration relates is in conformity with the following relevant Union harmonisation legislation:

- Regulation (EU) 2016/425 relating to personal protective equipment

And that the product is in conformity with the following standards and / or other normative documents:

- EU standard directive 86/686/EEC. EN 166/2002

Signed by or for the manufacturer

Director
Signed by:

Date:- 6th April 2020

INSTANT HAND SANITISER

Our Alcohol based hand sanitiser is tested to EN1276 standards - This test method evaluates how effectively the product to cause a reduction in the number of viable bacterial cells of the relevant test microorganisms

As well as EN1500 - another European Standard test method that evaluates the efficiency of a hygienic hand sanitiser.

70% Alcohol Gel Formulation

Material Safety Data Sheet

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

1.1. Product identifier

- **Product name** – Hand Sanitiser
- **Product code** –

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

- Sanitising of hands

1.3. Details of the supplier of the safety data sheet

-

1.4. Emergency telephone number

-

SECTION 2: Hazards identification

2.1. Classification of the mixture

Classification according to regulation (EC) No.1272/2008

Hazard Class	Hazard Category	Hazard Statements
Flammable Liquids	Category 2	H225
Eye Irritation	Category 2	H319

For the full text of the H-Statements mentioned in this section, see Section 16.

- **Primary route of exposure** – skin or eye contact, inhalation of vapours
- **Most important adverse effects**
  - **Human Health** – see section 11 for toxicological information
  - **Physical and Chemical Hazards** – see section 9 for physiochemical information
  - **Potential Environmental Effects** – see section 12 for environmental information

2.2. Label elements

Labelling according to regulation (EC) No. 1272/2008

Hazard symbols:	SGH02		SGH07	
Signal word:	Danger			
Hazard statements:	H225	Highly flammable liquid and vapour		
	H319	Causes serious eye irritation		
Precautionary statements				
Prevention	P210	Keep away from heat / sparks / open flames / hot surfaces. No smoking.		
	P233	Keep container tightly closed		
	P280	Use protective gloves / protective clothing / eye protection / face protection		
Response	P312	Call a POISON CENTER or doctor / physician if you feel unwell		
	P370+378	In case of fire use chemical powders, carbon dioxide for extinction		
	P305+351+338	IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing		
Storage	P403+233	Store in a well-ventilated place. Keep container tightly closed.		
Contains	Ethanol			

2.3. Other hazards

- No other data available

SECTION 3: Composition/information on ingredients

3.2 Mixtures

This product is a mixture.

Name	%	Index-No.	CAS-No.	EC-No.	EC Registration	Classification (Regulation EC 1972/2008	
Ethanol	70	603-002-00-5	64-17-5	200-578-6	01-2119457610-43-XXXX	Flam. Liq.2 Eye Irrit.2	H225 H319

For the full text of the H-Statements mentioned in this section, see Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

- **General advice**
  - In all cases of doubt, or when symptoms persist, seek medical advice
  - Never give anything by mouth to an unconscious person
- **Inhalation**
  - Move to fresh air
  - If breathing is irregular or stopped, consider artificial respiration
  - If unconscious place in recovery position
- **Skin Contact**
  - Take off all contaminated clothing immediately
  - Wash immediately with plenty of soapy water
- **Eye Contact**
  - Rinse immediately with plenty of water, also under the eyelids, for at least 10 minutes. Remove contact lenses
- **Ingestion**
  - Rinse mouth
  - Get immediate medical attention

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

- **Inhalation**
  - Possible drowsiness and dizziness. Risk of respiratory problems
- **Skin Contact**
  - Redness, pain. The skin absorbs part of the ingredients of this product. Can cause dry or chapped skin
- **Eye Contact**
  - Redness, watering, blurred vision. Risk of irritant effect on eyes
- **Ingestion**
  - Health risk even in small quantities. Product should not come into contact with food stuffs

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

- **Note to physicians**
  - Maintain adequate ventilation and oxygenation of the patient. Haemodialysis may be of benefit if substantial amounts have been ingested and the patient is showing signs of intoxication. No specific antidote. Treatment for exposure should be directed at the control of symptoms and the clinical condition of the patient.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- **Suitable extinguishing media**
  - Alcohol-resistant foam, carbon dioxide, dry chemical powder
- **Unsuitable extinguishing media**
  - High volume water jet

5.2. Special hazards arising from the mixture

- **Specific hazards during fire fighting**
  - The vapour may be invisible, heavier than air and spread along the ground

- Vapours may form an explosive atmosphere with air
- Flash back possible over considerable distance
- Fire produces carbon oxides (CO and CO2) and dense black smoke that is a health hazard; symptoms may not be immediately apparent
- Contaminated clothes are a fire risk

5.3. Advice for firefighters

- **Special protective equipment**
  - Wear self-contained breathing apparatus
  - Wear full protective suit
- **Further advice**
  - Cool closed containers with water spray / fog
  - Heating will cause pressure rise with risk of bursting
  - Collect contaminated fire extinguishing water separately; do not discharge to drains

SECTION 6: Accidental release measure

6.1. Personal precautions, protective equipment and emergency procedures

- Use personal protective equipment
- Provide adequate ventilation
- Keep away from heat and sources of ignition
- Avoid contact with skin, eyes and clothing
- Do not breathe vapours or mist

6.2. Environmental precautions

- Do not flush into surface water or sanitary sewer system
- Avoid subsoil penetration
- If the product contaminates rivers and lakes or drains inform respective authorities

6.3. Methods and material for containment and cleaning up

- Contain spillage
- Ground and bond all containers and handling equipment
- Collect with non-combustible absorbent material
- Place in container for disposal according to local / national regulations

6.4. Reference to other sections

- For personal protection refer to Section 8
- For disposal according to local / national regulations refer to Section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Keep container tightly closed
- Use personal protective equipment; avoid contact with skin, eyes and clothing
- Ensure adequate ventilation; do not breathe vapours
- Emergency eye wash fountains and emergency showers should be available in the immediate vicinity
- Vapours are heavier than air and may form explosive atmospheres
- Use-anti-static, non-sparking tools
- No smoking, naked-flames or sources of ignition; electrical equipment must be approved for use in a potentially explosive atmosphere
- Handle empty containers with care as residual vapours are flammable
- Limit the quantity of product in the workplace to a minimum
- Authorised persons only

7.2. Conditions for safe storage, including any incompatibilities

- Keep container tightly closed
- Store within a solvent-resistant bunded area

- Store in original container in a dry, cool and well-ventilated place
- Keep away from direct sunlight

7.3. Specific end use(s)

- No information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

UK. EH40 Workplace Exposure Limits (WELs)		
Component	Short-term exposure limit (STEL)	Time weighted average (TWA)
Ethanol	1.000ppm	1000ppm, 1900 mg/m^3

8.2. Exposure controls

- **Engineering controls**
  - Monitor airborne levels in and surrounding the workplace
  - Use engineering controls to maintain airborne level below exposure limits
  - Local exhaust ventilation may be necessary
  - If airborne levels exceed exposure limits then respiratory protection should be worn
- **Personal Protection**
  - Respiratory protection
    - Use an CE approved respirator with organic vapour cartridge with a particulate pre-filter, type AP2
  - Eye protection
    - Use chemical goggles consistent with EN 166 or equivalent
  - Hand protection
    - Use chemical resistant gloves consistent with EN 374 or equivalent
  - Skin protection
    - Use chemical resistant anti-static clothing
  - Hygiene
    - Handle in accordance with good industrial hygiene
    - Keep workplace clean and tidy as much as possible
    - Keep away from food, drink and animal feed
    - Wash hands and change clothes before and after each work shift
- **Environmental Protection**
  - Refer to Section 6, 7 and 13

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Form	: viscous liquid
Colour	: colourless / amber / pigmented
Odour	: esters
Odour threshold	: no data available
pH	: not applicable
Boiling point / range	: >77^{o}C
Flash point	: no data available
Evaporation rate	: no data available
Flammability (solid, gas)	: formation of explosive air/vapour mixture is possible
Explosion limits (%V)	: no data available
Vapour pressure	: no data available
Relative vapour pressure	: no data available
Relative density (g/cm^3 @ 20^{o}C)	: no data available
Water solubility	: no data available
Partition coefficient: n-octanol/water	: no data available
Auto-ignition temperature	: no data available
Decomposition temperature	: no data available
Viscosity	: no data available
Explosive properties	: formation of explosive air/vapour mixture is possible
Oxidising properties	: no data available

9.2. Other information

- No further data available

SECTION 10: Stability and reactivity

10.1. Reactivity

- No data available

10.2. Chemical stability

- Stable under recommended storage conditions. See Section 7

10.3. Possibility of hazardous reactions

- Polymerisation will not occur

10.4. Conditions to avoid

- Heat, flames, sparks, static discharge and direct sunlight

10.5. Incompatible materials

- Various plastics
- Acids, alkali, amines, bases, hydrides, metal, oxidisers

10.6. Hazardous decomposition products

- Decomposition products can include and not limited to: nitrogen oxides and carbon oxides

SECTION 11: Toxicological information

11.1. Information on toxicological effects

- There is no data available on the product itself and therefore bridging principles have been applied:

Toxicity	Value (estimated)	Result
Acute oral toxicity	>2000 mg / kg	No acute toxicity
Acute dermal activity	>2000 mg / kg	No acute toxicity
Acute inhalation activity	>20 mg / l	No acute toxicity
Eye irritation	Irritating	Eye irritant category 2

SECTION 12: Ecological information

12.1. Toxicity

- There is no data available for the product itself

12.2. Persistence and degradability

- No data available

12.3. Bio accumulative potential

- No data available

12.4. Mobility in soil

- No data available

12.5. Results of PBT and vPvB assessment

- No data available

12.6. Other adverse effects

- No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

- This product should be treated as hazardous waste according to EC 2008/98/EC
- Use authorised waste disposal services in compliance with all national, provincial, municipal or local laws
- Do not dispose of together with normal waste
- Do not dispose of into the environment, drains or sanitary sewer
- Do not burn or use cutting torch on empty drum
- Empty drums for storage or transport should continue to be labelled as flammable, class 3

SECTION 14: Transport information

Classification for Road and Rail Transport (ADR/RID)

14.1. UN number

- 1170

14.2. UN proper shipping name

- Ethanol Solution

14.3. Transport hazard class(es)

- Class 3

14.4. Packing group

- III

14.5. Environmental hazards

- No information available

14.6. Special precautions for user

- No information available

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

- No information available

Classification for Sea Transport (IMDG)

14.1. UN number

- 1170

14.2. UN proper shipping name

- Ethanol Solution

14.3. Transport hazard class(es)

- Class 3

14.4. Packing group

- III

14.5. Environmental hazards

- No information available

14.6. Special precautions for user

- No information available

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

- No information available

Classification for Air Transport (IATA/ICAO)

14.1. UN number

- 1170

14.2. UN proper shipping name

- Ethanol Solution

14.3. Transport hazard class(es)

- Class 3

14.4. Packing group

- III

14.5. Environmental hazards

- No information available

14.6. Special precautions for user

- No information available

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

- No information available

SECTION 15: Regulatory information

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

- This mixture contains only components that have been either pre-registered, registered, are exempt from registration, are regarded as registered or are not subject to registration according to Regulation (EC) No. 1907/2006 (REACH)

15.2. Chemical safety assessment

- Not applicable

SECTION 16: Other information

Full text of H-statements referred to previously in document:

- H225: Highly flammable vapour
- H319: Causes serious eye irritation

Revision: 200317 Material Safety Data Sheet Hand Sanitiser HS2020
200319 Material Safety Data Sheet Hand Sanitiser HS2020 Rev 2
200412 Material Safety Data Sheet Hand Sanitiser HS2020 Rev 3

urges each customer or recipient of this material safety data sheet to study it carefully and consult appropriate expertise, as necessary or appropriate, to become aware of and understand the data contained herein and any hazards associated with the product. The information herein is provided in good faith and believed to be accurate as of the effective date shown above. No warranty, express or implied, is given. Regulatory requirements are subject to change and may differ between various locations. It is the buyer's/ user's responsibility to ensure that his activities comply with all federal, state, provincial or local laws.

80% Alcohol Liquid Formulation

Material Safety Data Sheet

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

1.1. Product identifier

- **Product name** – Hand Sanitiser
- **Product code** – WHO 01

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

- Sanitising of hands

1.3. Details of the supplier of the safety data sheet

1.4. Emergency telephone number

SECTION 2: Hazards identification

2.1. Classification of the mixture

Classification according to regulation (EC) No.1272/2008

Hazard Class	Hazard Category	Hazard Statements
Flammable Liquids	Category 2	H225
Eye Irritation	Category 2	H319

For the full text of the H-Statements mentioned in this section, see Section 16.

- **Primary route of exposure** – skin or eye contact, inhalation of vapours
- **Most important adverse effects**
  - **Human Health** – see section 11 for toxicological information
  - **Physical and Chemical Hazards** – see section 9 for physiochemical information
  - **Potential Environmental Effects** – see section 12 for environmental information

2.2. Label elements

Labelling according to regulation (EC) No. 1272/2008

Hazard symbols:	SGH02		SGH07	
Signal word:	Danger			
Hazard statements:	H225	Highly flammable liquid and vapour		
	H319	Causes serious eye irritation		
Precautionary statements				
Prevention	P210	Keep away from heat / sparks / open flames / hot surfaces. No smoking.		
	P233	Keep container tightly closed		
	P280	Use protective gloves / protective clothing / eye protection / face protection		
Response	P312	Call a POISON CENTER or doctor / physician if you feel unwell		
	P370+378	In case of fire use chemical powders, carbon dioxide for extinction		
	P305+351+338	IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing		
Storage	P403+233	Store in a well-ventilated place. Keep container tightly closed.		
Contains	Ethanol			

2.3. Other hazards

- No other data available

SECTION 3: Composition/information on ingredients

3.2 Mixtures

This product is a mixture.

Name	%	Index-No.	CAS-No.	EC-No.	EC Registration	Classification (Regulation EC 1972/2008	
Ethanol	80	603-002-00-5	64-17-5	200-578-6	01-2119457610-43-XXXX	Flam. Liq.2 Eye Irrit.2	H225 H319

For the full text of the H-Statements mentioned in this section, see Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

- **General advice**
  - In all cases of doubt, or when symptoms persist, seek medical advice
  - Never give anything by mouth to an unconscious person
- **Inhalation**
  - Move to fresh air
  - If breathing is irregular or stopped, consider artificial respiration
  - If unconscious place in recovery position
- **Skin Contact**
  - Take off all contaminated clothing immediately
  - Wash immediately with plenty of soapy water
- **Eye Contact**
  - Rinse immediately with plenty of water, also under the eyelids, for at least 10 minutes. Remove contact lenses
- **Ingestion**
  - Rinse mouth
  - Get immediate medical attention

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

- **Inhalation**
  - Possible drowsiness and dizziness. Risk of respiratory problems
- **Skin Contact**
  - Redness, pain. The skin absorbs part of the ingredients of this product. Can cause dry or chapped skin
- **Eye Contact**
  - Redness, watering, blurred vision. Risk of irritant effect on eyes
- **Ingestion**
  - Health risk even in small quantities. Product should not come into contact with food stuffs

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

- **Note to physicians**
  - Maintain adequate ventilation and oxygenation of the patient. Haemodialysis may be of benefit if substantial amounts have been ingested and the patient is showing signs of intoxication. No specific antidote. Treatment for exposure should be directed at the control of symptoms and the clinical condition of the patient.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- **Suitable extinguishing media**
  - Alcohol-resistant foam, carbon dioxide, dry chemical powder
- **Unsuitable extinguishing media**
  - High volume water jet

5.2. Special hazards arising from the mixture

- **Specific hazards during fire fighting**
  - The vapour may be invisible, heavier than air and spread along the ground

- Vapours may form an explosive atmosphere with air
- Flash back possible over considerable distance
- Fire produces carbon oxides (CO and CO2) and dense black smoke that is a health hazard; symptoms may not be immediately apparent

5.3. Advice for firefighters

- **Special protective equipment**
  - Wear self-contained breathing apparatus
  - Wear full protective suit
- **Further advice**
  - Cool closed containers with water spray / fog
  - Heating will cause pressure rise with risk of bursting
  - Collect contaminated fire extinguishing water separately; do not discharge to drains

SECTION 6: Accidental release measure

6.1. Personal precautions, protective equipment and emergency procedures

- Use personal protective equipment
- Provide adequate ventilation
- Keep away from heat and sources of ignition
- Avoid contact with skin, eyes and clothing
- Do not breathe vapours or mist

6.2. Environmental precautions

- Do not flush into surface water or sanitary sewer system
- Avoid subsoil penetration
- If the product contaminates rivers and lakes or drains inform respective authorities

6.3. Methods and material for containment and cleaning up

- Contain spillage
- Ground and bond all containers and handling equipment
- Collect with non-combustible absorbent material
- Place in container for disposal according to local / national regulations

6.4. Reference to other sections

- For personal protection refer to Section 8
- For disposal according to local / national regulations refer to Section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Keep container tightly closed
- Use personal protective equipment; avoid contact with skin, eyes and clothing
- Ensure adequate ventilation; do not breathe vapours
- Emergency eye wash fountains and emergency showers should be available in the immediate vicinity
- Vapours are heavier than air and may form explosive atmospheres
- Use-anti-static, non-sparking tools
- No smoking, naked-flames or sources of ignition; electrical equipment must be approved for use in a potentially explosive atmosphere
- Handle empty containers with care as residual vapours are flammable
- Limit the quantity of product in the workplace to a minimum
- Authorised persons only

7.2. Conditions for safe storage, including any incompatibilities

- Keep container tightly closed
- Store within a solvent-resistant bunded area
- Store in original container in a dry, cool and well-ventilated place

- Keep away from direct sunlight

7.3. Specific end use(s)

- No information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

UK. EH40 Workplace Exposure Limits (WELs)		
Component	Short-term exposure limit (STEL)	Time weighted average (TWA)
Ethanol	1.000ppm, 1.920 mg/m^3	500ppm, 1.000 mg/m^3

8.2. Exposure controls

- **Engineering controls**
  - Monitor airborne levels in and surrounding the workplace
  - Use engineering controls to maintain airborne level below exposure limits
  - Local exhaust ventilation may be necessary
  - If airborne levels exceed exposure limits then respiratory protection should be worn
- **Personal Protection**
  - Respiratory protection
    - Use an CE approved respirator with organic vapour cartridge with a particulate pre-filter, type AP2
  - Eye protection
    - Use chemical goggles consistent with EN 166 or equivalent
  - Hand protection
    - Use chemical resistant gloves consistent with EN 374 or equivalent
  - Skin protection
    - Use chemical resistant anti-static clothing
  - Hygiene
    - Handle in accordance with good industrial hygiene
    - Keep workplace clean and tidy as much as possible
    - Keep away from food, drink and animal feed
    - Wash hands and change clothes before and after each work shift
- **Environmental Protection**
  - Refer to Section 6, 7 and 13

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Form	: viscous liquid
Colour	: colourless / amber / pigmented
Odour	: esters
Odour threshold	: no data available
pH	: not applicable
Boiling point / range	: >77°C
Flash point	: no data available
Evaporation rate	: no data available
Flammability (solid, gas)	: formation of explosive air/vapour mixture is possible
Explosion limits (%V)	: no data available
Vapour pressure	: no data available
Relative vapour pressure	: no data available
Relative density (g/cm^3 @ 20°C)	: no data available
Water solubility	: no data available
Partition coefficient: n-octanol/water	: no data available
Auto-ignition temperature	: no data available
Decomposition temperature	: no data available
Viscosity	: no data available
Explosive properties	: formation of explosive air/vapour mixture is possible
Oxidising properties	: no data available

9.2. Other information

- No further data available

SECTION 10: Stability and reactivity

10.1. Reactivity

- No data available

10.2. Chemical stability

- Stable under recommended storage conditions. See Section 7

10.3. Possibility of hazardous reactions

- Polymerisation will not occur

10.4. Conditions to avoid

- Heat, flames, sparks, static discharge and direct sunlight

10.5. Incompatible materials

- Various plastics
- Acids, alkali, amines, bases, hydrides, metal, oxidisers

10.6. Hazardous decomposition products

- Decomposition products can include and not limited to: nitrogen oxides and carbon oxides

SECTION 11: Toxicological information

11.1. Information on toxicological effects

- There is no data available on the product itself and therefore bridging principles have been applied:

Toxicity	Value (estimated)	Result
Acute oral toxicity	>2000 mg / kg	No acute toxicity
Acute dermal activity	>2000 mg / kg	No acute toxicity
Acute inhalation activity	>20 mg / l	No acute toxicity
Eye irritation	Irritating	Eye irritant category 2

SECTION 12: Ecological information

12.1. Toxicity

- There is no data available for the product itself

12.2. Persistence and degradability

- No data available

12.3. Bio accumulative potential

- No data available

12.4. Mobility in soil

- No data available

12.5. Results of PBT and vPvB assessment

- No data available

12.6. Other adverse effects

- No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

- This product should be treated as hazardous waste according to EC 2008/98/EC
- Use authorised waste disposal services in compliance with all national, provincial, municipal or local laws
- Do not dispose of together with normal waste
- Do not dispose of into the environment, drains or sanitary sewer
- Do not burn or use cutting torch on empty drum
- Empty drums for storage or transport should continue to be labelled as flammable, class 3

SECTION 14: Transport information

Classification for Road and Rail Transport (ADR/RID)

14.1. UN number

- 1170

14.2. UN proper shipping name

- Ethanol Solution

14.3. Transport hazard class(es)

- Class 3

14.4. Packing group

- III

14.5. Environmental hazards

- No information available

14.6. Special precautions for user

- No information available

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

- No information available

Classification for Sea Transport (IMDG)

14.1. UN number

- 1170

14.2. UN proper shipping name

- Ethanol Solution

14.3. Transport hazard class(es)

- Class 3

14.4. Packing group

- III

14.5. Environmental hazards

- No information available

14.6. Special precautions for user

- No information available

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

- No information available

Classification for Air Transport (IATA/ICAO)

14.1. UN number

- 1170

14.2. UN proper shipping name

- Ethanol Solution

14.3. Transport hazard class(es)

- Class 3

14.4. Packing group

- III

14.5. Environmental hazards

- No information available

14.6. Special precautions for user

- No information available

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

- No information available

SECTION 15: Regulatory information

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

- This mixture contains only components that have been either pre-registered, registered, are exempt from registration, are regarded as registered or are not subject to registration according to Regulation (EC) No. 1907/2006 (REACH)

15.2. Chemical safety assessment

- Not applicable

SECTION 16: Other information

Full text of H-statements referred to previously in document:

- H225: Highly flammable vapour
- H319: Causes serious eye irritation

Revision: 200317 Material Safety Data Sheet Hand Sanitiser
200409 Material Safety Data Sheet Hand Sanitiser WHO01 Rev

urges each customer or recipient of this material safety data sheet to study it carefully and consult appropriate expertise, as necessary or appropriate, to become aware of and understand the data contained herein and any hazards associated with the product. The information herein is provided in good faith and believed to be accurate as of the effective date shown above. No warranty, express or implied, is given. Regulatory requirements are subject to change and may differ between various locations. It is the buyer's/ user's responsibility to ensure that his activities comply with all federal, state, provincial or local laws.

SAFETY DATA SHEET

Pursuant to Annex of Commission Regulation (EU) 2015/830

[redacted]	[redacted]	Date of filling:	04-06-2019
		Last revision date:	19-02-2020
		Issue No.	1

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

Product identifier [redacted]

Relevant identified uses of the substance / mixture and uses advised against

Detergent / care product for professional use - isopropanol based disinfectant.

Disinfectant for personal hygiene; disinfectant not for direct human use; food area disinfectant (biocide type 1, 2, 4). For professional users only. Hygienic hand disinfection in public facilities and catering establishments; for quick disinfection of small surfaces, equipment, inventory other than medical devices in health care facilities (procedural and dental offices, nursing homes, etc.), public facilities (hairdressing salons, beauty and tattoo shops, etc.) and catering establishments. Cannot be used to treat wounds and damaged skin. Can not contact food directly. Read instruction manual and safety data sheet before use. Authorization Certificate of the biocidal product (10-14

72% Alcohol Liquid Formulation

Supplier / Manufacturer [redacted]

E-mail of the person responsible for the safety data sheet

Emergency telephone number

2. POTENTIAL HAZARDS

Classification of the substance / mixture and labelling elements

Signal word: Dangerous

Hazard class: Flammable liquid, Category 2; Serious eye damage / eye irritation, Category 2; Specific target organ toxicity - single exposure, Category 3.

GHS02

GHS07

Hazard statements:

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

Precautionary statements:

P210 Keep away from heat / sparks / open flames / hot surfaces. - Do not smoke.

P233 Keep container tightly closed.

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor / physician.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue to wash eyes.

P337 + P313 If eye irritation persists: Get medical advice / attention.

P403 + P235 Store in a well-ventilated place. Store in a cool place.

P501 Dispose of contents / container in accordance with national regulations.

Other hazards Substance / mixture does not meet the criteria for classification as PBT or vPvB; the substances are not on the Candidate List SVHC (Substances of Very High Concern) list at the time of writing the Safety Data Sheet.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Description of the substance / mixture Solution, a mixture of the following substances with non-dangerous impurities / additives.

Hazardous ingredients:

Ser. No.	CAS No.	EC No.	Index No.	Weight percentage,%	Chemical name, *registration number*	Classification
1.	67-63-0	200-661-7	603-117-00-0	72.0	isopropanol; isopropanol, isopropyl alcohol *01-2119457558-25-0000*	Flam. Liq. 2 H225 Eye Irrit. 2 H319 STOT SE 3 H336
2.	68424-85-1	270-325-2	-	0.03	quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides *01-2119965180-41-0000*	Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Dam. 1 H318 Aquatic Acute 1 H400 Aquatic Chronic 1 H410

Note: Explanations to hazard classes, phrases and other indications are given in sections 2 and 16.

4. FIRST AID MEASURES

Description of first aid measures:

First aid information — In all cases of doubt, or when symptoms persist, seek medical attention. If the victim is unconscious, do not give anything to drink or give anything to mouth. If poisoning is suspected or detected, contact the Poison Control and Information Bureau.

Inhalation — In case of inhalation of gas, immediately discontinue contact - remove or remove victim to fresh air and keep at rest. Get medical attention if symptoms of respiratory tract develop. In case of unconsciousness place patient stably in side position for transportation.

Dermal contact — Wash with soap and water. Get medical attention if symptoms occur. Wash contaminated clothing before re-use.

Eye contact — Wash eyes with plenty of running water for at least 15 minutes. Remove contact lenses, if possible. Get medical attention immediately.

Ingestion — Do not induce vomiting or give activated charcoal. If unconscious, remove remnants from the mouth, rinse mouth with water, drink plenty of water and seek medical advice immediately.

Most important symptoms and effects, both acute and delayed:

Eye effects are considered to be irritating. Skin contact is considered to be a mild irritant after prolonged and repeated use. Parathyroidism: central nervous system depression, nausea / vomiting, alcoholic beverage poisoning symptoms.

Inhalation effects: High vapour concentrations may cause short term irritation, respiratory tract, headache, nausea.

Indication of any immediate medical attention and special treatment needed:

The workplace must have an eye wash fountain, shower or bath. Also first aid measures, eye wash.

5. FIREFIGHTING MEASURES

Extinguishing media	The mixture is flammable. Suitable extinguishing media: water (spray), dry extinguishing powder, alcohol-resistant foam. In the event of fire, extinguishing media must be selected having regard to the properties of the combustible materials around.
Special hazards arising from the substance / mixture	Isopopanol is soluble in water and its solutions are flammable in water. Combustion generates soot, carbon monoxide, carbon dioxide and explosive peroxides may be formed. It is necessary to know the properties of other substances or mixtures used or stored.
Advice for fire-fighters	Wear self contained breathing apparatus and non-flammable fire-fighters clothing in the event of fire. Personal protective equipment shall be selected taking into account the properties of the combustible materials.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	Ensure adequate ventilation / respiratory protection, skin and eye contact. Do not breathe vapour. Use personal protective equipment as specified in Section 8.
Environmental precautions	Do not discharge spillage into local or rainwater sewage system, surface water bodies or natural environment.
Isolation and cleaning procedures / measures	Collect with liquid-binding material (sand, universal binder). Allow the residue to evaporate. Do not dispose of material in trash or in the original packaging. Dispose of collected material in accordance with instructions. In the event of large spills, inform the rescue service.
Reference to other sections	See sections 8 and 13.

7. HANDLING AND STORAGE

Precautions for safe handling	Store in tightly closed original containers in a dry, ventilated place. Do not store together with flammable materials, means. Do not damage the packaging. Do not smoke. Do not use tools that cause sparks. Store at temperatures below -15°C and not above +15°C and away from sources of heat, sunlight.
Conditions for safe storage, including any incompatibilities	For professional use only. Use only in well-ventilated areas, in areas with exhaust ventilation, in strict accordance with the instructions for use. Comply with general rules for handling chemicals. Do not mix with other chemicals. Do not eat, drink or smoke during use. Prevent the creation of airborne concentrations of vapours above the exposure limits. Wear suitable personal protective equipment as specified in Section 8.
Specific end use (s)	For professional use only.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters (occupational exposure limit values) according to HN 23: 2011:

CAS No.	Title	Maximum allowable concentration
67-63-0	isopropanol; isopropanol, isopropyl alcohol	LTEL = 350 mg/m^3, 150 ppm STEL = 600 mg/m^3, 250 ppm

Notes: LTEL – long-term exposure limit, STEL – short-term exposure limit

DNEL (for employees):

CAS No.	Title	Exposure
67-63-0	isopropanol; isopropanol, isopropyl alcohol	long-term, systemic, dermal: 888 mg/kg. long-term, systemic, inhalation: 500 mg/m^3

DNEL (for citizens):

CAS No.	Title	Exposure
67-63-0	isopropanol; isopropanol, isopropyl alcohol	long-term, systemic, dermal: 319 mg/kg. long-term, systemic, inhalation: 89 mg/m^3 long-term, systemic, ingestion: 26 mg/kg.

Exposure control

Technical measures to prevent exposure	General, local exhaust ventilation, avoid spillage, soil and sewage, see section 7.
Individual protection measures:	
General safety and hygiene measures	Keep away from food, drink and animal feeding stuffs. Take off immediately all contaminated, soaked clothing. Wash hands before breaks and at the end of work. Avoid contact with eyes.
Hand and body protection	Wash skin with water during breaks and / or at the end of work; apply oily skin care products. Non-flammable, antistatic protective work clothing.
Eye / face protection	Safety glasses (EN 166).
Respiratory protection	In case of inadequate ventilation, masks or half masks with filter A (colour code - brown) should be used in case of accidents - vapour protection.
Environmental Impact Control	Avoid spillage. See Sections 6 and 12.

9. PHYSICAL AND CHEMICAL PROPERTIES

State of aggregation	Liquid
Colour	Clear
Odour	Characteristic (alcohol)
pH, 100 %, 25°C	7-10
Relative density, g/cm^3, 20°C	0.83-0.85

Flash point, °C (72% aqueous solution of isopropanol)	18

10. STABILITY AND REACTIVITY

Reactivity	Reacts violently with oxidants, strong acids. The rate of degradation depends on temperature, concentration, pH.
Chemical stability	The mixture is stable under normal conditions and under strict conditions of safe use.
Possibility of hazardous reactions	No dangerous reaction known.
Conditions to avoid / incompatible materials	Avoid heat, light, flammable substances / materials, strong mineral acids, oxidizing agents, aluminium at high temperatures.
Hazardous decomposition products	Carbon oxides are released during decomposition. The reaction products also depend on the substances / mixtures involved in the chemical reactions.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Acute toxicity	Based on the chemical information it can be argued that the mixture does not fall into the acute toxicity category when ingested by the test animals. Acute toxicity of the components: isopropanol: oral (rat): LD50> 2000 mg / kg, dermal (rabbit): LD50> 5000 mg / kg by inhalation (rat): LC50> 20 mg/l / 8 h. quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides: oral (rat): LD50 344 mg/kg, dermal (rabbit): LD50 3340 mg/kg.
Skin corrosion and/or irritation	May cause skin irritation.
Serious eye damage / eye irritation	Causes serious eye irritation.
Respiratory or skin sensitization	The components are non-sensitizing.
Germ cell mutagenicity	Based on the chemical information it can be stated that the mixture is not mutagenic: there is no evidence of mutagenic effects of the components.
Carcinogenicity	Based on the chemical information it can be stated that the mixture has no carcinogenic effect: there is no evidence of carcinogenic effects of the components.
Reproductive toxicity	Based on the chemical information it can be stated that the mixture has no effects on reproduction: no evidence of reproductive toxicity of the components.
STOT (single exposure)	Vapours may cause drowsiness and dizziness.
STOT (multiple exposure)	Not applicable / no data available.

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Danger of aspiration	Not applicable / no data available.
Additional toxicological information	Exposure depends on the amount of concentration and duration of exposure.

12. ECOLOGICAL INFORMATION

Toxicity	Based on the chemical information, the mixture is not considered to be toxic to aquatic organisms. Calculated toxicity of the mixture to fish: LC50 ≥ 87 mg / l / 96 h.
Persistence and degradability	Based on the chemical information, the product can be said to be biodegradable. The biodegradability of surfactants (PAMs) in the mixture shall be in accordance with the provisions of Detergent Regulation No. 551/2009.
Bioaccumulative potential	Bioaccumulation is not expected.
Mobility in soil	Soluble in water, dispersed, neutralized. Dilute with water or neutralize before draining into drains or sewers.
Results of PBT and vPvB assessment	Ingredients are not classified as PBT and vPvB substances.
Other adverse effects	Not applicable / no data available.

13. WASTE HANDLING

Waste handling methods:

Product Disposal	Dispos in accordance with local waste disposal law. The product decomposes on burning in carbon dioxide and water. Incineration is the recommended method of disposing of the product.
Packaging disposal	Packaging waste must be disposed of in accordance with the Packaging and Packaging Waste Management Act. It is recommended to transfer the washed and dried packages to packaging waste management companies. Package waste codes: 15 01 02 plastic (including PET) packaging; 15 01 10 packaging containing residues of or contaminated by dangerous substances. It is recommended not to burn packages containing product residue.

14. TRANSPORT INFORMATION

Classification of transport	Land transport ADR / RID (international / domestic).
UN number	1219
UN proper shipping name	Isopropanol (isopropyl alcohol)
Transport hazard class (es)	3 flammable liquids
Packing group	II
Signs of danger	3
Environmental hazards	-

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Special precautions for user Do not damage the packaging.

15. REGULATORY INFORMATION

Safety, health and environmental regulations / legislation specific for the substance / mixture:

Commission Regulation (EC) No 551/2009 of 25 June 2009 amending Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents, in order to adapt Annexes V and VI thereto (surfactants derogation).

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

HN 23: 2011 Occupational Exposure Limits for Chemicals. General Requirements for Measurement and Impact Assessment "(Approved by Order No V-824 / A1-389 of 1 September 2011 of the Minister of Health and the Minister of Social Security and Labour of the Republic of Lithuania, Official Gazette, 2011, No. 112-5274).

List of Acute Health Disorders Caused by Dangerous Chemicals, Preparations and Biological Substances of the First Aid Measures (Approved by Order No. V-769 of 24 December 2003 of the Minister of Health of the Republic of Lithuania, Official Gazette, 2004, No. 7-157).

European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

Packaging and Packaging Waste Management Regulations (Approved by Order of the Minister of the Environment No. 348 of June 27, 2002, Official Gazette, 2002, No. 81-3503, as amended by Official Gazette, 2004 No. 78-2761; 2005 No. 2-23; 2007 No. 6-271; 2010 No. 53-2622, no. 79-4114, no. 91-4863; 2011 No. 28-1353; 2012 No. 84-4419).

Waste Management Regulations (New edition approved by Order No. D1-368 of the Minister of Environment of the Republic of Lithuania of May 3, 2011, Official Gazette, 2011, No. 57-2721).

Regulations on the Provision of Personal Protective Equipment to Employees (Approved by Order No. A1-331 of the Minister of Social Security and Labour of the Republic of Lithuania of 26 November 2007, Official Gazette, 2007, No. 123-5055).

Chemical safety assessment Contained substances (isopropanol) have undergone chemical safety assessments.

16. OTHER INFORMATION

Explanation of hazard symbols and numerical signs (referred to in section 3):

Flam. Liq. 2 Flammable liquid, Category 2

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Acute Tox. 4	Acute toxicity, Category 4.
Skin Corr. 1B.	Skin corrosion, subcategory 1B.
Eye Dam. 1	Serious eye damage, Category 1.
Eye Irrit. 2	Serious eye irritation, Category 2.
STOT SE 3	Specific target organ toxicity (single exposure), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment, Acute Category 1.
Aquatic Chronic 1	Hazardous to the aquatic environment, Chronic Category 1.
H225	Highly flammable liquid and vapor.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
H400	Very toxic to aquatic organisms.
H410	Very toxic to aquatic life with long lasting effects

Abbreviations and acronyms:

DNEL	derivative no effect level.
LD50/ LC50	the dose (concentration) of the substance which causes 50% death of the test animals.
NOEC	no observed effect concentration.
PBT	persistent, bioaccumulative and toxic chemicals.
vPvB	very persistent and very bioaccumulative substances.

The data given in this safety data sheet must be available to anyone working on the substance / mixture. The data is based on our current knowledge and are intended to describe the product in terms of safety and health at work and environmental aspects. The information in the safety data sheet will be updated as new data on health and environmental effects of the substance / mixture, preventive measures to reduce or eliminate hazards become available. The information provided in the safety data sheet does not reveal any other specific properties of the substance / mixture.

70% Alcohol Gel Formulation (Made in China)

Safety Data Sheet (SDS) Report

SDS number: **GZHH00358291S3**

Applicant: Zimpli Medical Limited
Gladstone Street, Greenbank Business Park, Blackburn,Lancashire,BB1 3ES

Issue Date: 2020-04-28

Sample Description:

The sample information was submitted and identified on client's behalf to be:

Product Name	:	Orcagel Hand Sanitiser Gel-70% alcohol/Handsafe Hand Sanitiser Gel-70% Alcohol
Physical State	:	Liquid
Data Received	:	Apr 17, 2020
Initial Version Date	:	Apr 26, 2020
Data Reviewed	:	Apr 28, 2020

Service Requested:

Based on the information provided by the applicant, the Safety Data Sheet (SDS) was generated according to requirements of Regulation (EC) No 1907/2006 (REACH) with its amendment Commission Regulation (EU) 2015/830, Regulation (EC) No 1272/2008, for details please refer to attached pages.

Authorized By:

On Behalf Of Regulatory Affairs in Intertek Testing Services Ltd., Shanghai

Anna Wang
Regulatory Consultant

Intertek Health, Environmental &Regulatory Services (HERS)

5th Floor,Building No.86,1198 QinZhou Road(North),Cao Hejing Development Zone,ShangHai,China.

Tel: +86 021 53397917 ZIP: 200233

E-mail:hers@intertek.com

Safety Data Sheet

Orcagel Hand Sanitiser Gel-70% alcohol/ Handsafe Hand Sanitiser Gel-70% Alcohol

Zimpli Medical Limited

SDS Number: **GZHH00358291S3**

Version No:**3.0**
Issue Date:**28/04/2020**
According to Regulation (EC) No 1907/2006(REACH) with its amendment Commission Regulation (EU) 2015/830
REACH.GBR.EN

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1. Product Identifier

Product name	Orcagel Hand Sanitiser Gel-70% alcohol/ Handsafe Hand Sanitiser Gel-70% Alcohol
Proper shipping name	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
Other means of identification	Not Available

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

Relevant identified uses	sanitizer
Uses advised against	Not Applicable

1.3. Details of the supplier of the safety data sheet

Supplier Name	**Zimpli Medical Limited**
Address	Gladstone Street, Greenbank Business Park, Blackburn,Lancashire,BB1 3ES
Telephone	+44 (0)845 459 1818
Email	eejay@zimplikids.com

1.4. Emergency telephone number

Association / Organisation	**Zimpli Medical Limited**
Emergency telephone numbers	**+44 (0)845 459 1818 (9:00-17:00 Monday-Friday)**

SECTION 2 HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. Classified as Dangerous Goods for transport purposes.

Classification according to regulation (EC) No 1272/2008 [CLP]	H225 - Flammable Liquid Category 2

2.2. Label elements

Hazard pictogram(s)	
SIGNAL WORD	**DANGER**

Hazard statement(s)

H225	Highly flammable liquid and vapour.

Supplementary statement(s)

Not Applicable

Precautionary statement(s) General

Precautionary statement(s) Prevention

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233	Keep container tightly closed.
P240	Ground and bond container and receiving equipment.
P241	Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment.
P242	Use non-sparking tools.
P243	Take action to prevent static discharges.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Page 1 continued...

Precautionary statement(s) Response

P370+P378	In case of fire: Use alcohol resistant foam or normal protein foam to extinguish.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

Precautionary statement(s) Storage

P403+P235	Store in a well-ventilated place. Keep cool.

Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

2.3. Other hazards

REACH-Art.57-59: The mixture does not contain Substances of Very High Concern(SVHC) at the SDS print date.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1.Substances

See 'Composition on ingredients' in Section 3.2

3.2.Mixtures

1.CAS No 2.EC No 3.Index No 4.REACH No	%[weight]	Name	Classification according to regulation (EC) No 1272/2008 [CLP]
1.64-17-5 2.200-578-6 3.603-002-00-5 4.Not Available	70	ethanol	Flammable Liquid Category 2; H225
1.7732-18-5 2.231-791-2 3.Not Available 4.Not Available	26.4556	water	Not Classified
1.56-81-5 2.200-289-5 3.Not Available 4.Not Available	3	glycerol	Not Classified
1.9007-20-9 2.Not Available 3.Not Available 4.Not Available	0.4	Carbomer	Not Classified
1.8001-97-6 2.Not Available 3.Not Available 4.Not Available	0.1	aloes	Not Classified
1.1310-73-2 2.215-185-5 3.011-002-00-6 4.Not Available	0.04	sodium hydroxide	Skin Corrosion/Irritation Category 1A; H314 SCL: Eye Irrit. 2; H319: 0,5 % ≤ C < 2 % Skin Corr. 1A; H314: C ≥ 5 % Skin Corr. 1B; H314: 2 % ≤ C < 5 % Skin Irrit. 2; H315: 0,5 % ≤ C < 2 %
1.860-22-0 2.212-728-8 3.Not Available 4.Not Available	0.0042	C.I. Acid Blue 74	Skin Sensitizer Category 1; H317
1.4430-18-6 2.224-618-7 3.Not Available 4.Not Available	0.0002	C.I. Acid Violet 43	Serious Eye Damage Category 1; H318

SECTION 4 FIRST AID MEASURES

4.1. Description of first aid measures

Eye Contact	If this product comes in contact with the eyes: ▸ Wash out immediately with fresh running water. ▸ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▸ Seek medical attention without delay; if pain persists or recurs seek medical attention. ▸ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin contact occurs: ▸ Seek medical attention in event of irritation.

Continued...

Inhalation	▸ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▸ Other measures are usually unnecessary.
Ingestion	▸ Immediately give a glass of water. ▸ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

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

For acute or short term repeated exposures to ethanol:

- Acute ingestion in non-tolerant patients usually responds to supportive care with special attention to prevention of aspiration, replacement of fluid and correction of nutritional deficiencies (magnesium, thiamine pyridoxine, Vitamins C and K).
- Give 50% dextrose (50-100 ml) IV to obtunded patients following blood draw for glucose determination.
- Comatose patients should be treated with initial attention to airway, breathing, circulation and drugs of immediate importance (glucose, thiamine).
- Decontamination is probably unnecessary more than 1 hour after a single observed ingestion. Cathartics and charcoal may be given but are probably not effective in single ingestions.
- Fructose administration is contra-indicated due to side effects.

SECTION 5 FIREFIGHTING MEASURES

5.1. Extinguishing media

- Alcohol stable foam.
- Dry chemical powder.

5.2. Special hazards arising from the substrate or mixture

Fire Incompatibility	▸ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

5.3. Advice for firefighters

Fire Fighting	▸ Alert Fire Brigade and tell them location and nature of hazard. ▸ May be violently or explosively reactive.
Fire/Explosion Hazard	▸ Liquid and vapour are highly flammable. ▸ Severe fire hazard when exposed to heat, flame and/or oxidisers. Combustion products include: carbon dioxide (CO_2) carbon monoxide(CO)

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

See section 8

6.2. Environmental precautions

See section 12

6.3. Methods and material for containment and cleaning up

Minor Spills	▸ Remove all ignition sources. ▸ Clean up all spills immediately.
Major Spills	▸ Clear area of personnel and move upwind. ▸ Alert Fire Brigade and tell them location and nature of hazard.

6.4. Reference to other sections

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 HANDLING AND STORAGE

7.1. Precautions for safe handling

Safe handling	▸ Containers, even those that have been emptied, may contain explosive vapours. ▸ Do NOT cut, drill, grind, weld or perform similar operations on or near containers. ▸ Limit all unnecessary personal contact. ▸ Wear protective clothing when risk of exposure occurs.
Fire and explosion protection	See section 5
Other information	▸ Store in original containers in approved flame-proof area. ▸ No smoking, naked lights, heat or ignition sources.

Continued...

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	‣ PET Container ‣ Plastic containers may only be used if approved for flammable liquid.
Storage incompatibility	‣ Avoid oxidising agents, acids, acid chlorides, acid anhydrides, chloroformates. ‣ Avoid strong bases.

7.3. Specific end use(s)

See section 1.2

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
Orcagel Hand Sanitiser Gel-70% Alcohol/ Handsafe Hand Sanitizer Gel-70% Alcohol	Not Available	Not Available

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
UK Workplace Exposure Limits (WELs)	ethanol	Ethanol	1000 ppm / 1920 mg/m3	Not Available	Not Available	Not Available
UK Workplace Exposure Limits (WELs)	glycerol	Glycerol, mist	10 mg/m3	Not Available	Not Available	Not Available
UK Workplace Exposure Limits (WELs)	sodium hydroxide	Sodium hydroxide	Not Available	2 mg/m3	Not Available	Not Available

8.2. Exposure controls

8.2.1. Appropriate engineering controls	Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.
8.2.2. Personal protection	
Eye and face protection	‣ Safety glasses with side shields. ‣ Chemical goggles.
Skin protection	See Hand protection below
Hands/feet protection	‣ Wear chemical protective gloves, e.g. PVC. ‣ Wear safety footwear or safety gumboots, e.g. Rubber The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
Body protection	See Other protection below
Other protection	‣ Overalls. ‣ PVC Apron. ‣ Some plastic personal protective equipment (PPE) (e.g. gloves, aprons, overshoes) are not recommended as they may produce static electricity. ‣ For large scale or continuous use wear tight-weave non-static clothing (no metallic fasteners, cuffs or pockets).

8.2.3. Environmental exposure controls

See section 12

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Blue Liquid

Physical state	Liquid	**Relative density (Water = 1)**	Not Available
Odour	Not Available	**Partition coefficient n-octanol / water**	Not Available
Odour threshold	Not Available	**Auto-ignition temperature (°C)**	Not Available

Continued...

pH (as supplied)	Not Available	**Decomposition temperature**	Not Available
Melting point / freezing point (°C)	Not Available	**Viscosity (cSt)**	Not Available
Initial boiling point and boiling range (°C)	Not Available	**Molecular weight (g/mol)**	Not Available
Flash point (°C)	Not Available	**Taste**	Not Available
Evaporation rate	Not Available	**Explosive properties**	Not Available
Flammability	Highly flammable liquid and vapour.	**Oxidising properties**	Not Available
Upper Explosive Limit (%)	Not Available	**Surface Tension (dyn/cm or mN/m)**	Not Available
Lower Explosive Limit (%)	Not Available	**Volatile Component (%vol)**	Not Available
Vapour pressure (kPa)	Not Available	**Gas group**	Not Available
Solubility in water	Not Available	**pH as a solution (1%)**	Not Available
Vapour density (Air = 1)	Not Available	**VOC g/L**	Not Available

9.2. Other information

Not Available

SECTION 10 STABILITY AND REACTIVITY

10.1.Reactivity	See section 7.2
10.2. Chemical stability	▸ Unstable in the presence of incompatible materials. ▸ Product is considered stable.
10.3. Possibility of hazardous reactions	See section 7.2
10.4. Conditions to avoid	See section 7.2
10.5. Incompatible materials	See section 7.2
10.6. Hazardous decomposition products	See section 5.3

SECTION 11 TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute Toxicity	ethanol Inhalation (rat) LC50: 124.7 mg/l/4H[2] glycerol Oral (guinea pig) LD50: 7750 mg/kg[2] Oral (mouse) LD50: 4090 mg/kg[2] Oral (rat) LD50: 12600 mg/kg[2] aloes Oral (rat) LD50: >5000 mg/kg[2] sodium hydroxide Dermal (rabbit) LD50: 1350 mg/kg[2] C.I. Acid Blue 74 Oral (mouse) LD50: 2500 mg/kg[2] Oral (rat) LD50: 2000 mg/kg[2]
Skin Irritation/Corrosion	Based on available data, the classification criteria are not met.
Serious Eye Damage/Irritation	Based on available data, the classification criteria are not met.
Respiratory or Skin sensitisation	Based on available data, the classification criteria are not met.
Mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Reproductivity	Based on available data, the classification criteria are not met.

Continued...

STOT - Single Exposure	Based on available data, the classification criteria are not met.
STOT - Repeated Exposure	Based on available data, the classification criteria are not met.
Aspiration Hazard	Based on available data, the classification criteria are not met.
Legend:	*1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances*

SECTION 12 ECOLOGICAL INFORMATION

12.1. Toxicity

Orcagel Hand Sanitiser Gel-70% Alcohol/ Handsafe Hand sanitizer gel-70% Alcohol	Based on available data, the classification criteria are not met.

12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
ethanol	LOW (Half-life = 2.17 days)	LOW (Half-life = 5.08 days)
glycerol	LOW	LOW
sodium hydroxide	LOW	LOW
C.I. Acid Blue 74	HIGH	HIGH
C.I. Acid Violet 43	HIGH	HIGH

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
ethanol	LOW (LogKOW = -0.31)
glycerol	LOW (LogKOW = -1.76)
sodium hydroxide	LOW (LogKOW = -3.8796)
C.I. Acid Blue 74	LOW (LogKOW = -0.9914)
C.I. Acid Violet 43	LOW (LogKOW = 3.0778)

12.4. Mobility in soil

Ingredient	Mobility
ethanol	HIGH (KOC = 1)
glycerol	HIGH (KOC = 1)
sodium hydroxide	LOW (KOC = 14.3)
C.I. Acid Blue 74	LOW (KOC = 99.07)
C.I. Acid Violet 43	LOW (KOC = 421.8)

12.5.Results of PBT and vPvB assessment

	P	B	T
Relevant available data	Not Applicable	Not Applicable	Not Applicable
PBT Criteria fulfilled?	Not Applicable	Not Applicable	Not Applicable

12.6. Other adverse effects

No data available

SECTION 13 DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product / Packaging disposal	Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. ▸ **DO NOT** allow wash water from cleaning or process equipment to enter drains. ▸ It may be necessary to collect all wash water for treatment before disposal. ▸ Recycle wherever possible. ▸ Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
Waste treatment options	Not Available
Sewage disposal options	Not Available

SECTION 14 TRANSPORT INFORMATION

Continued...

Marine Pollutant	NO
HAZCHEM	•2YE

Land transport (ADR)

14.1. **UN number**	1170
14.2. **UN proper shipping name**	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
14.3. **Transport hazard class(es)**	Class: 3 Subrisk: Not Applicable
14.4. **Packing group**	II
14.5. **Environmental hazard**	Not Applicable
14.6. **Special precautions for user**	Hazard identification (Kemler): 33 Classification code: F1 Hazard Label: 3 Special provisions: 144 601 Limited quantity: 1 L Tunnel Restriction Code: 2 (D/E)

Air transport (ICAO-IATA / DGR)

14.1. **UN number**	1170
14.2. **UN proper shipping name**	Ethanol. solution
14.3. **Transport hazard class(es)**	ICAO/IATA Class: 3 ICAO / IATA Subrisk: Not Applicable ERG Code: 3L
14.4. **Packing group**	II
14.5. **Environmental hazard**	Not Applicable
14.6. **Special precautions for user**	Special provisions: A3 A58 A180 Cargo Only Packing Instructions: 364 Cargo Only Maximum Qty / Pack: 60 L Passenger and Cargo Packing Instructions: 353 Passenger and Cargo Maximum Qty / Pack: 5 L Passenger and Cargo Limited Quantity Packing Instructions: Y341 Passenger and Cargo Limited Maximum Qty / Pack: 1 L

Sea transport (IMDG-Code / GGVSee)

14.1. **UN number**	1170
14.2. **UN proper shipping name**	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
14.3. **Transport hazard class(es)**	IMDG Class: 3 IMDG Subrisk: Not Applicable
14.4. **Packing group**	II
14.5. **Environmental hazard**	Not Applicable
14.6. **Special precautions for user**	EMS Number: F-E , S-D Special provisions: 144 Limited Quantities: 1 L

Inland waterways transport (ADN)

14.1. **UN number**	1170
14.2. **UN proper shipping name**	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

Continued...

14.3. **Transport hazard class(es)**	3 : Not Applicable
14.4. **Packing group**	II
14.5. **Environmental hazard**	Not Applicable
14.6. **Special precautions for user**	Classification code : F1 Special provisions : 144; 601 Limited quantity : 1 L Equipment required : PP, EX, A Fire cones number : 1

14.7. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

SECTION 15 REGULATORY INFORMATION

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

WATER IS FOUND ON THE FOLLOWING REGULATORY LISTS

Europe EC Inventory
Europe European Customs Inventory of Chemical Substances
European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

ETHANOL IS FOUND ON THE FOLLOWING REGULATORY LISTS

Europe EC Inventory
Europe European Customs Inventory of Chemical Substances
European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)
European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI
UK Workplace Exposure Limits (WELs)

GLYCEROL IS FOUND ON THE FOLLOWING REGULATORY LISTS

Europe EC Inventory
Europe European Customs Inventory of Chemical Substances
European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)
UK Workplace Exposure Limits (WELs)

CARBOMER IS FOUND ON THE FOLLOWING REGULATORY LISTS

Europe European Customs Inventory of Chemical Substances

ALOES IS FOUND ON THE FOLLOWING REGULATORY LISTS

Not Applicable

SODIUM HYDROXIDE IS FOUND ON THE FOLLOWING REGULATORY LISTS

Europe EC Inventory
Europe European Customs Inventory of Chemical Substances
European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)
European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI
UK Workplace Exposure Limits (WELs)

C.I. ACID BLUE 74 IS FOUND ON THE FOLLOWING REGULATORY LISTS

Europe EC Inventory
Europe European Customs Inventory of Chemical Substances
European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

C.I. ACID VIOLET 43 IS FOUND ON THE FOLLOWING REGULATORY LISTS

Europe EC Inventory
Europe European Customs Inventory of Chemical Substances
European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2015/830; Regulation (EC) No 1272/2008 as updated through ATPs.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16 OTHER INFORMATION

Full text Risk and Hazard codes

H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.

Other information

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings.

Continued...

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:
EN 166 Personal eye-protection
EN 340 Protective clothing
EN 374 Protective gloves against chemicals and micro-organisms
EN 13832 Footwear protecting against chemicals
EN 133 Respiratory protective devices

Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average
PC—STEL: Permissible Concentration-Short Term Exposure Limit
IARC: International Agency for Research on Cancer
ACGIH: American Conference of Governmental Industrial Hygienists
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit。
IDLH: Immediately Dangerous to Life or Health Concentrations
OSF: Odour Safety Factor
NOAEL :No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
LOD: Limit Of Detection
OTV: Odour Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index

APRONS

The NHS Standard is that aprons are 16mu and have 2 waist ties and a neck loop. This what is meant by NHS approved in the following document. We supply this product to NHS Trusts & Police Forces.

These approns are UK manufactured. The factory is also ISO 9001:2015 accredited and meets BRC Global Standards for packaging and packaging materials.

Product Specification Data Sheet

Product : NHS Approved Disposable Polythene Apron

Date: 14th April 2020

Product Specification

Product Description:	Flat Packed Aprons
Dimensions:	686 x 1170mm
Gauge:	16mu
Material:	Virgin LDPE
Colours:	White
Additives:	1% anti-static
Packaging:	600 Aprons per Box
Palletisation:	84 Boxes per pallet (50,400 Aprons)

This is to confirm that the above product is produced to the above specification using Virgin grade materials from prime sources of West European manufacture, unless otherwise stated.

Unless otherwise stated all materials used conform to European and USA FDA food contact regulations. It can be expected that materials and articles made from these polymer products shall pass overall migration testing for all food types in normal application.

NB: As a manufacturer we work to +/- 10% PAFA tolerances.

Signed on behalf of :

CERTIFICATE OF REGISTRATION

This is to certify that:

operates a

QUALITY MANAGEMENT SYSTEM

which complies with the requirements of

ISO 9001:2015

for the following scope

Blown film extrusion of mono and co-ex MDPE films blended with LDPE, LLDPE and HDPE. The slitting, sheeting, perforation and sealing of unprinted film into bags and sheets, for direct food contact applications with the option of flexographic printing for non-direct food applications.

Scope Exclusions: None.

Certificate No:

Issued: 21 November 2019

Expires: 19 November 2022

Originally Certified: 20 November 2019

Current Certification: 20 November 2019

Heather Mahon
Global Head of Technical Services
SAI Global Assurance

Certified System
ISO 9001

JAS-ANZ
WWW.JAS-ANZ.ORG/REGISTER

SAI GLOBAL

CERTIFICATE OF CONFORMITY

SAI Global, accredited Certification Body No certifies that:

BRC site code:

having conducted an audit for the scope of activities

Blown film extrusion of mono and co-ex MDPE films blended with LDPE, LLDPE and HDPE. The slitting, sheeting, perforation and sealing of unprinted film into bags and sheets, for direct food contact applications with the option of flexographic printing for non-direct food applications.

High Hygiene

Field(s) of Audit: 05 - Flexible plastics
07 - Print processes

Exclusions from Scope: Low-risk (industrial packaging) areas of the site.

Has Achieved Grade: A

Meets the requirements set out in the

BRC Global Standard for Packaging and Packaging Materials Issue 5: July 2015

Audit Programme: Announced

Certificate No:

Auditor Number:

Certificate Issue Date: 12 December 2019

Date(s) of Audit: 12 November 2019 to 13 November 2019

Certificate Expiry Date: 17 January 2021

Re-audit Due Date: 8 November 2020 to 6 December 2020

Heather Mahon
Global Head of Technical Services
SAI Global Assurance

BRCGS Packaging and Packaging Materials CERTIFICATED

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