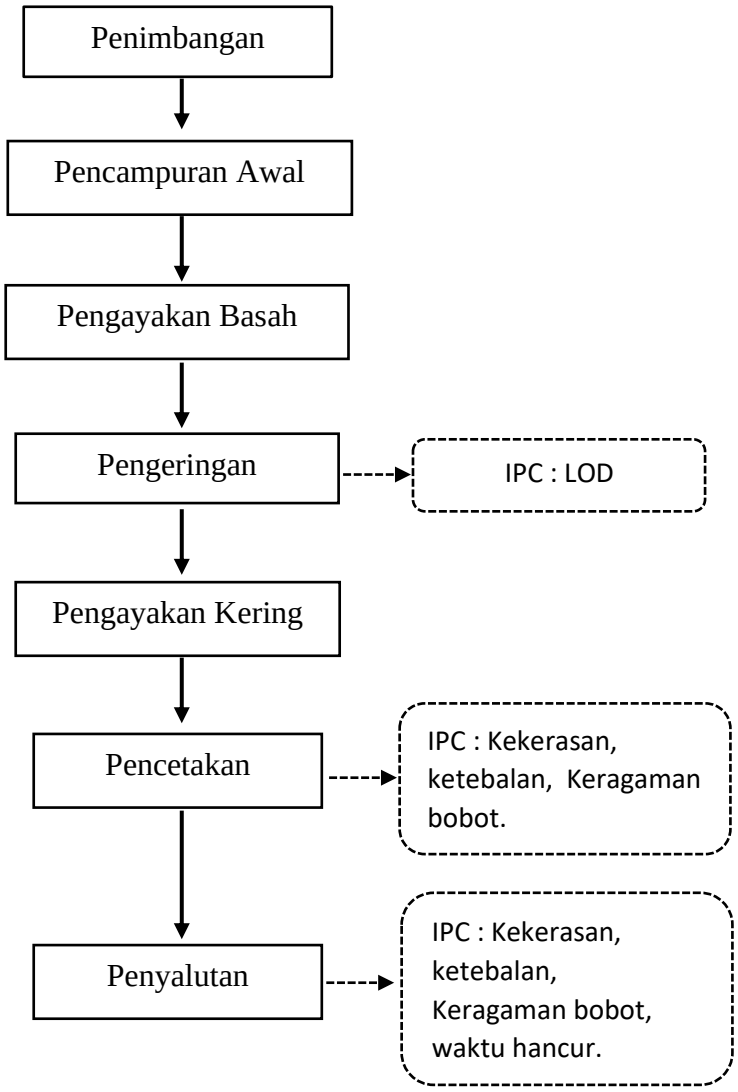
LAMPIRAN



Lampiran 1. Alur Proses Pembuatan Tablet Salut Tambah Darah

Lampiran 2. PT. Kimia Farma (Persero) Tbk. Plant Banjaran

Lampiran 3. Mesin *PMA, FBD, Dry Mill* (Granulasi Basah)

Lampiran 4. Mesin *Sieving (Quadro Sifter)*

Lampiran 5. Mesin *Coating (XL Cota 350)*

Lampiran 6. Mesin *Tableting (Romaco Killian KTP 720x*)

Lampiran 7. Mesin Pencampuran Larutan (Binde Vessel)

Lampiran 8. Mesin Larutan Coating (Mixer Vessel Coating)

Lampiran 9. Wadah Penyimpanan Masa Cetak, Tablet Inti, Tablet Salut (IBC Bin)

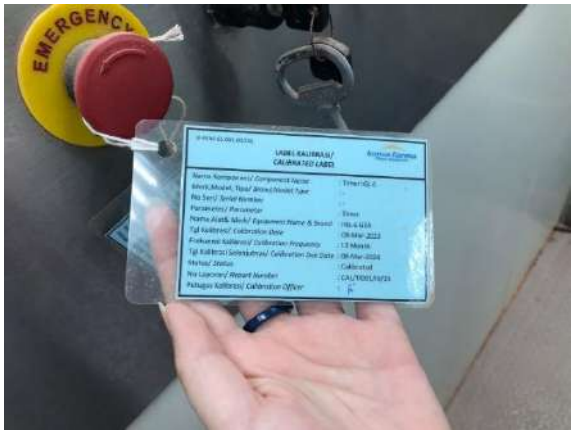
Lampiran 10. Timbangan Analitik (Precisa Es 520A)

Lampiran 11. Alat Uji Kekerasan, Ketebalan Tablet (Hardness Tester Analyzer)

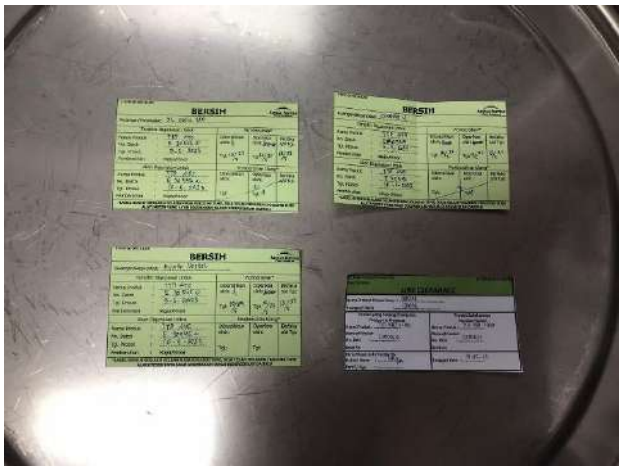
Lampiran 12. Masa Cetak

Lampiran 13. Tablet Inti

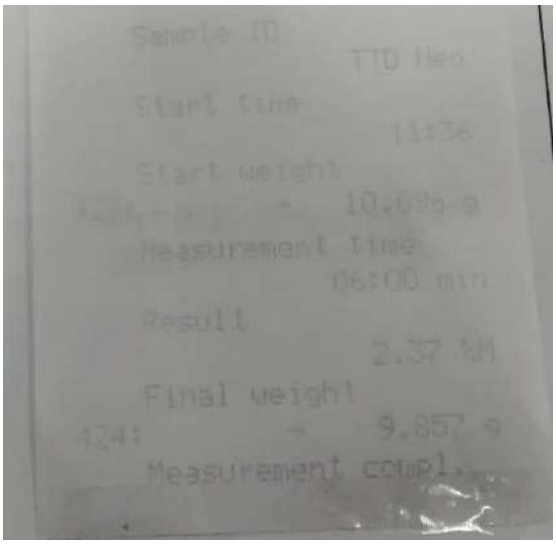
Lampiran 14. Tablet Hasil Coating



Lampiran 15. Kartu kalibrasi Mesin



Lampiran 16. Label Bersih



Lampiran 17. Pemeriksaan LOD I

Lampiran 18. Pemeriksaan LOD II

Number of samples: 20 20

MEASURING VALUES

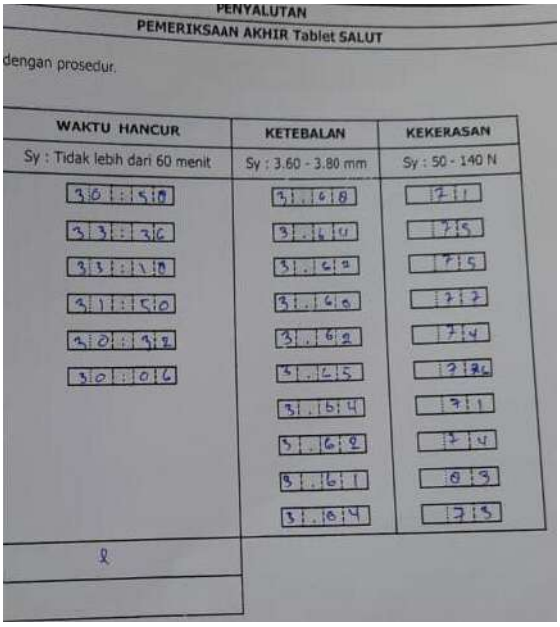
	Thickness	Hardness
1	3.61 mm	55 N
2	3.60 mm	56 N
3	3.63 mm	56 N
4	3.57 mm	71 N
5	3.62 mm	56 N
6	3.59 mm	55 N
7	3.59 mm	63 N
8	3.61 mm	53 N
9	3.65 mm	54 N
10	3.63 mm	56 N
11	3.62 mm	56 N
12	3.65 mm	57 N
13	3.60 mm	55 N
14	3.63 mm	49 N
15	3.63 mm	63 N
16	3.61 mm	64 N
17	3.59 mm	59 N
18	3.59 mm	52 N
19	3.56 mm	67 N
20	3.58 mm	61 N

STATISTICS

No. stat:	20	20
X min:	3.56 mm	49 N
X max:	3.65 mm	71 N
X max-min:	0.09 mm	22 N
X average:	3.61 mm	57.90 N
X S:	0.02 mm	5.39 N
X rel:	0.69 %	9.31 %

Signatures.....

Lampiran 19. Pemeriksaan Kekerasan, Ketebalan Tablet Inti



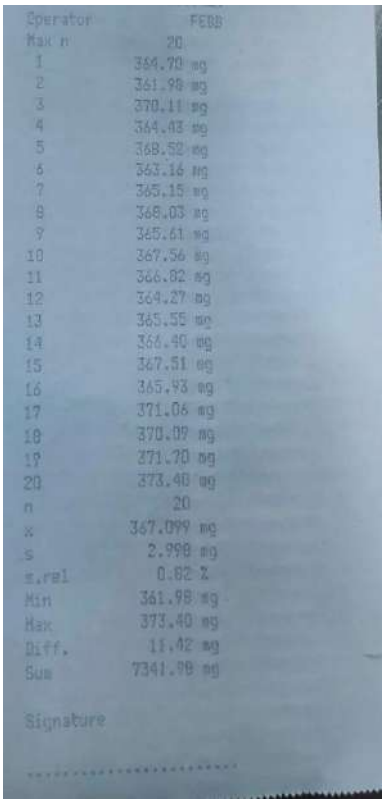
PENYALUTAN

PEMERIKSAAN AKHIR Tablet SALUT

dengan prosedur.

WAKTU HANCUR	KETEBALAN	KEKERASAN
Sy : Tidak lebih dari 60 menit	Sy : 3.60 - 3.80 mm	Sy : 50 - 140 N
3:0 : 5:0	3 . 6 8	7 1
3 : 3 : 3 6	3 . 6 4	7 5
3 : 3 : 1 0	3 . 6 2	7 5
3 : 1 : 5 0	3 . 6 0	7 7
3 : 0 : 3 2	3 . 6 2	7 4
3 0 : 0 6	3 . 6 5	7 6
	3 . 6 4	7 1
	3 . 6 2	7 4
	3 . 6 1	8 3
	3 . 6 4	7 5

Lampiran 20. Pemeriksaan Waktu hancur, Kekerasan, Ketebalan Tablet Salut

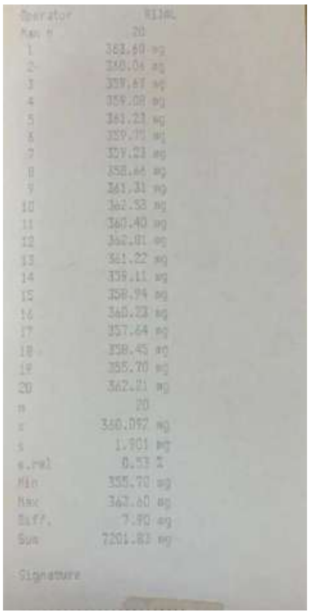


Operator	FEBB
Max n	20
1	364.70 mg
2	361.98 mg
3	370.11 mg
4	364.63 mg
5	368.52 mg
6	363.16 mg
7	365.15 mg
8	368.03 mg
9	365.61 mg
10	367.56 mg
11	366.82 mg
12	364.27 mg
13	365.55 mg
14	366.40 mg
15	367.51 mg
16	365.93 mg
17	371.06 mg
18	370.09 mg
19	371.70 mg
20	373.40 mg
n	20
x	367.099 mg
s	2.998 mg
s.rel	0.82 %
Min	361.98 mg
Max	373.40 mg
Diff.	11.42 mg
Sum	7341.98 mg

Signature

.....

Lampiran 21. Pemeriksaan Keragaman Bobot Tablet Salut

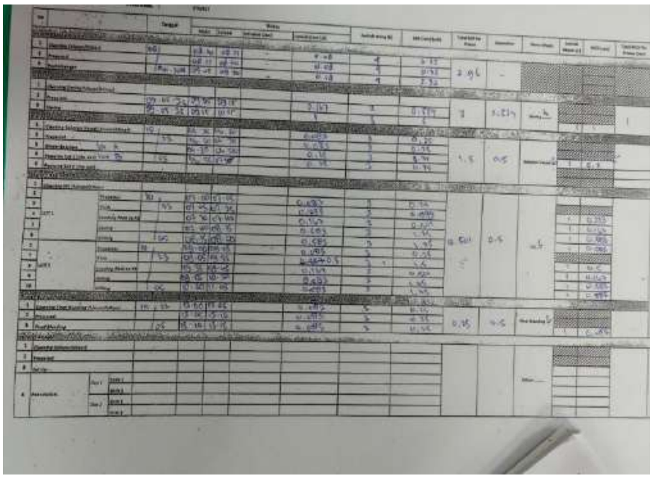


Operator RIJAL
Max n 20

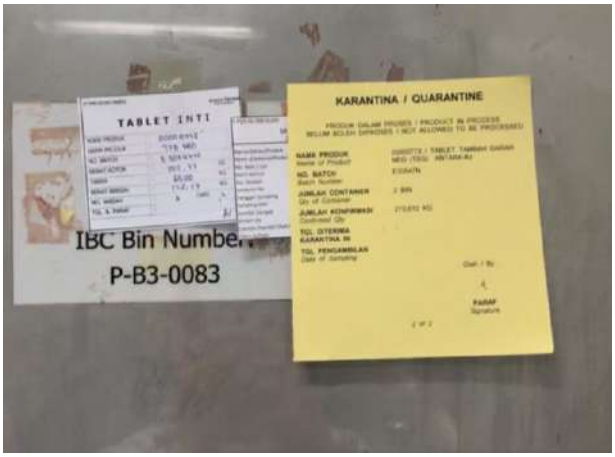
1	363.60 mg
2	360.04 mg
3	359.67 mg
4	359.08 mg
5	361.23 mg
6	359.75 mg
7	359.23 mg
8	358.66 mg
9	361.31 mg
10	362.53 mg
11	360.40 mg
12	362.01 mg
13	361.22 mg
14	359.11 mg
15	358.94 mg
16	360.23 mg
17	357.64 mg
18	358.45 mg
19	355.70 mg
20	362.21 mg
n	20
x	360.092 mg
s	1.901 mg
s.rel	0.53 %
Min	355.70 mg
Max	363.60 mg
Diff.	7.90 mg
Sum	7201.83 mg

Signature

Lampiran 22. Pemeriksaan Keragaman Bobot Tablet Inti



Lampiran 23. Waktu Proses Pembuatan Masa Cetak



Lampiran 24. Bobot Tablet Inti dan Setelah Proses Coating

Lampiran 25. Suhu dan Kelembaban Granulasi

Lampiran 26. Suhu dan Kelembaban Coating

Eurotrade World Commerce, S.L.

CERTIFICATE OF ANALYSIS

FERROUS FUMARATE

CAS Number	141-01-5
Molecular Formula	$C_4H_2FeO_4$
Molecular Weight	169.90

TEST	SPECIFICATION
ASSAY ($C_4H_2FeO_4$)	97.0-101.0 %
LOSS ON DRYING	-- 1.5 %
SULFATES (SO_4)	-- 0.2 %
ARSENIC (As)	-- 3 PPM
FERRIC IRON (Fe°)	-- 2.0 %
LEAD (Pb)	-- 0.001 %
MERCURY	-- 3 UG/G
IDENTIFICATION	TO PASS TEST
EXPIRATION DATE	
RESIDUAL SOLVENTS	TO PASS TEST

Lampiran 27. COA Ferrous Fumarate

Certificate of Analysis **Page 1 of 1**

ACROS ORGANICS

Version	00
Molecular weight	441.40
Quality Test / Release Date	07/08/2014
Molecular Formula	C19 H19 N7 O6
CAS No	59-30-3
Linear Formula	
Flash Point (°C)	

Certificate of Analysis

This is to certify that units of the above mentioned lot number were tested and found to comply with the specifications of the grade listed. Certain data have been supplied by third parties. Acros Organics expressly disclaims all warranties,expressed or implied, including the implied warranties of merchantability and fitness for a particular purpose. Unless otherwise stated, these products are not intended for dialysis, parenteral, or injectable use without further processing. The following are the actual analytical results obtained:

Catalog Number	38031	**Quality Test / Release Date** 07/08/2014
Lot Number	A0349649	
Description	Folic acid	
Country of Origin	SWITZERLAND	
Declaration of Origin	synthetic	

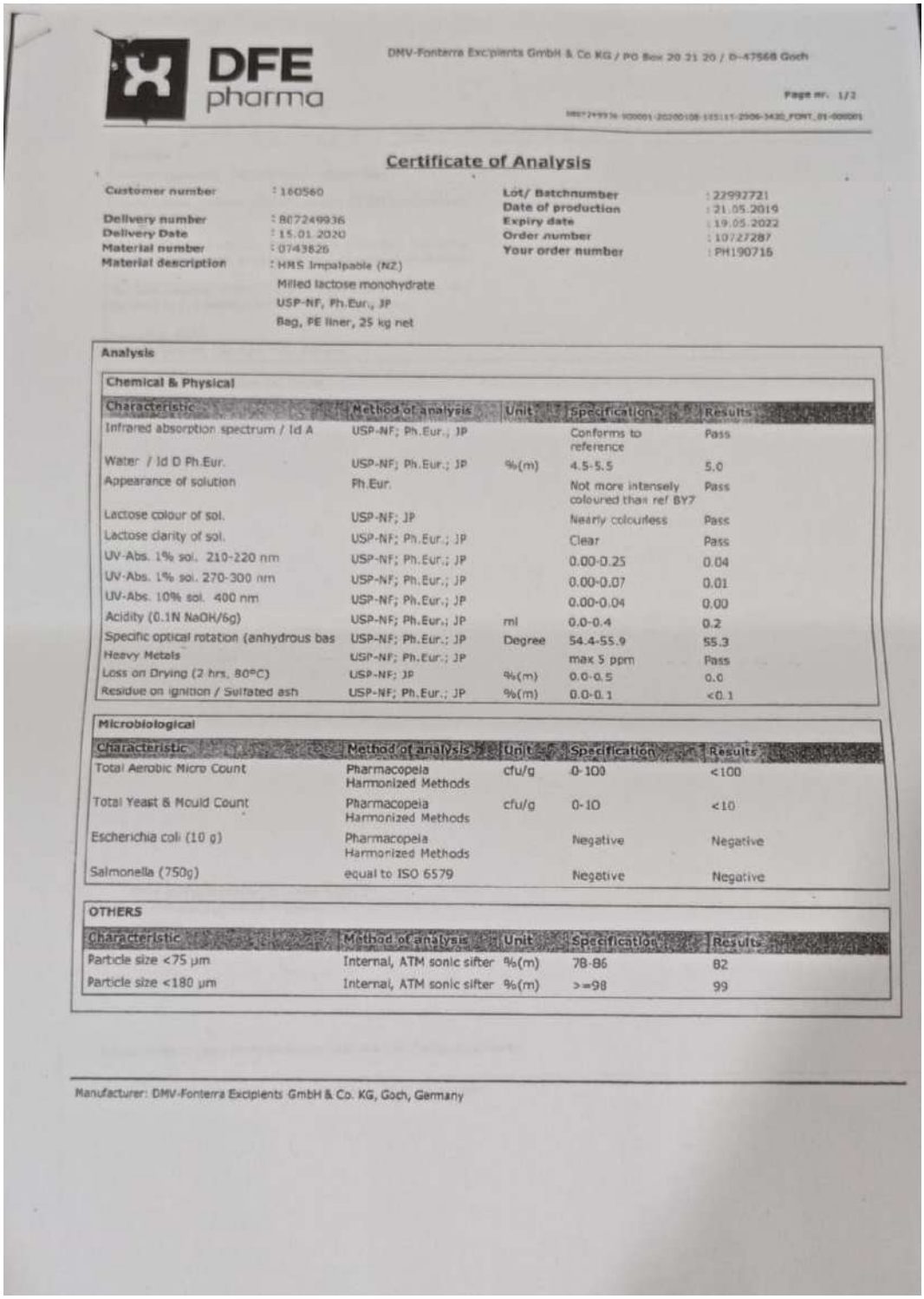
BSE/TSE comment	
Chemical Comment	

Result name	Units	Specifications	Test Value
Appearance		Yellowish to orange crystalline powder	Yellow crystalline powder
Separat. techn. HPLC		96.0 to 102.0 % (anhydrous substance)	99.6 % (anhydrous substance)
Specific optical rotation		+18.0° to +22.0° (20°C, 589 nm) (c=1, 0.1M NaOH)	+21.3° (20°C, 589 nm) (c=1, 0.1M NaOH)
Specific optical rotation		anhydrous substance	anhydrous substance
Water		5.0 to 8.5 % (K.F.) (on the pyridine)	8.3 % (K.F.) (on the pyridine)
Sulfated ash		=<0.2 % (PE)	0.02 % (PE)
Additional info		Identity by LC: positive (PE)	Identity by LC: positive (PE)
Related substances		(LC) : pass the test (PE)	(LC) : pass the test (PE)
Manufacturing date			January 27, 2014
Use by date			January 26, 2017

L. Van den Broek, QA Manager Issued: 10-13-2014

Acros Organics
ENA23, zone1, nr 1350, Janssen Pharmaceuticalaan 3a, B-2440 Geel, Belgium
Tel +32 14/57.52.11 - Fax +32 14/59.34.34 Internet: http://www.acros.com
1 Regent Lane, Fair Lawn, NJ 07410, USA Fax 201-796-1329

Lampiran 28. COA Folic Acid



DFE pharma

DMV-Fonterra Excipients GmbH & Co KG / PO Box 20 21 20 / D-47568 Goch

Page nr. 1/2

Certificate of Analysis

Customer number	: 160560	Lot/ Batchnumber	: 22992721
		Date of production	: 21.05.2019
Delivery number	: 807249936	Expiry date	: 19.05.2022
Delivery Date	: 15.01.2020	Order number	: 10727287
Material number	: 0743826	Your order number	: PH190716
Material description	: HMS Impalpable (NZ)		

Milled lactose monohydrate
USP-NF, Ph.Eur., JP
Bag, PE liner, 25 kg net

Analysis

Chemical & Physical

Characteristic	Method of analysis	Unit	Specification	Results
Infrared absorption spectrum / Id A	USP-NF; Ph.Eur.; JP		Conforms to reference	Pass
Water / Id D Ph.Eur.	USP-NF; Ph.Eur.; JP	%(m)	4.5-5.5	5.0
Appearance of solution	Ph.Eur.		Not more intensely coloured than ref BY7	Pass
Lactose colour of sol.	USP-NF; JP		Nearly colourless	Pass
Lactose clarity of sol.	USP-NF; Ph.Eur.; JP		Clear	Pass
UV-Abs. 1% sol. 210-220 nm	USP-NF; Ph.Eur.; JP		0.00-0.25	0.04
UV-Abs. 1% sol. 270-300 nm	USP-NF; Ph.Eur.; JP		0.00-0.07	0.01
UV-Abs. 10% sol. 400 nm	USP-NF; Ph.Eur.; JP		0.00-0.04	0.00
Acidity (0.1N NaOH/6g)	USP-NF; Ph.Eur.; JP	ml	0.0-0.4	0.2
Specific optical rotation (anhydrous bas	USP-NF; Ph.Eur.; JP	Degree	54.4-55.9	55.3
Heavy Metals	USP-NF; Ph.Eur.; JP		max 5 ppm	Pass
Loss on Drying (2 hrs. 80°C)	USP-NF; JP	%(m)	0.0-0.5	0.0
Residue on ignition / Sulfated ash	USP-NF; Ph.Eur.; JP	%(m)	0.0-0.1	<0.1

Microbiological

Characteristic	Method of analysis	Unit	Specification	Results
Total Aerobic Micro Count	Pharmacopeia Harmonized Methods	cfu/g	0-100	<100
Total Yeast & Mould Count	Pharmacopeia Harmonized Methods	cfu/g	0-10	<10
Escherichia coli (10 g)	Pharmacopeia Harmonized Methods		Negative	Negative
Salmonella (750g)	equal to ISO 6579		Negative	Negative

OTHERS

Characteristic	Method of analysis	Unit	Specification	Results
Particle size <75 µm	Internal, ATM sonic sifter	%(m)	78-86	82
Particle size <180 µm	Internal, ATM sonic sifter	%(m)	>=98	99

Manufacturer: DMV-Fonterra Excipients GmbH & Co. KG, Goch, Germany

Lampiran 29. COA Lactose

西安品诚生物科技有限公司
XI'AN PINCREDIT BIO-TECH CO., LTD

Certificate of Analysis

Product Name:	Povidon K30	Production Date:	2022.04.10
Lot No.:	PC20220410	Quantity:	10,000kg
Test Standard.:	CP/USP/EP/BP	Expiry Date:	2025.04.09

Item	**Specification**	**Result**
Characteristics	White to slightly creamy white, hygroscopic powder or flakes	Conforms
Solubility	Easily soluble in water, 96% ethanol, methanol, and microsoluble in acetone	Conforms
Solution appearance	Clear liquid	Conforms
K Value	27-32.4	31.61
Loss on drying	≤5	3.1
Residue on Ignition（%）	≤10	3.6
PH Value	3-5	3.5
Aldehyde, ppm	≤500	148
Superoxide, ppm	≤400	183
Methane acid, %	≤0.5	0.31
2-ketopyrrolidine, %	≤3	1.77
Heavy Metals, ppm	≤10	5.6
Hydrazine, ppm	≤1	0.52
Sulfate ash content	≤0.1	0.04
Nitrogen,%	11.56-12.8	11.9
Shelf Life	3 years when properly stored	
Conclusion:	Complied with BP standard	

ANALYST: 质检 刘超 QC004

INSPECTOR: 质检 冯涛 QC001

地址：陕西省西安市高新区科技西路 2825 号绿地鸿海大厦 A 座 19F
ADD: 19F, Greenland Building A, No.2825, West Keji Road, High-tech Zone, Xi'an, Shaanxi, China, 710086
Tel: 86-29-89198270 Web: www. Pureherbextract.com Email: pincredit@pureherbextract.com

Lampiran 30. COA Pavidon K30

HAIHANG INDUSTRY CO., LTD.
7/F, SANQING FENGRUN BUILDING, NO. 100 SOUTH GONGYE ROAD,
JINAN CITY , SHANDONG PROVINCE, CHINA. P.C.: 250100
EMAIL: sale45@haihangchem.com WEBSITE:www.haihangchem.com

CERTIFICATE OF ANALYSIS

Product Name:	Magnesium Stearate USP35-NF30		
CAS No.:	557-04-0	Quantity	500KG
Rep Date	May.26.2018	Batch NO.	20180526
MFG. Date	May.26.2018	Expiry Date	May.25.2020

Item	Specifications	Results
Appearance	A white,very fine,light,powder greasy to touch	Conform
Identification A	The test for Magnesium	Conform
Identification B	Conform	Conform
Acidity or alkalinity	Conform	Conform
Loss on Drying	≤6.0%	4.4%
Chloride	≤0.1%	<0.1%
Sulphates	≤1.0%	<1.0%
Lead	≤10ppm	0.14ppm
Cadmium	≤3ppm	0.11ppm
Nickel	≤5ppm	0.08ppm
Stearic Acid	≥40.0%	42.2%
Searic Acid&Palmitic Acid	≥90.0%	99.5
TAMC	≤1000cfu/g	50CFU/g
TYMC	≤500cfu/g	10CFU/g
Assay（Mg）	4.0%-5.0%	4.7
Escherichia coli	Absent	Absent
Salmonella species	Absent	Absent
Conclusion	The results conforms with enterprise standards	

Analyst:LiYa Checker:WeiChen Q.C.Director:XuLeilei

检验专用章 HAIHANG INDUSTRY CO., LTD.

Lampiran 31. COA Magnesium Stearate

GLORIA INTERCHEM

HACCP

ISO 9001:2015
Certificate No. :18DQC94

Certificate of Compliance
WHO-GMP
Certificate No.: UQ-1106

Certificate of Analysis

Product Name :	Sodium Starch Glycolate-USP(Maize)	CAS No:	9063-38-1
Batch No :	GIC/MS/509/2020	Batch Size :	4000 KG
Mfg. Date:	SEP 2020	Exp Date:	AUG 2025
Analysis Date:	4 SEP 2020	Re-Test date:	3 YEAR FROM MFG
Ref. No:	GIC/MS/114	Sample Quantity	100 GMS

SR. No.	TESTS	RESULT	SPECIFICATION
1	Appearance	White powder	A white tasteless, odourless, relatively free flowing powder
2	Solubility	pass	Practically insoluble in water, insoluble in most organic solvents It very hygroscopic gives a translucent suspension in water.
2	Identification : (A) (B) (C) (D)	Complies Complies Complies Complies	A) By IR B) An acidified solution of it is colored blue to violet C) A dense white precipitate is formed D) Imparts an intense yellow color to a nonluminous flame.
3	pH	6.92	5.5 to 7.5.
4	Limit of Sodium chloride	3.94%	NMT 7.0% w/w
5	Limit of Sodium Glycolate	< 2.0 %	NMT 2.0 %
6	Heavy Metals	Complies	NMT 20 ppm
7	Iron	Complies	NMT 0.002%
8	Loss on drying	7.18%	NMT 10.0% w/w
9	Assay (% of Na)	3.56%	2.8% to 4.2 %
10	Microbial Limit Test E.coli Salmonella	 Absent Absent	 Should be Absent Should be Absent

Reg office (Head office)
205,206 BBC Tower, World Trade Center, Sayajigunj, Vadodara – 390 005, Gujarat-India
Tel.No : +91-265-2362982, 2363350, 2361781/82

Factory address:
Survey plot no.373, opp. Ramakaka Deri, Chhani, Vadodara- 391 704, Gujrat-India.
Tel.No:+ 91-7043777520

Mumbai office:
205, SukhanadKrupa, Phirozshah Mehta Rd., Behind Hi Life Mall,Santacruz(w),Mumbai-400 054
Tel no. : +91-22-26000654, +91-9892417240

UAE office:
PO BOX NO. 932,
Ajman Free zone, Ajman, UAE
Tel No. : +971-551387750, +91-9987789620

Lampiran 32. COA Sodium Starch Glycolate

Colorcon

Certificate of Analysis

Product Code: **40L14940**

Product Description: **OPADRY® II COMPLETE FILM COATING SYSTEM 40L14940 PINK**

Material Description:	Pink Powder	Ship To:	
Lot No.:		Bill To:	
Date of Manufacture:	19-JUL-2021	Sales Order No.:	
Re-evaluation Date:	19-JUL-2022	Customer PO No.:	
Manufacturing Site:	Shanghai Colorcon Coating Technology Limited No 588 Chundong Road, Minhang District, Shanghai, 201108 China	Customer Item:	
		Shipped From:	Shanghai Colorcon Coating Technology Limited Shanghai, China

Test	Minimum	Maximum	Result	Method
COLOR DIFFERENCE DE, CIE	0.0	2.0 Or Visual Match	1.7 CIE	GLO-QC-TM-0576
COLOR DIFFERENCE VISUAL	COMPARES		COMPARES	GLO-QC-TM-0576
ASH, %	26.90	34.90	29.71 %	GLO-QC-TM-0699
APPEARANCE	PINK POWDER		PINK POWDER	GLO-QC-TM-0733
DISPERSION	PASS		PASS	GLO-QC-TM-0729
IR SCAN	COMPARES		COMPARES	GLO-QC-TM-0744

- Compliance Statement : This Product meets all agreed upon specifications <40L14940>.

The above analytical data has been reviewed and authenticated electronically by an authorised representative of the Quality Unit as evidenced by the application of an electronic signature.

Date : 20-JUL-2021

Global Headquarters
Colorcon
275 Ruth Road, Harleysville, PA 19438
Tel: +1 215.256.7700 Fax: +1 215.256.7799 **Website: www.colorcon.com**

Colorcon

Lampiran 33. COA Opadry Sugar Red

parchem
fine & specialty chemicals

Safety Data Sheet
(Ferrous Fumarate)
DATE PREPARED: 6/22/2016

Section 1. Product and Company Identification

Product Name Ferrous Fumarate
CAS Number 141-01-5

Parchem - fine & specialty chemicals
415 Huguenot Street
New Rochelle, NY 10801
(914) 654-6800 **(914) 654-6899**
parchem.com **info@parchem.com**

EMERGENCY RESPONSE NUMBER
CHEMTEL
Toll Free US & Canada: 1 (800) 255-3924
All other Origins: 1 (813) 248-0585
Collect Calls Accepted

Section 2. Hazards Identification

Classification of the substance or mixture
Not classified as a hazardous substance or mixture

GHS Label Elements
Pictograms: N/A
Signal word: None

Hazard and precautionary statements
N/A

Hazards not otherwise classified (HNOC) or not covered by GHS: None

Section 3. Composition / Information on Ingredients

Common Name Ferrous Fumarate
Synonym(s) Iron (II) Fumarate
Formula $C_4H_2FeO_4$
CAS Number 141-01-5

Section 4. First Aid Measures

Description of first-aid measures
General advice: Consult a physician. Show this safety data sheet to the doctor in attendance.
Inhalation: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
Skin contact: Wash off with soap and plenty of water. Consult a physician.
Eye contact: Flush eyes with water as a precaution.
Ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Lampiran 34. MSDS Ferrous Fumarate

Personal protective equipment
Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
Body Protection: Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection: Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Control of environmental exposure: Do not let product enter drains.

Section 9. Physical and Chemical Properties

Information on basic physical and chemical properties
Appearance: Powder
Color: Red brown
Odor: No data available
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): No data available
Upper/lower flammability or explosive limits: No data available
Vapor pressure: No data available
Vapor density: No data available
Relative density: 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: No data available
Oxidizing properties: No data available

Other safety information: no data available

Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labelling (see section 2) and/or in section 11.
Indication of any immediate medical attention and special treatment needed: No data available

Section 5. Firefighting Measures

Extinguishing media
Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special hazards arising from the substance or mixture: Carbon oxides, Iron oxides
Advice for firefighters: Wear self-contained breathing apparatus for firefighting if necessary.
Further information: No data available

Section 6. Accidental Release Measures

Personal precautions, protective equipment, and emergency procedures: Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist, or gas. Avoid breathing dust. For personal protection see section 8.
Environmental precautions: Do not let product enter drains.
Methods and materials for containment and cleaning up: Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.
Reference to other sections: For disposal see section 13.

Section 7. Handling and Storage

Precautions for safe handling: Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection. For precautions see section 2.

Conditions for safe storage, including any incompatibilities: Keep container tightly closed in a dry and well-ventilated place. Keep in a dry place.

Section 8. Exposure Controls / Personal Protection

Control parameters
Components with workplace control parameters: Contains no substances with occupational exposure limit values.

Exposure controls
Appropriate engineering controls: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment
Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
Body Protection: Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection: Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Control of environmental exposure: Do not let product enter drains.

Section 9. Physical and Chemical Properties

Information on basic physical and chemical properties
Appearance: Powder
Color: Red brown
Odor: No data available
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): No data available
Upper/lower flammability or explosive limits: No data available
Vapor pressure: No data available
Vapor density: No data available
Relative density: 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: No data available
Oxidizing properties: No data available

Other safety information: no data available

Section 10. Stability and Reactivity

Reactivity: No data available
Chemical stability: Stable under recommended storage conditions.
Possibility of hazardous reactions: No data available
Conditions to avoid: No data available
Incompatible materials: Strong oxidizing agents

Hazardous decomposition products
Other decomposition products: No data available
In the event of fire: see section 5

Section 11. Toxicological Information

Information on toxicological effects
Acute toxicity
LD50 Oral - rat: 3,850 mg/kg
Inhalation: No data available
Dermal: No data available
LD50 Intraperitoneal - rat: 185 mg/kg

Skin corrosion/irritation: No data available
Serious eye damage/eye irritation: No data available
Respiratory or skin sensitization: No data available
Germ cell mutagenicity: No data available

Carcinogenicity
IARC: No component of this product, present at levels greater than or equal to 0.1%, is identified as probable, possible or confirmed human carcinogen by IARC.
ACGIH: No component of this product, present at levels greater than or equal to 0.1%, is identified as a carcinogen or potential carcinogen by ACGIH.
NTP: No component of this product, present at levels greater than or equal to 0.1%, is identified as a known or anticipated carcinogen by NTP.
OSHA: No component of this product, present at levels greater than or equal to 0.1%, is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity: No data available
Specific target organ toxicity - single exposure: No data available
Specific target organ toxicity - repeated exposure: No data available
Aspiration hazard: No data available

Additional Information
RTECS: LT1950000

Section 12. Ecological Information

Toxicity: No data available
Persistence and degradability: No data available
Bioaccumulative potential: No data available
Mobility in soil: No data available
Results of PBT and vPvB assessment: PBT/vPvB assessment not available as chemical safety assessment not required/not conducted
Other adverse effects: No data available

Section 13. Disposal Considerations

Waste Treatment Methods: Dispose of product and contaminated packaging in accordance with all local, state, and federal environmental control regulations.

Section 14. Transport Information

DOT (US): Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods

Section 15. Regulatory Information

SARA 302 Components
SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards: No SARA Hazards

Massachusetts Right to Know Components
No components are subject to the Massachusetts Right to Know Act.
Pennsylvania Right to Know Components
Iron (II) fumarate (CAS-No. 141-01-5)
Revision Date: 1989-08-11
New Jersey Right to Know Components
Iron (II) fumarate (CAS-No. 141-01-5)
Revision Date: 1989-08-11

California Prop. 65 Components: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

Millipore

www.sigmaaldrich.com

LEMBARAN DATA KESELAMATAN

menurut Peraturan (EC) No. 1907/2006

Versi 8.2
Revisi tanggal 02.12.2021
Tanggal Cetak 04.01.2022
MSDS Umum Uni Eropa - Tidak ada data untuk negara tertentu - Tidak ada OEL Data

BAGIAN 1: Identitas Bahan dan Perusahaan

1.1 Pengidentifikasi produk

Nama produk	:	Folic acid for biochemistry
Nomor Produk	:	1.03984
No katalog	:	103984
Merek	:	Millipore
Nomor REACH	:	Nomor registrasi tidak tersedia untuk bahan ini karena bahan atau penggunaan dibebaskan dari pendaftaran, tonase tahunan tidak memerlukan pendaftaran atau pendaftaran dipertimbangkan untuk batas waktu pendaftaran akan datang.
No-CAS	:	59-30-3

1.2 Penggunaan yang relevan dari bahan atau campuran yang diidentifikasi dan penggunaan yang disarankan terhadap

Penggunaan yang teridentifikasi	:	Penelitian/analisis biokimia

1.3 Rincian penyuplai lembar data keselamatan

Perusahaan	:	Merck KGaA Frankfurter Str. 250 D-64271 DARMSTADT
Telepon	:	+49 (0)6151 72-0
Fax	:	+49 6151 727780
Alamat email	:	TechnicalService@merckgroup.com

1.4 Nomor telepon darurat

Nomer Telepon Darurat #	:	001-803-017-9114 (CHEMTREC)

BAGIAN 2: Identifikasi bahaya

2.1 Klasifikasi bahan atau campuran

Bukan bahan atau campuran berbahaya menurut Peraturan (EC) No 1272/2008.

2.2 Elemen label

Bukan bahan atau campuran berbahaya menurut Peraturan (EC) No 1272/2008.

Lampiran 35. MSDS Folic Acid

2.3 bahaya lainnya
Zat/campuran ini tidak mengandung satu komponen pun yang dianggap baik persisten, bioakumulatif, dan beracun (PBT) maupun sangat persisten dan sangat bioakumulatif (vPvB) pada kadar 0,1% atau lebih.

BAGIAN 3: Komposisi Bahan

3.1 Bahan

Rumus	:	C19H19N7O6
Berat Molekul	:	441,4 g/mol
No-CAS	:	59-30-3
No-EC	:	200-419-0

Tidak ada komponen perlu diungkapkan sesuai dengan ketentuan yang berlaku.

BAGIAN 4: Tindakan pertolongan pertama pada kecelakaan (P3K)

4.1 Penjelasan mengenai tindakan pertolongan pertama

Jika terhirup
Setelah menghirup: hirup udara segar.

Jika kontak dengan kulit
Bila terjadi kontak kulit: Tanggalkan segera semua pakaian yang terkontaminasi. Bilaslah kulit dengan air/ pancuran air.

Jika kontak dengan mata
Setelah kontak pada mata : bilaslah dengan air yang banyak. Lepaskan lensa kontak.

Jika tertelan
Setelah tertelan: beri air minum kepada korban (paling banyak dua gelas). Konsultasi kepada dokter jika merasa tidak sehat.

4.2 Kumpulan gejala / efek terpenting, baik akut maupun tertunda
Gejala dikenal dan efek yang paling penting dijelaskan dalam label (lihat bagian 2.2) dan / atau di bagian 11

4.3 Indikasi pertolongan medis pertama dan perawatan khusus yang diperlukan
Data tidak tersedia

BAGIAN 5: Tindakan Penanggulangan Kebakaran

5.1 Media pemadaman api

Media pemadaman yang sesuai
Air Busa Karbon dioksida (CO2) Serbuk kering

Media pemadaman yang tidak sesuai
Untuk bahan/campuran ini, tidak ada batasan agen pemadaman yang diberika n.

5.2 Bahaya khusus yang muncul dari bahan atau campuran
Karbon oksida
Nitrogen oksida (NOx)
Mudah menyala.
Perkembangan gas atau uap menyala yang berbahaya mungkin terjadi dalam kejadian kebakaran.

5.3 Saran bagi petugas pemadam kebakaran
Jika terjadi kebakaran, pakai alat bantu pernapasan SCBA.

5.4 Informasi lebih lanjut
Tekan (pukul kebawah) gas/uap/kabut dengan semprotan air jet. Cegah air pemadam kebakaran mengkontaminasi air permukaan atau sistim air tanah.

BAGIAN 6: Tindakan terhadap tumpahan dan kebocoran

6.1 Langkah-langkah pencegahan diri, alat pelindung dan prosedur tanggap darurat
Nasihat untuk personel nondarurat Hindari penghisapan debu. Evakuasi dari daerah bahaya, amati prosedur darurat, hubungi ahli.
Untuk perlindungan pribadi lihat seksi 8.

6.2 Langkah-langkah pencegahan bagi lingkungan
Jangan biarkan produk masuk ke saluran pembuangan.

6.3 Metode dan bahan untuk penangkalan (containment) dan pembersihan
Tutup saliran. Kumpulkan, ikat dan pompa keluar tumpahan. Amati kemungkinan pembatasan bahan (lihat bagian 7 dan 10). Ambil dalam keadaan kering. Teruskan ke pembuangan. Bersihkan area yang terkena. Hindari pembentukan debu.

6.4 Rujukan ke bagian lainnya
Untuk pembuangan lihat bagian 13.

BAGIAN 7: Penyimpanan dan Penanganan Bahan

7.1 Kehati-hatian dalam menangani secara aman
Untuk tindakan pencegahan lihat bagian 2.2.

7.2 Kondisi penyimpanan yang aman, termasuk adanya inkompatibilitas

Kondisi penyimpanan
Tertutup sangat rapat. Kering.

Suhu penyimpanan yang direkomendasikan, lihat label produk.

Kelas penyimpanan
Kelas penyimpanan Jerman (TRGS 510): 11: Zat-zat padat yang mudah terbakar

7.3 Penggunaan akhir khusus
Selain penggunaan yang disebutkan dalam bagian 1.2, tidak ada penggunaan spesifik lain yang diantisipasi

BAGIAN 8: Kontrol paparan/ perlindungan diri

8.1 Parameter pengendalian

Komponen dengan parameter pengendalian di tempat kerja

8.2 Pengendalian paparan

Alat perlindungan diri

Perlindungan mata/wajah
Gunakan peralatan untuk perlindungan mata yang sudah diuji dan disetujui di bawah standar pemerintah yang tepat seperti NIOSH (US) atau EN 166 (EU).
Kacamata pengaman

Perlindungan kulit
Rekomendasi ini berlaku hanya untuk produk yang disebutkan dalam lembar data keselamatan dan disuplai oleh kami sesuai tujuan yang kami maksud. Ketika dilarutkan dalam atau dicampur dengan bahan lain dan dalam kondisi yang menyimpang dari yang disebutkan dalam EN374 silahkan hubungi suplier sarung tangan CE-resmi (misalnya KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).
Kontak penuh
Materi: Karet nitril
ketebalan lapisan minimal: 0,11 mm
Waktu terobosan: 480 min
Bahan yang diuji:KCL 741 Dermatril® L

Rekomendasi ini berlaku hanya untuk produk yang disebutkan dalam lembar data keselamatan dan disuplai oleh kami sesuai tujuan yang kami maksud. Ketika dilarutkan dalam atau dicampur dengan bahan lain dan dalam kondisi yang menyimpang dari yang disebutkan dalam EN374 silahkan hubungi suplier sarung tangan CE-resmi (misalnya KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).
percikan
Materi: Karet nitril
ketebalan lapisan minimal: 0,11 mm
Waktu terobosan: 480 min
Bahan yang diuji:KCL 741 Dermatril® L

Perlindungan pernapasan
diperlukan ketika debu dihasilkan.
Rekomendasi kami tentang filter perlindungan pernapasan didasarkan atas standar berikut: DIN EN 143, DIN 14387, dan standar lainnya yang menyertai terkait dengan sistem perlindungan pernapasan yang digunakan.
Jenis filter yang direkomendasikan: Filter tipe P1

Pengusaha harus memastikan bahwa perawatan, pembersihan, dan pengujian perangkat perlindungan pernafasan telah dilakukan sesuai dengan petunjuk dari pabriknya. Tindakan ini harus didokumentasikan dengan benar.

Kontrol pemaparan lingkungan
Jangan biarkan produk masuk ke saluran pembuangan.

BAGIAN 9: Sifat-sifat Fisika dan Kimia

9.1 Informasi tentang sifat fisik dan kimia

a)	Tampilan	Bentuk: padat Warna: kuning
b)	Bau	Data tidak tersedia
c)	Ambang Bau	Data tidak tersedia
d)	pH	Data tidak tersedia
e)	Titik lebur/titik beku	Titik lebur: kira-kira250 °C - Pedoman Tes OECD 102
f)	Titik didih awal/rentang didih	- Pedoman Tes OECD 103Terdekomposisi di bawah titik didih.
g)	Titik nyala	Data tidak tersedia
h)	Laju penguapan	Data tidak tersedia
i)	Flamabilitas (padatan, gas)	Data tidak tersedia
j)	Batas bawah/atas flamabilitas atau ledakan	Data tidak tersedia
k)	Tekanan uap	Data tidak tersedia
l)	Densitas uap	Data tidak tersedia
m)	Densitas	Data tidak tersedia
	Kerapatan (den-sitas) relatif	Data tidak tersedia
n)	Kelarutan dalam air	kira-kira0,0016 g/l pada 20 °C - Pedoman Tes OECD 105
o)	Koefisien partisi (n-oktanol/air)	log Pow: -2,41 pada 20 °C - Diperkirakan tidak ada potensi bioakumulasi.
p)	Suhu dapat membakar sendiri (auto-ignition temperature)	Data tidak tersedia
q)	Suhu penguraian	Data tidak tersedia
r)	Kekentalan (viskositas)	Viskositas, kinematis: Data tidak tersedia Viskositas, dinamis: Data tidak tersedia
s)	Sifat peledak	Data tidak tersedia
t)	Sifat oksidator	tidak ada

9.2 informasi keselamatan lainnya

Densitas curah	kira-kira110 kg/m3

BAGIAN 10: Reaktifitas dan Stabilitas

10.1 Reaktifitas

Hal berikut ini berlaku secara umum untuk campuran dan senyawa organik y ang mudah terbakar: sehubungan dengan penyebaran yang halus, saat diputa r kemungkinan ledakan debu secara umum dapat diasumsikan.

SAFC®

www.sigmaaldrich.com

LEMBARAN DATA KESELAMATAN BAHAN
menurut Peraturan (UE) No. 1907/2006
Revisi tanggal 14.12.2018 Versi 2.6

BAGIAN 1. Identitas Bahan dan Perusahaan

1.1 Pengidentifikasi produk

No katalog	137045
Nama produk	Lactose monohydrate serbuk sesuai untuk produksi biopharmaceutical EMPROVE® EXPERT Ph Eur,BP,NF,JP
Nomor Registrasi REACH	Nomor registrasi tidak tersedia untuk bahan ini karena bahan atau penggu naannya dibebaskan dari pendaftaran sesuai dengan Pasal 2 peraturan REAC H (EC) No 1907/2006, tonase tahunan tidak memerlukan pendaftaran atau pe ndaftaran diantisipasi untuk batas waktu pendaftaran akan datang.
No-CAS	10039-26-6

1.2 Penggunaan yang relevan dari bahan atau campuran yang diidentifikasi dan penggunaan yang disarankan terhadap

Penggunaan yang teridentifikasi	Produksi farmasi, Reagen untuk analisis, Bahan baku kosmetik Untuk informasi tambahan mengenai penggunaan, silakan rujuk ke portal Merck Chemicals (www.merckgroup.com).

1.3 Rincian penyuplai lembar data keselamatan

Perusahaan	Merck KGaA * 64271 Darmstadt * Germany * Phone: +49 6151 72-0
Bagian Yang Menangani	LS-QHC * e-mail: prodsafe@merckgroup.com

1.4 Nomor telepon darurat **Customer Call Centre : + 62 0800 140 1253 (TollFree)**

BAGIAN 2. Identifikasi bahaya

2.1 Klasifikasi bahan atau campuran
PERATURAN (EC) No 1272/2008 Bukan bahan atau campuran berbahaya menurut Peraturan (EC) No 1272/2008.

2.2 Elemen label
Pelabelan (PERATURAN (EC) No 1272/2008)

Bukan bahan atau campuran berbahaya menurut Peraturan (EC) No 1272/2008.

Lampiran 36. MSDS Lactose

LEMBARAN DATA KESELAMATAN BAHAN
menurut Peraturan (UE) No. 1907/2006

No katalog	137045
Nama Produk	Lactose monohydrate serbuk sesuai untuk produksi biopharmaceutical EMPROVE® EXPERT Ph Eur,BP,NF,JP

Tidak ada yang diketahui.

BAGIAN 3. Komposisi Bahan

3.1 Bahan

Rumus	$C_{12}H_{22}O_{11} * H_2O$ (Hill)
No-EC	200-559-2
Massa molar	360,32 g/mol
Komentar	Tidak ada bahan berbahaya menurut Peraturan (EC) No. 1907/2006.

3.2 Campuran
Tidak berlaku

BAGIAN 4. Tindakan pertolongan pertama pada kecelakaan (P3K)

4.1 Penjelasan mengenai tindakan pertolongan pertama
Setelah menghirup: hirup udara segar.

Bila terjadi kontak kulit: Tanggalkan segera semua pakaian yang terkontaminasi. Bilaslah kulit dengan air/ pancuran air.

Setelah kontak pada mata : bilaslah dengan air yang banyak. Lepaskan lensa kontak.

Setelah tertelan: beri air minum kepada korban (paling banyak dua gelas). Konsultasi kepada dokter jika merasa tidak sehat.

4.2 Kumpulan gejala / efek terpenting, baik akut maupun tertunda
Kami tidak memiliki penjelasan berbagai gejala toksik.

4.3 Indikasi pertolongan medis pertama dan perawatan khusus yang diperlukan
Tidak tersedia informasi.

BAGIAN 5. Tindakan Penanggulangan Kebakaran

5.1 Media pemadaman api
Media pemadaman yang sesuai
Air, Busa, Karbon dioksida (CO2), Serbuk kering

Media pemadaman yang tidak sesuai
Untuk bahan/campuran ini, tidak ada batasan agen pemadaman yang diberika n.

5.2 Bahaya khusus yang muncul dari bahan atau campuran
Mudah menyala.
Perkembangan gas atau uap menyala yang berbahaya mungkin terjadi dalam kejadian kebakaran.

5.3 Saran bagi petugas pemadam kebakaran
Alat pelindung khusus bagi petugas pemadam kebakaran
Jika terjadi kebakaran, pakai alat bantu pernapasan SCBA.

Informasi lebih lanjut
tidak ada

BAGIAN 6. Tindakan terhadap tumpahan dan kebocoran

6.1 Langkah-langkah pencegahan diri, alat pelindung dan prosedur tanggap darurat
Nasihat untuk personel nondarurat Hindari penghisapan debu. Evakuasi dari daerah bahaya, amati prosedur darurat, hubungi ahli.

Saran bagi responden darurat:

Perlengkapan pelindung, lihat bagian 8.

6.2 Langkah-langkah pencegahan bagi lingkungan
Tidak ada tindakan pencegahan khusus diperlukan.

6.3 Metode dan bahan untuk penangkalan (containment) dan pembersihan
Amati kemungkinan pembatasan bahan (lihat bagian 7 dan 10). Ambil dalam keadaan kering. Teruskan ke pembuangan. Bersihkan area yang terkena. Hindari pembentukan debu.

6.4 Rujukan ke bagian lainnya
Indikasi mengenai pengolahan limbah, lihat bagian 13.

BAGIAN 7. Penyimpanan dan Penanganan Bahan

7.1 Kehati-hatian dalam menangani secara aman

Langkah-langkah pencegahan untuk penanganan yang aman
Taati label tindakan pencegahan.

Tindakan higienis
Ganti pakaian yang terkontaminasi . Cuci tangan setelah bekerja dengan bahan tersebut.

7.2 Kondisi penyimpanan yang aman, termasuk adanya inkompatibilitas
Kondisi penyimpanan
Tertutup sangat rapat. Kering.

Suhu penyimpanan yang direkomendasikan, lihat label produk.

7.3 Penggunaan akhir khusus
Selain penggunaan yang disebutkan dalam bagian 1.2, tidak ada penggunaan spesifik lain yang diantisipasi.

BAGIAN 8. Pengendalian pemajanan dan perlindungan diri

8.1 Parameter pengendalian

LEMBARAN DATA KESELAMATAN BAHAN
menurut Peraturan (UE) No. 1907/2006

No katalog	137045
Nama Produk	Lactose monohydrate serbuk sesuai untuk produksi biopharmaceutical EMPROVE® EXPERT Ph Eur,BP,NF,JP

Tidak mengandung bahan-bahan yang mempunyai nilai batas eksposur pekerjaan.

8.2 Pengendalian paparan

Pengendalian teknik yang sesuai
Langkah-langkah teknis dan operasi kerja yang sesuai harus diberikan pri oritas dalam penggunaan alat pelindung diri.
Lihat bagian 7.1.

Tindakan perlindungan individual
Pakaian pelindung harus dipilih secara spesifik untuk tempat bekerja, tergantung konsentrasi dan jumlah bahan berbahaya yang ditangani. Daya tahan pakaian pelindung kimia harus dipastikan dari masing-masing suplier.

Perlindungan mata/wajah
Kacamata-pengaman

Perlindungan tangan
kontak penuh:

Bahan sarung tangan:	Karet nitril
Tebal sarung tangan:	0,11 mm
Waktu terobosan:	> 480 min

kontak percikan:

Bahan sarung tangan:	Karet nitril
Tebal sarung tangan:	0,11 mm
Waktu terobosan:	> 480 min

Sarung tangan pelindung yang digunakan harus mengikuti spesifikasi pada EC directive 89/686/EEC dan standar gabungan d EN374, untuk contoh KCL 741 Dermatril® L (kontak penuh), KCL 741 Dermatril® L (kontak percikan).
Waktu terobosan yang disebutkan diatas ditentukan oleh KCL dalam uji laboratorium berdasarkan EN374 dengan sampel tipe sarung tangan yang dianjurkan.
Rekomendasi ini berlaku hanya untuk produk yang disebutkan dalam lembar data keselamatan dan disuplai oleh kami sesuai tujuan yang kami maksud. Ketika dilarutkan dalam atau dicampur dengan bahan lain dan dalam kondisi yang menyimpang dari yang disebutkan dalam EN374 silahkan hubungi suplier sarung tangan CE-resmi (misalnya KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Perlindungan pernapasan
diperlukan ketika debu dihasilkan.
Jenis filter yang direkomendasikan: Filter P 1 (menurut DIN 3181) untuk partikel padat bahan inert
Pengusaha harus memastikan bahwa perawatan, pembersihan, dan pengujian perangkat perlindungan pernafasan telah dilakukan sesuai dengan petunjuk dari pabriknya. Tindakan ini harus didokumentasikan dengan benar.

Kontrol eksposur lingkungan
Tidak ada tindakan pencegahan khusus diperlukan.

LEMBARAN DATA KESELAMATAN BAHAN
menurut Peraturan (UE) No. 1907/2006

No katalog	137045
Nama Produk	Lactose monohydrate serbuk sesuai untuk produksi biopharmaceutical EMPROVE® EXPERT Ph Eur,BP,NF,JP

BAGIAN 9. Sifat-sifat Fisika dan Kimia

9.1 Informasi tentang sifat fisik dan kimia

Bentuk	padat
Warna	putih
Bau	Tak berbau
Ambang Bau	Tidak berlaku
pH	4,0 - 6,5 pada 100 g/l 20 °C
Titik lebur	202 °C
Titik didih	Tidak tersedia informasi.
Titik nyala	Tidak tersedia informasi.
Laju penguapan	Tidak tersedia informasi.
Flamabilitas (padatan, gas)	Tidak tersedia informasi.
Terendah batas ledakan	Tidak tersedia informasi.
Tertinggi batas ledakan	Tidak tersedia informasi.
Tekanan uap	Tidak tersedia informasi.
Kerapatan (densitas) uap relatif	Tidak tersedia informasi.
Densitas	Tidak tersedia informasi.
Kerapatan (den-sitas) relatif	Tidak tersedia informasi.
Kelarutan dalam air	161 g/l pada 20 °C
Koefisien partisi (n-oktanol/air)	log Pow: -5,03 (dihitung) (senyawa anhydrat) Diperkirakan tidak ada potensi bioakumulasi.
Suhu dapat membakar sendiri (auto-ignition temperature)	Tidak tersedia informasi.

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)
according to Regulation (EU) No. 2020/878

DC Fine Chemicals

Trade name :	**110780 - Povidone K30, Ph. Eur.**		
Revision date :	04/11/2022	**Version (Revision) :**	2.0.0 (1.0.0)
Print date :	16/11/2022		

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

1.1 Product identifier

Povidone K30, Ph. Eur. (110780)
Povidone K30 ; CAS No. : 9003-39-8 ; EC No. : 618-363-4 ; REACH No. : N/D

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

Relevant identified uses

For manufacturing, processing, laboratory or repacking use only.

Uses advised against

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet

Supplier (manufacturer/importer/only representative/downstream user/distributor)

DC Fine Chemicals Ltd
Street : 88 Hill Top
Postal code/City : NW11 6DY London United Kingdom
Telephone : +44 (0)20 7586 6800
Telefax : +44 (0)20 7504 1701
Information contact : info@dcfinechemicals.com

1.4 Emergency telephone number

(Only available during office hours; Monday-Friday; 08:00-18:00)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.3 Other hazards

None

SECTION 3: Composition/information on ingredients

3.1 Substances

Substance name : Povidone K30
EC No. : 618-363-4
REACH No. : N/D
CAS No. : 9003-39-8
Purity : 100 % [mass]

Lampiran 37. MSDS Povidone K30

Safety Data Sheet
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SECTION 4: First aid measures

4.1 Description of first aid measures

Due to the composition and type of the substances present in the product, no particular warnings are necessary.

Following inhalation

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

In case of skin contact

Remove contaminated clothing.

After eye contact

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance. Dont let the person to rub the affected eye.

Following ingestion

Keep calm. NEVER induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

No known acute or delayed effects from exposure to the product.

4.3 Indication of any immediate medical attention and special treatment needed

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Extinguisher powder or CO2. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the substance or mixture

Fire can cause thick, black smoke. As a result of thermal decomposition, dangerous products can form: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account.

Special protective equipment for firefighters

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For exposure control and individual protection measures, see section 8.

For non-emergency personnel

Follow established procedures.

Hints on joint storage

Storage class (TRGS 510) : 13

7.3 Specific end use(s)

None

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

The product does NOT contain substances with Professional Exposure Environmental Limit Values.The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls

Only wear fitting, comfortable and clean protective clothing.

Personal protection equipment

Eye/face protection

Eye glasses EN 166

Skin protection

Hand protection

Tested protective gloves must be worn EN ISO 374 The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances.

Body protection

No special measures are necessary.

Respiratory protection

No special measures are necessary.

Thermal hazards

No special measures are necessary.

Environmental exposure controls

No information available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : solid

Safety characteristics

Melting point/freezing point :	(1013 hPa)	220	°C
Initial boiling point and boiling range :	(1013 hPa)	No data available	

For emergency responders
Follow established procedures.

6.2 Environmental precautions
Product not classified as hazardous for the environment, avoid spillage as much as possible.

6.3 Methods and material for containment and cleaning up
The contaminated area should be immediately cleaned with an appropriate de-contaminator. Pour the decontaminator on the remains in an opened container and let it act various days until no further reaction is produced.

For containment
Follow established procedures.

For cleaning up
Follow established procedures.

6.4 Reference to other sections
For exposure control and individual protection measures, see section 8. For later elimination of waste, follow the recommendations under section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
The product does not require special handling measures, the following general measures are recommended: For personal protection, see section 8. Never use pressure to empty the containers. They are not pressure-resistant containers. In the application area, smoking, eating, and drinking must be prohibited. Follow legislation on occupational health and safety. Keep the product in containers made of a material identical to the original.

Protective measures


Measures to prevent aerosol and dust generation
No special measures are necessary.

Environmental precautions
No special measures are necessary.

Specific requirements or handling rules
No special measures are necessary.

Advices on general occupational hygiene
No special measures are necessary.

7.2 Conditions for safe storage, including any incompatibilities
As general storage measures, sources of heat, radiation, electricity and contact with food should be avoided. Keep away from oxidising agents and from highly acidic or alkaline materials. Store according to local legislation. Observe indications on the label. The product is not affected by Directive 2012/18/EU (SEVESO III).

Technical measures and storage conditions
Storage temperature :
Keep in a cool, well-ventilated place.

Requirements for storage rooms and vessels
Only use containers specifically approved for the substance/product.

Decomposition temperature :	(1013 hPa)	No data available		
Flash point :		No data available		
Auto-ignition temperature :		440	°C	
Lower explosion limit :		No data available		
Upper explosion limit :		No data available		
Vapour pressure :	(50 °C)	No data available		
Density :	(20 °C)	1.2	g/cm³	
Solvent separation test :	(20 °C)	not applicable		
Water solubility :	(20 °C)	No data available		
Fat solubility :	(20 °C)	No data available.		
pH :		No data available		
log P O/W :		No data available		
Flow time :	(20 °C)	No data available		DIN-cup 4 mm
Viscosity :	(20 °C)	No data available		
Relative vapour density :	(20 °C)	No data available		
Evaporation rate :		No data available		
Flammable solids :	No data available.			
Flammable gases :	No data available.			
Explosive properties :	No data available.			

9.2 Other information

None

SECTION 10: Stability and reactivity

10.1 Reactivity

The product does not present hazards by their reactivity.

10.2 Chemical stability

Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid

Avoid any improper handling.

10.5 Incompatible materials

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products

No decomposition if used for the intended uses.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Acute oral toxicity

Parameter :	LD50 (Povidone K30 ; CAS No. : 9003-39-8)
Exposure route :	Oral
Species :	Rat

spectrum®

SAFETY DATA SHEET

Preparation Date: 04/06/2015 **Revision Date:** 07/06/2018 **Revision Number:** G2

1. IDENTIFICATION

Product identifier

Product code: S1962
Product Name: SODIUM STARCH GLYCOLATE, PH 5.5-7.5, TYPE A, NF

Other means of identification
Synonyms: Sodium carboxymethoxystarch
Starch, carboxymethyl ether, monosodium salt
Carboxymethyl starch sodium salt
Sodium carboxymethyl starch

CAS #: 9063-38-1
RTECS # Not available
CI#: Not available

Recommended use of the chemical and restrictions on use
Recommended use: No information available.
Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000

Order Online At: https://www.spectrumchemical.com
Emergency telephone number Chemtrec 1-800-424-9300
Contact Person: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Combustible dust	-

Label elements

Warning

May form combustible dust concentrations in air

Hazards not otherwise classified (HNOC)

Lampiran 38. MSDS Sodium Starch Glycolate

Not Applicable

Other hazards
Not available

Precautionary Statements - Prevention
Keep away from all ignition sources including heat, sparks, and flame
Keep container closed and grounded
Prevent dust accumulations to minimize explosion hazard

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Sodium Starch Glycolate	9063-38-1	100

4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms May cause eye/skin irritation
May cause digestive (gastrointestinal) tract irritation
Dust is irritating to respiratory tract

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders
First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Carbon dioxide (CO2). Dry chemical. Water spray mist or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products:	Carbon Monoxide, Carbon Dioxide.
Specific hazards:	May be combustible at high temperatures. Avoid generating dust. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Special Protective Actions for Firefighters

Specific Methods:	No information available.
Special Protective Equipment for Firefighters:	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions:	Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Remove all sources of ignition. Avoid dust formation. Avoid dispersal of dust in the air. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Non-sparking tools should be used.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Do not flush into surface water or sanitary sewer system.

Methods and material for containment and cleaning up

Methods for containment	Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.
Methods for cleaning up	Sweep up and shovel into suitable containers for disposal. Avoid creating dust. Use only non-sparking tools. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:
Provide sufficient air exchange and/or exhaust in work rooms. Minimize dust generation and accumulation. Avoid dust formation. Dry powders can build static electricity charges when subjected to friction of transfer and mixing operations. All equipment used when handling the product must be grounded. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Keep away from incompatible materials.

Safe Handling Advice
Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:
Hygroscopic. Keep container tightly closed in a dry and well-ventilated place. Keep away from heat and sources of ignition. Store at room temperature in the original container. Store away from incompatible materials.

Incompatible Materials:

Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Sodium Starch Glycolate	9063-38-1	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Sodium Starch Glycolate	9063-38-1	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Sodium Starch Glycolate	9063-38-1	None	None

Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e. there is no leakage from the equipment) It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in the handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Goggles or Safety glasses with side-shields

Skin and body protection: Long sleeved clothing
Chemical resistant apron
Gloves

Respiratory protection: Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

Hygiene measures: Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	**Appearance:** Powder.	**Color:** White.
Odor: Odorless.	**Taste** No information available.	**Formula:** No information available
Molecular/Formula weight: No information available	**Flammability:** No information available	**Flashpoint (°C/°F):** No information available.
Flash Point Tested according to: Not available	**Autoignition Temperature (°C/°F):** No information available	**Lower Explosion Limit (%):** No information available
Upper Explosion Limit (%): No information available	**Melting point/range(°C/°F):** No information available	**Decomposition temperature(°C/°F):** No information available
Boiling point/range(°C/°F): No information available	**Bulk density:** No information available	**Density (g/cm3):** No information available
Specific gravity: 0.95	**pH:** 5.5-7.5	**Vapor pressure @ 20°C (kPa):** No information available
Evaporation rate: No information available	**Vapor density:** No information available	**VOC content (g/L):** No information available
Odor threshold (ppm): No information available	**Partition coefficient (n-octanol/water):** No information available	**Viscosity:** No information available
Miscibility: No information available	**Solubility:** Insoluble in most organic solvents Solubility in Water: 5 g/L @ 20°C	

10. STABILITY AND REACTIVITY

Reactivity
Reactive with oxidizing agents

Chemical stability

Stability: Hygroscopic. Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Ignition sources. Avoid dust formation. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to moisture. Exposure to moist air.

Incompatible Materials: Oxidizing agents

Hazardous decomposition products: Sodium oxides.

Other Information

Sigma-Aldrich.

www.sigmaaldrich.com

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 6.6
Revision Date 15.04.2023
Print Date 28.05.2023
GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

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

1.1 Product identifiers

Product name	:	Magnesium stearate
Product Number	:	415057
Brand	:	Aldrich
REACH No.	:	A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.
CAS-No.	:	557-04-0

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

Identified uses	:	Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company	:	Sigma-Aldrich Pte Ltd (Co. Registration No. 199403788W) 2 Science Park Drive #05-01/12 Ascent Building SINGAPORE 118222 SINGAPORE
Telephone	:	+65 6890 6633
Fax	:	+65 6890 6639
E-mail address	:	TechnicalService@merckgroup.com

1.4 Emergency telephone

Emergency Phone #	:	1-800-262-8200

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

Lampiran 39. MSDS Magnesium Stearate

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

Synonyms	:	Stearic acid magnesium salt
Formula	:	$C_{36}H_{70}MgO_4$
Molecular weight	:	591,24 g/mol
CAS-No.	:	557-04-0
EC-No.	:	209-150-3

No components need to be disclosed according to the applicable regulations.

SECTION 4: First aid measures

4.1 Description of first-aid measures

If inhaled
After inhalation: fresh air.

In case of skin contact
In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.

In case of eye contact
After eye contact: rinse out with plenty of water. Remove contact lenses.

If swallowed
After swallowing: make victim drink water (two glasses at most). Consult doctor if feeling unwell.

4.2 Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed
No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Unsuitable extinguishing media
For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture
Carbon oxides
Magnesium oxide

5.3 Advice for firefighters
In the event of fire, wear self-contained breathing apparatus.

5.4 Further information
none

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Advice for non-emergency personnel: Avoid inhalation of dusts. Evacuate the danger area, observe emergency procedures, consult an expert.
For personal protection see section 8.

6.2 Environmental precautions
No special precautionary measures necessary.

6.3 Methods and materials for containment and cleaning up
Observe possible material restrictions (see sections 7 and 10). Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

6.4 Reference to other sections
For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions
Tightly closed. Dry.

Storage class
Storage class (TRGS 510): 13: Non Combustible Solids

7.3 Specific end use(s)
Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

8.2 Exposure controls

Personal protective equipment

Eye/face protection
Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

Skin protection
This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please

contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Full contact
Material: Nitrile rubber
Minimum layer thickness: 0,11 mm
Break through time: 480 min
Material tested:KCL 741 Dermatril® L

Splash contact
Material: Nitrile rubber
Minimum layer thickness: 0,11 mm
Break through time: 480 min
Material tested:KCL 741 Dermatril® L

Respiratory protection
required when dusts are generated.
Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.
Recommended Filter type: Filter type P1

The entrepeneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Control of environmental exposure
No special precautionary measures necessary.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a)	Physical state	powder
b)	Color	white
c)	Odor	No data available
d)	Melting point/freezing point	Melting point/range: 200 °C - lit.
e)	Initial boiling point and boiling range	No data available
f)	Flammability (solid, gas)	No data available
g)	Upper/lower flammability or explosive limits	No data available
h)	Flash point	No data available
i)	Autoignition temperature	No data available
j)	Decomposition	No data available

	temperature	
k)	pH	No data available
l)	Viscosity	Viscosity, kinematic: No data available Viscosity, dynamic: No data available
m)	Water solubility	No data available
n)	Partition coefficient: n-octanol/water	No data available
o)	Vapor pressure	No data available
p)	Density	No data available
	Relative density	No data available
q)	Relative vapor density	No data available
r)	Particle characteristics	No data available
s)	Explosive properties	No data available
t)	Oxidizing properties	No data available

9.2 Other safety information
No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
No data available

10.2 Chemical stability
The product is chemically stable under standard ambient conditions (room temperature) .

10.3 Possibility of hazardous reactions
No data available

10.4 Conditions to avoid
no information available

10.5 Incompatible materials
Strong oxidizing agents

10.6 Hazardous decomposition products
In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity
LD50 Oral - Rat - > 2.000 mg/kg
Remarks: (External MSDS)

Material Safety Data Sheet

Colorcon

OPADRY AG YA-38-19180 CLEAR

Section 1. Chemical product and company identification

Identification of the substance or preparation

Product name	:	**OPADRY AG**
Product code	:	**YA-38-19180**
Manufacturer	:	Colorcon 415 Moyer Boulevard West Point, PA 19486 USA www.colorcon.com E-mail: safety@colorcon.com Phone: +001-215-699-7733 Fax: +001-215-661-2503
Emergency telephone number	:	US - 800-424-9300 International - +001-703-527-3887

Section 2. Composition, Information on Ingredients

POLYETHYLENE GLYCOL	25322-68-3	10 - 30	**AIHA WEEL (United States, 1/2004).** TWA: 10 mg/m³ 8 hour(s). Form: Aerosol

Section 3. Hazards identification

Physical state	:	Solid. (Powder.)
Appearance	:	Off White Powder
Emergency overview	:	No specific hazard.
Routes of entry	:	Eye contact. Inhalation. Ingestion.

Potential acute health effects

Eyes	:	This product may irritate eyes upon contact.
Skin	:	No known significant effects or critical hazards.
Inhalation	:	Over-exposure by inhalation may cause respiratory irritation.
Ingestion	:	No known significant effects or critical hazards.

See toxicological Information (section 11)

Section 4. First aid measures

Eye contact	:	Affected individual should remove contact lens, if present. In case of contact with eyes, rinse immediately with plenty of water or saline solution. Get medical attention if irritation occurs.
Skin contact	:	Wash contaminated skin with soap and water. Get medical attention if irritation develops.
Inhalation	:	If inhaled, remove to fresh air. Get medical attention if symptoms appear. If exposed person is not breathing, give artificial respiration or oxygen applied by trained personnel.
Ingestion	:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention if symptoms appear.

Section 5. Fire fighting measures

Flammability of the product	:	Non-flammable.
Products of combustion	:	During combustion, product may emit but not limited to carbon dioxide, carbon monoxide.
Fire fighting media and instructions	:	Use DRY chemicals, CO_2, water spray or foam. Use an extinguishing agent suitable for surrounding fires.
Special protective equipment for fire-fighters	:	Fire fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full facepiece operated in positive pressure mode.

Lampiran 40. MSDS Opadry

Colorcon

Special remarks on explosion hazards : Fine dust clouds may form explosive mixtures with air.

Section 6. Accidental release measures

Personal precautions : Keep unnecessary personnel away. Use suitable protective equipment (Section 8).

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Methods for cleaning up : If emergency personnel are unavailable vacuum or carefully scoop up spilled materials and place in an appropriate container for disposal. Avoid creating dusty conditions and prevent wind dispersal.

Section 7. Handling and storage

Handling : Avoid breathing dust.

Storage : Keep container tightly closed. Keep container in a cool, well-ventilated area.

Section 8. Exposure Controls, Personal Protection

Engineering controls : Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal protection

Eyes : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts.

Skin : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory : Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary.Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Hands : Chemical-resistant, impervious gloves or gauntlets complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Personal protection in case of a large spill : Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

** Occupational Exposure Limit(s), if available, are listed in section 2*

Section 9. Physical and chemical properties

Physical State and Appearance : Solid. (Powder.)

Melting/freezing point : 230°C (446°F) based on data for: polyvinyl alcohol. Weighted average: 204.49°C (400.1°F)

Values provided should not be construed as specifications. See product specification for additional information.

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Section 10. Stability and reactivity

Stability and reactivity : The product is stable.

Hazardous polymerization : Will not occur.

Section 11. Toxicological information

Ingredient name	Test	Result	Route	Species
polyvinyl alcohol	LD50	23854 mg/kg	Oral	Rat
	LD50	14270 mg/kg	Oral	Mouse
	LD50	14700 mg/kg	Oral	Mouse
poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	LD50	27500 mg/kg	Oral	Rat
poly(1-vinyl-2-pyrrolidinone)	LD50	1040 mg/kg	Oral	Rabbit
hueper's polymer no.6				
dioctyl sodium sulfosuccinate	LD50	1900 mg/kg	Oral	Rat
	LD50	2643 mg/kg	Oral	Mouse

Chronic effects on humans : **CARCINOGENIC EFFECTS** Classified A4 (Not classifiable for human or animal.) by ACGIH [Ethanol].

Other toxic effects on humans : Slightly hazardous in case of eye contact (irritant), of inhalation (lung irritant). Non-corrosive for skin. Non-irritant for skin. Non-sensitizer for skin. Non-permeator by skin. Non-hazardous in case of ingestion. Non-sensitizer for lungs. Non-corrosive to the eyes. Non-corrosive for lungs.

Specific effects

Carcinogenicity / Mutagenicity / Reproductive toxicity : No known significant effects or critical hazards.

Section 12. Ecological information

Ingredient name	Species	Period	Result
poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-	Oncorhynchus mykiss (LC50)	96 hour(s)	>20000 mg/l
dioctyl sodium sulfosuccinate	Oncorhynchus mykiss (LC50)	96 hour(s)	<24 mg/l
	Oncorhynchus mykiss (LC50)	96 hour(s)	28 mg/l

Products of degradation : These products are carbon oxides (CO, CO_2) and water, nitrogen oxides (NO, NO_2...), sulfur oxides (SO_2, SO_3...). Some metallic oxides.

Toxicity of the products of biodegradation : The product itself and its products of degradation are not toxic.

Section 13. Disposal considerations

Waste disposal : Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Consult your local or regional authorities.

Section 14. Transport information

DOT Classification : Refer to the bill of lading for proper shipping information.

Section 15. Regulatory information

United States

HCS Classification : Not regulated.

U.S. Federal regulations : TSCA 8(a) PAIR: dimethyl silicones and siloxanes
TSCA 8(b) inventory: polyvinyl alcohol; poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-; maltodextrin; Sulphuric acid; water; dimethyl silicones and siloxanes; dioctyl sodium sulfosuccinate; Ethanol; poly(1-vinyl-2-pyrrolidinone) hueper's polymer no.6
SARA 302/304/311/312 hazardous chemicals: Not applicable.
Clean Water Act (CWA) 311: Sulphuric acid
Clean Water Act (CWA) 307: No products were found.
Clean air act (CAA) 112 accidental release prevention: No products were found.
Clean air act (CAA) 112 regulated flammable substances: No products were found.
Clean air act (CAA) 112 regulated toxic substances: No products were found.

State regulations : Pennsylvania RTK: Sulphuric acid: (environmental hazard, generic environmental hazard); Ethanol: (generic environmental hazard)
Massachusetts RTK: Sulphuric acid; Ethanol
New Jersey: Sulphuric acid; Ethanol

Canada

WHMIS (Canada) : Not controlled under WHMIS (Canada).
CEPA DSL: polyvinyl alcohol; poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-; maltodextrin; Sulphuric acid; water; dimethyl silicones and siloxanes; dioctyl sodium sulfosuccinate; Ethanol; poly(1-vinyl-2-pyrrolidinone) hueper's polymer no.6

International regulations

DSCL (EEC) : This product is not classified according to the EU regulations.

Section 16. Other information

Hazardous Material Information System (U.S.A.) :

Health	0
Fire hazard	0
Reactivity	0
Personal protection	E

National Fire Protection Association (U.S.A.) :

History

Date of issue : 20 April 2005

Date of previous issue : No Previous Validation.

Version : 1

Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

201FF01023 GHINA HIDAYANTI J

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KARTU BIMBINGAN TUGAS AKHIR

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Nama Mahasiswa	: Ghina Hidayanti J
NPM	: 201FF01023
Bidang Ilmu	: Teknologi Farmasi

No	Hari/Tanggal	Waktu	Tempat	Materi	Paraf Dosen
1.	Rabu/ 21 Desember 2022	15.30	Kampus	Perkenalan dan Pengajuan Judul KTI	
2.	Senin/26 Desember 2022	16.00	Kampus	Perubahan Judul KTI	
3.	Kamis/5 Januari 2023	13.00	Kampus	Revisi Bab I Metode 1.	
4.	Jumat/13 Januari 2023	16.00	Kampus	Revisi Bab I Metode 2.	
5.	Kamis/19 Januari 2023	M.30	Kampus	Revisi	
6.	Rabu/ 25 Januari 2023	13.30	Kampus	Revisi	
7	Sabtu / 27 mei 2023	16.00	kampus	Revisi kemajuan KTI	
8.	Senin / 29 mei 2023	16.00	kampus	Revisi kemajuan KTI	
9.	Selasa / 30 juni 2023	16.00	kampus	Revisi KTI	
10	Rabu / 07 Juni 2023	16.00	kampus	Revisi KTI	
11	Kamis / 08 juni 2023	16.00	kampus	Revisi KTI	
12	Jumat / 09 juni 2023	16.00	kampus	Revisi KTI	

Catatan : Kartu ini harus dibawa setiap kali melakukan bimbingan dan harus diisi oleh dosen pembimbing.

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Pembimbing Serta	: Dr. Apt. Fauzan Zein M.M,Si
Nama Mahasiswa	: Ghina Hidayanti J
NPM	: 201FF01023
Bidang Ilmu	: Teknologi Farmasi

No	Hari/Tanggal	Waktu	Tempat	Materi	Paraf Dosen
1.	Rabu 31 mei 2023	13.00	kampus	kemajuan KTI	
2.	Kamis 08 juni 2023	14.30	kampus	Revisi KTI	

Catatan : Kartu ini harus dibawa setiap kali melakukan bimbingan dan harus diisi oleh dosen pembimbing.

RIWAYAT HIDUP

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2013 – 2016 : SMPN 1 Rancaekek

2016 – 2019 : SMK Bhakti Sejahtera Jatinangor

2020 – 2023 : D3 Farmasi Universitas Bhakti Kencana