CERTIFICATE OF ANALYSIS

Polysorbate 80

Batch Number: 4401501
Best Before Date: July 2023

TEST	SPECIFICATION	RESULT
Appearance	Yellow to Amber oily liquid	Conforms
pH (5% Solution)	6 - 8	6.88
Moisture	Max 3 %	1.72 %
Saponification	45 -55	48
Hydroxyl Value	65 - 80	73
Acid Value	Max 2	1.42

Date: 15th October,2019

TO WHOMSOEVER IT MAY CONCERN

FOOD ALLERGENS ABSENCE CERTIFICATE

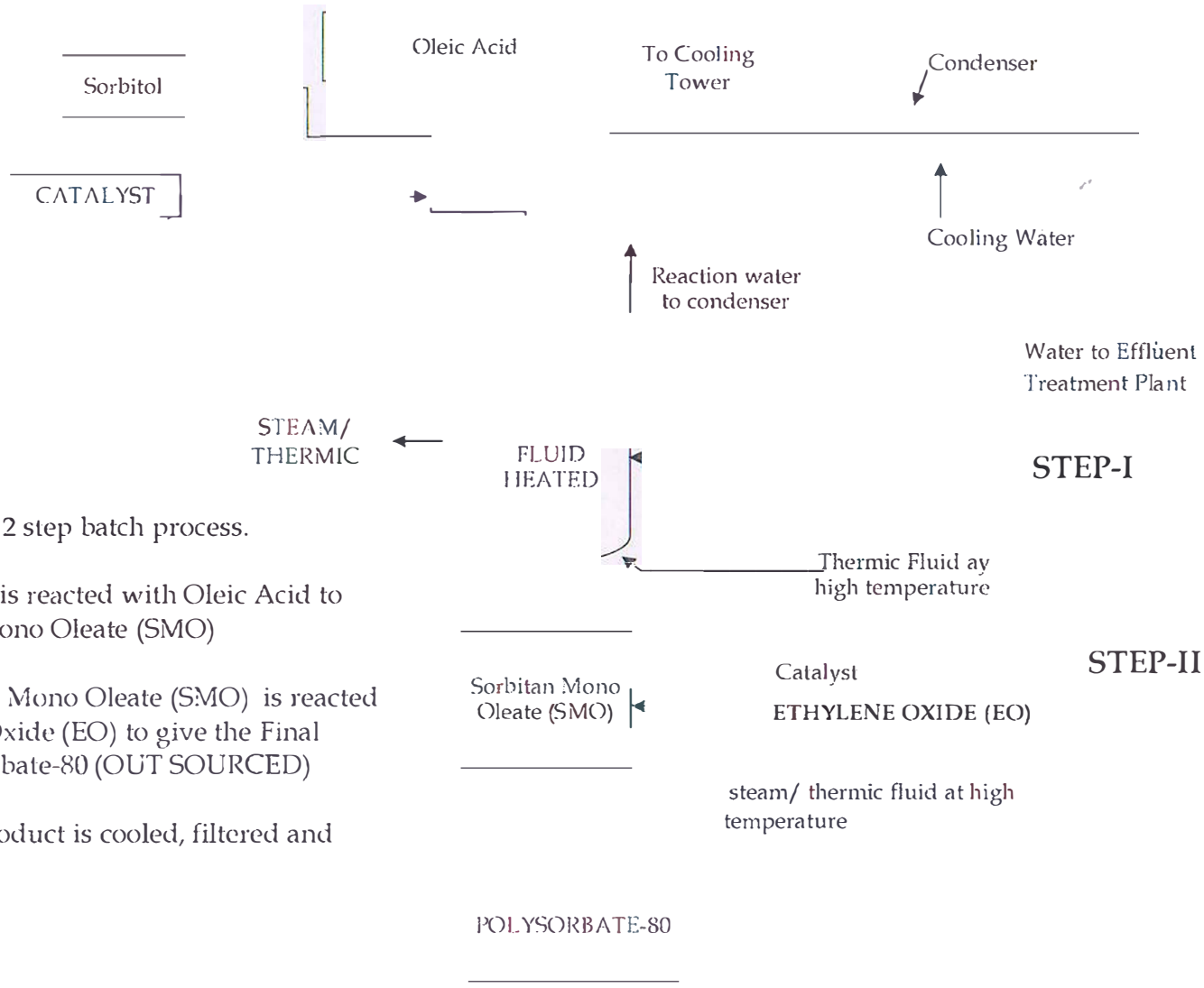
We certify that our product Polysorbate-80

is free from food allergens as per

Regulation (CE) No 2003/89/ECC.

Thanking you with regards

FLOW CHART FOR MFG FOR Polysorbate-80



The Process is a 2 step batch process.

Step-1: Sorbitol is reacted with Oleic Acid to give Sorbitan Mono Oleate (SMO)

Step-2: Sorbitan Mono Oleate (SMO) is reacted with Ethylene Oxide (EO) to give the Final Product Polysorbate-80 (OUT SOURCED)

The finished product is cooled, filtered and packed

Date: 15th October,2019

TO WHOMSOEVER IT MAY CONCERN

NON-GMO DECLARATION

We certify that we do not use any Genetically Modified Organisms(GMO) in production of Polysorbate-80 and it is GMO-free.

No GMO substances are detectable in the product.

Any contamination with materials of GMO-origin during production, packaging and storage can be ruled out.

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

· **Trade name: Sorbitan mono oleate, ethoxylated**
· **CAS Number:**
1 · 9005-65-6
· **Registration number** – Exempted
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
· **Application of the substance / the mixture**
It is used as a emulsifying agents, essential oils solublizer, fragrance solublizer and surfactants.
· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Madar Corporation Limited
· **19-20 Sandleheath Industrial Estate**
· **Fordingbridge**
· **SP6 1PA**
Phone: + 44 (0)1425 655 555
Email: technical@madarcorporation.co.uk
· **1.4 Emergency telephone number:**

Emergency telephone number: +44 (0)1425 655 555

Opening hours: Monday to Friday 9am to 5pm

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008** The substance is not classified according to the CLP regulation.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.

(Contd. on page 2)

· **Trade name: Sorbitan mono oleate, ethoxylated**

(Contd. of page 1)

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.1 Chemical characterisation: Substances**
· **CAS No. Description**
· 9005-65-6 Sorbitan mono oleate, ethoxylated
· **Identification number(s)**
· **Additional information:**
Molecular Formula: $C_{64}H_{124}O_{26}$
· Molecular Weight: 1310 g/mol
· **SVHC** the substance is not in the list of SVHC substances

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information:** No special measures required.
· **After inhalation:**
If breathed in, move person into fresh air. If not breathing, give artificial respiration.
· **After skin contact:** Wash off with soap and plenty of water.
· **After eye contact:** Flush eyes with water as a precaution.
· **After swallowing:**
Never give anything by mouth to an unconscious person. Rinse mouth with water.
· **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
· **Information for doctor:** Treat symptomatically.
· **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**
· **Suitable extinguishing agents:**
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
· **For safety reasons unsuitable extinguishing agents:** Do not use water jet.
· **5.2 Special hazards arising from the substance or mixture** Carbon oxides.
· **5.3 Advice for firefighters**
· **Protective equipment:**
Wear self contained breathing apparatus for fire fighting if necessary.
· **Additional information** No further relevant information available.

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SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures** Avoid breathing vapours, mist or gas.
· **6.2 Environmental precautions:** Do not let product enter drains.
· **6.3 Methods and material for containment and cleaning up:** Dispose of the material collected according to regulations.
· **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling** Prevent formation of dust.
· **Information about fire - and explosion protection:**
Keep away from sources of ignition.
Empty containers pose a fire risk, evaporate the residue under a fume hood.

· **7.2 Conditions for safe storage, including any incompatibilities**
Store in cool place. Keep container tightly closed in a dry and well-ventilated place.
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** Keep away from heat.
· **Information about storage in one common storage facility:**
Keep away from incompatibles such as oxidizing agents.
· **Further information about storage conditions:** Ground all equipment containing material.
· **7.3 Specific end use(s)**
It is used as a emulsifying agents,essential oils solublizer,fragrance solublizer and surfactants.

SECTION 8: Exposure controls/personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.

· **8.1 Control parameters**
· **Ingredients with limit values that require monitoring at the workplace:** Not required.
· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.

(Contd. on page 4)

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· **Respiratory protection:**
Respiratory protection not required. For nuisance exposures use type OV/AG (US) or type ABEK (EU EN 14387) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
· **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
Appearance:	Liquid
· **Form:**	Colourless
· **Colour:**	Colourless
· **Odour:**	Odourless
· **Odour threshold:**	Not determined.
· **pH-value at 23 °C:**	6-8 (concentration:5 vol %)
· **Change in condition**	
Melting point/Melting range:	45-50 °C
Boiling point/Boiling range:	>100 °C
· **Flash point:**	>148 °C (Closed cup)
· **Flammability (solid, gaseous):**	Product is not flammable.
· **Ignition temperature:**	
Decomposition temperature:	Not determined.
· **Self-igniting:**	Product is not selfigniting.

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· **Danger of explosion:**	Product does not present an explosion hazard.
· **Vapour pressure at 20 °C:**	<0.1 kPa
· **Density at 25 °C:**	1.07 g/cm³
· **Solubility in / Miscibility with water at 23 °C:**	300 mg/l
· **Partition coefficient (n-octanol/water) at 23 °C:**	0.03 log POW
· **Viscosity:**	
Dynamic:	Not determined.
Kinematic:	Not determined.
· **9.2 Other information**	No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability** Stable under normal temperatures and pressures.
· **Thermal decomposition / conditions to be avoided:** Incompatible materials, strong oxidants.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known.
· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:** Strong oxidizing agents, bases, heavy metal salts.
· **10.6 Hazardous decomposition products:**
Carbon monoxide, irritating and toxic fumes and gases, carbon dioxide.
· **Additional information:** Not available

SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

Oral	LD50	>60000 mg/kg bw (rat male) (acute toxic class method)
Dermal	LD50	2325 mg/Kg bw (rabbit (New Zealand White)) (OECD Guideline 402 (Acute Dermal Toxicity))

Inhalative LC50 (6 hrs.) 85.037 mg/l air (rat) (OECD Guideline 403 (Acute Inhalation Toxicity))

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· ***Primary irritant effect:***
· ***Skin corrosion/irritation***
By primary dermal irritation index (PDII) from QSAR , skin irritation score of Sorbitan mono oleate, ethoxylated *estimated as 0.303.Based on this score it is indicated that* Sorbitan mono oleate, ethoxylated *is not irritating to the skin of rabbit.*
· ***Serious eye damage/irritation***
Tween 60 used in the niosomal formulations as well as the other excipients were non-irritant to the eye.
· ***Respiratory or skin sensitisation***
Cream containing polysorbate 60 was found to be non sensitizing to the human skin.
· ***CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)***
Not listed as a carcinogen by ACGIH, IARC, NTP, or CA Prop 65.
· ***Germ cell mutagenicity*** *Based on available data, the classification criteria are not met.*
· ***Carcinogenicity*** *Based on available data, the classification criteria are not met.*
· ***Reproductive toxicity*** *Based on available data, the classification criteria are not met.*
· ***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.*

SECTION 12: Ecological information

· ***12.1 Toxicity***

· ***Aquatic toxicity:***	
EC50 (48 hrs)	*114.602 mg/L (Daphnia magna) (QSAR prediction data)*
LC50	*121.98 mg/l (Fish Onchorhynchus mykiss(Rainbow trout)) (QSAR prediction data)*

· ***12.2 Persistence and degradability***
Sorbitan mono oleate, ethoxylated *was estimated to be 50% biodegradable in water in 15days (half-life) indicating that* Sorbitan mono oleate, ethoxylated *is readily biodegradable in water since the half life is less than the threshold of 60 days (to qualify the chemical as persistent).*
· ***12.3 Bioaccumulative potential***
The estimated bioconcentration factor (BCF) for Sorbitan mono oleate, ethoxylated *is 18 which does not exceed the EPA bioconcentration criteria of 1000. From this it is concluded that* Sorbitan mono oleate, ethoxylated *is not expected to bioaccumulate in the food chain.*
· ***12.4 Mobility in soil***
Soil Adsorption Coefficient i.e Koc value of Sorbitan mono oleate, ethoxylated *was estimated as 8780000000 (Log Koc = 9.9434).*
· ***Additional ecological information:***
· ***General notes:*** *Not known to be hazardous to water.*
· ***12.5 Results of PBT and vPvB assessment***
· ***PBT:*** *Not applicable.*
· ***vPvB:*** *Not applicable.*

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· ***12.6 Other adverse effects*** *No further relevant information available.*

SECTION 13: Disposal considerations

· ***13.1 Waste treatment methods***
· ***Recommendation*** *Smaller quantities can be disposed of with household waste.*
· ***Waste disposal key:*** *Dispose of as unused product.*
· ***European waste catalogue*** *Not available*

· ***Uncleaned packaging:***
· ***Recommendation:*** *Dispose off according to Federal, State and Local Regulations.*
· ***Recommended cleansing agents:*** *Not available*

SECTION 14: Transport information

· ***14.1 UN-Number***	
· ***ADR, ADN, IMDG, IATA***	*Not applicable*
· ***14.2 UN proper shipping name***	
· ***ADR, ADN, IMDG, IATA***	*Not applicable*
· ***14.3 Transport hazard class(es)***	
· ***ADR, ADN, IMDG, IATA***	
· ***Class***	*Not applicable*
· ***14.4 Packing group***	
· ***ADR, IMDG, IATA***	*Not applicable*
· ***14.5 Environmental hazards:***	*Not applicable.*
· ***14.6 Special precautions for user***	*Not applicable.*
· ***14.7 Transport in bulk according to Annex II of Marpol and the IBC Code***	*Not applicable.*
· ***UN "Model Regulation":***	*Not applicable*

SECTION 15: Regulatory information

· ***15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture***
· ***Labelling according to Regulation (EC) No 1272/2008*** *Void*
· ***Hazard pictograms*** *Void*
· ***Signal word*** *Void*
· ***Hazard statements*** *Void*

(Contd. on page 8)

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· ***Directive 2012/18/EU***
· ***Named dangerous substances - ANNEX I*** *Substance is not listed.*

· ***National regulations:***

· ***Information about limitation of use:*** *User to follow national laws and regulations*

· ***Other regulations, limitations and prohibitive regulations***
· ***Substances of very high concern (SVHC) according to REACH, Article 57***
The substance is not listed as SVHC.
· ***15.2 Chemical safety assessment:***
A Chemical Safety Assesment shall be carried out at the time of REACH Registration.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· ***Department issuing MSDS:*** *Product safety department.*
· ***Contact:***
Phone: + 91 22 25220083/ 25230030/ 25293450
Fax: +91 22 25233504
Email: marketing@spakorgochem.in, spak@mtnl.net.in, spakorgochem@gmail.com
Website: www.spakorgochem.in
· ***Abbreviations and acronyms:***
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative
· ***Sources***
**• REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL 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*
**http://echa.europa.eu/registration-dossier/-/registered-dossier/11403/5/5/2*
**http://www.sigmaaldrich.com/MSDS/MSDS/PleaseWaitMSDSPage.do?language=&country=IN&brand=SIGMA&productNumber=P1629&PageToGoToURL=http%3A%2F%2Fwww.sigmaaldrich.com%2Fcatalog%2Fsearch%3Fterm%3D9005-67-8%26interface%3DCAS%2520No.%26N%3D0%2B%26mode%3Dpartialmax%26lang%3Den%26region%3DIN%26focus%3Dproduct*

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· **** Data compared to the previous version altered.***
- *Section 1 - Identification of the substance /preparation & of the company/ undertaking*
- *Section 3 - Composition /Information on ingredients*
- *Section 4 - First Aid Measures*
- *Section 5 - Fire Fighting Measures*
- *Section 6 - Accidental Release Measures*
- *Section 7 - Handling and Storage*
- *Section 8 - Exposure Controls / Personal Protection*
- *Section 9 - Physical & Chemical Properties*
- *Section 10 -Stability and reactivity*
- *Section 11 - Toxicological Information*
- *Section 12 - Ecological Information*
- *Section 13 - Disposal Considerations*
- *Section 14 - Transport information*
- *Section 15 - Regulatory Information*
- *Section 16 - Other information*

IN

Polysorbate-80

MIXTURE OF THE PARTIAL ESTERS OF SORBITOL AND ITS MONO- AND DIANHYDRIDES WITH EDIBLE COMMERCIAL FATTY ACID AND CONDENSED WITH APPROXIMATELY 20 MOLES OF ETHYLENE OXIDE PER MOLE OF SORBITOL AND ITS ANHYDRIDES.

Specifications:

Product	**SPAKESE-80**
CAS NO.	9005-65-6
EINECS	500-019-9
PRODUCT	Polysorbate-80
PHYSICAL APPEARANCE	Yellow to Amber oily liquid
PH OF 5% SOLUTION	6 to 8
MOISTURE	3% Max
SOLUBILITY	Miscible in water, ethanol
SAP VALUE	45 to 55
HYDROXYL VALUE	65 to 80
ACID VALUE	2 Max
HS-NO	3402.1300
Storage (Temp)	20-25°C
Packing	HDPE Drums, Steel drums, Iso-Tanks, IBCs.

Typical Properties:

HLB Value	**15**

Applications:

POLYSORBATE-80

1) **Polysorbate-80** is used as an emulsifier in foods.
2) **Polysorbate-80** is used as a vitamin solubilizer.
3) **Polysorbate-80** is also used as a surfactant in soaps and cosmetics (including eye drops), or a solubilizer such as in a mouthwash.
4) **Polysorbate-80** is an excipient that is used to stabilize aqueous formulations of medications, and used as an emulsifier in the manufacture of many medicines.

Date: 15th October,2019

TO WHOMSOEVER IT MAY CONCERN

VEGAN STATEMENT

Madar Corporation Limited guarantees that our Polysorbate-80 does not and will not contain ingredients or sourced materials that contain animal or animal by-products."