



CERTIFICATE OF ANALYSIS

Polysorbate 80

Batch Number: 4418119

Best Before Date: December 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

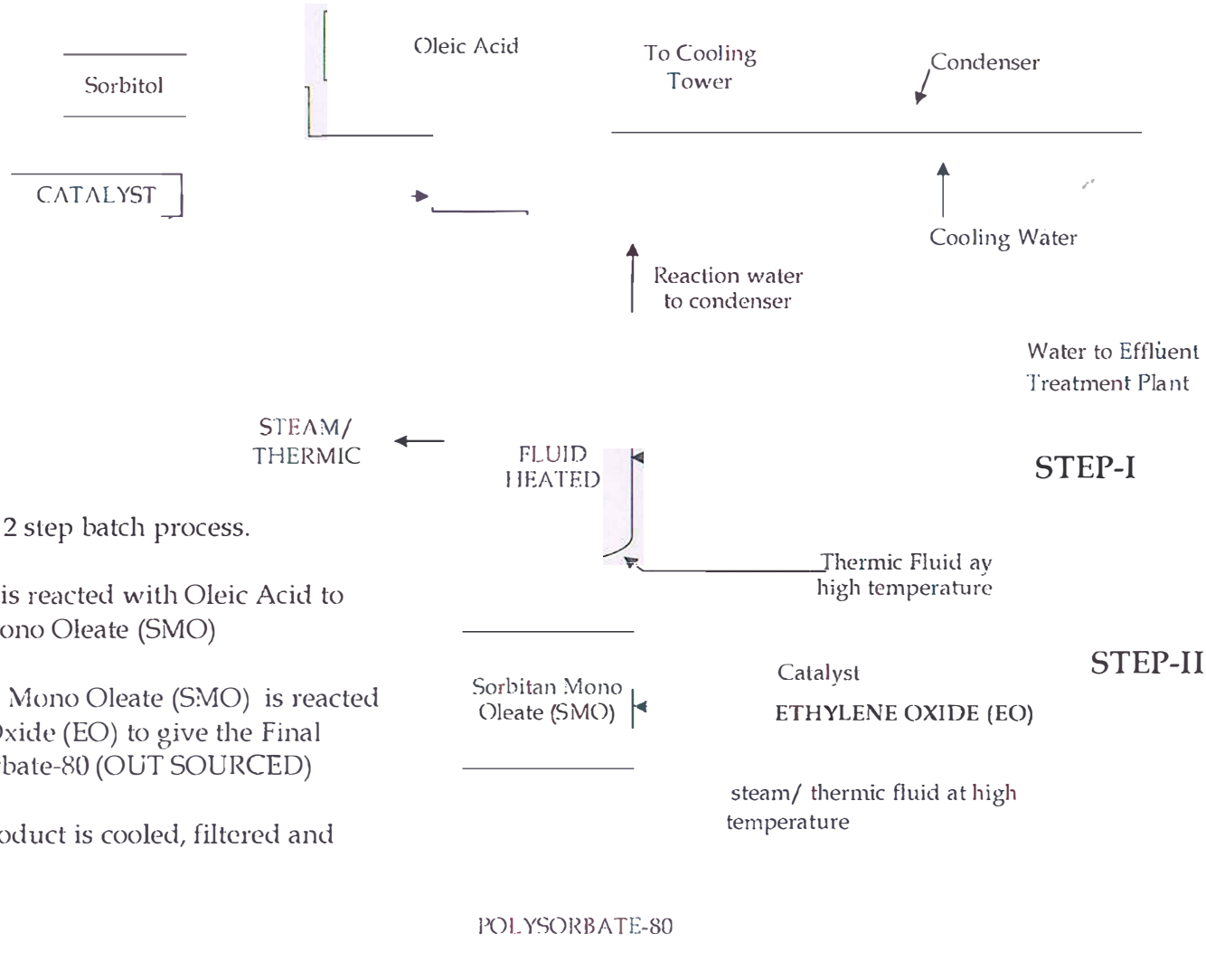
TO WHOMSOEVER IT MAY CONCERN

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.

Safety data sheet

COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Printing date 05.05.2018

Revision: 05.05.2018

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)

IN

Safety data sheet

COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Printing date 05.05.2018

Revision: 05.05.2018

· 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.

(Contd. on page 3)

Safety data sheet

COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Printing date 05.05.2018

Revision: 05.05.2018

Trade name: Sorbitan mono oleate, ethoxylated

(Contd. of page 2)

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)

IN

Safety data sheet

COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Printing date 05.05.2018

Revision: 05.05.2018

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

(Contd. of page 3)

· **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.

(Contd. on page 5)

Safety data sheet

COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Printing date 05.05.2018

Revision: 05.05.2018

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

(Contd. of page 4)

· Danger of explosion:	<i>Product does not present an explosion hazard.</i>
· Vapour pressure at 20 °C:	<0.1 kPa
· Density at 25 °C:	1.07 g/cm ³
· 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:	<i>Not determined.</i>
Kinematic:	<i>Not determined.</i>
· 9.2 Other information	<i>No further relevant information available.</i>

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))		

(Contd. on page 6)

IN

Safety data sheet

COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Printing date 05.05.2018

Revision: 05.05.2018

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

(Contd. of page 5)

- **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 (carcinogenicity, 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 (<i>Daphnia magna</i>) (QSAR prediction data)
LC50	121.98 mg/l (<i>Fish Onchorhynchus mykiss</i> (Rainbow trout)) (QSAR prediction data)

• 12.2 Persistence and degradability

Sorbitan mono oleate, ethoxylated was estimated to be 50% biodegradable in water in 15 days (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.

(Contd. on page 7)

Safety data sheet

COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Printing date 05.05.2018

Revision: 05.05.2018

Trade name: Sorbitan mono oleate, ethoxylated

(Contd. of page 6)

- **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)

IN

Safety data sheet

COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of Regulation (EU) No 453/2010

Printing date 05.05.2018

Revision: 05.05.2018

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

(Contd. of page 7)

- **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 Assessment 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=I&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>

(Contd. on page 9)

IN

Safety data sheet
COMMISSION REGULATION (EU) No 2015/830 of 1 June 2015 amending Annex II of
Regulation (EU) No 453/2010

Printing date 05.05.2018

Revision: 05.05.2018

Trade name: Sorbitan mono oleate, ethoxylated

(Contd. of page 8)

- *** 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."