SABO S.p.A.
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DATA SET

SABOSORB MLE

CHEMICAL IDENTITY

INCI (CTFA) NAME: POLYSORBATE 20
CAS REGISTRY NUMBER: 9005-64-5
EC No. NA
REACH NUMBER: exempted, polymer
INVENTORY:

- AUSTRALIA: AICS
- CANADA: DSL
- CHINA: IECSC
- JAPAN: ENCS
- KOREA: ECL
- MEXICO: INSQ
- NEW ZEALAND: NZIoC
- PHILIPPINES: PICCS
- SWITZERLAND: SWISS
- USA: FDA, FIFRA, TSCA

1. PRODUCT SPECIFICATION

(SEE TDS DOCUMENT)

COMPOSITION: POLYSORBATE 20 > 97%

2. TECHNICAL INFORMATION

(SEE TDS DOCUMENT)

3. PRODUCTION

- **Manufacturer:** Sabo S.p.a
- **Country of origin:** Italy
- **Manufacturing process:** esterification, ethoxylation and de-dioxanation process

Company Certification:

- ISO 9001/2008
- ISO 14001/2004
- OHSAS 18001/2007
- EFfCI GMP
- FAMI-QS

4. STORAGE CONDITIONS AND TEMPERATURE

(SEE TDS DOCUMENT)

5. STABILIZATION OF THE PRODUCT

- **Preservatives**: no
- **Antioxidant:** no
- **Stabilizer:** no
- **OTHER:** no

6. ADDITIONAL PRODUCT INFORMATION

6.1 RAW MATERIAL:

Based on our actual knowledge, the raw materials are:

- Fatty acid from plant,
- ethylene oxide : synthetic

Fatty acid composition:

C8	2-10%
C10	4-10%
C12	44-59%
C14	15-27%
C16	6-14%
C18	< 7%
C18:1	3-17%
C18:3	<4%

6.2 SOLVENTS

Based on our actual knowledge of our production process, raw material and equipment used we do not expect solvent to be present.

6.3 HEAVY METALS

Heavy metals in sum (as Pb) max ≤ 10 ppm

6.4 PESTICIDES

Based on our actual knowledge of our production process, raw material and equipment used we do not expect pesticides to be present.

6.5 OTHER IMPURITES

Based on our actual knowledge of our production process, raw material and equipment used we do not expect, dioxins, polycyclic aromatic hydrocarbons, amine or nitrosamine to be present.

- 1-4 dioxane < 1 ppm
- Ethylene oxide, traces < 1 ppm
- Water: max 3%
- Free acidity (as lauric acid) < 0.7%

6.6 ALLEGENES

Based on our actual knowledge of our production process, raw material and equipment used we do not expect allergens to be present. (listed in 2007/15/CEE and 76/768/CEE) .

6.7 PHTHALATES

Based on our actual knowledge of our production process, raw material and equipment used we do not expect phthalates to be present.

6.8 GLYCOL ETHER

Based on our actual knowledge of our production process, raw material and equipment used we do not expect glycol ether to be present.

7. SUBSTANCE LISTED

- **CMR (DIRECTIVE 67/548/EEC)**

Based on our actual knowledge of our production process, raw material and equipment used we do not expect CMR substances to be present.

8. CONFORMITY DIRECTIVE:

- 1907/2006/EEC, REACH
- Dir. 76/768/EEC
- Reg. 1223/2009/EEC

- California Proposition 65 (1-4 dioxane < 1 ppm())
- EC COSMETIC GUIDELINE / 7th MODIFICATION GUIDELINE:
  Sabo S.p.a has never made any animal test for the production of cosmetic raw materials.
- The product doesn't contain any nanomaterials according to the new European Cosmetic Regulation 1223/2009/EC and any nanotechnology is used to produce it
- The product is not from animal origin. Furthermore it doesn't contain any ingredient of animal origin, it is not produced using ingredients of animal origins and it doesn't come into contact with animal origin ingredients at any stage of its production. It is therefore BSE free.
- Raw material of vegetal origin is GMO-free

9. MICROBIOLOGICAL INFORMATION

SABO's products intended for cosmetic use - at the end of the manufacturing or formulation process - are subjected to microbiological analysis. Products are approved for sale only if the total bacterial count provide a value less than 100 UFC/gr (bacteria and moulds).

10. SAFETY AND ENVIRONMENT

- *(SEE SDS DOCUMENT)*
- Acute toxicity: oral, rat LD50 > 2000 mg/Kg(CIR: BRADNER,1974)
- Chronic toxicity: 0.5-2.0%; rat, no toxicological effect (CIR: KRANTZ,1970-1971; KRANTZ ET AL.,1948)
- Acute toxicity, dermal, guinea pig, patch, 24 h/7days, no effect (CIR : CTFA , 1979)
- Acute irritation: draize test, rabbit: no irritation or low irritation (CIR:CTFA,1979)
- Carcinogenesis: no effect (CIR : HARRIS ET AL. , 1951)
- Sensitization: skin, guinea pig, no effect or low effect (CIR : CTFA , 1978)