

Date of issue: 19.09.2022

Version: 1.0

MY HERO  
LIQUID HAND SOAP  
LAVANDER 500 ml



## SAFETY DATA SHEET

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

1.1. Product identifier: My Hero HAND SOAP

1.2. Relevant identified uses of the substance or mixture and uses advised against: Liquid Hand SOAP

1.3. Details of the supplier of the safety data sheet: HAPPY SH.P.K – 810079691

Magj. Prishtine-Ferizaj km 10te  
14000 Lipjan / Kosovo  
+38349406060

email: [info@happy.com.al](mailto:info@happy.com.al), [faik.hoti@almgroup-ks.com](mailto:faik.hoti@almgroup-ks.com)

1.3. Emergency telephone number: [+38349151518](tel:+38349151518)

### SECTION 2: HAZARD IDENTIFICATION

2.1. Classification of the substance or mixture: This product is defined as mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS] Not classified

2.2. Label elements:

Hazard pictograms:

No

Signal word:

No signal word

Hazard statements:

No known significant effects or critical hazards

2.3. Other hazards: None known

2.4. Classification criteria as PBT or vPvB: None known

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances: Does not apply to the product which is a mixture

3.2. Mixtures:

| Ingredient name  | INCI name/ Identification  | %     | Classification   |
|--|--|-------|--|
| Alcohols, C <sub>12</sub> -14, ethoxylated, sulfates, sodium salts | Sodium Laureth Sulfate/CAS 68891-38-3<br>EC 500-234-8<br>REACH 01-21194889639-16 | 1 - 7 | Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Chronic 3, H412 |

Happy

MY HERO  
LIQUID HAND SOAP  
LAVANDER 500 ml

|  |   |       |  |
|--|---|-------|--|
| Amides, C8-18 (even numbered) and C18-unsatd., N, N-bis(hydroxyethyl)  | Cocamide DEA/<br>CAS 68603-42-9<br>EC 271-657-0<br>REACH 01-2119490100-53           | 1 - 5 | Skin Irrit. 2,<br>H315 Eye Dam. 1,<br>H318 Aquatic Chronic 2, H411 |
| 1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(C12-18 (even numbered) acyl) derivs., hydroxides, inner salts | Cocamidopropyl Betaine/<br>CAS 61789-40-0<br>EC 931-513-6<br>REACH 01-2119513359-38 | < 1   | Eye Dam. 1, H318<br>Aquatic Chronic 3, H412                        |
| Fatty acids, C16-18 (even numbered), esters with ethylene glycol   | Glycol Distearate/CAS 91031-31-1<br>EC 292-932-1                                    | 0.5-1 | N/A  |

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs or vPvBs or have been assigned a workplace exposure limit and hence require reporting in this section.

See section 16 for the full text of the H statements declared above

**SECTION 4: FIRST AID MEASURES**

**4.1. Description of first aid measures:**

|                            |  |
|----------------------------|--|
| <b>General information</b> | As in all cases of potential poisoning obtain medical advice immediately   |
| <b>Eye contact</b>         | Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.  |
| <b>Skin contact</b>        | Adverse effects are not expected with the correct and recommended use.   |
| <b>Ingestion</b>           | Wash out mouth with water. Remove victim to fresh air. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur. |
| <b>Inhalation</b>          | Adverse effects are not expected with the correct and recommended use.   |

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

Happy

MY HERO  
LIQUID HAND SOAP  
LAVANDER 500 ml

**Potential acute health effects**

**Inhalation:** No known significant effects or critical hazards.  
**Ingestion:** May be irritating to mouth, throat and stomach.  
**Skin contact:** No known significant effects or critical hazards.  
**Eye contact:** No known significant effects or critical hazards

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

**Notes to physician:** Treat symptomatically.

**Specific treatment:** No specific treatment

**SECTION 5: FIREFIGHTING MEASURES**

**5.1. Extinguishing media:**

Product is not flammable but in case of surrounding fire:

**5.1.1. Suitable extinguishing media:**

Use an extinguishing agent suitable for the surrounding fire (water spray, water + additive or carbon dioxide) according to regulation on fire.

**5.1.2. Unsuitable extinguishing media:**

None known.

**5.2. Special hazards arising from the substance or mixture:**

No specific hazards.

**5.3. Advice for firefighters:**

Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

**6.1. Personal precautions, protective equipment and emergency procedures:**

Avoid contact with eyes and inhalation of vapors.

If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials.

**6.2. Environmental precautions:**

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution.

**6.3. Methods and material for containment and cleaning up:**

Absorb the material on a porous, inert material such as earth or sand and pumping water

Happy

MY HERO  
LIQUID HAND SOAP  
LAVANDER 500 ml

rinse after recovery of specific waste in plastic containers and disposed of in accordance with local regulations (see section 13).

**6.4. Reference to other sections:**

See Section 1 for emergency contact information.

See Section 8 for information on appropriate personal protective equipment.

See Section 13 for additional waste treatment information.

**SECTION 7: HANDLING AND STORAGE**

**7.1. Precautions for safe handling:**

Do not ingest. Avoid contact with eyes. Keep in the original packaging. Do not reuse packaging.

Do not handle near from high temperature source or any sources ignition. Do not eat, drink, smoke in the rooms where material is stored as well as where production is carried out.

Workers should wash their hands and face before eating, drinking and smoking.

**7.2. Conditions for safe storage, including any incompatibilities:**

Store away from children. Store between the following temperatures: 5 to 40°C. Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers.

**7.3. Specific end use(s):**

No specific data

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

**8.1. Control parameters:**

| Product/Ingredient name  | Type | Exposure             | Value                  | Population | Effects  |
|--|------|----------------------|------------------------|------------|----------|
| Alcohols, C <sub>12-14</sub> , ethoxylated, sulfates, sodium salts | DNEL | Long term dermal     | 2750 mg/kg bw/day      | Workers    | Systemic |
|  | DNEL | Long term inhalation | 175 mg/m <sup>3</sup>  | Workers    | Systemic |
|  | DNEL | Long term dermal     | 1650 mg/kg bw/day      | Consumers  | Systemic |
|  | DNEL | Long term inhalation | 52 mg/m <sup>3</sup>   | Consumers  | Systemic |
|  | DNEL | Long term oral       | 15 mg/kg bw/day        | Consumers  | Systemic |
| Amides, C <sub>8-18</sub> (even numbered) and C <sub>18-</sub>     | DNEL | Long term dermal     | 4,16 mg/kg bw/day      | Workers    | Systemic |
|  | DNEL | Long term inhalation | 73,4 mg/m <sup>3</sup> | Workers    | Systemic |

Happy

MY HERO  
LIQUID HAND SOAP  
LAVANDER 500 ml

|  |                                      |  |   |   |  |
|--|--------------------------------------|--|---|---|--|
| unsatd., N, N-bis(hydroxyethyl)  | DNEL<br>DNEL<br>DNEL<br>DNEL<br>DNEL | Long term dermal<br>Long term dermal<br>Long term inhalation<br>Long term oral<br>Long term dermal | 0,09mg/cm <sup>2</sup><br>2,5 mg/kg bw/day<br>21,73 kg/m <sup>3</sup><br>6,25 mg/kg bw/day<br>0,056 mg/m <sup>3</sup> | Workers<br>Consumers<br>Consumers<br>Consumers<br>Consumers | Local<br>Systemic<br>Systemic<br>Systemic<br>Local |
| 1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(C <sub>12-18</sub> (even numbered) acyl) derivs., hydroxides, inner salts | DNEL<br>DNEL<br>DNEL<br>DNEL         | Long term dermal<br>Long term inhalation<br>Long term oral<br>Long term dermal                     | 12,5 mg/kg bw/day<br>44 mg/m <sup>3</sup><br>7,5 mg/kg bw/day<br>7,5 mg/kg bw/day                                     | Workers<br>Workers<br>Consumers<br>Consumers                | Systemic<br>Systemic<br>Systemic<br>Systemic       |

PNEC

| Product / ingredient name  | Compartment detail  | Value   | Method detail   |
|--|---|---|---|
| Alcohols, C <sub>12-14</sub> , ethoxylated, sulfates, sodium salts                     | Fresh water<br>Marine water<br>Sewage Treatment Plant<br>Fresh marine sediment<br>Marine water sediment<br>Soil | 0,24 mg/l<br>0,024 mg/l<br>10000 mg/l<br>5,45 mg/kg dwt<br>0,545 mg/kg dwt<br>0,946 mg/kg dwt | Assesment Factors<br>Assesment Factors<br>Assesment Factors<br>Equilibrium Partitioning<br>Equilibrium Partitioning<br>Equilibrium Partitioning |
| Amides, C <sub>8-18</sub> (even numbered) and C <sub>18</sub> -unsatd.,                | Fresh water<br>Marine   | 2,4 µg/l<br>0,24 µg/l   | Assesment Factors<br>Assesment Factors  |
| N, N-bis(hydroxyethyl)   | Sewage treatment plant<br>Fresh water sediment<br>Soil  | 830 µg/l<br>14,5 µg/kg dwt<br>6,48 µg/kg dwt  | Assesment Factors<br>Assesment Factors<br>Assesment Factors   |
| 1-Propanaminium, 3-amino-  | Fresh water   | 0,0135 mg/l   | Assessment factors  |
| N-(carboxymethyl)-N, N-dimethyl-, N-(C <sub>12-18</sub> (even numbered) acyl) derivs., | Marine  | 0,00135 mg/l  | Assessment factors  |
| hydroxides, inner salts  | Fresh water sediment  | 1 mg/kg   | Equilibrium partitioning  |
|  | Marine water sediment   | 0,1 mg/kg   | Assessment factors  |
|  | Soil  | 0,8 mg/kg   | Equilibrium partitioning  |
|  | Sewage treatment plant  | 3000 mg/l   | Assessment factors  |

8.2. Exposure controls:

|                                  |            |
|----------------------------------|------------|
| Appropriate engineering controls | None known |
|----------------------------------|------------|



MY HERO  
LIQUID HAND SOAP  
LAVANDER 500 ml

|  |   |
|--|---|
| <b>Hygiene measures</b>                                    | None known  |
| a) Eye/face protection                                     | Avoid direct contact with eyes. In case of contact with the eyes, rinse immediately and thoroughly with water and consult a doctor. |
| b) Skin protection<br>-hand protection<br>-body protection | It is not necessary during appropriate use of the product.  |
| v) Respiratory protection                                  | None known  |
| Environmental exposure controls                            | In accordance with local/national regulations   |

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**9.1. Information on basic physical and chemical properties:**

|  |                         |
|--|-------------------------|
| <b>Appearance/physical state:</b>                    | Viscous Liquid          |
| <b>Colour:</b>                                       | Purple                  |
| <b>Odour:</b>  | Lavander                |
| <b>Odor threshold:</b>                               | Not available           |
| <b>pH value:</b>                                     | 5 ± 1.5                 |
| <b>Melting point:</b>                                | Not available           |
| <b>Initial boiling point and boiling range:</b>      | Not available           |
| <b>Flash point:</b>                                  | Not available           |
| <b>Evaporation rate:</b>                             | Not available           |
| <b>Flammability (solid, gas):</b>                    | Not available           |
| <b>Upper/lower flammability or explosive limits:</b> | Not available           |
| <b>Vapor density:</b>                                | Not available           |
| <b>Density:</b>                                      | 1.025 g/cm <sup>3</sup> |
| <b>Solubility:</b>                                   | Soluble in water        |
| <b>Partition coefficient: n-octanol/water:</b>       | Not available           |
| <b>Decomposition temperature:</b>                    | Not available           |
| <b>Drooping point:</b>                               | Not available           |
| <b>Viscosity (Dynamic):</b>                          | Not available           |
| <b>Explosive properties:</b>                         | Not available           |
| <b>Oxidizing properties:</b>                         | Not available           |

**9.2. Other information:**

No additional information

**SECTION 10: STABILITY AND REACTIVITY**

**10.1. Reactivity:**

No specific test data related to reactivity available for this product or its ingredients.



MY HERO  
LIQUID HAND SOAP  
LAVANDER 500 ml

**10.2. Chemical stability:**

The product is stable under normal conditions of storage and use

**10.3. Possibility of hazardous reactions:**

Under normal conditions of storage and use, hazardous reactions will not occur

**10.4. Conditions to avoid:**

No specific data

**10.5. Incompatible materials:**

No specific data

**10.6. Hazardous decomposition products:**

Under normal conditions of storage and use, hazardous decomposition products should not be produced

## SECTION 11: TOXICOLOGICAL INFORMATION

**11.1. Information on toxicological effects**

No known toxicological effects related to the mixture. Data of a toxicological effects of its ingredients:

Acute toxicity

| Product/ingredient name  | Result                                   | Species  | Dose                                      |   |
|--|--|--|---|---|
| Alcohols, C12-14, ethoxylated, sulfates, sodium salts  | LD50 Oral<br>LD50<br>Dermal LD50<br>Oral | Rat<br>Rat<br>Rat                              | >2000 mg/kg<br>>2000 mg/kg<br>>2000 mg/kg | - |
| Amides, C8-18 (even numbered) and C18-unsatd., N, N-bis(hydroxyethyl)  | LD 50 Dermal<br>LD 50 Oral               | Rabbit<br>Rat                                  | >2 g/kg<br>> 2000 mg/kg                   |   |
| 1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(C12-18 (even numbered) acyl) derivs., hydroxides, inner salts | LD50<br>Dermal LD50<br>Oral              | Rat - male,<br>female<br>Rat - male,<br>female | >2000 mg/kg<br>2430 mg/kg                 |   |

Irritation / Corrosion:

Skin: Non-irritating to the skin

Eyes: Non-irritating to the eyes

Respiratory: Not available

Sensitier:

Happy

MY HERO  
LIQUID HAND SOAP  
LAVANDER 500 ml

**Skin:** Not available

**Respiratory:** Not available

**Mutagenicity:** Not available

**Carcinogenicity:** Not available

**Reproductive toxicity:** Not available

**Teratogenicity:** Not available

**Specific target organ toxicity (single exposure):** Not available

**Specific target organ toxicity (repeated exposure):** Not available

**Potential acute health effects**

**Inhalation :** No known significant effects or critical hazards.

**Ingestion :** May cause irritation to mouth, throat and stomach.

**Skin contact :** No known significant effects or critical hazards.

**Eye contact :** May cause slightly eye irritation.

**Symptoms related to the physical, chemical and toxicological characteristics**

**Skin contact:** No specific data

**Ingestion:** No specific data

**Inhalation:** No specific data

**Eye contact:** No specific data

**Potential chronic health effects:**

| Product/ingredient name  | Result  | Species                                | Dose                   |
|--|---|--|------------------------|
| Amides, C8-18 (even numbered) and C18-unsatd., N, N-bis(hydroxyethyl)  | Sub-acute NOAEL Oral<br>Sub-chronic NOEL Oral | Rat- male, female<br>Rat- male, female | >750 mg/kg<br>50 mg/kg |
| 1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(C12-18 (even numbered) acyl) derivs., hydroxides, inner salts | Sub.chronic NOEL Oral                         | Rat-male,female                        | 300 mg/kg              |

**SECTION 12: ECOLOGICAL INFORMATION**

**12.1. Toxicity:**



MY HERO  
LIQUID HAND SOAP  
LAVANDER 500 ml

| Product/ Ingredient name  | Result  | Species  | Exposure   | Test   |
|---|---|--|--|--|
| Alcohols, C <sub>12</sub> -14, ethoxylated, sulfates, sodium salts  | Acute EC <sub>50</sub> - 27,7 mg/l<br>Acute EC <sub>50</sub> - 7,4 mg/l<br>Acute LC <sub>50</sub> - 7,1 mg/l<br>Chronic NOEC 0,95 mg/l  | Algae<br>Daphnia<br>Fish<br>Algae                    | 72h<br>48h<br>96h<br>72h                         | OECD 201 Alga, growth inhibition test<br>OECD 202 Daphnia sp. Acute immobilization test and reproduction test<br>OECD 203 fish, Acute toxicity test<br>OECD 201 Alga, growth inhibition test   |
| Amides, C <sub>8</sub> -18 (even numbered) and C <sub>18</sub> -unsatd., N, N-bis(hydroxyethyl)   | Acute EC <sub>50</sub> - 18,6 mg/l; fresh water<br>Acute EC <sub>50</sub> - 3,2 mg/l; fresh water<br>Acute LC <sub>50</sub> - 2,4 mg/l<br>Chronic NOEC 2 mg/l<br>Chronic NOEC 0,07 mg/l/fresh water<br>Chronic NOEC 0,32 mg/l | Alge<br>Dafnia<br>Riba<br>Algae<br>Daphnia<br>Fish   | 72 h<br>48h<br>96h<br>72 h<br>21 days<br>28 days | EU M.C <sub>3</sub><br>OECD 202 Daphnia sp. Acute immobilization test and reproduction test<br>OECD 203 fish, acute toxicity test<br>EU method c.3 (alga inhibition test)<br>OECD 211 Daphnia Magna Reproduction Test<br>OECD 204 Fish, Prolonged toxicity test: 14 test study and 215 Fish, Juvenile Grow |
| 1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-(C <sub>12</sub> -18 (even numbered) acyl) derivs., hydroxides, inner salts | Acute EC <sub>50</sub> 2,4 mg/l<br>Acute EC <sub>50</sub> 1,9 mg/l<br>Acute LC <sub>50</sub> 1,11 mg/l<br>Chronic NOEC 0,6 mg/l<br>Chronic NOEC 0,3 mg/l<br>Chronic NOEC 0,135 mg/l   | Algae<br>Daphnia<br>Fish<br>Algae<br>Daphnia<br>Fish | 72h<br>48h<br>96h<br>72h<br>21h<br>100 days      | OECD 202 Daphnia sp. Acute immobilization test and reproduction test<br>OECD 203 fish, acute toxicity test<br>OECD 211 Daphnia Magna Reproduction Test<br>OECD 210 Fish, early-life stage toxicity Test  |

12.2. Persistence and degradability: Not available

12.3. Bioaccumulative potential: Not available

12.4. Mobility in soil: Not available

12.5. Results of PBT and vPvB assessment: Not available

12.6. Other adverse effects: Not available



MY HERO  
LIQUID HAND SOAP  
LAVANDER 500 ml

### SECTION 13: DISPOSAL CONSIDERATIONS

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

#### Product

**Methods of disposal:** The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Dispose of surplus and non-recycle products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

**Hazardous waste:** None known.

#### Packaging

**Methods of disposal:** The generation of waste packaging should be avoided or minimized wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

### SECTION 14: TRANSPORT INFORMATION

|   | ADR/RID       | ADN           | IMGD          | IATA          |
|---|---------------|---------------|---------------|---------------|
| <b>14.1. UN number</b>                    | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.2. UN proper shippingname</b>       | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.3. Transport hazard class(es)</b>   | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.4. Packing group</b>                | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.5. Environmental Hazards</b>        | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.6. Special precautions for user</b> | Not regulated | Not regulated | Not regulated | Not regulated |

### SECTION 15: REGULATORY INFORMATION

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

Refer to the following standards when applicable:



MY HERO  
LIQUID HAND SOAP  
LAVANDER 500 ml

EU Regulation (EC) No. 1907/2006 (REACH)

Substances of very high concern: None of the components are listed Regulation (EC) n° 1272/2008 (CLP) and its successives amendments Directive 2000/39/EC (Occupational exposure limits) Directive 98/24/EC (Safety of workers) Regulation (EC) n° 648/2004 (Detergents)

**15.2. Chemical safety assesment**

No chemical safety assessment has been carried out on the mixture itself.

**SECTION 16: OTHER INFORMATION**

**Abbreviations and acronyms:**

ADN – European Agreement concerning the International Carriage of Dangerous Goods by inland Waterways

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road  
CAS - Chemical Abstract Service

EINECS - EU Inventory of Existing Commercial Chemical Substances

LC50 - Lethal Concentration

LD50 - Lethal Dose

IATA - International Air Transport

Association IMDG - International Maritime

Dangerous Goods NOAEL - No Observed

Adverse Effect Level

**PBT- Persistent, bioaccumulative, toxic**

REACH - Regulation of the EU, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals

RID - International Rule for Transport of Dangerous Substances by Railway

STEL - Short term exposure limit

TWA - Time weighted average

vPvB - Very persistent, very bioaccumulative

**Key literature references and sources for data**

Suppliers data : MSDS of ingredients and TDS of ingredients

CLP

ECHA

Guidance on the compilation of safety data sheets of ECHA

REACH

**Full text of classifications (CLP/GHS) from the chapter 3**

Eye Dam. 1; H318  
Skin Irrit. 2; H315

SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 1  
SKIN CORROSION/IRRITATION – Category 2



MY HERO  
LIQUID HAND SOAP  
LAVANDER 500 ml

Aquatic Chronic 2, H411  
Aquatic Chronic 3, H412

AQUATIC HAZARD (LONG-TERM) – Category 2  
AQUATIC HAZARD (LONG-TERM) – Category 3

Full text of abbreviated H statements from the chapter 3

H318 Causes serious eye damage  
H315 Causes skin irritation  
H411 Toxic to aquatic life with long lasting effects  
H412 Harmful to aquatic life with long lasting effects.

Notice to reader: We believe that the information contained herein is current as of the date of this safety datasheet. Since the use of this information and the conditions of use of the products are not within the control of APA, it is the user's obligation to determine conditions of safe use of the product.

