# WATER BASED LUBRICANT QUESTIONNAIRE

1. **QUALITY ASSURANCE CORRESPONDENT INFORMATION**

*If Same as Manufacturer (specify below)*

|  |  |  |  |
| --- | --- | --- | --- |
| Contact Name and Title: | | Company ID (if known): | |
| Company Name: | | | |
| Telephone: | Fax: | E-mail: | |
| Street: | | Suite: | P.O. Box: |
| City: | Province/State: | Country: | Postal/Zip Code: |

1. **MANUFACTURER INFORMATION (as it appears on the label)**

|  |  |  |  |
| --- | --- | --- | --- |
| Contact Name and Title: | | Company ID (if known): | |
| Company Name: | | | |
| Telephone: | Fax: | E-mail: | |
| Street: | | Suite: | P.O. Box: |
| City: | Province/State: | Country: | Postal Code: |

**3. CONTRACT MANUFACTURER INFORMATION (as it appears on the label)**

|  |  |  |  |
| --- | --- | --- | --- |
| Contact Name and Title: | | Company ID (if known): | |
| Company Name: | | | |
| Telephone: | Fax: | E-mail: | |
| Street: | | Suite: | P.O. Box: |
| City: | Province/State: | Country: | Postal Code: |

**4. PRODUCT REGULATORY APPROVAL – Attach copies of all certificates**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Regulatory Agency/Body** | **Certification** | **Date if Issue** | **Expiry** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**5. MANUFACTURER REGULATORY APPROVAL – Attach copies of all certificates**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Regulatory Agency/Body** | **Certification** | **Date if Issue** | **Expiry** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**6. QUALITY MANAGEMENT SYSTEM CERTIFICATE – Attach a copy of certificate**

|  |
| --- |
| Quality Management System Certificate Number: Name of Registrar: |

**7. COMPOSITION**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Non-proprietary Name | Specification | Purpose | Amount per sachet | Concentration %w/w | Amount per commerical batch (kg or Litres etc.) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**8. LABELLING – Attach a copy of sample packaging**

**9. MANUFACTURING PROCESS**

*A description of the manufacturing process, if sterile, include a detailed description of the sterilization method (a flow chart is acceptable). Please show stages of quality control testing*

**9a. ANNUAL PRODUCTION CAPACITY and Standard Batch sizes and data to support site has installed capacity to match the quantity**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Production Capacity | | |
| Commercial Batch sizes | 2013 | 2014 | 2016 |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**10. SPECIFICATION OF THE LUBRICANT** – **Attach copies of Certificate of Analysis of three batches**

|  |  |  |
| --- | --- | --- |
| Parameter | Acceptance Criteria | Method Number |
| Colour |  |  |
| Flavouring |  |  |
| Fragrance |  |  |
| Osmolality (mOsm/kg) |  |  |
| pH\* |  |  |
| Fill volume |  |  |
| Viscosity |  |  |
|  |  |  |
|  |  |  |

\*state the temperature

**11. DESCRIPTION OF METHOD FOR ESTIMATING OSMOLALITY**

**12. VISCOSITY**

|  |  |
| --- | --- |
| Type of equipment used to measure viscosity |  |
| Temperature |  |
| Spindle type used for the viscosity measurement |  |
| Rotation speed/shear rate used for the viscosity measurement |  |

**13. SHELF-LIFE AND STORAGE CONDITIONS**

**14. STABILITY STUDIES**

Summary of three batches

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Batch Number | Name and address of manufacturer | Date of Manufacture | Date of commencement of stability studies | Date of completion of study | Parameters Monitored |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Accelerated stability studies

Temperature:

Humidity:

Long-term stability studies

Temperature:

Humidity:

**Checklist of documentation required**

☐ A. Copy of manufacturing license

☐ B. Copy of label (in English/French/Spanish)

☐ C. Copy of ISO 9001: 2008 Certificate

☐ D. Copy of ISO 13485:2016 Certificate

☐ E. Copy of ISO 19671:2018 Certificate

☐ E. Copy of ISO 14001:2004 Certificate

☐ F. Declaration of conformity (specifying the relevant standard and attaching copy of certificate)

☐ G. CE certificate

☐ H. 510k Premarket approval device letter/ Device license (Australia, Japan, Canada)

☐ I. Complete and detailed technical specifications of the product

☐ J. Certificates of analysis of three batches- recently manufactured

☐ K. Instruction for use in English, Spanish and French