

Agreement on Quality Assurance Concerning Deliveries to Weckerle Cosmetics and Affiliated Companies

Weckerle Cosmetics-AQA

Date	Revision index	Description of revision	Name
29.06.2009	01		Dr. S. Barth

Table of Contents

1. General	3
2. Scope of application	3
3. Demands on the Quality Management System of the supplier	3
4. Audits and inspection rights	3
5. Supplier assessment	4
6. Specifications –special releases	4
7. Documents / documentation on quality	4
8. Planning / quality planning	5
9. Labelling and traceability	5
10. Corrective action and warranty agreement.....	5
11. Viewing of samples, initial samples and batch delivery	6
12. Industrial property rights of the supplier	7
13. Material handling / storage / packing / dispatch	7
14. Delivery commitment	8
15. Material – monitoring	8
16. REACH.....	8
17. Testing facilities / inspection equipment monitoring.....	9
18. Third-party liability.....	10
19. Suppliers' safety advice	10
20. Term / application	10
21. Applicable law / place of jurisdiction	10
22. .Miscellaneous.....	10

1. General

The company Weckerle Cosmetics expects its suppliers to deliver optimal quality with the investment of economically justifiable time and effort. The term optimal quality in this case does not mean the highest possible quality of a product but rather the fulfilment of all specified requirements and on the basis of the zero-error philosophy. In order to achieve this objective, Weckerle Cosmetics has set up an effective Quality Management System. The contractual partners agree in this system that high, optimised quality and reliability can only be attained if the business relationship is based on cooperation as equal partners in the manufacture of products, the inspections accompanying the process as well as the testing equipment to be used. Weckerle Cosmetics undertakes to inform its suppliers about all known and specified requirements regarding the product. The supplier shall examine this information with due diligence. Notification of any discrepancies, particularly objections or deviations from the “Principles of Good Manufacturing Practice” in accordance with § 5 c KosmetikVO (German Cosmetics Ordinance) is to be given. Should discrepancies arise, the supplier is responsible for bringing about clarification with Weckerle Cosmetics. Such clarification is to take place prior to materials or raw materials being produced and/or delivered.

2. Scope of application

This agreement on quality assurance concerning deliveries to Weckerle Cosmetics (hereinafter referred to as “Weckerle Cosmetics-AQA”) is binding for all suppliers of primary and secondary packaging, raw materials, job-order production and additionally purchased finished products. The Weckerle Cosmetics-AQA applies to Weckerle Cosmetics and all affiliated companies (such as Weckerle Cosmetics Eislungen GmbH, Premium Cosmetics GmbH, Weckerle GmbH: Location Peissenberg, Weckerle GmbH: Location Weilheim). The Weckerle Cosmetics-AQA constitutes an integral part of the contractual relationship and forms the legal framework of the business relationship with Weckerle Cosmetics together with orders, the supplier’s contract, the terms of purchase and ordering of Weckerle Cosmetics and any additional agreements that may be concluded with the supplier, whereby the status of the individual integral parts of the contractual relationship is specified in the supplier’s contract.

The version of Weckerle Cosmetics-AQA, as amended in each case, shall be applicable. This version can be obtained from the member of staff responsible in the department “Strategic Procurement” at Weckerle Cosmetics.

3. Demands on the Quality Management System of the supplier

The supplier undertakes to set up and maintain a quality management system which comprehensively regulates the processes relevant with regard to the assurance of quality. The quality management system must, at a minimum, meet the requirements set forth in DIN EN ISO 9001 in the current valid version. Weckerle Cosmetics (department “Strategic Procurement” and the contact person responsible for issues of quality) must be notified of changes in the quality management system of the supplier within 48 hours after the change is made.

4. Audits and inspection rights

The supplier shall allow Weckerle Cosmetics and – if desired by Weckerle Cosmetics – also Weckerle Cosmetics customers to carry out process, procedural or system audits. The costs of the audits (e.g. including auditors’ travel expenses) shall be borne by the supplier insofar as they do not exceed a reasonable amount. The content and scope of the audit shall be stipulated by Weckerle Cosmetics. The audits will be conducted after prior consultation with regard to time. The supplier undertakes to allow an audit to be carried out within 48 hours after the occurrence of a problem concerning quality. Within the framework of the audit, Weckerle Cosmetics is entitled to obtain unrestricted information about the goods

to be manufactured for Weckerle Cosmetics as well as with regard to the operating resources of the supplier required for production.

The findings from the audit conducted at the supplier's company, particularly the assessment of the supplier, is based on Weckerle Cosmetics's own supplier assessment, which is prepared at the sole discretion of Weckerle Cosmetics.

Weckerle Cosmetics and the supplier undertake to treat all information in confidence which becomes known to them as part of the audit. The supplier is entitled to conclude relevant agreements on the maintenance of secrecy with customers of Weckerle Cosmetics with regard to information concerning the audit.

Weckerle Cosmetics is entitled to conduct its own checks or to arrange for checks to be carried out by authorised officers at the manufacturing facilities of the supplier – insofar as products intended for Weckerle Cosmetics are manufactured or stored there – as to whether the obligations arising from the Weckerle Cosmetics-AQA are being met; such inspections will take place during normal business hours and prior notice shall not be required. The supplier reserves the right for itself and for Weckerle Cosmetics to carry out inspections of the facilities of any sub-suppliers accordingly.

5. Supplier assessment

Weckerle Cosmetics reserves the right to assess its suppliers by classifying them into categories “A”, “B” or “C”. The assessment criteria are at the sole discretion of Weckerle Cosmetics and the supplier is not entitled to review them. Consequently, the supplier does not have any right to obtain information regarding the methods of such classification. Weckerle Cosmetics will primarily base its assessment of the supplier on the parameters “product quality”, “process quality” and “delivery performance”. Weckerle Cosmetics will inform the supplier on an annual basis of the outcome of the classification into one of the aforementioned categories.

6. Specifications – special releases

The supplier is responsible for ensuring that the products supplied entirely comply with the specifications of Weckerle Cosmetics (particularly material specifications, raw material specifications, technical drawings, specifications sheet etc.). These specifications constitute an integral part of the order placed by Weckerle Cosmetics in each case. Amendments shall require prior written confirmation by Weckerle Cosmetics. Consignments which deviate from the specifications of Weckerle Cosmetics shall not be admissible.

The supplier undertakes to notify Weckerle Cosmetics within 24 hours of all circumstances arising which may have an impact on the quality of the ordered products. Any changes in the product quality shall, as a matter of principle, be processed according to clause 11. Should the changes concerned be of a temporary nature, e.g. from the faulty manufacture of one batch, a written special release shall be required from Weckerle Cosmetics (responsible: contact for quality issues). The dispatch of such batches to Weckerle Cosmetics is subject to Weckerle Cosmetics having granted a special release. The batches affected must be labelled “special release” upon their delivery. The supplier shall notify Weckerle Cosmetics (responsible: purchasing staff and contact for quality issues) within 24 hours of the occurrence of problems that have already arisen or of imminent problems which could impair the quality or reliability of the delivered products or which could jeopardise future deliveries.

7. Documents / documentation on quality

The supplier shall set up and maintain at least one quality management system in accordance with DIN EN ISO 9001 in the current valid version for the identification, amendment, collection, archiving and distribution of quality records. The system must ensure that sufficient documentation is prepared for each delivery to Weckerle Cosmetics. This includes documentation at the companies of sub-suppliers. In the

case of facts subject to documentation, the supplier is obliged to fully document quality assurance measures taken by himself or his sub-supplier and the results thereof and to retain these records for a period of at least 10 years after their preparation.

8. Planning / quality planning

The supplier shall ensure that the requirements of § 5 b KosmetikVO concerning the holding of and access to documents (especially vis-à-vis surveillance authorities) are fully met.

In addition, the supplier shall, in accordance with the scope provided for by § 5 b KosmetikVO, grant Weckerle Cosmetics the right of inspection of and access to the documents stated in § 5 b KosmetikVO for a period of 10 years (commencing from the time of manufacture).

Furthermore, the supplier shall ensure that the documents which are material to the quality of packaging materials are made available at each place of work. This includes, for instance, drawings, specifications, manufacturing and testing instructions. These documents are to be examined with regard to their correctness and compliance with the specifications of Weckerle Cosmetics and are to be subsequently released.

The supplier shall ensure his product quality in the product development stage and in the case of modifications by verifiably applying effective QM methods.

Moreover, the supplier must list all steps in production and testing in internal working papers which are to be prepared by him (QM plan – product quality forward planning). Features subject to monitoring are to be specified and the nature of the monitoring is to be indicated. The supplier shall maintain verifiable documentation on process control and process capability for all important features (reference dimensions, chemical characteristics) by recording the performance data and processing them statistically. These features are to be checked statistically and documented in the manufacturing process by the supplier.

In the case of critical materials, Weckerle Cosmetics reserves the right to subject the supplier to additional product-specific specifications concerning quality assurance.

The mutual determination of separate AQL values (Accepted Quality Level) shall remain unaffected.

9. Labelling and traceability

The systematic labelling of products, materials and raw materials guarantees the identification of the inspection status and the identification of the delivered products, materials and raw materials. The traceability of products, materials and raw materials (insofar as they are procured by sub-suppliers) is to be guaranteed by means of this labelling and the accompanying documentation.

10. Corrective action and warranty agreement

Should deviations from the specifications be detected by Weckerle Cosmetics regarding the delivered products, materials or raw materials of the supplier, the latter will be notified of such defects (inspection report with non-release or objection). If the supplier is responsible for the deviation, Weckerle Cosmetics will charge the supplier a flat-rate sum of 100.00 EUR per delivered item for the preparation of the inspection report for the assertion of possible claims due to defects. The supplier is obliged to initiate corrective action without delay and to maintain the supply of materials/raw materials. In the event of the order being urgently required, the supplier shall, without delay, provide appropriate number of staff to sort the consignment, to rework the goods or to put together a defect-free replacement consignment.

Should it be necessary to return the consignment, the supplier is obliged to collect the goods within two working days at his own expense. A debit note will automatically be issued, which will be set off accordingly upon delivery of a new consignment. The initiated corrective action is to be communicated to the person in charge of preparing the inspection report within the stated time limit by means of an 8-D report. This corrective action is to be examined to determine its sustained effectiveness in the case of future production.

Should additional costs be incurred due to the delivery of defective products/materials/raw materials for which the supplier is responsible, also such costs shall be fully reimbursed by the supplier. Except as otherwise agreed upon in writing with Weckerle Cosmetics, this also applies, in particular, to additional creations of value regarding the products/materials/raw materials.

For the purpose of limiting damage, Weckerle Cosmetics reserves the right – in the event of a defect whose cause is not a matter of contention between the supplier and Weckerle Cosmetics – to arrange for the faulty products/materials/raw materials to be disposed of directly on the premises of the end customer without a separate analysis by the supplier.

Any rights of Weckerle Cosmetics regarding defects in accordance with the law and/or on the basis of any other agreements (particularly supplier's contract and terms of procurement and order) shall remain unaffected.

11. Sampling, initial samples and batch delivery

In the case of sampling, the cosmetic products manufactured by the supplier under laboratory conditions are to be submitted to Weckerle Cosmetics (distribution department) or to a third party designated by Weckerle Cosmetics (e.g. Premium Cosmetics GmbH) for examination. Should Weckerle Cosmetics or the third party decide on a sample presented by the supplier, the latter shall, without delay, provide Weckerle Cosmetics or the third party with the quantitative recipe, the specification, possible advertising statements, warning notices and instructions for use (e.g. information on best-before date) as well as documentation for this product in accordance with clause 8 of this agreement. Furthermore, the supplier shall ensure that the initial samples and the serially manufactured products have the same characteristics of the sampled products in all respects (particularly regarding quality).

Initial samples are products, materials and raw materials manufactured completely with serial operating resources and under serial conditions. Initial samples are to be submitted to Weckerle Cosmetics (VTB department or R&D and QAS) together with full initial sample test report. The initial sample test report is to be presented together with the accompanying labelled samples (quantity in accordance with the order for samples or after consultation with the testing office for initial samples of the aforementioned departments). Parts made using multi-purpose tools must be tested, labelled and recorded separately for each mould cavity. The life cycle of the part is to be enclosed with the test report for the initial samples. All modifications of a part, the date of presentation of the sample and the first serial delivery are to be fully and clearly documented in the life cycle of the parts.

The initial sample test report must include:

- A measurement report with a target/actual comparison for all quality features. Certificates of process capability are to be retained for significant features (reference dimension in the drawing) and they are to be enclosed with the initial sample test report as a machinability inspection.
- The working materials are to be tested according to the specifications of the drawings with a target/actual comparison. Should the drawing not contain any specifications, at least three working material identity inspections will be required. The following material test certificates must be enclosed :
- For raw materials: Safety data sheet in accordance with Reach regulation (EC) No. 1907/2006 with the statement of the identified use (e.g. use in cosmetics)

- Specification of the packaging material used, as well as bio-compatibility verification, where applicable,
- Analysis certificate and specification in the case of raw materials
- Batch of the delivered product
- Where a function test has been performed, a target/actual comparison according to drawing requirements and to specification.

An initial viewing of samples is always necessary:

- in the case of new or modified products/processes
- prior to the start of the serial manufacture of products made from new materials or with new tools
- prior to the start of the serial manufacture of products of new sub-suppliers
- in the case of outsourced tools or outsourced production
- if production has been interrupted for one year or longer

In the case of modifications of whatever nature (e.g. product, process, tool, material), the modified features are to be re-sampled. Reference is to be made in this case to the previous initial sample test report.

Serial delivery may not be effected until a release for the initial samples has been issued in writing. Should this not be possible for reasons relating to deadlines, the supplier must obtain a special release from Weckerle Cosmetics (responsible: contact for engineering issues).

The supplier shall retain all initial samples for a period of time corresponding to the intended best-before date of the product/material/raw material initially sampled but for not less than three years calculated from the respective date of inspection of the initial samples. The samples must be kept in a due and proper manner. During this period of time the supplier will grant Weckerle Cosmetics access to the initial samples at all times.

12. Industrial property rights of the supplier

The supplier shall inform Weckerle Cosmetics about planned measures with which the products/materials/raw materials are to be protected by industrial property rights. Should such property rights arise, the supplier shall assign them without delay in their entirety to Weckerle Cosmetics against reimbursement of any registration costs but otherwise without any charge.

13. Material handling / storage / packing / dispatch

The supplier shall set up and maintain a system for the correct identification of his products as well as for their storage (FIFO principle), packing and dispatch. The system must ensure the prevention of mix-ups, damage or impairment of parts. For the first three serial deliveries following a modification, the packaging units and the delivery note are to be marked "modified" and with the current modification status (E index). Weckerle Cosmetics will determine on a case to case basis whether further deliveries are to be labelled. Deliveries of samples are to be marked clearly as such and the recipient of the consignment of samples must be indicated (name and department).

14. Delivery commitment

The supplier shall fully meet delivery commitments in terms of quality and adherence to delivery dates. He shall ensure that the serial products are manufactured; tested and documented on the basis of the specifications and that they comply with the specifications of Weckerle Cosmetics. Adherence to delivery

dates and freight costs for unscheduled tours are to be monitored and assessed. Weckerle Cosmetics is to be notified immediately in the event of non-fulfilment.

Costs for unscheduled tours for which the supplier is responsible are to be borne by the same. At the same time, suggestions for improvement shall be submitted to Weckerle Cosmetics as to how additional tours can be avoided and the observance of delivery dates can be improved in the future.

15. Material - monitoring

The supplier shall ensure that only tools and processes are used which are permitted according to the specifications. All statutory safety requirements for materials with restricted approval and for materials which are toxic, hazardous and prohibited must be complied with. Furthermore, the applicable conditions in the country of production and the country of the customer concerning the environment, electricity and electro-magnetic fields are to be met. The inspection certificate (DIN EN 10204 3.1B) and the safety data sheet in accordance with Reach regulation (EC) No. 1907/2006 are to be retained at the premises of the supplier for serial deliveries and are to be made available to Weckerle Cosmetics upon request. The supplier is obliged to collect and keep reference samples of the batches of products delivered. Weckerle Cosmetics shall determine the period of time for which they are to be retained.

16. REACH

Upon request the supplier undertakes to immediately provide free of charge all information, documents and documentation required by Weckerle Cosmetics to fulfil the duties and obligations of REACH Regulation (EC) No. 1907/2006. Further, at the request of Weckerle Cosmetics, within one week the supplier will provide meaningful information showing that the substances used in his product are safe for use by Weckerle Cosmetics, in particular for use in cosmetic products.

Substances of very high concern in articles (SVHC) - obligations according to Article 33 of REACH Regulation (EC) No. 1907/2006:

In accordance with Article 33 of REACH Regulation (EC) No. 1907/2006 it must be ensured that sufficient information about substances of high concern in articles is available throughout the supply chain to ensure their safe use.

Manufacturers and suppliers of articles containing substances of very high concern from the Candidate List (see the website of the European Chemicals Agency (ECHA), <http://echa.europa.eu>) in concentrations above 0.1% by weight must provide the available information directly and without request. The supplier of an article must also inform Weckerle Cosmetics if an article contains no substances from the Candidate List ("negative Information"). In accordance with the obligation to Article 33 (1) this information on the SVHC must be made available without request together with the CAS number, the EINECS number, the name of the substance and the SVHC content. This obligation is independent of the tonnage. The obligation to provide available information about SVHC on the Candidate List (implemented later in Annex XIV of Regulation (EC) 1907/2006) relates to the packaging materials for cosmetic products (= article). To this end, for every article delivery the supplier of the articles must provide Weckerle Cosmetics with "analysis certificate per article" containing information about the SVHC content.

To comply with the REACH obligation the supplier of an article must always monitor the Candidate List, because this is constantly updated and expanded over the course of time. Furthermore, the "Guidance on requirements for substances in articles" must be followed. With

every addition of an SVHC to the Candidate List the supplier of the articles must provide Weckerle Cosmetics without request with information about the content of this SVHC newly added to the Candidate List.

If insufficient information about the SVHC (presence, content,...) is provided to Weckerle Cosmetics by the supplier of the articles, reserves the right to commission chemical analyses taking the current Candidate List into consideration. The costs of these analyses will be borne by the supplier.

17. Testing facilities / inspection equipment monitoring

The supplier shall hold ready the measuring and testing equipment corresponding to the purpose of application which he requires for checking Weckerle Cosmetics specifications during serial production. The supplier must label all inspection devices and test control units which could have an effect on product quality. The inspection devices must be gauged with calibrated apparatus and adjusted prior to their application and at stipulated inspection intervals. The measuring equipment must clearly display the calibration status and/or documents concerning the calibration are to be prepared and retained. Capabilities of measuring equipment shall be verified for critical characteristics.

18. Third-party liability

The supplier shall take out third-party business insurance in accordance with the scope of his liability and indemnification obligations. The insured amounts of this insurance shall be at least 10 million EUR per event of damage for personal injury and damage to property and 10 million EUR for each event of damage for pecuniary loss. The insured amounts may be increased but not reduced during the term of this agreement without the consent of Weckerle Cosmetics. The supplier undertakes to effect payment of the premiums within the stipulated time and in the full amount and to diligently meet all other obligations arising from the insurance agreement. Upon request, confirmation of the insurance is to be made accessible to Weckerle Cosmetics within five working days.

19. Suppliers' safety advice

By way of fulfilment of his duty to maintain safety, the supplier shall mark his products with any necessary safety notices. Weckerle Cosmetics is to be notified of amendments of safety data sheets without delay; furthermore, updated safety data sheets are to be made available to Weckerle Cosmetics immediately.

20. Term / application

The Weckerle Cosmetics-AQA is valid for the term of the contractual relationship between the supplier and Weckerle Cosmetics.

21. Applicable law / place of jurisdiction

The contractual relationship between Weckerle Cosmetics and affiliated companies of Weckerle Cosmetics on the one hand, and the supplier on the other, shall be exclusively subject to the laws of the Federal Republic of Germany with the exclusion of the provisions of CISG.

Where the supplier is a businessman, a juristic entity under public law or a special fund under public law, the place of jurisdiction shall be the competent court for the registered seat of Weckerle Cosmetics in Eislingen, including in proceedings based on bills of exchange and cheques. Weckerle Cosmetics is entitled, at its own discretion, to also appeal to the competent courts for the registered seat of the supplier or his leading branch.

22. Miscellaneous

Should any individual provisions of this Weckerle Cosmetics-AQA be wholly or partially invalid or should the Weckerle Cosmetics-AQA contain a loophole, the validity of the remaining provisions shall in no way be affected by this. Instead of the invalid provision, a provision shall be agreed upon which corresponds to the sense and purpose of the invalid provision. In the event of a loophole, a provision is to be agreed upon which corresponds to that which would have been agreed upon with regard to sense and purpose if consideration had been given to the matter from the outset.

For the purpose of implementing this Weckerle Cosmetics-AQA, the parties shall each name one internal contact to whom, among other things, all notifications and declarations mentioned in this Weckerle Cosmetics-AQA are to be submitted.

Weckerle Cosmetics hereby appoints the following contact until further notice:

Weckerle Cosmetics Eislingen GmbH:	Dr. Saskia Barth, Director Quality Assurance saskia.barth@weckerle.com
Premium Cosmetics GmbH:	Dr. Saskia Barth, Director Quality Assurance Saskia.barth@weckerle.com
Weckerle GmbH: Location Peissenberg:	Andreas Zellner, Manager Quality Assurance andreas.zellner@weckerle.com
Weckerle GmbH: Location Weilheim:	Dr. Joachim Jäger, Director R & D joachim.jaeger@weckerle.com

The supplier hereby appoints unrequested Weckerle Cosmetics and all affiliated companies a counterpart for issues of quality.

Should one of the contacts appointed by one party leave the services of the company, a new contact is to be named vis-à-vis the other party without delay
