## **IKW**

# Cosmetics GMP Checklist for Self Assessment

# The German Cosmetic, Toiletry, Perfumery and Detergent Association

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#### **Foreword**

IKW has already published guidelines for the manufacturing of cosmetic products for many years, together with a checklist for self-assessment based on them. Since 2007 an international standard ISO 22716 on Cosmetics GMP has been available, which was published in a German translation in 2008. The standard as well as the former IKW Guideline on Cosmetics GMP are especially adapted to the cosmetic industry and permit an implementation in co-ordination with specific corporate needs and rules.

Current cosmetics legislation provides both in Germany and in the EU amongst other things for the manufacturing of cosmetic products taking into account cosmetics good manufacturing practices (GMP = Good Manufacturing Practices). The manufacturers of cosmetic products meet these statutory requirements if they manufacture their products in accordance with the above-mentioned guidelines. In future the next amendment to cosmetics legislation will expressly refer to the standard DIN EN ISO 22716 in a European regulation which will hence obtain a high relevance as state of the art.

The Working Group "Cosmetics GMP" of IKW has revised the already existing Checklist for Self-Assessment and oriented it towards the new standard. This Checklist can simplify necessary self-controls for manufacturers of cosmetic products through the completeness and effectiveness of corporate Cosmetics GMP rules in their plants.

In this way the Checklist is to provide orientation but should not represent a tick-off list. It possibly needs to be adjusted to the company and the processed products. It is also designed as an honest self-assessment, not for disclosure to third parties. By way of evidence for compliance with the provisions vis a vis third parties such as public authorities or customers, a document can be used which is attached as an annex.

The German Cosmetic, Toiletry, Perfumery and Detergent Association

Frankfurt am Main, July 2009

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- ONLY FOR INTERNAL USE -

# **Cosmetics GMP**

# **Checklist for Self Assessment**

Assessed area:		
Company:		
Address:		
Plant / Department:		
Responsible Persons:		
	Head of Manufacturing	Head of Quality Assurance
Conducted by:		
Date:		

# Cosmetics GMP Checklist for Self Assessment

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The basis for the content of this Checklist is the standard special print "Cosmetics GMP – Standard DIN EN ISO 22716; commented by IKW, to be obtained from Verlag für chemische industrie H. Ziolkowski GmbH, Beethoven Straße 16, 86150 Augsburg, <a href="https://www.sofw.com">www.sofw.com</a> or the original version of standard DIN EN ISO 22716 which can be obtained from Beuth-Verlag in Berlin under <a href="https://www.beuth.de">www.beuth.de</a>

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	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
	3.	Personnel					
	3.1	Principle					
	3.2	Organisation					
	3.2.1	Organisation chart					
1	3.2.1.1	Is an updated organisation chart available, which is comprehensible and appropriate for the size of the company and the diversity of its products					
2	3.2.1.2	Are adequate staffing levels available according to the respective production in the individual fields of activity?					
3	3.2.1.3	Does the organisation chart show the independence of the quality unit (quality assurance / quality control) from the other units of the					

	Reference			Complied v	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
	3.2.2	plant?  Is a sufficiently trained personnel with regard to the activities defined in these guidelines available:					
4 5	3.2.2a 3.2.2b	- in the field of production? - in the field of quality					
6	3.2.2c	<ul><li>control?</li><li>in the field of purchasing / procurement?</li></ul>					
7	3.2.2.d	- in the field of gateway / incoming goods?					
	3.3	Key Responsibilities					
	3.3.1	Management responsibilities					
8	3.3.1.1	Is the organisation supported by the top management of the company?					
9	3.3.1.2a	Does the responsibility for the implementation of Good Manufacturing Practices lie with the top					

	Reference			Complied w	/ith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		management?					
10	3.3.1.2b	Does the top management involve the personnel of all departments and positions of the company in the implementation of Good Manufacturing Practices?					
11	76/768/EC	Does the Head of Manufacturing have a basic scientific or technical education?					
12	76/768/EC	Does the Head of Quality Control have a basic scientific or technical education?					
13	3.3.1.3	Are the areas in the manufacturing plant which may only be accessed by authorised personnel defined?					
	3.3.2	Responsibilities of					
		Personnel					
14	3.3.2a	Does the personnel know its position in the					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		organisational structure?					
15	3.3.2b	Does the personnel know its defined responsibilities and activities?					
16	3.3.2c	Does the personnel have access to the documents which are relevant for its particular scope of responsibility?					
17	3.3.2d	Are the provisions of the documents complied with in the respective scopes of responsibly?					
18	3.3.2e	Does the personnel comply with personal hygiene requirements?					
19	3.3.2f	Does the personnel report irregularities or non-conformities within its scope of responsibility?					
20	3.3.2g	Does the personnel have adequate education training and skills to perform the assigned responsibilities and					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		activities?					
	3.4	Training					
	3.4.1	Training and Skills					
	3.4.2	Training and Good					
		Manufacturing Practices					
21	3.4.2.1	Is the personnel offered appropriate Good Manufacturing Practices training?					
22	3.4.2.2a	Are the training needs of all personnel determined?					
23	3.4.2.2b	Is a training programme developed and implemented on the basis of the identified training needs?					
24	3.4.2.2c	Is the training programme documented?					
25	3.4.2.3	Are the training courses of the respective personnel tailored to be appropriate to the jobs and responsibilities of individuals considering their					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		expertise and experience?					
26	3.4.2.4	Are the training courses developed and implemented by internal or external personnel?					
27	3.4.2.5a	Are trainings carried out on a regular basis and adjusted to current circumstances?					
28	3.4.2.5b	Are any trainings carried out documented?					
29	3.4.3	Is newly recruited personnel provided with basic training on the theory and practice of Good Manufacturing Practices as well as training appropriate to the duties assigned to it?					
30	3.4.4	Is the knowledge accumulated by personnel evaluated during or after training?					
	3.5	Personnel Hygiene and Health					

	Reference			Complied w	vith	Not applicable	Note	
				As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation						
	3.5.1	Personnel Hygiene						
31	3.5.1.1a	Has a hygiene programme been established for the production, quality control and storage areas?						
32	3.5.1.1b	Has the hygiene programme been adapted to the needs of the plant?						
33	3.5.1.1c	Are the requirements defined in the hygiene programme understood and followed?						
34	3.5.1.2a	Are sufficient facilities for hand washing and hand disinfection available?						
35	3.5.1.2b	Has the personnel been instructed in respect of hand washing and disinfection?						
36	3.5.1.2c	Are the facilities for hand washing and disinfection used?						
37	3.5.1.3a	Does the personnel wear appropriate clothing and						

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		protective garments to avoid contamination of cosmetic products?					
38	3.5.1.3b	Does the quality control personnel wear appropriate and prescribed clothing and protective garments to avoid contamination of cosmetic products?					
39	3.5.1.3c	Does the warehouse personnel wear appropriate and prescribed clothing and protective garments in order to avoid contamination of the cosmetic products?					
40	3.5.1.4a	Is there a ban on eating and drinking, chewing and smoking in the production, quality control and storage areas?					
41	3.5.1.4b	Is there a ban on storing food, drink or smoking materials or personal					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		medication in the production, quality control and storage areas?					
42	3.5.1.4c	Is there a provision in the production, quality control and storage areas concerning the wearing of a watch and any jewellery (including a wedding ring), artificial finger nails and visible piercings, etc?					
43	3.5.1.5	Is there an instruction for the production, quality control and storage areas forbidding any unhygienic practice in order to avoid the product from being adversely affected?					
	3.5.2	Personnel Health					
44	3.5.2	Have steps been taken to avoid that any person affected by an illness or having open lesions is excluded from the area of					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		open products?					
	3.6	Visitors and Untrained					
		Personnel					
45	3.6a	Are visitors and untrained personnel kept away from the production, quality control and storage areas?					
46	3.6b	If it is unavoidable to keep them away from the mentioned areas, is this group of persons given information and supervised in terms of personal hygiene and the prescribed protective clothing?					
47	3.6c	Is there any provision for the conduct of visitors and third party handicrafts in the production and storage areas?					
	4.	Premises /					
		<b>Production Plan</b>					
	4.1	Principle					

	Reference			Complied w	/ith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
48.	4.1.1a	Are the premises designed, constructed and utilised so as to ensure protection of the product?					
49	4.1.1b	Is efficient cleaning, if necessary, sanitising and maintenance of the premises possible?					
50	4.1.1c	Are the premises designed, constructed and utilised so as to minimise the risk of confusion when moving products, raw materials and packaging materials?					
51	4.1.2	Have areas of different hygienic requirements been defined, identified and have measures been assigned to the areas?					
	4.2	Types of Area					
52	4.2	Have separate or defined areas been provided for storage, production, quality control, ancillary, washing					

	Reference			Complied w	/ith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		and toilets?					
	4.3	Space					
53	4.3	Is sufficient space provided?					
	4.4	Flow					
54	4.4	Has the flow of personnel, materials and products been defined and is it complied with?					
	4.5	Floors, Walls, Ceilings,					
		Windows					
55	4.5.1a	Are floors / walls / ceilings / windows kept clean and in good repair?					
56	4.5.1b	Are floors / walls / ceilings / windows designed in such a way that thorough cleaning is possible?					
57	4.5.1c	Have floors / walls / ceilings / windows been designed in such a way that sanitisation is possible?					
58	4.5.2	Are windows which are opened to the outside					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		environment (eg to the outside or to other production / storage areas) designed in such a way that an adverse effect on cosmetics is not possible (eg screen)?					
59	4.5.3a	Did / has the design of the production area incorporated considerations, depending on the product type, for appropriate, crack-free and smooth floor condition?					
60	4.5.3b	Was / has the design of the production area incorporated considerations, depending on product type, for proper cleaning and sanitisation?					
61	4.5.3c	Was / has the design of the production area, depending on product type, incorporated considerations					

	Reference			Complied w	/ith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		for the resistance of floors and walls to corrosive cleaning and sanitising agents?					
	4.6	Washing and Toilet					
		Facilities					
62	4.6	Are sufficient toilet and washing facilities available which are exclusively intended for employees of areas with relevance for hygiene and can these be accessed directly from the corresponding areas?					
	4.7	Lighting					
63	4.7.1	Is lighting adequate?					
64	4.7.2	Is lighting protected from potential breakage?					
	4.8	Ventilation					
65	4.8	Is ventilation sufficient and is it ensured that there is no adverse influencing of the cosmetic product (eg					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		screen, ventilation with filter stages, no direct flow of air onto the products)?					
	4.9	Pipework, Drains and Ducts					
66	4.9.1a	Is pipework designed in such a way that in the event of leakage there can be no contamination of plants, materials, cosmetic products, etc?					
67	4.9.1b	Is pipework designed in such a way that condensation does not contaminate plants, materials, cosmetic products, etc?					
68	4.9.1c	Is pipework designed in such a way that there can be no contamination of plants, materials, cosmetic products, etc as a result of drip of soil?					

	Reference			Complied w	vith	Not applicable	Note
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	IKW Cosmetics GMP based on ISO 22716	Designation					
69	4.9.2a	Are drains designed in such a way that they are always clean?					
70	4.9.2b	Are drains designed in such a way that a backflow of waste water can be excluded?					
71	4.9.3a	Are exposed overhead roof beams, pipes and ducts etc avoided?					
72	4.9.3b	Are exposed pipes installed at a sufficient distance from the wall / ceiling in order to allow thorough cleaning?					
73	4.9.3c	Are there any technical alternatives concerning pipework, drains and ducts to protect the product?					
	4.10	Cleaning and Sanitisation					
74	4.10.1	Is the production area and in particular the areas which are relevant for hygiene in a					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		clean condition?					
75	4.10.2	Is cleaning / sanitisation carried out for the protection of the product?					
76	4.10.3a	Are the cleaning agents used defined?					
77	4.10.3b	Are the defined cleaning agents effective?					
78	4.10.3c	Are the sanitisation agents used defined?					
79	4.10.3d	Are the defined sanitisation products effective?					
80	4.10.4a	Are cleaning / sanitisation measures adjusted to the respective needs and carried out with appropriate, effective and defined agents?					
81	4.10.4b	Are cleaning / sanitisation measures adjusted to the respective needs with appropriate, effective and defined agents documented?					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
	4.11	Maintenance					
82	4.11	Is a corresponding maintenance plan for buildings, premises etc, available? Are the measures documented?					
	4.12	Consumables					
83	4.12	Is it ensured that consumables (lubricants, cleaning wipes, auxiliaries) do not have an adverse effect on the cosmetic products?					
	4.13	Pest Control					
84	4.13.1	Are the production premises designed so as to avoid access to insects, rodents, pests and other vermin etc?					
85	4.13.2	Is there a programme for pest control and is it documented?					
86	4.13.3	Are there any preventive					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		measures in the outdoor area which prevent harbouring or the advance of pests (trees very close to the buildings as well as waste containers, etc)?					
	5.	Equipment					
	5.1	Principle					
	5.2	<b>Equipment Design</b>					
87	5.2.1	Is contamination of the product prevented by the equipment and plants?					
88	5.2.2	Are the containers of bulk and intermediate products closed?					
89	5.2.2	Are the products protected from moisture, dust and contaminants?					
90	5.2.3	Are transfer hoses and accessories cleaned / sanitised and then dried?					
91	5.2.3	Are transfer hoses and accessories protected in a					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		dry location from dust, splash or other contamination?					
92	5.2.4	Is the material used in the construction of equipment compatible with products and the cleaning and sanitising agents?					
	5.3	Installation					
93	5.3.1	Is good drainage of the equipment / devices and plants ensured, in order to facilitate cleaning and sanitisation?					
94	5.3.2	Is/are the equipment / devices and plants placed so that no risk for product quality by materials, mobile equipment and personnel is to be expected?					
95	5.3.3	Is reasonable access under, inside and around equipment provided for maintenance and cleaning					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		work?					
96	5.3.4	Is the major equipment sufficiently marked and readily identifiable?					
	5.4	Calibration					
97	5.4.1	Are the laboratory and production measuring instruments that are important for the quality of the product calibrated regularly?					
98	5.4.2	Are the measuring instruments identified and removed from service if the calibration results are out of acceptance criteria?					
99	5.4.3	Are there any investigations in the event of unacceptable calibration results in order to determine whether there is any impact to the quality of the product and are appropriate steps taken?					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
100	Calibration Act	Are scales and measuring instruments regularly checked?					
101	Calibration Act	Are scales and measuring instruments regularly calibrated?					
	5.5	Cleaning and					
		Sanitisation					
102	5.5.1	Is there an appropriate cleaning and, if necessary, sanitisation programme for all equipment / devices and plants?					
103		Are CIP / SIP procedures applied for plant cleaning? (cleaning in place, sanitisation in place)					
104	5.5.2	Have cleaning and sanitising agents been specified?					
105	5.5.2	Has the effectiveness of the defined cleaning and sanitising agents been confirmed?					

	Reference			Complied w	/ith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
106	5.5.3a	Is the equipment / the plant cleaned and, if necessary, sanitised at appropriate intervals in continuous production?					
107	5.5.3b	Is the cleaning / sanitisation carried out for continuous production documented?					
108	5.5.3c	Is the equipment / the plant cleaned and, if necessary, sanitised at appropriate intervals for discontinuous productions, if successive batches of the same product are produced?					
109	5.5.3d	Is the cleaning / sanitisation carried out for discontinuous production documented?					
	5.6	Maintenance					
109	5.6.1	Is there any maintenance and servicing programme for the equipment / plants					
110	5.6.2	Is it ensured that the					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		maintenance operations do not affect the quality of the product?					
111	5.6.3	Are defective parts of equipment / plants identified, marked, excluded from use and isolated if possible?					
	5.7	Consumables					
112	5.7	Is it ensured that the consumables / auxiliaries used do not affect the quality of the product?					
	5.8	Authorisations					
113	5.8	Are the equipment or production systems and control systems used in production and monitoring / (control) only used by authorised personnel?					
	5.9	Backup Systems /					
		Redundancies					
114	5.9	Are adequate alternative					

	Reference			Complied w	/ith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		systems (backup) available to continue the processes in the event of a failure or breakdown?					
	6.	Raw Materials and					
		Packaging Materials					
	6.1	Principle					
	6.1	Do all raw materials and packaging materials that are supplied meet the defined acceptance criteria which are relevant to the quality of the finished product?					
115	6.1a	Have specifications been defined for all raw materials and packaging materials?					
116	6.1b	Have all checkpoints been defined in the specifications for raw materials and packaging materials which are relevant for the quality of the finished product?					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
117	6.1c	Do the test points in the specifications for raw materials and packaging materials include defined limit values as acceptance criteria?					
	6.2	Purchasing					
118	6.2.a.a	Is there a process to evaluate and select appropriate suppliers / producers of materials?					
119	6.2.a.b	Is the process for the evaluation and selection of appropriate materials suppliers / producers applied in a reliable manner?					
120	6.2b	Are there any agreements with the supplier / producer which define, for instance, the type of selection to be conducted, the acceptance criteria, actions in the case of defect or modifications,					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		transport conditions?					
121	6.2c	Do the agreements include statements on the setting up of relations such as assistance and audits by the contract giver?					
	6.3	Receipt					
122	6.3.1a	Is there a process to check whether the purchase order, the delivery note and the delivered materials match?					
123	6.3.1b	Are possibly any additional checks made in respect of the identity of the producer?					
124	6.3.2	Are the shipping containers checked visually for integrity and, if necessary, additional checks of transport data performed?					
125		Are all incoming goods subject to a defined sampling?	_				

	Reference			Complied w	/ith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
126		Is sampling equipment prescribed for all raw materials?					
127		Is the prescribed or defined sampling equipment adequate for raw materials to secure their quality control results?					
	6.4	Identification and Status					
128	6.4.1	Are the raw materials provided with labels which contain information on the supplier / producer, identity and badge?					
129		Are the raw materials labelled with information on the container number, amount, gross / tare weight?					
130	6.4.2	Are incoming goods with visible defects that might affect product quality					

	Reference			Complied w	vith	Not applicable	Note
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	IKW Cosmetics GMP based on ISO 22716	Designation					
		retained pending a decision on their use?					
131	6.4.3	Are the materials identified physically as "accepted", "rejected" or "quarantined" or is this ensured by another system with the same level of assurance?					
	6.4.4	Does the material identification include:					
132	6.4.4a	- the name of the product of the supplier / producer and recipient (if different)?					
133	6.4.4b	- the date of receipt?					
134	6.4.4c	- the name of the supplier and producer (if different)?					
135	6.4.4d	<ul> <li>the batch reference of the supplier / producer and recipient (if different)?</li> </ul>					
	6.5	Release					
136	6.5.1	Are there any physical or alternative release systems?					
137	6.5.2	Is the release carried out by					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		authorised personnel responsible for quality?					
	6.5.3	If releases are based partially or as a whole on supplier certificates, have in this case:					
133	6.5.3a	- the technical requirements of the supplier been assessed?					
139	6.5.3b	- the experience and knowledge of the supplier been assessed?					
140	6.5.3c	- audits been carried out at the supplier?					
141	6.5.3d	- test methods been agreed with the supplier?					
	6.6	Storage					
142	6.6.1 / 6.6.2	Are the storage conditions appropriate for the materials?					
143	6.6.3	Are specific storage conditions respected and monitored?					

	Reference			Complied w	/ith	Not applicable	Note
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	IKW Cosmetics GMP based on ISO 22716	Designation					
144	6.6.4	Are the materials stored closed and off the floor (eg on pallets)?					
145	6.6.5	Are newly and / or repacked materials provided with the same labelling as in incoming goods?					
146	6.6.6	Are rejected materials and / or materials in quality tests stored in a separate / identified location and / or managed by a corresponding data system?					
147	6.6.7	Does the FIFO principle (First In First Out) apply for the use of the materials?					
148	6.6.8a	Are inventories performed on a periodic level?					
149	6.6.8b	Are significant discrepancies investigated after inventories and is corrective action taken, if necessary?					
	6.7	Re-Evaluation					
150	6.7	Is an adequate system used					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		to re-evaluate and assess the materials after a defined period of storage?					
	6.8	Quality of Water Used in Production					
151	6.8.1	Does the water treatment system supply the defined quality of water?					
152	6.8.2a	Is the water quality regularly monitored / tested?					
153	6.8.2b	Are monitoring / testing measures and all results documented?					
154	6.8.3	Can the water treatment system be sanitised?					
155	6.8.4	Is a permanent circulation ensured in the water treatment system (reduction of the contamination risk)?					
156	6.8.5	Is it ensured that the materials used in water					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		treatment do not influence water quality?					
157		Is it ensured that the materials used for water treatment do not affect the product quality?					
	7.	Production					
	7.1	Principle					
	7.2	<b>Bulk Production</b>					
		Procedures					
	7.2.1	Availability of Relevant Documents					
158	7.2.1.1	Is each stage of bulk manufacturing operations documented in the production record?					
	7.2.1.2	Does the manufacturing					
		documentation include:					
159	7.2.1.2a	- the equipment / plant used?					
1060	7.2.1.2b	- the formula?					
161	7.2.1.2c	- the list of all raw materials (including batch number					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		and quantities)?					
162	7.2.1.2d	- detailed manufacturing operations for each stage (eg addition of raw materials, temperatures, speeds, mixing times, sampling, cleaning / sanitisation, bulk product transfer)?					
	7.2.2	Start Up Checks					
163	7.2.2a	Is all documentation relevant to the manufacturing operations available?					
164	7.2.2b	Are all raw materials available and released?					
165	7.2.2.c	Is the equipment in working order?					
166	7.2.2.c	Is the equipment cleaned and, if necessary, sanitised?					
167	7.2.2.d	Is the production area free from materials from previous operations ("line clearance")?					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		Are sufficient exhaust systems for operations involving dust development:					
168		- Available?					
169		- Sufficiently dimensioned?					
170		- Correctly positioned?					
171		- In working order?					
	7.2.3	Assignment of a Batch Number					
172	7.2.3a	Does every batch of bulk product (eg filling product) have a batch number?					
173	7.2.3b	Can the batch number of a bulk product be easily assigned to the batch number of the finished product?					
	7.2.4	Identification of In-Process					
		Operations					
174	7.2.4.1	Are all materials measured / weighed in accordance with					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		the formula?					
175	7.2.4.1	Are all measured / weighed raw materials filled into clean and suitable containers labelled with appropriate identification and / or directly into the equipment used for bulk manufacturing?					
176	7.2.4.2	Is an identification of major equipment and containers of raw materials possible at all times?					
177	7.2.4.2	Is an identification of the main equipment and the containers with the bulk products possible?					
	7.2.4.3	Does the identification of containers of bulk products include:					
178	7.2.4.3a	- name or identifying code?					
179	7.2.4.3b	- batch number?					
180	7.2.4.3c	- storage conditions (if important for product					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		quality)?					
	7.2.5	In-Process Control					
181	7.2.5.1a	Have in-process controls with their acceptance criteria been defined?					
182	7.2.5.1b	Are the conduct of the in- process controls and their results documented?					
183	7.2.5.2	Are the in-process controls performed according to a defined programme?					
184	7.2.5.3	Are any results outside the acceptance criteria reported and appropriately investigated?					
	7.2.6	Bulk Product Storage					
185	7.2.6.1	Are bulk products stored in suitable containers, in defined areas and under appropriate conditions?					
186	7.2.6.2	Has a maximum bulk product storage duration been defined?					
187	7.2.6.3	Is there a defined procedure					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		if this duration is exceeded?					
	7.2.7	Re-stocking of Raw Materials					
188	7.2.7	Are residual amounts of raw materials stored in closed and properly identified containers?					
	7.3	Packing Operations					
	7.3.1	Availability of Relevant Documents					
189	7.3.1.1	Is each stage of packaging operations documented in the manufacturing record?					
	7.3.1.2	Does the packaging documentation include:					
190	7.3.1.2a	- the equipment / plant used?					
191	7.3.1.2b	- the list of packaging materials?					
192	7.3.1.2c	- a list of detailed packaging operations (filling, closing, labelling, coding)?					
	7.3.2	Start-Up Checks					

	Reference			Complied w	/ith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
193	7.3.2a	Is it checked before starting any packaging operation whether the area has been cleared of materials from previous operations ("line clearance")?					
194	7.3.2b	Are all relevant documents available?					
195	7.3.2c	Are all packaging materials available and released?					
196	7.3.2d	Is the equipment in working order?					
197	7.3.2d	Is the equipment cleaned and, if necessary, sanitised?					
198	7.3.2e	Is any coding available to permit identification of the product?					
		Are appropriate exhaust systems for operations with dust formation:					
199		- Available?					
200		- Sufficiently dimensioned?					
201		- Correctly					

	Reference			Complied w	vith	Not applicable	Note
			As a Partly Not whole				
	IKW Cosmetics GMP based on ISO 22716	Designation					
		positioned?					
202		- In working order?					
	7.3.3	Assignment of a Batch Number					
203	7.3.3.1	Does each unit of finished product have a batch number?					
204	7.3.3.2	Is it easy to relate the batch of the bulk product to the finished product batch? (traceability?)					
	7.3.4	Packing Line Identification					
205	7.3.4	Is it possible to identify the packaging line with the finished product and its batch number?					
	7.3.5	Checks of Online Control Equipment					
206	7.3.5	Is online control equipment, if used, regularly checked according to a defined programme?					
	7.3.6	In-Process Control	_				
207	7.3.6.1a	Have in-process controls					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		and their acceptance criteria been defined during packaging?					
208	7.3.6.1b	Are the performance of the in-process controls and their results documented?					
209	7.3.6.2	Are in-process controls performed according to a defined programme?					
210	7.3.6.3	Are any results outside the acceptance criteria reported and appropriately investigated?					
	7.3.7	Re-Stocking of Packaging Materials					
211	7.3.7	Are residual amounts of packaging materials stored in closed and properly identified containers or outer packaging?					
	7.3.8	Identification and Handling of Work-in-Process					
212	7.3.8	Is a mix-up or mislabelling excluded if the processes of					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		filling and labelling are carried out during separate periods of time?					
	8.	<b>Finished Products</b>					
	8.1	Principle					
	8.2	Release					
213	Calibration Act / ISO 2859-1	Are there any binding specifications including acceptance criteria?					
214	8.2.1.a	Are finished products controlled in accordance with established test methods prior to being placed on the market?					
215	8.2.1b	Do the finished products comply with the acceptance criteria prior to being placed on the market?					
216	8.2.2a	Is the product release carried out by the authorised personnel responsible for quality?					
217	8.2.2b	Is the product release					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		adequately documented?					
	8.3	Storage					
218	8.3.1	Are the finished products stored in defined areas under appropriate (if necessary, monitored) conditions and for an appropriate length of time?					
219	8.3.2	Are the storage areas equipped and organised for this purpose?					
220	8.3.3	Are finished products which are released, quarantined or rejected, stored in their respective physical locations or is a data system available which ensures segregation?					
	8.3.4	Are the containers with the finished products (shipment unit and / or pallet) identified with:					
221	8.3.4a	- name or identifying code (material number)?					
222	8.3.4b	- batch number?					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
223	8.3.4c	<ul> <li>storage conditions (if necessary for product quality)?</li> </ul>					
224	8.3.4d	- quantity?					
225	8.3.5	Is the finished product with the oldest release date used first (FIFO principle)?					
226	8.3.6a	Are periodic inventory checks carried out?					
227	8.3.6b	Are the quantities recorded by quality status?					
228	8.3.6c	Is every significant discrepancy investigated after the inventory?					
	8.4	Shipment					
229	8.4a	Are there any measures which ensure the shipment of the defined finished product?					
230	8.4b	Have precautions been taken to maintain the finished product quality?					
	8.5	Returns					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
231	8.5.1	Are returns identified and stored in defined areas?					
232	8.5.2	Are returns evaluated against established criteria?					
233	8.5.3	Are returns released again before they are placed back on the market?					
234	8.5.4a	Is it possible to clearly identify reprocessed returns?					
235	8.5.4b	Is an inadvertent redistribution of unreleased, returned finished products excluded?					
	9.	<b>Quality Control</b>					
		Laboratory					
	9.1	Principle					
236	9.1.1	Do the principles described for personnel, premises, equipment, subcontracting and documentation also apply to the quality control laboratory?					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
237	9.1.2	Is the quality control laboratory responsible for sampling, controls and releases according to defined acceptance criteria?					
	9.2	Test Methods					
238	9.2.1	Does the quality control laboratory use all test methods which are necessary to confirm that the product complies with the acceptance criteria?					
239	9.2.2	Are the controls performed on the basis of defined, appropriate and available test methods?					
	9.3	Acceptance Criteria					
240	9.3	Have acceptance criteria for raw materials, packaging materials, bulk products and finished products been defined to meet the requirements?					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
	9.4	Results					
241	9.4a	Are the laboratory results documented?					
242	9.4b	Are the laboratory results reviewed?					
243	9.4c	Is this review used in order to decide about a release or rejection or a temporary suspension of the decision (quarantine)?					
244	9.4d	Are the decisions which are derived through control results adequately documented?					
	9.5	Out-of-Specification					
		Results					
245	9.5.1	Are the out-of-specification results reviewed by authorised personnel and properly investigated and is a corresponding decision about uses taken subsequently?					

	Reference			Complied w	/ith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
246	9.5.2	Is any retesting sufficiently justified?					
247	9.5.3	Is after the new investigation a decision in terms of deviation or rejection or pending only made by authorised personnel?					
	9.6	Are reagents, Solutions, Reference Standards, Culture Media – identified through					
248	9.6a	- name?					
239	9.6b	- concentration or strength?					
250	9.6c	- expiration date?					
251	9.6d	<ul> <li>name and / or signature of the person who prepared it?</li> </ul>					
252	9.6e	- opening date?					
253	9.6f	- storage conditions?					
254		<ul> <li>labelling according to the German Hazardous</li> </ul>					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		Substances Ordinance?					
	9.7	Sampling					
255	9.7.1	Is sampling performed by authorised personnel?					
	9.7.2	Has the following been defined for sampling:					
256	9.7.2a	- sampling method?					
257	9.7.2b	- equipment to be used?					
258	9.7.2c	- amounts to be taken?					
259	9.7.2d	<ul> <li>any precautions to be observed to avoid contamination or deterioration?</li> </ul>					
260	9.7.2e	- identification of sample?					
261	9.7.2f	- frequency of sampling?					
	9.7.3	Do the samples include for clear traceability:					
262	9.7.3a	- name or identifying code (material number)?					
263	9.7.3b	<ul><li>- batch numbers, own and supplier's / manufacturing numbers?</li></ul>					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
264	9.7.3c	- date of sampling and possibly time?					
265	9.7.3d	- container from which the sample was taken?					
266	9.7.3e	- the sampling point, if necessary?					
	9.8	Retained Sample					
267	9.8.1	Are the samples of finished products retained in an appropriate manner and in designated areas?					
268	9.8.2	Does the sample size of finished products allow analyses to be carried out in accordance with local regulations?					
269	9.8.3	Are the samples of finished products retained kept in their primary package for an appropriate time under the storage conditions recommended by the manufacturer? (Product Liability 85/347/EC Article					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		7E to be observed)					
270	9.8.4a	Are samples of raw materials and possibly bulk products retained according to company practice?					
271	9.8.4b	Are samples of raw materials retained in accordance with local regulations?					
	10.	Treatment of					
		Products that are					
		Out of Specification					
	10.1	Rejected Finished					
		Products, Bulk					
		Products,. Raw					
		Materials and					
		Packaging Materials					
272	10.1.1	Are investigations of rejected finished products / bulk products or raw materials / packaging materials performed by					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		personnel authorised to do so?					
273	10.1.2	Is the decision about rejected products / materials (destruction, reprocessing) taken by the personnel responsible for quality?					
	10.2	Reprocessed Finished Products and Bulk Products					
274	10.2.1	Is the decision to reprocess, rework or mix (bulk) products which are not in conformity only taken by the personnel responsible for quality?					
275	10.2.2	Is the method of reprocessing defined and approved?					
276	10.2.3	Are controls performed on the reprocessed finished products or bulk products					

	Reference			Complied w	rith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		by authorised personnel and are the corresponding results reviewed in order to verify the conformity with the acceptance criteria?					
	11.	Wastes					
	11.1	Principle					
277	11.1	Are wastes disposed of in a timely and sanitary manner?					
	11.2	Types of Waste					
278	11.2a	Are the types of waste for the given production processes that could affect the quality of the finished products defined?					
279	11.2b	Are the types of waste defined for the work of the quality control laboratory which could affect the quality of the finished products?					
	11.3	Flow					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
280	11.3.1	Does the flow of waste not impair the operations in production and laboratories?					
281	11.3.2	Have measures been taken in view of the collection, transportation, storage and disposal of wastes?					
282	11.3.2	Are the individual measures of collection, transportation, storage and disposal of wastes adequately documented?					
	11.4	Containers					
283	11.4	Are the containers of waste properly identified (possibly with additional information)?					
	11.5	Disposal					
284	11.5	Is the destruction of waste performed in an appropriate way?					
285	11.5	Is the destruction of waste					

	Reference			Complied w	/ith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		monitored?					
	12.	Subcontracting /					
		Services and					
		Contract					
		Manufacturing					
	12.1	Principle					
286	12.1a	Are subcontracting / services and contract manufacturing defined in a written contract?					
287	12.1b	Are the requirements clearly defined in the contract by the contract giver?					
	12.2	Types of					
		Subcontracting					
	12.2	Have the following types of subcontracting been clearly defined in terms of contracts and requirements:					
288	12.2a	- manufacturing of					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		intermediary bulk products?					
289	12.2b	- manufacturing of bulk products?					
290	12.2c	- packaging of bulk products in primary packaging?					
291	12.2d	- packaging in primary packaging = consumer unit?					
292	12.2e	- packaging in secondary packaging = trading unit?					
293	12.2f	- packaging in tertiary packaging = pallet unit?					
294	12.2g	- sensorial analysis?					
295	12.2h	- chemical analysis?					
296	12.2i	- physical analysis?					
297	12.2j	- microbiological analysis?					
298	12.2k	<ul> <li>cleaning / sanitisation, if necessary, including the premises?</li> </ul>					
299	12.21	- pest control?					
200	12.2m	- maintenance equipment?					
201	12.2n	- maintenance premises?					
	12.3	Contract Giver					
	12.3.1	The contract giver should					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		assess whether the contract acceptor:					
302	12.3.1a	- is able to carry out the contracted operations?					
303	12.3.1b	- can carry out the contracted operations as agreed?					
304	12.3.1c	- is able to meet the Cosmetics GMP requirements (according to ISO 22716)?					
		The contract giver should assess whether the contract acceptor has the necessary resources to					
		carry out the contract:					
305	12.3.1d	- technical equipment?					
306	12.3.1e	- appropriate premises?					
307	12.3.1f	- appropriate site?					
308	12.3.2	Has all the information required to carry out the operations correctly been made available by the contract giver? (examples:					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		defined documents such as specifications, manufacturing rules etc)?					
	12.4	Contract Acceptor					
	12.4.1	Is it ensured through the contract acceptor that in view of the fulfilment of the contractually defined requirements he:					
309	12.4.1a	- has the necessary resources?					
310	12.4.1b	- has the necessary experience?					
311	12.4.1c	- has the necessary competent personnel?					
312	12.4.2a	Is it ensured that the contract acceptor will not pass on to a third party any of the work entrusted to him without the prior approval and consent of the contract giver?					
313	12.4.2b	Is it ensured through the contract acceptor or any					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		third parties involved that all information about operations are made available as represented in the contract / agreement?					
314	12.4.2c	Is the information defined which has to be made available by the contract acceptor or third parties involved to the contract giver?					
315	12.4.3a	Are checks and audits by the contract giver at the contract acceptor contractually fixed?					
316	12.4.3b	Does the contract giver facilitate the contractually agreed checks and audits?					
317	12.4	Does the contract acceptor inform the contract giver of any planned changes that may affect the quality of the services or products? (Note: "Change Control")					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
	12.5	Contract					
318	12.5.1	Are the duties and responsibilities (delimitation of obligations / responsibilities, "matrix") of the two parties defined in the contract?					
319	12.5.2	Does the contract acceptor keep or make available to the contract giver all data?					
	13.	Deviations					
320	13.1	Are measures available which regulate the approach in the event of deviations from specified requirements?					
321	13.1	Are sufficient data available for the decision about a possible correction?					
322	13.2	Are the corrective measures implemented in such a way that recurrence of deviations is avoided?					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
	14.	Complaints and					
		Recalls					
	14.1	Principle					
323	14.1.1 14.1.2a	Are all complaints that fall within the scope of these guidelines and are communicated to the plant reviewed, investigated and followed up, as appropriate?  Are appropriate steps taken in the event of a product recall decision in order to complete the recall within					
		the scope of these GMP guidelines?					
325	14.1.2b	In the case of a product recall decision, are corresponding corrective and preventive measures initiated?					
326	14.1.3	Is the process of dealing with complaints agreed in					

	Reference			Complied w	/ith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		the event of contracted operations between the contract giver and contract acceptor? (see 12.1)					
	14.2	Product Complaints					
327	14.2.1	Are complaints centralised by authorised personnel?					
328		In the event of any complaints concerning a product defect, are the original details and follow-up information kept together?					
329	14.2.2	Are corresponding follow- up measures performed for the batch of the product complained about completed?					
	14.2.3	Do the complaint investigations and follow-up include:					
330	14.2.3a	- steps to prevent recurrence of the defect?					
331	14.2.3b	- checking other batches in					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		order to determine whether they are also affected?					
332	14.2.4	Are complaints reviewed periodically to check for trends or recurrence of a defect on a precautionary basis?					
	14.3	Product Recalls					
333	14.3.1	Is the recall process co- ordinated by authorised personnel in each case?					
334	14.3.2	Are product recall operations initiated promptly and in a timely manner?					
335	14.3.3	Are the appropriate authorities notified of recalls which could have an impact on consumer safety?					
336	14.3.4	Are recalled products stored separately in a secure area while awaiting a decision?					
337	14.3.5	Is the product recall process evaluated periodically?					

	Reference			Complied w	/ith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
	15.	<b>Change Control</b>					
338	15a	Has a process been defined for changes (plants, material, process etc) which could affect the quality of the product?					
339	15b	Are changes performed by a defined authorised personnel?					
340	15c	Are the changes authorised and completed on the basis of sufficient data?					
341	15d	Are the changes documented?					
	16.	Internal Audit					
	16.1	Principle					
	16.2	Approach					
342	16.2.1	Are internal audits conducted by specially designated competent personnel in an independent and detailed manner, regularly or on					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		demand?					
343	16.2.2	Are all observations made during the internal audit evaluated and shared with appropriate management?					
	16.3	Follow-Up					
344	16.3	Are corrective measures completed or implemented in a satisfactory manner which are based on the observations?					
	17.	Documentation					
	17.1	Principle					
345	17.1.1	Does the company have an adequate system of documentation established and implemented that is appropriate to its organisational structure and the type of products and does it maintain such a system?					
	17.2	Types of Documents					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
346	17.2.1 / 17.2.2	Does the documentation system include all instructions, specifications, test protocols, reports, methods and records appropriate to the activities covered by the GMP guidelines? (as hard copy paper or electronic data processing record)					
	17.3	Writing, Approval and Distribution					
347	17.3.1	Do the defined documents describe the corresponding operations to be carried out, precautions to be taken and measures to be applied with appropriate detail?					
348	17.3.2	Are the title, nature and purpose of documents stated?					
	17.3.3	Are the documents:					
349	17.3.3a	- legible?					

	Reference			Complied w	vith	Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
350	17.3.3b	- approved, signed and dated by authorised persons before being used?					
351	17.3.3c	- prepared, updated, withdrawn, distributed and classified (confidential)?					
352	17.3.3d	- referenced to ensure that obsolete documents are not used?					
353	17.3.3e	- made available to appropriate personnel?					
354	17.3.3f	- removed from the job area and destroyed if they are outdated?					
	17.3.4	Do records which require the entry of handwritten data include:					
355	17.3.4a	- indications as to what is to be entered?					
356	17.3.4b	- legible entries, with permanent ink?					
357	17.3.4c	- signature and date?					
358	17.3.4d	- corrections which leave the original entry readable					

	Reference		Complied with			Not applicable	Note
			As a whole	Partly	Not		
	IKW Cosmetics GMP based on ISO 22716	Designation					
		and where appropriate state the reason for the correction?					
	17.4	Revision					
359	17.4	Are documents, where necessary, updated and is the reason for revision and number and / or reason for the revision and version number stated?					
	17.5	Archiving					
360	17.5.1	Are only original documents or controlled copies archived?					
361	17.5.2	Does the duration of archiving correspond to the applicable legislation (Product Liability 85/374/EC Article 11) and internal regulations?					
362	17.5.3 / 17.5.4	Are the stored / saved documents (in paper or electronic form) legible and					

	Reference		Complied with		Not applicable	Note	
			As a	Partly	Not		
			whole				
	IKW Cosmetics	Designation					
	GMP based on						
	ISO 22716						
		secured?					
363	17.5.5	Are backup data stored at a					
		separate and secure					
		location at regular					
		intervals?					

## IKW Form (example)

to confirm the requirements in accordance with Article 7a of Directive 76/768/EEC (EC Cosmetics Directive)

## Certificate

concerning the application of Good Manufacturing Practices for Cosmetic Products (Cosmetics GMP) at the manufacturing of all products

It is hereby certified that in the plant	·
Cosmetics GMP includes:	
Personnel	
Premises	
Equipment	
Raw materials and packaging materials	
Production	
Finished products	
Quality control laboratory	
Treatment of products that are out of specification	r
Wastes	
Subcontracting / services and contract manufactur	ing
Deviations	
Complaints and recalls	
Change control	
Internal audit	
Documentation	
Reference is made to the standard DIN EN ISO 227	16 on Cosmetics GMP.
Date	Date
Signature (for Manufacturing)	Signature (for Quality Control)

## Request form for additional brochures

Additional copies of this Checklist can be requested from IKW by email under <a href="mailto:info@ikw.org">info@ikw.org</a> as a pdf file.

To the German Cosmetic, Toiletry, Perfumery and Detergent Association
Department Bodycare Products
Mainzer Landstraße 55
60329 Frankfurt am Main

Please send us a copy of the brochure "Cosmetics GMP – Checklist for Self Assessment", edition July 2009

By email

Name

Company

Street

Zip / Place

**Email address** (in block letters)