

## **REGULATORY INFORMATION FILE (RIF)**

### **GSA - GSSA**

<b>PART 1</b>	<b>Regulatory Attestation Relating to Packaging Items</b>
<b>PART 2</b>	<b>Description and materials status</b>
<b>PART 3</b>	<b>Regulatory scope</b>

**Application field:**

Products manufactured by Aptar Beauty + Home EMEA and intended for use in cosmetics and similar technical products.

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**PACKAGING SUPPLIER**

Company name (packaging supplier)	Aptar Beauty + Home EMEA
Address (packaging supplier)	Aptar Chieti, Via Po, 49, 66020 San Giovanni Teatino, ITALY

**PACKAGING**

Reference(s) relative to this certificate	GSA - GSSA
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**NECESSARY INFORMATION FOR COMPLIANCE WITH THE REGULATORY REQUIREMENTS APPLICABLE TO COSMETIC PRODUCTS**

A confidential agreement is signed, if necessary.

Cosmetic Regulation on cosmetic product safety obligation, taking into account the relevant characteristics of the packaging in direct contact with the cosmetic formula and any other useful information for this specific purpose

**Packaging composition, purity, stability data (substance migration from the packaging)**

Is it a multi-materials packaging?	See part 2 "Description and materials status"
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**Material(s) classification**

For multi-materials, please indicate content from inside to outside	See part 2 "Description and materials status"
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**Chemical nature of the material (% to be given)**

For multi-materials, please indicate from inside to outside layers	See part 2 "Description and materials status"
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**Impurities present in the material, which are technically unavoidable**

To be identified with the chemical name, CAS number: Concentration to be given	Unknown
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**Technical substances (additives) used for the production of the packaging (colorant, antioxidant, UV filter, lubricant...)**

To be identified with the chemical name, CAS number: Concentration to be given	See part 2 "Description and materials status"
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**Presence of substances listed in the annex II of the Cosmetic Regulation or classified as CMR 1A, 1B, 2 according to the Regulation n° 1272/2008**

If yes, identification of the substance and its concentration (all supporting elements to be indicated and enclosed).

Available information is included in the document RIF PM "Additional information in accordance with Cosmetics Europe Packaging Advisory Document"

**Additional information on the packaging that can be useful for the safety evaluator of the finished cosmetic product**

The packaging material(s) complies with the composition requirement of :

- The regulation on materials intended to come into contact with food	See part 2 "Description and materials status"
- The European Pharmacopoeia on recipients for pharmaceutical usage	Non applicable
- The toys safety regulation	Non applicable

Indicate the type of product(s) compatible with the packaging :

- all types of product
- aqueous products
- fatty / oily products
- products with an acidic pH
- products with a basic pH
- alcoholic products

To be verified by the client
<input type="checkbox"/> Yes / <input type="checkbox"/> No
<input type="checkbox"/> Yes / <input type="checkbox"/> No
<input type="checkbox"/> Yes / <input type="checkbox"/> No
<input type="checkbox"/> Yes / <input type="checkbox"/> No
<input type="checkbox"/> Yes / <input type="checkbox"/> No
<input type="checkbox"/> Yes / <input type="checkbox"/> No

Migration data available

Any migration data provided by raw material suppliers based on food contact regulation is included in RIF PM

Other useful information

Specific migration limits may exist for one or more of the plastic materials, to be respected in the case of food contact applications

### **Packaging and packaging waste Regulation** (Directive 94/62/EC)

-The above-named company (packaging supplier) certifies that the packaging complies with the Directive 94/62/EC as well as the heavy metals level: the total concentration levels of lead, cadmium, mercury and hexavalent chromium shall not exceed 100 ppm by weight in the packaging (any supporting documents on heavy metals to be sent).

-For glass packaging containing crystal or recycled materials, indicate the total concentration levels of cadmium, mercury, hexavalent chromium:

Non applicable

### **REACH Regulation** (Regulation EC n°1907/2006)

- The above-named company (packaging supplier) certifies that the packaging is strictly in accordance with the REACH Regulation, and in particular complies with the restrictions included in annex XVII and with the authorizations/bans included in annex XIV, and commits to inform the recipient of this certificate (the customer) of any compliance gap in relation to REACH Regulation.

- The above-named company (packaging supplier) commits to be conform with the REACH regulation application to clearly and systematically communicate to the addressee of this certificate (the customer) the presence of substances of very high concern\* (SVHC) which are included in the "candidate list», exceeding more than 0.1% (weight/weight) in the packaging, taking into account in particular the evolutions of the 'candidate list\*".

\*[http://echa.europa.eu/chem\\_data/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/candidate_list_table_en.asp)

Presence of SVHC substances included in the "candidate list" exceeding 0.1% w/w. If yes, identification of the substance and its concentration (all supporting documents to be indicated and enclosed).

See part 2 "Description and materials status"

### **CUSTOMER SPECIFIC REQUIREMENTS**

- The addressee of this certificate (the customer) reserves the right to verify the accuracy of the information provided.

**Aptar Beauty + Home EMEA**

**Regulatory Department**

Email address: [bhregdept.eu@aptar.com](mailto:bhregdept.eu@aptar.com)

*This document is valid without signature*

MATERIAL		REGULATORY INFORMATION ** (see PART 3)				INTERACTION BULK/PACKAGING
COMPONENTS	NATURE	REACH : Article 33	Food Contact: Europe	Food Contact: US	Heavy Metals: EU Dir 94/62	Contact Yes/No
<b>COLLAR</b> All versions except N052 NN and N047 NN	Aluminium	ok	N/A	N/A	ok	<b>No</b>
<b>COLLAR</b> Version N052 NN and N047 NN	TPO (thermoplastic polyolefin)	ok	ok	177.1520 176.170	ok	<b>No</b>
<b>INSERT</b> Resin Alternative 1	PP R	ok	ok	177.1520 FCN	ok	<b>Yes</b>
<b>INSERT</b> Resin Alternative 2	PP R	ok	ok	177.1520 176.170	ok	
<b>INSERT</b> Additive	Additive masterbatch	ok	ok	177.1520 178. GRAS	ok	
<b>INSERT</b> Version PCR	PP PCR	ok	Risk assessment performed by Aptar		ok	<b>Yes</b>
<b>ACTUATOR</b> Version biobased	Biobased HDPE	ok	ok	177.1520	ok	<b>Yes</b>
<b>ACTUATOR</b> All versions except for J1, E7, K2T, K5 and biobased PE Alternative 1	PP R	ok	ok	177.1520 FCN	ok	<b>Yes</b>
<b>ACTUATOR</b> All versions except for J1, E7, K2T, K5 and biobased PE Alternative 2	PP R	ok	ok	177.1520 176.170	ok	
<b>ACTUATOR</b> Version J1 Alternative 1	PP H	ok	ok	177.1520 176.170 FCN	ok	<b>Yes</b>
<b>ACTUATOR</b> Version J1 Alternative 2	PP H	ok	ok	177.1520	ok	
<b>ACTUATOR</b> Version E7	PP H	ok	ok	177.1520 176.170	ok	<b>Yes</b>
<b>ACTUATOR</b> Version K2T	PP R	ok	ok	177.1520	ok	<b>Yes</b>
<b>ACTUATOR</b> Version K5	PP R	ok	ok	177.1520	ok	<b>Yes</b>
	Additive	Waiting for updated information				
<b>ACTUATOR</b> Version PCR	PP PCR	ok	Risk assessment performed by Aptar		ok	<b>Yes</b>

MATERIAL		REGULATORY INFORMATION ** (see PART 3)				INTERACTION BULK/PACKAGING
COMPONENTS	NATURE	REACH : Article 33	Food Contact: Europe	Food Contact: US	Heavy Metals: EU Dir 94/62	Contact Yes/No
<b>FIXTURE</b> Version 24/410-2N Biobased	Biobased HDPE	ok	ok	177.1520	ok	<b>No</b>
	EVA	ok	ok	177.1350	ok	
<b>FIXTURE</b> Version 28/410-1N/1S/2N/2S Biobased	Biobased HDPE	ok	ok	177.1520	ok	<b>No</b>
<b>FIXTURE</b> Version PP R Alternative 1	PP R	ok	ok	177.1520 FCN	ok	<b>No</b>
<b>FIXTURE</b> Version PP R Alternative 2	PP R	ok	ok	177.1520 176.170	ok	
<b>FIXTURE</b> Version PCR blend with PP R	PP PCR	ok	Risk assessment performed by Aptar		ok	<b>No</b>
<b>FIXTURE</b> Version 25/173-4N, 28/21S-4N, 28/200-5N, 28/21L-4N Alternative 1	PP H	ok	ok	177.1520	ok	<b>No</b>
<b>FIXTURE</b> Version 25/173-4N, 28/21S-4N, 28/200-5N, 28/21L-4N Alternative 2	PP H	ok	ok	177.1520 176.170 FCN	ok	
<b>FIXTURE</b> Version 27/230 Additive	Additive	ok	ok	177.1520 176.170 177.500 177.1580	ok	<b>No</b>
<b>DIP_TUBE</b> Version Biobased	Biobased LDPE	ok	ok	177.1520	ok	<b>Yes</b>
	Biobased LLDPE	ok	ok	177.1520	ok	
<b>DIP_TUBE</b> Alternative 1	LDPE	ok	ok	177.1520 176.170	ok	<b>Yes</b>
	LLDPE	ok	ok	177.1520	ok	
<b>DIP_TUBE</b> Alternative 2	LDPE / LLDPE	ok	ok	177.1520	ok	
<b>DIP_TUBE</b> Alternative 3	LDPE / LLDPE	ok	ok	177.1520	ok	
<b>DIP_TUBE</b> Alternative 4	LDPE	ok	ok	177.1520	ok	
	LLDPE	ok	ok	177.1520	ok	

MATERIAL		REGULATORY INFORMATION ** (see PART 3)				INTERACTION BULK/PACKAGING
COMPONENTS	NATURE	REACH : Article 33	Food Contact: Europe	Food Contact: US	Heavy Metals: EU Dir 94/62	Contact Yes/No
<b>FOIL</b>	PET-ALU-PE	ok	ok	PE: 177.1520; GRAS; 178 ALU: GAS (rolling oils: 178.3910) PET: 177.1630 INKS and LACQUERS: Presence of functional barrier, which prevents their migration	ok	<b>Yes</b>
<b>CLIP Alternative 1</b>	PP R	ok	ok	177.1520 FCN	ok	<b>No</b>
<b>CLIP Alternative 2</b>	PP R	ok	ok	177.1520 176.170	ok	
<b>CLIP Version K and Q Additive</b>	Additive	ok	ok	177.1520 176.170 177.500 177.1580	ok	
<b>CLIP Version PCR</b>	PP PCR	ok	Risk assessment performed by Aptar		ok	<b>No</b>
<b>LOWER STEM Alternative 1</b>	POM C	ok	ok	177.2470 178.3297	ok	<b>Yes</b>
<b>LOWER STEM Alternative 2</b>	POM C	ok	ok	177.2470 (base resin) Additives comply with appropriate, specific FDA Regulations.	ok	
<b>LOWER STEM Silicone oil</b>	Silicone oil	ok	ok	175.300	ok	
<b>HOUSING Alternative 1</b>	PP H	ok	ok	177.1520 176.170 FCN	ok	<b>Yes</b>
<b>HOUSING Alternative 2</b>	PP H	ok	ok	177.1520	ok	
<b>PISTON</b>	LLDPE	ok	ok	177.1520	ok	<b>Yes</b>
	Additive	ok	ok	175.300 177.1350 175.105	ok	
	Silicone oil	ok	ok	175.300	ok	
<b>STEM Alternative 1</b>	PP H	ok	ok	177.1520 176.170 FCN	ok	<b>Yes</b>
<b>STEM Alternative 2</b>	PP H	ok	ok	177.1520	ok	
<b>GASKET Version GK01</b>	IIR (butyl rubber)	ok	ok	177.2600	ok	<b>Yes</b>
<b>GASKET Version GA08</b>	NBR	ok	ok	177.2600	ok	<b>Yes</b>

MATERIAL		REGULATORY INFORMATION ** (see PART 3)				INTERACTION BULK/PACKAGING
COMPONENTS	NATURE	REACH : Article 33	Food Contact: Europe	Food Contact: US	Heavy Metals: EU Dir 94/62	Contact Yes/No
<b>GASKET</b> Version GT04 Alternative 1	3 layers (LDPE/LDEPE foam/LDPE)	ok	ok	Film in direct contact: '177.1520 178.3297 174	ok	<b>Yes</b>
<b>GASKET</b> Version GT04 Alternative 2	#N/A	#N/A	N/A	N/A	N/A	
<b>GASKET</b> Version GT04 Alternative 3	3 Layers (Contact Layer LDPE)	ok	ok	177.1210 '177.1520	ok	
<b>SPRING</b>	Stainless steel	ok	N/A	N/A	ok	<b>No</b>
<b>BALL</b>	POM H	ok	ok	177.2480	ok	<b>Yes</b>
<b>RETAINER</b>	PP C	ok	ok	177.1520	ok	<b>Yes</b>

**Components may be colored** and, as a general rule, the regulatory status of colorants is not reported in the table above. All colorants involved do not contain any SVHC > 0.1%, and comply with EU Dir. 94/62 (heavy metals content).

**N/A:** Non Applicable

**Ok:** Compliance with the stated regulations is limited to the chemical composition

## APPLICATION FIELD

Products manufactured by Aptar Beauty + Home EMEA and intended to be used in cosmetic and technical products.

## CONTEXT

The Cosmetic Regulation (EC) 1223/2009 refers principally to the cosmetic formulation and not to the packaging thereof. Nevertheless the provision of some information concerning the packaging material is required – Annex I, Part A, 4, information about packaging material – the relevant characteristics of packaging material, in particular purity and stability.

The Regulation is not specific regarding the requirement of cosmetic packaging. Due to this lack of clarity, it is commonly accepted that the legislative requirements of packaging for food contact are useful references for cosmetic packaging. A recent guideline from the EU Commission states that “*reference to Regulation (EC) No 1935/2004 on food contact materials could be useful for characteristics of packaging materials*”. However Aptar Beauty+Home applies the food contact legislation as far as it is relevant for cosmetic packaging.

## **\*\* REGULATORY INFORMATION**

**REACH SVHC** - Our suppliers of raw materials or components have a duty to inform us if their products contain substances of very high concern (SVHC) on the SVHC candidate list at a concentration above 0.1% w/w. In the event of notification by our suppliers of the existence of one of the substances exceeding the 0.1% w/w threshold, we will inform you as soon as possible, if the products you purchase are impacted.

*The above information is based upon the certificates provided by our suppliers of raw materials/components.*

### **Packaging and Packaging waste regulation (Directive 94/62/EC and CONEG)**

The packaging complies with these regulations with regards to heavy metals level: the total concentration levels of lead, Cadmium, mercury and hexavalent chromium shall not exceed 100 ppm by weight in the packaging,

### **Food contact Europe**

Regulation EU 1935/2004 on materials and articles intended to come into contact with food.

#### **Appropriate regulations per type of raw materials for example:**

Plastics - EU Regulation 10/2011 Plastics intended to come into contact with foodstuffs

Silicones - Council of Europe Resolution AP (2004)5 Silicones used for food contact applications

*Compliance with the stated regulations is limited to the chemical composition.*

### **Food contact US** - stated chapters of FDA 21CFR or FCN (Food Contact substance Notification)

*Compliance with the stated regulations is limited to the chemical composition.*

*Aptar Beauty + Home EMEA has no access to the detailed composition of raw materials, and does not, routinely, carry out any chemical analysis of these materials. The presence of non-intentionally added substances cannot therefore be totally excluded, and as a consequence, provision of "Free of" certificates is not possible. Aptar Beauty + Home EMEA does not implement migration studies on the finished products as it has no control over neither the nature nor composition of the product with which it is filled*

*This document does not exempt the client from ensuring the compatibility of the packaging requested with his product and verifying that the finished product conforms to the analytical requirements (specific and/or global migration, restriction and/or specification) according to the expected conditions of use of the product.*

*This statement is based on our current state of knowledge and related to products currently produced by Aptar Beauty + Home EMEA.*

*The present regulatory information is the property of Aptar and may not be communicated to any other third party, with the exception of independent laboratories, without the prior written consent of Aptar.*

*This statement is based on the laws and regulations being considered at the date of issue. It remains valid until the next relevant change in legislation.*