

Appendix: Required Technical Information for registration of specific purpose cosmetics containing new substance, new purpose or new maximum concentration

item	information	New substance	New purpose	New maximum concentration (elevating maximum concentration)
origin of substances, research and develop history, foreign application status	origin of substances, research and develop history	○	○	○
	foreign application status	○	○	○
	Characteristic comparison information	○	○	○
Characteristics, specification of analysis	Chemical structure	○	×	×
	Physical/chemical Characteristics	○	×	×
	specification and method of analysis	○	○	○
Stability test	Long-term test	○	○	○
	Stress test	○	○	○
	Acceleration test	○	○	○
Safety test report	Acute toxicity test	○	△	△
	subacute toxicity test	○	△	△
	Chronic toxicity test	○	△	△
	Local sensitizing test	○	△	△
	Antigenicity test	○	△	×
	*Mutagenicity test	△	×	×
	*Carcinogenicity test	△	×	×
*Reproductive toxicity test	△	×	×	
Test report of Absorption, Distribution, Metabolism, Excretion	Absorption	△	△	△
	Distribution	△	△	△
	Metabolism	△	△	△
	Excretion	△	△	△
Purpose-related information	Functionality or efficacy data	○	○	○
	Human test data	○	○	○
	Approval document Of other country	△	△	△

Notes :

1. 「○」means that the information under that item shall be provided.「△」means that it depends via a case-by-case basis. 「×」 means that the information under that item is not necessary to be provided.
2. 「Foreign application status」 : No need to provide if developed domestically.
3. 「Test specifications and results」 : Including materials and preparations.
4. 「Stability test」 :Including materials and preparations. No need to provide preparations for the ones bearing 「*」 mark.
5. Antigenicity tests shall include skin allergen tests and photoallergic tests; local irritation tests shall include skin irritation tests and mucosal stimulation tests.
6. Operation of stability tests may refer to international guideline or 「Guidelines on the Drug Stability Study」as announced by the central health competent authority °
7. To conduct safety evaluation of cosmetics or cosmetic ingredients, cosmetics businesses shall comply with paragraph 4 and paragraph 6 of article 6 of the Act.