

6 August 2025

To whom it may concern

AAK-PC products and TGA status:

Australia operates with two kinds of sunscreen products: primary and secondary.

Primary sunscreens (products used primarily for protection from UV radiation, and with an SPF of 4 or more) are regulated as therapeutic goods by the TGA.

Some secondary sunscreens (those with a primary purpose other than sun protection but also containing suncreening agents) are regulated as therapeutic goods. These products include:

- moisturisers containing sunscreen and an SPF greater than 15

Primary sunscreens and the secondary sunscreens defined as above are regulated as therapeutic goods by TGA, hence requiring the use of ingredients approved by TGA.

The appendices 1-4 summaries the AAK-PC products with respect to their TGA status.



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Appendix 1

Product	Code	EU INCI	CAS number	TGA listed (Australian Approved Names List for Therapeutic Substances)
Akocare Coconut Oil	7716	Cocos Nucifera	8001-31-8	Yes
Akofine P™	7481	Elaeis guineensis	8002-75-3	Yes
Akofine P™	7481	Hydrogenated Vegetable Oil	68334-28-1	Yes, with no CAS
Akofine R™	7169	HYDROGENATED RAPESEED OIL	84681-71-0	Yes. Fully hydrogenated rapeseed oil is acceptable on toxicological grounds as a topical excipient for dermal use (over the counter medicines): • at concentrations not above 5.0 % in the final formulation, • not in topical products intended for use on damaged skin or in the eye.
Akofine R™	7169	Hydrogenated Vegetable Oil	68334-28-1	Yes, with no CAS
Akogel		Cocos nucifera (and) Glycine soja (and) Elaeis guineensis (and) Canola Oil	8001-31-8 (and) 8001-22-7 (and) 8002-75-3 (and) 120962-03-0	Yes, all CAS
Akogel Plus		Cocos nucifera (and) Glycine soja (and) Elaeis guineensis (and) Canola Oil	8001-31-8 (and) 8001-22-7 (and) 8002-75-3 (and) 120962-03-0	Yes, all CAS
Akogel Plus™	8074	Hydrogenated Vegetable oil	68334-28-1	Yes, with no CAS
Akogel™	8080	Hydrogenated Vegetable oil	68334-28-1	Yes, with no CAS
Akomed R™	8652/8510	Caprylic/Capric triglyceride	73398-61-5	Yes
Akosoft 36™	8547	Hydrogenated Coco-glycerides	91744-42-2	Yes. For dermal use only, the concentration of the ingredient is not to exceed 3% and is not to be used in topical products intended for use in the eye (over the counter medicines).
Akosun™	8553	Helianthus Annuus hybrid oil	8001-21-6	Yes
High Oleic Brassica Oil™	6200	BRASSICA CAMPESTRIS (RAPESEED) SEED OIL	8002-13-9	Yes, with CAS 185323-46-0
Kristal Special	7002	Hydrogenated Coconut Oil	84836-98-6	Yes
Kristal™	7001	Cocos Nucifera	8001-31-8	Yes

Appendix 2:

Product	Code	EU INCI	CAS number	TGA listed (Australian Approved Names List for Therapeutic Substances)
Akoline LC™	8049	Glyceryl Stearate Citrate	55840-13-6	Yes. For dermal use only. The concentration is not to exceed 5%. It is not to be included in topical products intended for use in the eye (over the counter medicines).
Akoline MCM™	8515	Caprylic/capric glyceride	85409-09-2	Yes. Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance in listed medicines. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
Akoline PGPR™	8616	Polyglyceryl-3 Ricinoleate	29894-35-7	Yes
Akoline SL™	8690	Sodium Stearoyl Lactylate	25383-99-7	Yes. Topical use only.

Appendix 3:

Product	Code	EU INCI	CAS number	TGA listed (Australian Approved Names List for Therapeutic Substances)
LIPEX® 102™	8520	Butyrospermum ParkiiButter	194043-92-0	Yes
LIPEX® 109S™	8549	Gossypium HerbaceumSeed oil	8001-29-4	Yes, with no CAS
LIPEX® 120™	8533	Canola Oil	120962-03-0	Yes. The concentration of allyl isothiocyanatefrom all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
LIPEX® 204 TR/FLL		Butyrospermum ParkiiButter	194043-92-0	Yes
LIPEX® 205™	8546	Butyrospermum ParkiiButter	194043-92-0	Yes
LIPEX® 512™	8552	Butyrospermum ParkiiButter	194043-92-0	Yes
LIPEX® Bassol C™	8627	Canola Oil	120962-03-0	Yes. The concentration of allyl isothiocyanate from all ingredients in the product must be nomore than 10 mg/kg or 10 mg/L or 0.001%.
LIPEX® BC™	8076	Hydrogenated Vegetable oil	68334-28-1	Yes, with no CAS
LIPEX® BC™	8076	Glycine soja (and) Elaeis guineensis	8001-22-7 (and) 8002-75-3	Yes, both CAS numbers
LIPEX® CocoaSoft™	8602	Theobroma Cacao SeedButterN	68956-68-3	Yes
LIPEX® CocoaSoft™	8602	Theobroma Cacao SeedButter	8002-31-1	Yes, Theobroma oil
LIPEX® CocoaSoft RA MB™	5071	Theobroma Cacao SeedButter	68956-68-3	Yes
LIPEX® CocoaSoft RA MB™	5071	Theobroma Cacao SeedButter	8002-31-1	Yes, Theobroma oil
LIPEX® IllipeSoft™	8653	Shorea Stenoptera SeedButter	68956-68-3	Yes
LIPEX® Omega3/6™	8628	Olus Oil (and) CamelinaSativa Seed Oil (EU)	68956-68-3	Yes
LIPEX® PreAct™	8563	Canola Oil	120962-03-0	Yes. The concentration of allyl isothiocyanate from all ingredients in the product must be nomore than 10 mg/kg or 10 mg/L or 0.001%.
LIPEX® SMP™	7326	Elaeis guineensis	8002-75-3	Yes
LIPEX® SMP™	7326	Hydrogenated Vegetableoil	68334-28-1	Yes, with no CAS

Appendix 4:

Product	Code	EU INCI	CAS number	TGA listed (Australian Approved Names List for Therapeutic Substances)
LIPEX® Shea WM™	8642	Shea Butter Oleyl Esters	3687-45-4 (and) 225234-14-0	Yes, CAS 3687-45-4 only
LIPEX® SheaClear™	8543	Butyrospermum Parkii Oil	91080-23-8	Yes, with CAS 194043-92-2
LIPEX® SheaLight™	8658	Ethyl oleate (and) Ethyl stearate (and) Ethyl linoleate (and) Ethyl palmitate (and) Butyrospermum Parkii (shea butter) unsaponifiables	111-62-6 (and) 111-61-5 (and) 544-35-4 (and) 628-97-7 (and) 225234-14-0	Yes, with restrictions 111-62-6 and 628-97-7 (in Listed Medicines): Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. Flavour: total flavour concentration ≤ 5%. Fragrance: total fragrance concentration ≤ 1%. 111-61-5 (in Listed Medicines): Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. Flavour: total flavour concentration ≤ 5%. 544-35-4: topical use only.
LIPEX® SheaLight™	8658	Shea butter ethyl esters		Yes, with CAS 1456887-14-1 Restrictions: Shea butter ethyl esters must: (a) Only be used in topical medicines for dermal application; and (b) Not be included in medicines intended for use on broken skin. The total concentration of shea butter ethyl esters in the medicine must not be more than 30%.
LIPEX® SheaSolve™	5046	Shea butter ethyl esters		Yes, with CAS 1456887-14-1 Restrictions: Shea butter ethyl esters must: (a) Only be used in topical medicines for dermal application; and (b) Not be included in medicines intended for use on broken skin. The total concentration of shea butter ethyl esters in the medicine must not be more than 30%.
LIPEX® SheaLuxe TR™	5127	Ethyl Oleate (and) Ethyl Stearate	111-62-6 (and) 111-61-5	Yes, with restrictions 111-62-6 (in Listed Medicines): Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. Flavour: total flavour concentration ≤ 5%. Fragrance: total fragrance concentration ≤ 1%. 111-61-5 (in Listed Medicines): Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. Flavour: total flavour concentration ≤ 5%.
LIPEX® SheaLiquid™ TR	8782	Butyrospermum Parkii Butter	194043-92-0	Yes

Appendix 5:

LIPEX® SheaSoft TR™	7601	Butyrospermum Parkii Butter	194043- 92-0	Yes
LIPEX® SheaSoft™	8660	Butyrospermum Parkii Butter	194043- 92-0	Yes
LIPEX® SheaTris™	8649	Butyrospermum Parkii Butter Extract	91080- 23-8	Yes, with CAS 194043-92-0
LIPEX® Shea™	8599	Butyrospermum Parkii Butter	194043- 92-0	Yes
LIPEX® Shea- U™	8556	Butyrospermum Parkii Extract	91080- 23-8	Yes, with CAS 194043-92-1