

Description of content of Rath products implicated in the Khayelitsha affidavits in the light of Government Notice Nr 559, 15 March 1985

Government Notice Nr 559 states that all oral preparations containing a vitamin (including food supplements, but excluding foodstuffs as defined in Act 54 of 1973), whether alone or in combination with other agents, whether accompanied by a medicinal claim or not, are registrable in terms of Act 101 of 1965 if they contain or exceed per recommended total daily dose any of the respective doses stated in the Notice (or, in the absence of a dosage schedule, the stated dose is contained or exceeded per oral dosage form).

Ingredient	Maximum daily dose as per Notice Nr 559	Labelled maximum dose per day				Maximum dose advised as per affidavits			
		VitaCell ^a	Lysin C ^b drink	Epican forte ^b	Vitacor Plus ^b	VitaCell ^c	Lysin C drink ^d	Epican forte ^e	Vitacor Plus ^f
Vitamin A ^g	5000 IU	nil ^h			1665 IU	nil ^h			4995 IU
Vitamin B1 (thiamine)	5mg	9/4.5mg			7mg	60/30mg			21mg
Vitamin B2 (riboflavin)	5mg	9/4.5mg			7mg	60/30mg			21mg
Vitamin B6 (pyridoxine)	7.5mg	9/4.5mg			10mg	60/30mg			30mg
Vitamin B12	6µg	19.8/9µg			20µg	132/60µg			60µg

^a Two maxima are stated, based on the two different labels seen for VitaCell – in each case the stated dose is 1-3 tablets daily.

^b Doses for Lysin C, Epican forte and Vitacor Plus are as per the Rath web site (<http://store.dr-rath-vitamins.com>) – Lysin C 3 scoops daily, Epican forte 6 capsules per “serving” and Vitacor Plus 1 tablet 3 times a day.

^c Based on a dose of 10 tablets twice a day (as stated by Zondani Magwebu).

^d Based on a dose of 1 scoop twice a day (as stated by Nandipha Ntsholo).

^e Based on a dose of 3 capsules 3 times a day (as stated by Nandipha Ntsholo).

^f Based on a dose of 3 tablets 3 times a day (as stated by Nandipha Ntsholo).

^g Vitamin A is also mentioned in the Schedules, under Schedule 2: “Vitamin A; preparations thereof for injection and oral preparations and mixtures thereof containing more than 10 000 I.U. per recommended daily dose, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.”

^h Labelled as containing beta-carotene 382 IU/190 IU, a precursor of vitamin A (retinol).

(cyanocobalamin)									
Vitamin C (ascorbic acid)	300mg	600/240mg	3060mg ⁱ	710mg	600mg ^j	4000/1600mg	2040mg	1065mg	1800mg
Vitamin D ^k	500 IU	120/60 IU			130 IU	800/400 IU			390 IU
Vitamin E	30 IU	60/30 IU			130 IU	400/200 IU			390 IU
Vitamin K	All doses								
Biotin	400µg	60/30µg			65µg	400/200µg			195µg
Folic acid	800µg	450/225µg			90µg	3000/1500µg			270µg
Niacin	25mg	60/30mg ^l			10mg ^m	400/200mg			30mg
Pantothenic acid	5mg	30/15mg ⁿ			40mg	200/100mg			120mg

As appears from this analysis:

- 1 Epican forte and Lysin C exceed the registrable limit for vitamin C, on the basis of the website dosage alone.

ⁱ Labelled as containing vitamin C “from” ascorbic acid 220mg, calcium ascorbate 400mg, magnesium ascorbate 400mg per scoop – it is not clear whether the stated contents are for the salts or for the vitamin C (ascorbic acid) content provided from those salts. However, the ascorbic acid content alone exceeds the registrable limit of 300mg/day when the powder is taken as labeled (3 scoops daily). Magnesium ascorbate is normally given as a magnesium source in the treatment of hypomagnesaemia.

^j Labelled as containing vitamin C “from” ascorbic acid 230mg, ascorbyl palmitate 170mg, calcium ascorbate 100mg, magnesium ascorbate 100mg per 3 tablets– it is not clear whether the stated contents are for the salts or for the vitamin C (ascorbic acid) content provided from those salts. However, the content of the acid alone will exceed the limit of 300mg/day even if the contribution of the other components is deducted. Ascorbyl palmitate is normally used an antioxidant in food, for which an acceptable daily intake of up to 1.25mg/kg body weight has been set (17th Report of the Joint FAO/WHO Expert Committee on Food Additives. *Tech. Rep. Ser. Wld. Hlth. Org. No. 539*, 1974), as cited in Martindale, The Extra Pharmacopoeia. This remains the current suggested limit (see <http://jecfa.ilsa.org/evaluation.cfm?chemical=ASCORBYL%20PALMITATE&keyword=ASCORBYL%20PALMITATE>)

^k Vitamin D is also listed in the Schedules, under Schedule 2: “Vitamin D; preparations thereof for injection and oral preparations and mixtures thereof containing more than 500 I.U. per recommended daily dose, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947”.

^l Labelled as Vitamin B3 (nicotinate) – niacin and nicotinic acid are synonymous.

^m Also contains 35mg of the amide form (niacinamide) per 3 tablets, hence 105mg per daily dose as told to Nandipha Ntsholo.

ⁿ Labelled as Vitamin B5 (pantothenate).

- 2 Vitacor Plus exceeds the limits for Vitamin B1 (thiamine), Vitamin B2 (riboflavin), Vitamin B6 (pyridoxine), Vitamin B12 (cyanocobalamin), Vitamin C (ascorbic acid), Vitamin E and Pantothenic acid, on the basis of the website dosage alone.
- 3 According to the affidavit of Nandipha Ntsholo, the verbally recommended doses of Vitacor Plus was 3 times the labelled dose (3 tablets 3 times a day), while the verbally recommended dose of Epican forte was 1.5 times higher than the labelled dose (3 capsules 3 times a day, rather than 6 capsules per “serving”).
- 4 Two examples of VitaCell have been recovered from patients. The labelled contents of one version exceed the limits for Vitamin B1 (thiamine), Vitamin B2 (riboflavin), Vitamin B6 (pyridoxine), Vitamin B12 (cyanocobalamin), Vitamin C (ascorbic acid), Vitamin E, Niacin and Pantothenic acid, if taken as labelled as a maximum of 3 tablets daily. However, an affidavit by Zondani Magwebu states that a dose of 10 tablets twice a day was prescribed to her. Xolisa Magwebu states that she was told to take 2 tablets 3 times a day of the same product.

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