

**Taking of samples**

28. (1) An inspector may take a sample or any quantity of samples of a medicine or substance for purposes of testing, examination or analysis in terms of the Act, or for any other investigational purposes, by a designated person.
- (2) The sample or samples contemplated in sub-regulation (1) must—
- (a) be taken in the presence of the person who is in charge of such medicine or substance, or in the absence of such person, in the presence of any witness present;
  - (b) be taken and stored in such a manner as to ensure its integrity during the entire examination process of the sample;
  - (c) be packed and sealed and suitably labelled or marked in such a manner as its nature may permit and must be transmitted by any suitable means to the designated person together with the certificate signed by the inspector, a copy of which must be issued to the person contemplated in paragraph (a) by the inspector at the earliest possible time.
- (3) A sample or samples contemplated in sub-regulation (1) must as soon as possible be tested, examined or analysed and a report of the results thereof be submitted to the Registrar.
- (4) An inspector referred to in sub-regulation (1) may take a sample during a routine inspection from a manufacturer, a wholesaler, practitioner, therapist or retailer for testing, examination or analysis in terms of these regulations.
- (5) Notwithstanding sub-regulation (1), the Council may require any applicant or holder of a certificate of registration for a medicine or substance or substance to supply the Council with a sample of a particular medicine or substance, or documentation relating to the medicine or substance, in order to test, examine or analyse such sample.
- (6) Certificates or reports issued in terms of this regulation must be submitted to the Registrar within seven days from the date of issue.

**Seizure of CAMS**

29. (1) A CAMS may be seized if it—
- (a) is unregistered or does not have an allocated application number and is being sold in contravention of the Act;

- (b) is suspected counterfeit;
  - (c) is misbranded;
  - (d) has expired;
  - (e) is suspected stolen;
  - (f) is scheduled and is possessed by an unauthorised person or by an authorised person but in unauthorised quantities;
  - (g) has been declared undesirable in terms of the Act;
  - (h) belongs to the State and is found in possession of an unauthorised person; or
  - (i) is used in an unauthorised clinical trial.
- (2) An inspector seizing any item shall as soon as possible, and at the scene of seizure, make a written inventory of all items seized and the inventory shall include—
- (a) the date, place and time of seizure;
  - (b) the name and personal details of the person from whom the items were seized;
  - (c) the name and quantity of every item seized; and
  - (d) the name of the inspector conducting the seizure.
- (3) An seized item may be used as evidence in any criminal proceedings in terms of the Act.

#### **Offences and penalties**

30. (1) Any person who fails to comply with, or contravenes the provisions of or wilfully furnishes incorrect information in respect of
- (a) Regulation 10 with regard to labelling;
  - (b) Regulation 11 with regard to package inserts;
  - (c) Regulation 12 with regard to the patient information leaflet;
  - (d) Regulation 13 with regard to the marketing;
  - (e) Regulation 14 with regard to advertising;
  - (f) Regulations 15 and 16 with regard to importation;
  - (g) Regulation 16 with regard to exportation;
  - (h) Regulation 17 with regard to possession;
  - (i) Regulation 18 with regard to the prescription book;
  - (j) Regulation 22 with regard to the destruction of medicines;
  - (k) Regulation 23 with regard to the conduct of trials;
  - (l) Regulation 24 with regard to the licence to compound or dispense;
  - (m) Regulation 25 with regard to the licence to manufacture, act as a wholesaler or a distributor,

shall be guilty of an offence and upon conviction be liable to a fine, or to imprisonment for a period not exceeding 10 years.

- (2) Generally any person who fails to comply with, or contravenes the provisions of, or wilfully furnishes incorrect information in respect of these regulations, or sells adulterated, counterfeit, unregistered, expired medicines or substances without an application number allocated to him, shall be guilty of an offence and upon conviction be liable to a fine or to imprisonment for a period not exceeding 10 years.

#### **Guidelines**

31. (1) The Council shall determine the guidelines for the evaluation of the safety, efficacy and quality of CAMS and shall publish such guidelines in the *Gazette*.

#### **Commencement**

32. These regulations shall come into operation twelve months from the date of publication.



**ME TSHABALALA-MSIMANG**

**MINISTER OF HEALTH**

No. R. 870

22 August 2008

**MEDICINES AND RELATED SUBSTANCES ACT, 1965****SCHEDULES ON COMPLEMENTARY AND ALTERNATIVE MEDICINES  
MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES  
ACT, 1965 (ACT NO. 101 OF 1965): AMENDMENT**

The Minister of Health, on the recommendation of the Medicines Control Council intends, in terms of section 22A(2) of the Medicines and Related Substances Act, 1965, (hereinafter referred to as "the Act") to make the Schedules in the Schedule.

Interested persons are invited to submit, within three months from the date of publication of this notice, comments on the proposed Schedules to the Director-General: Health (for the attention of the Cluster Manager: Medicines Regulatory Affairs) Private Bag X828, PRETORIA, 0001.

## SCHEDULE

ANTHROPOSOPHY						
SCHEDULE 0						
APPROVED NAME	Synonym/ Abbreviation Code/ Pin Yin Name for Plant	COMMON NAME	Lowest potency permitted for Anthroposophical and Homoeopathic substances	Upper potency - Label warning to appear between lowest potency and upper potency	Upper allowable Potency	
Abies alba			2		30	
Abies sibirica	Picea		7 % P	4	30	
Acetum vini			1	4	30	
Achillea millefolium	Millefolium		P	1	30	
Acidum benzoicum e resina			1	2	30	
Acidum cholalicum			4		30	
Acidum formicae			6	4	30	
Acidum formicum			6		30	
Acidum hydrochloricum			2	6	30	
Acidum hydrofluoricum			6	8	30	
Acidum lacticum			1 %	2	30	
Acidum nitricum			1,1 %	6	30	
Acidum phosphoricum			2	3	30	
Acidum sulphuricum			2	6	30	
Acidum tannicum			0,125 %	3	30	
Acidum tartaricum			3		30	
Acidum uricum			4		30	

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Aconitum napellus			1	6	30
Aconitum napellus Plumbo cultum			3	6	30
Acorus calamus	Calamus	Calamus aromaticus	0	3	30
Adenohypophysys			4	8	30
Adonis vernalis			0	4	30
Aesculinum			4	6	30
Aesculus hippocastanum			1	1	30
Aethiops antimonialis			3	8	30
Agaricus bulbosus			6	6	30
Agaricus muscarius			3	4	30
Agathosma betulina	Buchu		P	1	30
Agnus castus	Vitex- Agnus Castus		2	1	30
Agropyron repens			3		30
Alkali comp			3		30
Allium cepa	Cepa		1		30
Allium sativum			1	1	30
Aloe ferox			2	1	30
Althaea officinalis			0,6 % P	MT	30
Alumen	Aluminium Potassium Sulphuricum		3	4	30
Alumen chromicum			4	4	30
Alveoli dentales			5		30

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Amanita caesarea			6	4	30
Amaryllis hippeastrum			6		30
Ambra grisea			3		30
Amethyst			6		30
Ammi visnaga			0		30
Ammonium carbonicum			3	3	30
Amnion			5		30
Amygdalae amarae			2		30
Anacardium orientale			3	6	30
Anagallis arvensis			0		30
Anamirta cocculus	Cocculus		3	4	30
Ananassa comosus			2		30
Angelica archangelica			10 % P		30
Anhalonium			3	4	30
Anhydrite			2		30
Anis-Pyrit			2	4	30
Anthyllis vulneraria			0		30
Antimonite			2	4	30
Antimonite magnetised			Ext		30
Antimonium crudum			2	3	30
Anus			5		30
Aorta abdominalis			5		30

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Aorta thoracica			5		30
Aorta (tota)			5		30
Apatite			3	6	30
Apis cum Levistico			1	7	30
Apis mellifica			1	7	30
Apis regina			2	7	30
Apisinum			5	7	30
Apocynum cannabinum			1	3	30
Appendix vermiformis			4		30
Aqua maris			1		30
Arachis hypogaea			6		30
Aragonite			3		30
Aralia racemosa			1	1	30
Arandisite			6	3	30
Aranea diadematus		Aranea diadema	3	6	30
Arcus aortae			5		30
Argentite			4		30
Argentum - Corpus vitreum			6		30
Argentum arsenicosum			6	6	30
Argentum carbonicum			0,0000005 %	3	30
Argentum colloidal			3	6	30
Argentum metallicum			3		30



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Argentum naturale			3		30	
Argentum nitricum			3	6	30	
Argentum sulphuratum			6		30	
Aristolochia clematidis			10	11	30	
Arnica - Cerebrum			6	7	30	
Arnica montana			20 % P	7	30	
Arsenicum album			4	6	30	
Arsenopyrite			4	6	30	
Arsenum iodatum			4	7	30	
Arsenum naturale			6	8	30	
Artemisia abrotanum			0	1	30	
Artemisia absinthium			P	4	30	
Artemisia cina	Cina		2		30	
Arteria basilaris			5		30	
Arteria brachialis			5		30	
Arteria carotis communis et sinus caroticus			5		30	
Arteria carotis externa			5		30	
Arteria carotis interna			5		30	
Arteria cerebri media			5		30	
Arteria coronaria			5		30	
Arteria et vena ophthalmica			5		30	

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Arteria femoralis			5		30
Arteria ilenalis			5		30
Arteria mesenterica superior			5		30
Arteria pancreaticoduodenales			5		30
Arteria poplitea			5		30
Arteria pulmonalis			5		30
Arteria renalis			5		30
Arteria tibialis posterior			5		30
Arteria vertebralis			5		30
Arteriae			5		30
Articulatio coxae			5		30
Articulatio cubiti			5		30
Articulatio genus			5		30
Articulatio humeri			5		30
Articulatio interphalangea			10		30
Articulatio radiocarpea			5		30
Articulatio sacroiliaca			5		30
Articulatio subtalaris			4		30
Articulatio talocalcaneonavicularis			5		30
Articulatio talocruralis			4		30
Articulatio temporomandibularis			5		30
Articulationes intercarpeae			5		30

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Articulationes intervertebr. cervicales			5		30
Articulationes intervertebr. lumbales			5		30
Arum maculatum			2	2	30
Arum triphyllum			2	1	30
Asa foetida			2	1	30
Asclepias tuberosa			2	3	30
Aspidium filix-mas			4,5 % P	4	30
Aspidosperma quebracho-bianco	Quebracho		2		30
Astragalus exscapus			3		30
Atlas			5		30
Atropa belladonna			0	6	30
Atropinum sulphuricum			3	6	30
Aurum chloratum			4	4	30
Aurum chloratum natronatum			4	6	30
Aurum iodatum			4	6	30
Aurum metallicum			2	4	30
Aurum naturale			3	4	30
Aurum sulphuratum			6	3	30
Avena sativa			50 % P		30
Axis			5		30
Balsamum copaivae			4	6	30
Bambusa viridiglaucescens	Bambusa		3		30

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Baptisia tinctoria			2		30	
Barium citricum			3		30	
Barium iodatum			3	6	30	
Barysilite			6	8	30	
Baryta carbonica			3	6	30	
Baryte			3	6	30	
Bellis perennis			3		30	
Benzoe			Ext	2	30	
Berberis aquifolium			1		30	
Berberis vulgaris			0		30	
Berthierite			6	3	30	
Betonica officinalis			3		30	
Betula pendula			100 % P		30	
Bismutum metallicum			1	6	30	
Bismutum subnitricum			2	6	30	
Borago officinalis			0	0	30	
Boswellia carteri	Olibanum		0		30	
Boswellia sacra resin	Olibanum		0		30	
Brainstem			4		30	
Brainstem Stibio tractatus			4		30	
Brassica nigra			Ext	4	30	
Bronchi			4		30	

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Bronchioli			5		30
Bryonia cretica spp. dioica			1		30
Bryophyllum Argento cultum			2		30
Bryophyllum Mercurio cultum			2		30
Bufo Rana			3	6	30
Bulbus olfactorius			5		30
Bursae articulationis coxae-komplex			5		30
Bursae articulationis cubiti-komplex			5		30
Bursae articulationis humeri-komplex			5		30
Bursae praepatellares-komplex			5		30
Calcareo fluorica			6	6	30
Calcareo formicica			2		30
Calcareo jodata			3	6	30
Calcareo phosphorica			4		30
Calcium carbonicum cum quercu			12		30
Calcium carbonicum e cinere ossium			2		30
Calcium hypophosphorosum			3		30
Calcium lacticum			10 %	4	30
Calcium metallicum			3		30
Calcium metallicum oxydatum			3		30
Calcium Oxide			P		30
Calcium phosphoricum			4		30

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Calcium silicicum comp			4	7	30
Calcium sibiato-sulfuratum			4	4	30
Calendula officinalis			P	1	30
Caix jurassica			3		30
Campanula rotundifolia			3		30
Cantharis vesicatoria			2	4	30
Capsella bursa-pastoris			20 % P	1	30
Capsicum annuum			2	3	30
Capsula fibrosa (gld. thyreoid)			5		30
Capsula fibrosa (ren)			4		30
Caramel			2		30
Carbo animalis e Sanguine			2		30
Carbo animalis ex Ossibus			3		30
Carbo Betulae cum Methano			2		30
Carbo vegetabilis			100 %		30
Cardia			5		30
Carduus benedictus			1		30
Carex arenaria			Ext		30
Carica papaya			3		30
Carneol	Carnelian		8		30
Cartilago articularis			4	7	30
Cartilago articularis (Coxae)			4	7	30

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Cartilago articularis (Genus)			4	7	30
Cartilago articularis (Humeri)			5	7	30
Carum carvi			10 % P		30
Cassia angustifolia	Senna		1	4	30
Cassiterite			2	3	30
Catoptrite			4	3	30
Caulophyllum thalictroides			2	3	30
Causiticum Hahnemanni			3	2	30
Cavum tympani			5		30
Cephaelis ipecacuanha	Ipecacuanha		1		30
Cera flava	Cera	Bees wax	5 %	1	30
Cerebellum			3		30
Cerebellum Sibio tractatum			4		30
Cerebrum			5		30
Cerebrum, regio motorica			5		30
Cerite			4	6	30
Cerussite			4	8	30
Cervix uteri			5		30
Cetraria islandica			P		30
Chalcedon	Chalcedony		15		30
Chalcocite			2		30
Chalkopyrite			6		30

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Chamomilla Cupro culta			2	1	30	
Chelidonium Ferro cultum			2		30	
Chelidonium majus			P		30	
Chiasma opticum			6		30	
Chinetum arsenicosum			4	7	30	
Chionanthus virginicus			2		30	
Chlorophyceae			2		30	
Chlorophyllum			Ext		30	
Cholesterinum			3	3	30	
Chrysolite			6		30	
Chrysopenium			2		30	
Chrysopraxe			15		30	
Cichorium intybus			0	1	30	
Cichorium Plumbo cultum			P	1	30	
Cichorium Stanno cultum			1	1	30	
Cimicifuga racemosa			2	1	30	
Cinchona pubescens	China		0	4	30	
Cineraria maritima	Senecio bicolor		2		30	
Cinis Avenae cum Magnesio Phosphorica			0,001 % P		30	
Cinis Capsellae comp			Ext	7	30	
Cinnabar			2	1	30	



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Cinnamomum camphora	Camphora	Camphora officinalis	10 % P	4	30
Cinnamomum ceylanicum			P		30
Circulus arteriosus cerebri			5		30
Cissus - Ossa			3		30
Cissus gongylodes			3		30
Cisterna chyli			5		30
Citrullus colocynthis	Colocynthis		0	3	30
Citrus medica			10 % P		30
Cladonia rangiferina			P	3	30
Clematis recta			3	3	30
Cobaltum chloratum oxydulatum			3	4	30
Cobaltum metallicum			3	6	30
Coccus cacti			2		30
Cochlea			5		30
Cochlearia armoracia			Ext	1	30
Cochlearia officinalis			P		30
Coffea tosta			P		30
Colchicum autumnale			1	6	30
Colliculus seminalis			3		30
Colon			4		30
Colon, ansa distalis			4		30
Columna anterior (Cervicales)			5		30

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Columna anterior (Lumbalis)			5		30
Columna posterior			6		30
Commiphora abyssinica gum resin	Myrrha		3	6	30
Commiphora gum resin	Myrrha		0	3x	30
Commiphora molmol gum resin	Myrrha		0	3x	30
Conchae			100 %		30
Conium maculatum			2	4	30
Conjunctiva			5		30
Connective Tissue			4		30
Convallaria majalis			0	3	30
Cor			3		30
Cor (dextrum)			3		30
Cor (sinistrum)			3		30
Corallium rubrum			3		30
Coriandrum sativum	Coriandrum		1 % P		30
Cornea			5		30
Cornu Cervi			6		30
Corpora cavernosa			5		30
Corpora quadrigemina			5		30
Corpus amygdaloideum			5		30
Corpus luteum			4		30
Corpus striatum			5		30

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Corpus vitreum			4		30
Corpus vitreum - Stannum			4	2	30
Corylus avellana			1	1	30
Crataegus oxyacantha			P	1	30
Creosotum			4	6	30
Crocus sativus			1	3	30
Crotalus terrificus			10	8	30
Cucumis melo			30		30
Cucurbita pepo	Cucurbita		2		30
Cuprammonium Sulphate Monohydrate			4		30
Cuprite			2	6	30
Cupro - Stibium			6	3	30
Cuprum - Ren			4		30
Cuprum aceticum			3	4	30
Cuprum arsenicosum			3	6	30
Cuprum citricum			Ext	4	30
Cuprum metallicum			3	3	30
Cuprum oxydulatum rubrum			2	6	30
Cuprum sulphuricum			2	4	30
Curcuma xanthorrhiza	Curcuma		P	2	30
Cutis (Feti femin.)			4		30
Cutis (Feti masc.)			4		30

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Cutis (Feti)			4		30
Cyclamen europaeum			3	4	30
Cydonia oblonga	Cydonia		P		30
Cynara scolymus			0		30
Cynips quercifolii			4		30
Cytisus laburnum			3	4	30
Cytisus scoparius	Sarothamnus		1	2	30
Datura stramonium	Stramonium		2	6	30
Delphinium staphisagria	Staphisagria		2	9	30
Dens			5		30
Diamond			10		30
Diaphragma			5		30
Diaphragma pelvis			5		30
Diaphragma urogenitale			5		30
Diaspore			3		30
Diencephalon			4	8	30
Diencephalon Sibbio tractatum			4	8	30
Digitalis purpurea			0	6	30
Dioptase			6		30
Dioscorea villosa			2	4	30
Disci intervertebrales (Cervicales)			5	7	30

ANTHROPOSOPHY						
SCHEDULE 0						
APPROVED NAME	Synonym/ Abbreviation Code/ Pin Yin Name for Plant	COMMON NAME	Lowest potency permitted for Anthroposophical and Homoeopathic substances	Upper potency - Label warning to appear between lowest potency and upper potency	Upper allowable Potency	
Disci intervertebrales (Cerv. Thorac et Lumb.)			5	7	30	
Disci intervertebrales (Lumbales)			5	7	30	
Disci intervertebrales (Thoracici)			5	7	30	
Discus intervertebralis embryonalis			2	7	30	
Dolichos pruriens			2		30	
Draba verna			2		30	
Drosera rotundifolia			1		30	
Ductus choledochus			4		30	
Ductus cysticus			4		30	
Ductus deferens			5		30	
Ductus hepaticus			4		30	
Ductus pancreaticus			5		30	
Ductus thoracicus			5		30	
Duodenum			4		30	
Duodenum, pars ascendens			5		30	
Duodenum, pars descendens			5		30	
Duodenum, pars horizontalis			5		30	
Duodenum, pars superior			5		30	
Dura mater encephali			5		30	
Dyscrasite			2	3	30	
Echinacea angustifolia			20 % P	4	30	

## ANTHROPOSOPHY

## SCHEDULE 0

APPROVED NAME	Synonym/ Abbreviation Code/ Pin Yin Name for Plant	COMMON NAME	Lowest potency permitted for Anthroposophical and Homoeopathic substances	Upper potency - Label warning to appear between lowest potency and upper potency	Upper allowable Potency
Echinacea pallida			20 % P	4	30
Echinacea purpurea			20 % P	4	30
Endocardium			4		30
Endometrium			5		30
Ephedra vulgaris			2	3	30
Epididymis (Dextra)			5		30
Epididymis (Sinistra)			5		30
Epiphysis			2	6	30
Equisetum arvense			P		30
Equisetum arvense Silicea cultum			2		30
Equisetum cum Sulfure tostum			1		30
Equisetum limosum			4		30
Erythraea centaureium			0		30
Erythrocytes			5	6	30
Eucaalyptus globulus			10 % P	2	30
Eupatorium cannabinum			1	1	30
Eupatorium perfoliatum			1		30
Euphorbium resinifera			3	4	30
Euphrasia rostkoviana			P		30
Euspongia officinalis	Spongia		0	4	30
Fasciculus atrioventricularis			5		30
Fasciculus opticus			6		30

ANTHROPOSOPHY					
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Fel			5	4	30
Fel Piscis			3	4	30
Fel Tauri			2	4	30
Femur			5		30
Ferric Potassium Tartrate			3		30
Ferrosulfuric Oxide			4		30
Ferrum - Quartz			17 %	1	30
Ferrum arsenicosum			6	8	30
Ferrum chloratum oxydulatum			3	2	30
Ferrum citricum			3	3	30
Ferrum gluconicum			3		30
Ferrum hydroxydatum			1		30
Ferrum metallicum			3		30
Ferrum phosphoricum			2		30
Ferrum pomatum			1		30
Ferrum sesquichloratum			2	2	30
Ferrum sidereum			3		30
Ferrum sulphuricum			75 %		30
Ferrum ustum			3		30
Ferrum / Acidum cholalicum			4		30
Filipendula ulmaria	Spiraea		1		30
Flexura coli dextra			3	3	30

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Flexura coli sinistra			3		30
Flexura duodenojejunalis			5		30
Flint			2		30
Fluorite			6	6	30
Foeniculum vulgare			P		30
Folliculi lymphatici aggregati			5		30
Folliculi lymphatici laryngei			5		30
Formatio reticularis			5		30
Formica parva			6	4	30
Formica rufa			2	4	30
Fragaria vesca			P	1	30
Fucus vesiculosus			P	4	30
Fumaria officinalis			P		30
Funiculus umbilicalis			4	6	30
Galanthus nivalis			4		30
Galea aponeurotica			5		30
Galenit			3	8	30
Gallae			2		30
Gallae Quercus			4		30
Ganglia phrenica			3		30
Ganglion cervicale medium			3		30
Ganglion cervicale superius			3		30



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Ganglion cervicothoracicum			3		30
Gelsemium sempervirens			1	4	30
Genista tinctoria			6		30
Gentiana acaulis			34 % P	1	30
Gentiana lutea			34 % P	1	30
Geranium robertianum			50 %		30
Geum urbanum			0	1	30
Gingiva			4		30
Glacies Mariae			3		30
Glandula lacrimalis			5		30
Glandula parotis			5		30
Glandula sublingualis			5		30
Glandula submandibularis			5		30
Glandula suprarenalis			3	8	30
Glandula suprarenalis dextra			3	8	30
Glandula suprarenalis sinistra			3	8	30
Glandula suprarenalis (cortex)			4	8	30
Glandula suprarenalis (medulla)			5	8	30
Glandula Thymus			3	30	30
Glandula thyroidea			1	8	30
Glandula vestibularis major			3		30
Glandulae parathyreoideae			4	8	30