



WORLD CUSTOMS ORGANIZATION  
ORGANISATION MONDIALE DES DOUANES

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SCIENTIFIC SUB-COMMITTEE

41.665 E

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13th Session

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SC-3

Brussels, 3 December 1997.

CLASSIFICATION OF CERTAIN INN PRODUCTS

(Item II.5 on Agenda)

Reference documents :

40.753 (SSC/12)  
40.870, Annex A/6 (SSC/12 - Report)  
41.100, Annex D/1 (HSC/19 - Report)  
41.141 (SSC/Working Group)  
41.169 (SSC/Working Group)  
41.150, Annex II (SSC/Working Group - Report)

I. REPORT OF THE WORKING GROUP

1. As agreed by the Sub-Committee at its last session, classification of certain INN products was examined by the Working Group which met in June 1997. The products considered by the Working Group consisted of two categories.
2. The first category was with respect to certain INNs covered by WHO lists 1 to 69 (and already included in the WTO Agreement) for which reclassification was proposed by the EC. This was based on the EC's own review of the classifications. The classifications agreed by the Working Group are set out in Part I of Annex II to Doc. 41.150 (Report of the Working Party). In this regard, the Secretariat was asked to indicate the reasons for change in classification of INN products in question. Brief explanations for each item are set out in Annex I to this document.
3. The second category covered INN lists 74 - 76 which are yet to be included in the WTO Agreement (see Part II of Annex II to Doc. 41.150).

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## II. NEW INN LIST 77

4. During the intersession, the Secretariat received from the WHO a new INN list 77 which contain 43 INN products. The list is reproduced in Annex II to this document together with Secretariat proposal concerning the classification of these products. The chemical structures of the products concerned would be made available for reference by delegates during the meeting.

## III. NEW PROPOSAL BY THE EC

5. During the intersession, the EC informed the Secretariat that it had noticed a few more cases of errors in the classification of INNs included in the current WTO Agreement (WHO lists 1-69) and furnished a list of these products indicating the current classification and the proposed classification. The list is set out in Annex III to this document. The EC has also provided the chemical structures of the products concerned and these would be made available for reference by delegates during the meeting.
6. The Secretariat agrees with the classification proposed by the EC on all these products except ferrotrenine. Ferrotrenine is a co-ordination compound with iron as its central atom. Its classification depends on the scope of co-ordination compounds yet to be discussed by the Sub-Committee (see Agenda item II.3).

## IV. PENDING CLASSIFICATION

7. The Sub-Committee, at its 11th Session, postponed the classification of certain INNs (see Annex A/6 to Doc. 40.870, list A) for lack of adequate technical information concerning these products. The Secretariat had asked administrations, the WHO and manufacturers of these products to provide additional information. The list of products along with Secretariat's comments are given at Annex IV to this document.
8. In this regard, the Japanese Administration informed the Secretariat that it analysed polysorbate 21, 40, 60, 61, 65, 80, 81 and 85 (see test results reproduced at Annex V to this document). According to the information from Japan, all of polysorbates except polysorbate 65 meet the criteria as organic surface active agents provided in Note 3 to Chapter 34. The Secretariat, therefore, agrees that all these products (except polysorbate 65) should be classified in subheading 3402.13. The average number of monomer units of polysorbate 65 is 22.6 and therefore it merits classification in subheading 3907.20.
9. With regard to the other products, the Secretariat has not been able to obtain any additional information. The Sub-Committee is invited to re-examine these classification questions on the basis of any additional information from delegates. It is also invited to provide guidance to the Secretariat on how to proceed in the matter of getting required information.

V. CONCLUSION

10. The Sub-Committee is invited to :
- (i) examine the conclusions of the Working Group on the classification of INNs set out at Parts I and II of Annex II to Doc. 41.150, taking into account the information in Annex I to this document;
  - (ii) examine the classification of new INN products listed at Annex II to this document;
  - (iii) examine the classification of INNs listed in the EC proposal at Annex III to this document; and
  - (iii) re-examine the classification of products listed at Annex IV to this document.

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**REASONS FOR CHANGE IN CLASSIFICATION OF CERTAIN INN PRODUCTS**  
**EXAMINED BY THE WORKING GROUP**  
(Part I of Annex II to Doc. 41.150)

<b><u>INN</u></b>	<b><u>Proposed HS code</u></b>	<b><u>Remarks</u></b>
busulfan	2905.39	other diol
treosulfan	2905.49	other polyhydric alcohol
petrichloral	2911.00	hemiacetal
chloralodol	2911.00	hemiacetal
toloxychlorinol	2911.00	hemiacetal
fluindarol	2914.70	halogenated derivative of ketone
isoprednidene	2937.29	glucocorticoid
amadinone	2937.92	progestogen
cloprednol	2937.22	hologenated derivative of adrenal cortical hormone
clofenoxyde	2914.70	halogenated derivative of ketone
quinbolone	2937.99	anabolic steroid
desaspidin	2914.50	ketone-phenol
tocamphyl	2922.19	amino-alcohol
pleuromulin	2941.90	antibiotic
fluocortin	2937.22	hologenated derivative of adrenal cortical hormone
ubenimex	2941.90	antibiotic
thiomersal	2930.90	organo-sulphur compound
mercaptomerin	2930.90	organo-sulphur compound
sodium timerfonate	2930.90	organo-sulphur compound
thiocolchicoside	2939.90	derivative of colchicine
merbromin	2932.99	No possibility of a lactone because of its salt form. (No change in classification)
meralein sodium	2932.99	No possibility of a sultone because of its sulphonate form. (No change in classification)
mefeserpine	2939.90	derivative of reserpine
metergoline	2939.69	derivative of ergot alkaloid
glaziovine	2939.90	alkaloid
rescimetol	2939.90	derivative of reserpine
proterguride	2939.69	derivative of ergot alkaloid
datelliptium chloride	2939.90	derivative of reserpine
retelliptine	2939.90	derivative of ellipticine
teniposide	2938.90	derivative of etopocide
acronine	2939.90	alkaloid
securinine	2939.90	alkaloid
rifabutin	2941.90	antibiotic
disulergine	2939.69	derivative of ergot alkaloid
etisulergine	2939.69	derivative of ergot alkaloid

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## NEW INN LIST 77

INN product	HS code	Remarks
iocanlidic acid	2844.40	
acrezast	2924.29	
aseripide	2934.10	
avotermin	[2934, 2937 or 3001]	Need for more information whether it is a hormone or not.
cedelizumab		
ceftizoxime alapivoxil	2934.10	
celgosivir	2933.90	
clenoliximab	3002.10	
colesevelam	[2934, 2937 or 3001]	Need for more information whether it is a hormone or not.
eniluracil	2933.59	
enlimomab pegol	3002.10	
eplerenone	2932.29	
felvizumab	3002.10	
fudosteine	2930.90	
gavestinel	2933.90	
glufosfamide	[2940.00]	Need for information whether it is a phosphoric ester of sugar.
infliximab	3002.10	
interferon alfacon-1	[3002 or 3504]	Need for more information whether it is a modified immunological product or not.
lanepitant	2933.39	
licostinel	2933.59	
lumefantrine	2922.19	
milacainide	2933.39	
mivobulin	2933.59	
nateglinide	2922.50	
nonacog alfa	[3002]	Need for more information whether it is a modified immunological product or not.
oberadilol	2933.59	
opanixil	2933.59	
orazipone	2935.00	
pegmusirudin	[3504]	Need for more information whether it is protein substances or not.
pifonakin	[3002]	Need for more information whether it is a modified immunological product or not.
pleconaril	2934.90	
pralmorelin	3504.00	
rituximab	3002.10	
rivastigmine	2922.49	
roflumilast	2924.29	
roxifiban	2933.39	
seve lamer		Need for more information concerning the chemical structure of this product..
sibrafiban	2933.39	
tazomeline	2934.90	
trecovirsen		Need for more information concerning the chemical structure of this product..
upenazime	[2925.20]	Need for more information whether it is a derivative of imine.
urokinase alfa	3507.90	

Annex to  
Doc. E

vatanidipine	2933.59	
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**FRESH PROPOSAL BY THE EC FOR AMENDMENTS TO THE HS CODES FOR CERTAIN  
INN PRODUCTS  
(WHO lists 1 - 69)**

<b><u>INN</u></b>	<b><u>Current HS code</u></b>	<b><u>Proposed HS code</u></b>	<b><u>Secretariat comments</u></b>
pafenolol	2924.29	2924.21	Agrees to EC proposal.
pararosaniline embonate	2925.20	3204.13	Agrees to EC proposal.
ferrotrenine	2929.90	2925.20	Depending on the classification of the co- ordination compounds
tolindate	2930.90	2930.20	Agrees to EC proposal.
stibamine glucoside	2931.00	2932.99	Agrees to EC proposal.
thiopental sodium	2933.51	2933.59	Agrees to EC proposal.
sudoxicam	2935.00	2934.90	Agrees to EC proposal.
tetracosactide	2937.29	2937.10	Agrees to EC proposal.
codactide	2937.29	2937.10	Agrees to EC proposal.
tosactide	2937.29	2937.10	Agrees to EC proposal.
giractide	2937.29	2937.10	Agrees to EC proposal.
seractide	2937.29	2937.10	Agrees to EC proposal.
tricosactide	2937.29	2937.10	Agrees to EC proposal.
alsactide	2937.29	2937.10	Agrees to EC proposal.
ethylestrenol	2937.92	2937.99	Agrees to EC proposal.
pentoxifylline	2939.50	2939.90	Agrees to EC proposal.
propentofylline	2939.50	2939.90	Agrees to EC proposal.
pivmecillinam	2941.10	2941.90	Agrees to EC proposal.
bacmecillinam	2941.10	2941.90	Agrees to EC proposal.
brobactam	2941.10	2941.90	Agrees to EC proposal.
betamicin	2941.20	2941.90	Agrees to EC proposal.
propikacin	2941.20	2941.90	Agrees to EC proposal.
etisomicin	2941.20	2941.90	Agrees to EC proposal.
nogalamycin	2941.30	2941.90	Agrees to EC proposal.
sucralox	2942.00	3003.90	Agrees to EC proposal.
glucalox	2942.00	3003.90	Agrees to EC proposal.

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INN PRODUCTS AND PHARMACEUTICAL INTERMEDIATES WHOSE  
CLASSIFICATION WAS POSTPONED AT THE PREVIOUS SESSION

<u>Description</u>	<u>Classification</u>	<u>Secretariat's comments</u>	<u>Additional information required by SSC</u>
Onapristone	[2922.50 or 2937.99]		Depending on the scope of hormones of heading 29.37.
Macrogol ester	[3402.13, 3404.20 or 3907.20]		Need for more information on specific products.
Polysorbates	Polysorbate 60 [3402.13, 3824.90 or 3907.20] Polysorbate 65 [3402.13, 3824.90 or 3907.20] Polysorbate 85 [3402.13, 3824.90 or 3907.20]	Polysorbate 20 3402.13 Polysorbate 21 3402.13 Polysorbate 40 3402.13 Polysorbate 60 3402.13 Polysorbate 61 3402.13 Polysorbate 65 3907.20 Polysorbate 80 3402.13 Polysorbate 81 3402.13 Polysorbate 85 3402.13	According to information from Japan. (see Annex IV)
Tyloxapol	[3402.13 or 3907.20]		Additional information needed regarding pharmacological function.
Aglepristone	[2922.50 or 2937.99]		Depending on the scope of hormones in heading 29.37.
Epoetin epsilon	[Ch. 29, 3002.10 or 3504.00]		In the absence of further information regarding pharmacological function.
Insulin lispro	[2937.99]		Depending on the scope of hormones in heading 29.37.
Teverelix	[2933.39 or 2937.99]		Depending on the scope of hormones of heading 29.37.
Lexacalcitol	[2909.49 or 2936.29]		Need for more information whether it is used as a vitamin, and also whether it is a derivative containing parent structure of vitamin D.
Zinostatin stimalamer	[2941.90 or 3003.20]		Need for more information as to whether it is an antibiotic or a medical preparation.
Taltirelin	[2933.59 or 2937.99]		Need for more information as to whether it is a hormone or a derivative used primarily as hormone.
Lanoteplase	[2934.90, 30.01, 3504.00 or 3507.90]		Need for more information as to whether it is an enzyme, etc.
Tasonermin	[2937.99 or 29.33]		Need for more information as to whether it is a hormone.
Valdaclidine	[2933.90]		Depending on whether it is an antibiotic derivative or not.

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NOTE FROM THE JAPANESE ADMINISTRATION CONCERNING POLYSORBATES

Since at the Scientific Sub-Committee's Twelfth Session, the Sub-Committee reported that further information would be needed regarding the surface activity, etc., for the classification of polysorbates 60, 65 and 85 (Annex A/6 to Doc. 40.870), we obtained 14 samples of polysorbates from Japanese manufacturers and analysed those samples.

We performed the following 7 analyses on these samples.

- (1) Main fatty acid included.
- (2) Solubility (see Note 3(a) to Chapter 34).
- (3) Surface tension (dyne/cm) (see Note 3 (b) to Chapter 34).
- (4) An average of molecular weight using GPC method.
- (5) An average of molecular weight using NMR method.
- (6) An average number of monomer units (ethylene oxide) using GPC method.
- (7) An average number of monomer units (ethylene oxide) using NMR method.

The results are shown in a table, which is set out at Annexe hereto.

Number of polysorbate	Commercial name	Main fatty acid included	solubility	Surface Tension [dyne/cm]	Average of molecular weight		Average Number of monomer units	
					GPC method <sup>1)</sup>	NMR method <sup>2)</sup>	GPC method <sup>1)</sup>	NMR method <sup>2)</sup>
20	Rheodol TW-L120	Lauric acid	o	36.9	1,150	1265	18.3	20.9
	Sorbone T-20	Lauric acid	o	35.6	1,120	1234	17.6	20.2
21	Rheodol TW-L106	Lauric acid	o	29.5	563	510	4.9	3.7
40	Rheodol TW-P120	Palmitic acid	o	39.8	1170	1372	17.5	22.1
	Sorbone T-40	Palmitic acid	o	39.9	1120	1326	16.3	21.0
60	Rheodol TW-S120	Stearic acid	o	41.9	1250	1306	18.6	19.9
	Sorbone T-60	Stearic acid	o	43.6	1470	1625	23.6	27.2
61	Rheodol TW-S106	Stearic acid	o	40.6	745	680	7.2	5.7
65	Rheodol TW-S320	Stearic acid	x	-	1165	1955	<sup>-3)</sup>	22.6
80	Rheodol TW-0120	Oleic acid	o	40.5	1400	1602	22.1	267
	Sorbone T-80	Oleic acid	o	40.5	1390	1333	21.9	20.6
	Polysorbate 80	Oleic acid	o	40.5	1380	1257	21.6	18.8
81	Rheodol TW-0106	Oleic acid	o	35.6	728	621	608	4.4
85	Rheodol TW-0320	Oleic acid	o	34.3	1202	2054	<sup>-3)</sup>	25.0

- 1) Standard substances are polyethylene glycols, the average of molecular weight of which is known.
- 2) <sup>1</sup>H-NMR method using a ratio of peak area between terminal methyl group of fatty acid (CH<sub>3</sub>-) and methylene group of polyethylene oxide (-CH<sub>2</sub>-CH<sub>2</sub>-O-).
- 3) The sample is a mixture of di- and tri-fatty acid esters.

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