



# Implementation of Barcode Labeling of Ethical Drugs in Japan

15 June 2006

The global language of business

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## The Barcode Labeling of Ethical Drugs by GS1-128 & RSS composite symbology

The Japanese ministry of Health and Welfare notified the Pharmaceutical manufacturers industry the document entitled “Standardizing a code system to specify the Ethical Drugs (In hospital use) & Blood products” on 13, September 2005.

March 2006, “Implementation of Bar Code labeling of Ethical Drugs” for preventing accidents of mix-up drugs and assuring traceability has been developed.

The three medical industry group will begin the source marking by the GS1-128 bar code and RSS composite symbology by these ministry’s Notification documents.

The medical industry group are,

- Japan Federation of Pharmaceutical Industry Associations (≒1,500members)
  - The Association of Dental manufacturers & Distributers in Japan
  - The Association of Blood products manufacturers in Japan
- **July 2006, The source marking guidelines (manuals) will issued.**
- **The time limit of source marking is 2 years.**

# Labeling items & data to be indicated (1) Formulation (unit dose) package unit

Labeling items shall be **ethical drugs (In hospital use)**.

A product code (GTIN) , expiration date, manufacturing No. or code and quantity shall be indicated as mentioned below according to the unit of packaging forms

And types of ethical dugs (Note 1, Page 6).

## (1) Formulation (unit dose) package unit (Note 2)

(Note 6)

Type of ethical drug <sup>o</sup>	Product code <sup>o</sup>	Expiration date <sup>o</sup>	Manufacturing No. or code <sup>o</sup>
Specific biological product <sup>o</sup>	⊙ <sup>o</sup>	⊙ <sup>o</sup>	⊙ <sup>o</sup>
Biological product (excluding specific biological products) <sup>o</sup>	⊙ <sup>o</sup>	○ <sup>o</sup>	○ <sup>o</sup>
Oral medicine (excluding biological products) <sup>o</sup>	⊙ <sup>o</sup>	○ <sup>o</sup>	○ <sup>o</sup>
Injection (excluding biological products) <sup>o</sup>	⊙ <sup>o</sup>	○ <sup>o</sup>	○ <sup>o</sup>
External medicine (excluding biological products) <sup>o</sup>	⊙ <sup>o</sup>	○ <sup>o</sup>	○ <sup>o</sup>

⊙: shall be indicated (essential indication) , ○: not necessary (voluntary indication)

### (2) Marketing (inner) package unit (Note 3)

Type of ethical drug <sup>⓪</sup>	Product code <sup>⓪</sup>	Expiration date <sup>⓪</sup>	Manufacturing No. or code <sup>⓪</sup>
Specific biological products <sup>⓪</sup>	⓪ <sup>⓪</sup>	⓪ <sup>⓪</sup>	⓪ <sup>⓪</sup>
Biological products (excluding specific biological products) <sup>⓪</sup>	⓪ <sup>⓪</sup>	⓪ <sup>⓪</sup>	⓪ <sup>⓪</sup>
Oral medicine (excluding biological products) <sup>⓪</sup>	⓪ <sup>⓪</sup>	○ <sup>⓪</sup>	○ <sup>⓪</sup>
Injection (excluding biological products) <sup>⓪</sup>	⓪ <sup>⓪</sup>	○ <sup>⓪</sup>	○ <sup>⓪</sup>
External medicine (excluding biological products) <sup>⓪</sup>	⓪ <sup>⓪</sup>	○ <sup>⓪</sup>	○ <sup>⓪</sup>

⓪: shall be indicated (essential indication), ○: not necessary (voluntary indication)

Additional data



### (3) Logistics (outer) package unit (Note 4)

Type of ethical drug <sup>⓪</sup>	Product code <sup>⓪</sup>	Expiration date <sup>⓪</sup>	Manufacturing No. or code <sup>⓪</sup>	Quantity (Note 5) <sup>⓪</sup>
Specific biological products <sup>⓪</sup>	Ⓢ <sup>⓪</sup>	Ⓢ <sup>⓪</sup>	Ⓢ <sup>⓪</sup>	Ⓢ <sup>⓪</sup>
Biological products (excluding specific biological products) <sup>⓪</sup>	Ⓢ <sup>⓪</sup>	Ⓢ <sup>⓪</sup>	Ⓢ <sup>⓪</sup>	Ⓢ <sup>⓪</sup>
Oral medicine (excluding biological products) <sup>⓪</sup>	○ <sup>⓪</sup>	○ <sup>⓪</sup>	○ <sup>⓪</sup>	○ <sup>⓪</sup>
Injection (excluding biological products) <sup>⓪</sup>	○ <sup>⓪</sup>	○ <sup>⓪</sup>	○ <sup>⓪</sup>	○ <sup>⓪</sup>
External medicine (excluding biological products) <sup>⓪</sup>	○ <sup>⓪</sup>	○ <sup>⓪</sup>	○ <sup>⓪</sup>	○ <sup>⓪</sup>

Ⓢ: shall be indicated (essential indication), ○: not necessary (voluntary indication)



## Note of labeling items and data

### (Note 1)

“⊙” means those which shall be indicated (essential indication), and “○” means those which are not necessarily indicated (voluntary indication).

### (Note 2)

The formulation package unit refers to the smallest unit of the package of drugs marketed by marketing business license holders; i.e. a PTP sheet and pill bottle for tablets and capsules, and an ampoule and vial for injections.

### (Note 3)

The marketing package unit refers to, in general, the smallest package unit of drugs sold by wholesale distributors to medical institutions; i.e. a box containing 100 formulation package units PTP sheets for tablets and capsules, and a box containing 10 ampoules for injections.

### (Note 4)

The logistics package unit refers to a package unit that several marketing package units are packed by marketing business license holders; i.e. a carton box containing 10 marketing package units of boxes.

### (Note 5)

The quantity refers to the number of marketing package units included in an original package unit.

### (Note 6)

Biological products : Medicine that extraction refinement is done from human and animal



**Conditions:**

Pharmaceutical manufacturers will be allocated a new GS1 company prefix.

New EAN-13 code : "4 5 XXXXXXXX 000 c/d"

Current EAN-13 code : "49 87XXXX00000 c/d"

※ c/d :

Check digit

# Tablets

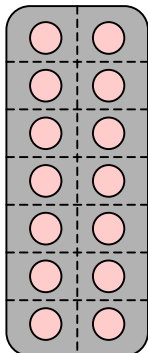
21 tablets sheet

500 tablets bottle

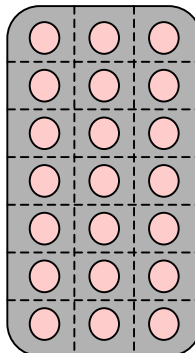
1000 tablets bottle

14 tablets sheet

Product A

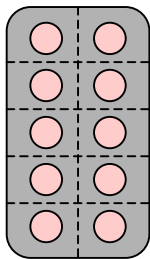


Product A



10 tablets sheet

Product A



< Unit dose

(Individual package) >

(01) 0 45XXXXXXX 555 c/d

Set New EAN-13 & GTIN

45 XXXXXXX 555 c/d or

49 87XXX 55555 c/d

< Unit dose

(Individual package) >

(01) 0 45XXXXXXX 666 c/d

Case of New EAN-13 code

45 XXXXXXX 666 c/d or

49 87XXX 66666 c/d

< Unit dose

(Individual package) >

(01) 0 45XXXXXXX 777 c/d

Case of New EAN-13 code

45 XXXXXXX 777 c/d or

49 87XXX 77777 c/d

< Unit Dose

(Individual bottle) >

(01) 0 45XXXXXXX 888

c/d

Case of New EAN-13 code

45 XXXXXXX 888 c/d or

49 87XXX 88888 c/d

< Unit Dose

(Individual bottle) >

(01) 0 45XXXXXXX 999 c/d

Case of New EAN-13 code

45 XXXXXXX 999 c/d or

49 87XXX 99999 c/d

Unit dose Indicator = "0"



**Conditions:**

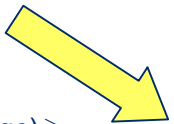
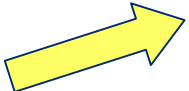
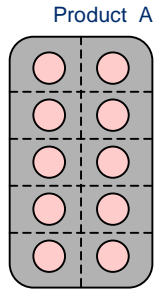
Pharmaceutical manufacturers will be allocated a new GS1 company prefix.

New EAN-13 code : “ 4 5 XXXXXXXX 000 c/d”

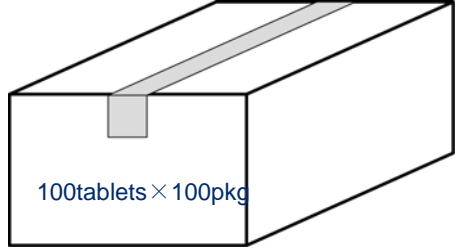
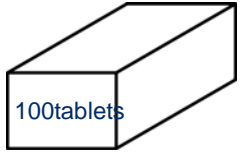
Current EAN-13 code : “ 4 9 87XXX00000 c/d”

※ c/d : Check digit

# Tablets



## 100 tablets sales unit



### < Sales package unit >

(01) **1** 4987XXX 99999 c/d  
Create GTIN from current EAN-13 (49 87XXX 99999 c/d) , and keep using

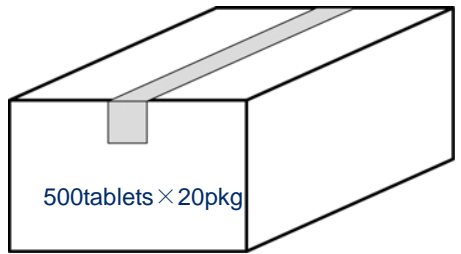
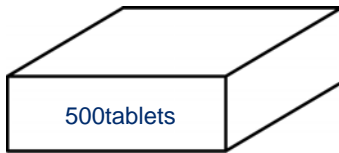
### < Logistics (carton) unit >

(02) **2** 4987XXX 99999 c/d (37 ) 100 C/D  
Create GTIN from current EAN-13 (49 87XXX 99999 c/d) ,and keep using

**Indicator = “1”**

**Indicator = “2”**

## 500 tablets sales unit



### < Sales package unit >

(01) **1** 4987XXX 88888 c/d  
Create GTIN from current EAN-13 (49 87XXX 88888 c/d) ,and keep using

### < Logistics (carton) unit >

(02) **2** 4987XXX 88888 c/d (37 ) 10 C/D  
Create GTIN from current EAN-13 (49 87XXX 88888 c/d) ,and keep using

### < Unit dose

(Individual package) >

(01) **0** 45XXXXXXXX 555 c/d

Set new EAN-13 & GTIN

45 XXXXXXXX 555 c/d or

49 87XXX 55555 c/d

**Indicator = “0”**





**Conditions:**

Pharmaceutical manufacturers will be allocated a new GS1 company prefix.

New EAN-13 code : " 4 5 XXXXXXXX 000 c/d"

Current EAN-13 code : " 4 9 87XXX 000000 c/d"

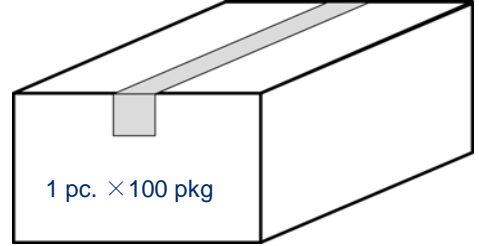
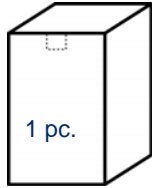
※ c/d :

Check digit

# Vials



## 1 vial sales unit



### < Sales package unit >

(01) 1 4987XXX 22222 c/d

Create GTIN from current EAN-13 (49 87XXX 22222 c/d) , and keep using

**Indicator = "1"**

### < Logistics (carton) unit >

(02) 2 4987XXX 22222 c/d (37 ) 100 C/D

Create GTIN from current EAN-13 (49 87XXX 22222 c/d) , and keep using

**Indicator = "2"**

## < Unit dose

(Individual package)>

(01) 0 4987XXX 11111 c/d

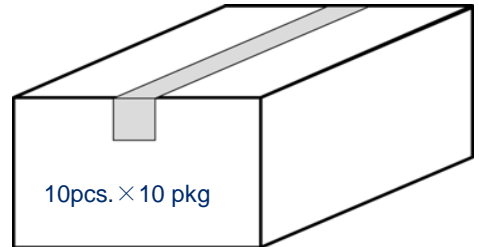
Set new EAN-13 & GTIN

49 87XXX 11111 c/d or

45 XXXXXXXX 111 c/d

**Indicator = "0"**

## 10 vials sales unit



### < Sales package unit >

(01) 1 4987XXX 33333 c/d

Create GTIN from current EAN-13 (49 87XXX 33333 c/d) , and keep using

### < Logistics (carton) unit >

(02) 2 4987XXX 33333 c/d (37 ) 10 C/D

Create GTIN from current EAN-13 (49 87XXX 33333 c/d) , and keep using



**Conditions:**

Pharmaceutical manufacturers will be allocated a new GS1 company prefix.

New EAN-13 code : “4 5 XXXXXXXX 000 c/d”

Current EAN-13 code : “49 87XXX000000 c/d”

※ c/d :

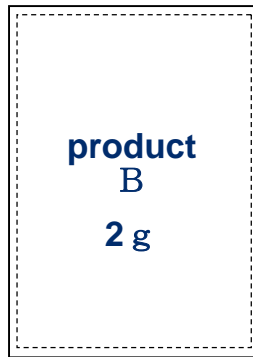
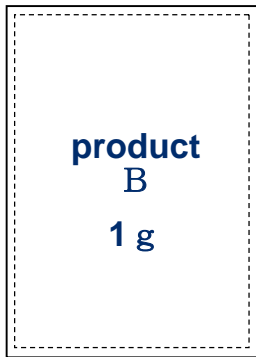
Check digit

# Powder Medicine (granule • powder)

1 g Powder pack

2 g Powder pack

500 g powder bottle



< Unit dose (1 pack each) >

(01) 0 45XXXXXXX 123 c/d

Set new EAN-13 & GTIN

45 XXXXXXX 123 c/d or

49 87XXX 12345 c/d

< Unit dose (1 pack each) >

(01) 0 45XXXXXXX 456 c/d

Set new EAN-13 & GTIN

45 XXXXXXX 456 c/d or

49 87XXX 45678 c/d

< Unit dose (1 bottle each) >

(01) 0 45XXXXXXX 789 c/d

Set new EAN-13 & GTIN

45 XXXXXXX 789 c/d or

49 87XXX 78901 c/d

## Unit dose indicator = “0”



**Conditions:**

Pharmaceutical manufacturers will be allocated a new GS1 company prefix.

New EAN-13 code : "4 5 XXXXXXXX 000 c/d"

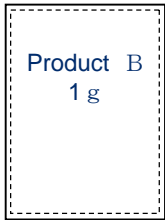
Current EAN-13 code : "49 87XXX000000 c/d"

※ c/d :

Check digit

# Powder Medicine (granule • powder)

Powder pack



< Unit dose (1 pack each) >

(01) 0 45XXXXXXXX 123 c/d

Set new EAN-13 & GTIN

45 XXXXXXXX 123 c/d or

49 87XXX 12345 c/d

**Indicator = "0"**

## 100 packs sales unit

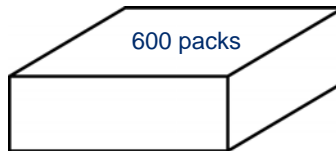


< Sales package unit >

(01) 1 4987XXX 98765 c/d  
Create GTIN from current EAN-13 (49 87XXX 98765 c/d),  
and keep using

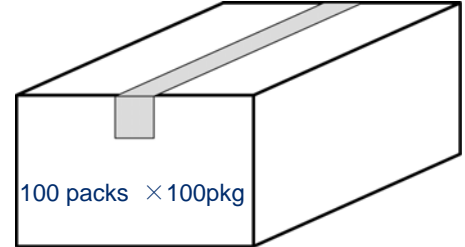
**Indicator = "1"**

## 600 packs sales unit



< Sales package unit >

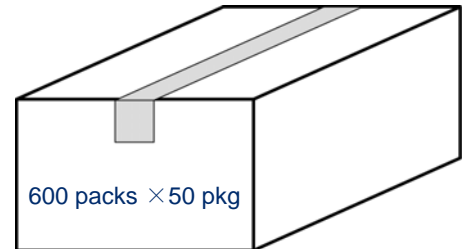
(01) 1 4987XXX 12121 c/d  
Create GTIN from current EAN-13 (49 87XXX 12121 c/d),  
and keep using



< Logistics (carton) unit >

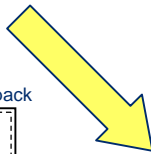
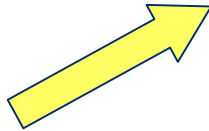
(02) 2 4987XXX 98765 c/d (37 )  
100  
Create GTIN from current EAN-13  
(4987XXX 98765 c/d),  
and keep using

**Indicator = "2"**

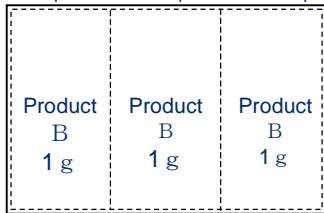


< Logistics (carton) unit >

(02) 2 4987XXX 12121 c/d (37 ) 50  
Create GTIN from current EAN-13  
(4987XXX 12121 c/d), and keep  
using



Powder pack Powder pack Powder pack



Source-marking 1 pc. each



# Source-marking label sample

Unit dose package (Bottles, Cans )

Product Name : AA Tablets 200mg  
Expiration Date : 2005.8.22  
Lot / Batch No. : 123456

## < Sales / Logistics unit >

GTIN : 14987111111111  
EAN-13 : 4987111111114

GS1-128

EAN-13



(01) 14987111111111  
(17)050822(10)123456



4 987111 111114

## < Unit dose >

GTIN : 04511111110008

R S S-14 stack Composite  
symbology

OR

R S S limited Composite symbology

(17) 050822 (10) 123456

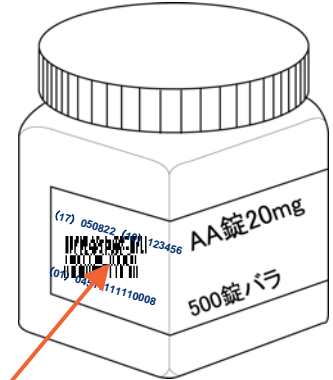


(01) 04511111110008

## < Unit dose >



## < Unit dose >



Sample : R S S-14 stack Composite symbology



# Source-marking

Symbology sample is not actual size.

	Unit dose	Sales unit	Logistics unit
<p><b>Standardized Marking (addition)</b></p> <p>The time limit of source marking is 2 years.</p>	<p>R S S-14 stack Composite symbology OR R S S limited Composite symbology</p>  <p>(01) 04987111111114 (17) 050822 (10) 123456</p> <p>GTIN : 04987111111114 New source-marking New data format</p>	<p>R S S-14 stack Composite symbology OR R S S limited Composite symbology</p>  <p>(01) 14987111111114 (17) 050822 (10) 123456</p> <p>GTIN : 14987111111111 New source-marking New data format</p>	<p>GS1-128</p>  <p>(02) 24987111111111 (17)050822(37)25000(10)123456</p> <p>AI : (02) &amp; (37) GTIN : 24987111111118 New source-marking New data format</p>
<p><b>Current Marking</b></p>	<p>Unit dose</p>	<p>Sales unit</p>	<p>Logistics unit</p>
	<p><b>Marking none</b></p>	<p>Parallel Marking 5 years</p> <p>EAN-13</p>  <p>4 987111 111114</p> <p>EAN-13 : 4987111111114</p>	<p>Parallel Marking 5 years</p> <p>ITF-14</p>  <p>1 4 9 8 7 1 1 1 1 2 3 4 5 9</p> <p>GTIN : 14987111123459</p>



# Appendix

**Label samples,**

**Laser direct marking,**

**Scanners,**

**Verification system,**

### Label samples

RSS stacked  
Composite  
symbology

OR

RSS limited  
Composite  
symbology

Drug treatment label

(In hospital issue)



Ampoule label



Ampoule label



Inner package label



Vaccine label



Inner package label



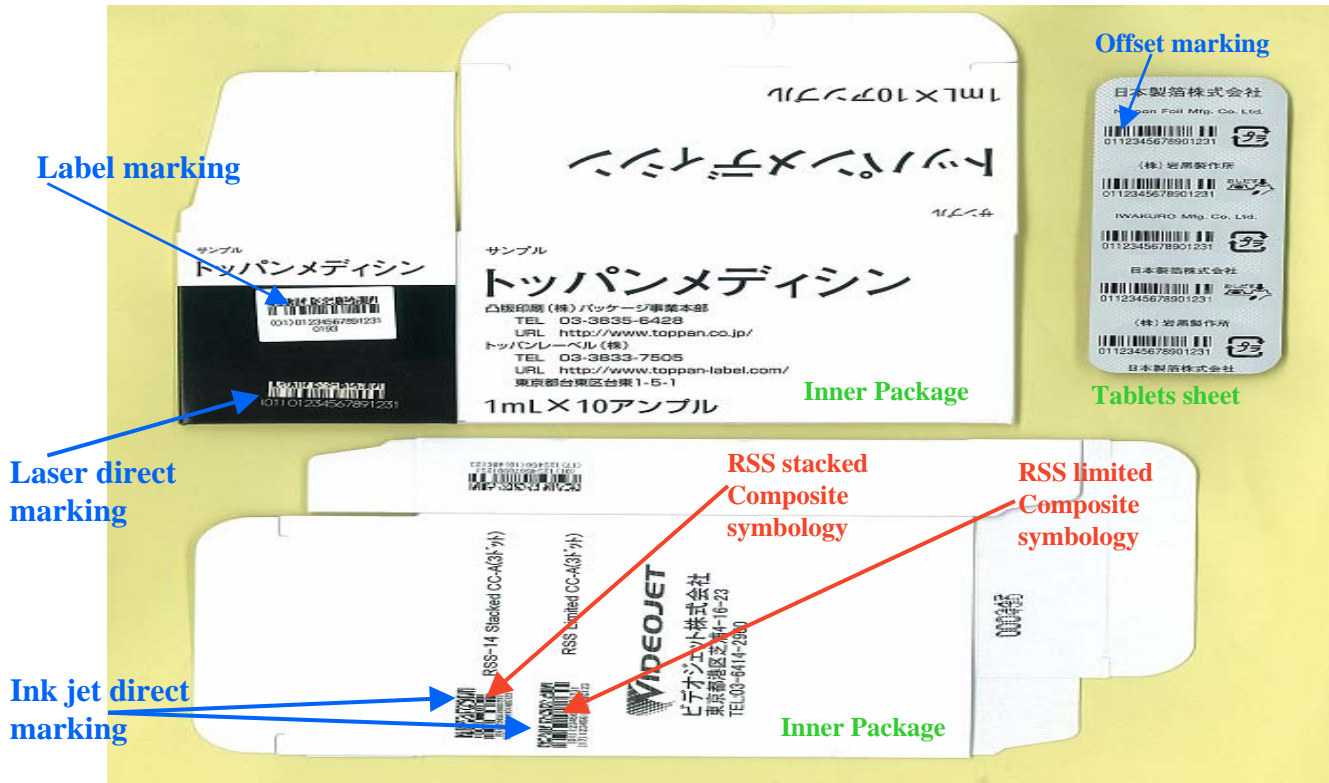
### Tablet sheet marking samples in packaging line



( Aluminium coting films)



### The inner package samples



### The Laser direct marking equipment (label-less marking)

各種RSSコードに対応

RSSコードに加え、  
Composite Component コードも  
標準装備。多様なRSSコードに  
対応が可能です。

RSSコード印字見本



RSS-14



RSS Limited CC-A



# Ampoule Vials



RSS limited  
Composite  
symbology

RSS-14

RSS limited  
Composite  
symbology

CO<sub>2</sub> Gas Laser beam

ヒューマンリーダブルの配置、  
移動もソフトで簡単操作。  
スペースに合わせ  
レイアウトが自在です。

RSSコード



# Appendix

## Label sample, Laser marker, Scanners

### The RSS / Composite Scanners (Handheld & Fixed Mount )



### The In-line (automatic) RSS Verification system



RSS marked Tablets sheet

Laser scanner head

特徴

\*\*\*\*\*  
**Tru in-line**  
 ISO/IEC15415-2004規格適合  
 ISO/IEC15416-2000規格適合  
 EAN/UCC Gen Spec v.6.0-2005規格適合  
 ISO/IEC15426/p1-2000規格適合  
 ISO/IEC15426/p2-2005規格適合  
 JISx0520-2001規格適合

0100354321100155  
 RSS Stacked / CS  
 10mil NB 1.5 BWR  
 Quint Plates/Metronic imprint  
 EXP 01 JAN 05  
 LOT 14B024C

RSS合成(Composite)シンボル



## Contact details

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