

Welcome to the

WHO Drug Dictionary Enhanced

This document is a guide to the general features of the WHO Drug Dictionary Enhanced. You will get information about the structure and content of the dictionary as well as information about some services provided by *the* Uppsala Monitoring Centre (UMC) – the WHO Drug Dictionary Enhanced maintenance organisation.

Some basic facts about the WHO Drug Dictionary Enhanced

The WHO Drug Dictionary Enhanced (WHO-DDE) is the world's most comprehensive dictionary of medicinal product information. It is used by pharmaceutical companies, clinical trial organisations and drug regulatory authorities for identifying drug names, their active ingredients and therapeutic use, in the course of their clinical research. It translates a drug name to useful information which is used for analysis. The dictionary is used for coding and analysing clinical research data – pre- and post-marketing.

The main benefits offered by the WHO-DD are:

- Consistent, quality-assured, and up-to-date information
- A hierarchical structure that allows easy and flexible data-retrieval and analysis at different levels of precision
- Chemical and therapeutic classifications - using the WHO drug record number system and the ATC classification
- Computerised software-independent format for easy implementation in user systems

The hierarchical record number system allows for easy, flexible information retrieval. Drugs are classified according to the Anatomical-Therapeutic-Chemical classification (ATC) which allows for grouping of drugs in different ways for comparison purposes. The dictionary also contains cross-references to market authorization holders and reference sources.

New drug names are routinely classified and added, but at a small cost it is possible to have drugs entered on request within three working days. Drugs are not deleted from the dictionary, although the products may no longer be on the market.

For hundreds of organisations round the world, the WHO -DD is a prime desk-reference for a wide range of tasks. *the* UMC is keen that it should fully meet the needs of all its users (and of users to come), and responds quickly to requests for new entries or to other suggestions for services, tools and modifications which are compatible with the fundamental structure and will enhance its usefulness.

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Content of the WHO Drug Dictionary Enhanced

Drug information has been entered into the WHO database since 1968, as part of the WHO Programme for International Drug Monitoring. The database now covers drugs from over 70 member countries of the Programme and some countries no longer existing (e.g. German Democratic Republic). Historically the drugs that have been recorded are those which have occurred in adverse reaction reports, but as all drugs taken by patients are included (whether they are suspected of having caused the reaction or not), the database covers most drugs used in countries in the Programme. The data is taken from official data from drug regulators, national drug compendia or other trustworthy sources.

An increasing number of companies and regulators submit files with product data when products are launched on the market, which means that the entries get into the dictionary faster. Products and substances registered by the US Food and Drug Administration (FDA) and the European Medicines Evaluation Agency (EMA) are also routinely recorded.

The majority of the entries refer to conventional medicinal products but a number of other types of products are also included, such as herbal remedies, biotech products, blood products, diagnostic substances and contrast media.

The dictionary contains the trade names of tens of thousands of marketed products. The C format contains a growing number of entries containing information about the country in which the product is marketed as well as dosage form and strength. All entries are coded with the ATC classification and with the WHO Drug Dictionary Enhanced coding system which can be used to group all products containing the same active ingredient – or unique combination of substances. The system can also be used to group products with a specific salt or ester form of an ingredient or even with the same product name. This system is described in more detail in the section Codes and IDs. Depending on your organisation's coding protocol you can use the dictionary to code data on different information level. You can code only on drug name level, but if you have access to information about dosage form or strength you can choose to code more detailed information.

The dictionary also contains generic entries – the preferred names. These should be used if you only know the active ingredient of the products you want to code. A few entries are also included with even higher level of information, such as Penicillin NOS (not otherwise specified).

Due to the special coding principles for herbal remedies *the* UMC are introducing a special Herbal Dictionary which codes drugs of natural origin. This dictionary will be a separate product from the WHO DD, but it will follow the same structure and general principles. The dictionary will contain trade names of herbal remedies together with the active ingredients in the form of herbal plants. All products in the WHO Herbal Dictionary will be coded with the Herbal ATC classification.

What You Get

Deliverables

The WHO Drug Dictionary Enhanced is an information service. The data can be imported into your Clinical Data or Adverse Event database system or any other system. To make the dictionary independent of all possible database systems it is delivered in basic flat files.

To get started you need to understand the relationship between the dictionary's different files and the meaning of the different fields. To understand the relationship between the files please look at the document 'Format C -File Diagram'. To understand how to identify the different fields, please look at the document 'Format C File Descriptions'.

The definitions of the different files are described in this document in the section 'Definitions – Main Files'. A description of the different fields is given in the section 'Definitions – Data Fields'.

When you have a clear idea of the content of the dictionary and how you are going to use it you need to map the data to your in-house database system. If you have commercial software you might get support from the software provider on how to do this. *The Uppsala Monitoring Centre* is collaborating with some providers, if you want to know more please contact your provider or *the UMC* – drugdictionary@umc-products.com.

Support

As a subscriber to the WHO Drug Dictionary Enhanced you will have full access to our support services. Support will help you with questions about your files and how to interpret documents and files. You should also report any errors or inconsistency to Support so we can solve the problems. The WHO Drug Dictionary Enhanced Support is manned during European office hours. We suggest that you may find it easier to communicate via e-mail.

New Drug Requests

We provide a service called 'New Drug Request' which makes it possible for customers to propose new entries to the dictionary. This service has two options - regular updates and expedited updates. To enter a drug in the dictionary you need to provide us with some basic facts about the requested drug. If you request a large number of entries you might prefer to enter the request in an electronic Excel format. Contact the UMC for more information.

If you choose the regular service you will get the drug coded in the next quarterly release of the dictionary unless you have provided the information after the production deadline. After you have made a request you will get a reply telling you when you can expect the entry to be added to the dictionary. If a request can't be added because of incorrect information, lack of adequate sources or if it is already coded, you will be informed.

If you choose the expedited service, the UMC will enter the request within three days and the data will be sent to you. The data will also appear in the next quarterly release of the dictionary. For the expedited service we will charge you an hourly fee.

To request an entry please write to newdrugs@umc-products.com.

User Group

As a WHO Drug Dictionary Enhanced user you will be invited to the User Group activities. We have a number of face-to-face meetings per year where we discuss future development and issues and problems with the dictionary or UMC services.

The User Group Portal

A portal dedicated to the WHO Drug Dictionary and WHO Herbal Dictionary users has been set up at <http://usergroup.umc-products.com/>.

The User Group Portal is designed to:

- introduce the WHO Drug Dictionary to new customers
- support experienced customers with the latest updates
- keep a library of articles and documents related to the User Group
- advertise forthcoming User Group Meetings
- provide a forum for discussion among subscribers

We hope you will find this a useful way to keep up-to-date with the WHO Drug Dictionary.

Introduction to the WHO Drug Dictionary Enhanced

The WHO Drug Dictionary Enhanced is a computer register containing information on all drugs mentioned on adverse reaction reports submitted by countries participating in the WHO International Drug Monitoring Programme from 1968 onwards. This makes the WHO Drug Dictionary Enhanced a unique source of drug names from all major pharmaceutical markets - of both single and multiple ingredient drugs.

A new format of the WHO Drug Dictionary has been available since 2002. The new format is known as the C Format and the old formats are known as A and B. Any new customer should implement the C Format.

Notice that the examples used in this document are created to illustrate specific principles. They are not marketed products and the codes and IDs used in the examples may be used in the dictionary for other products.

Sources of substances and drug names

The primary name source for **non-proprietary names** of substances is the International Non-proprietary Names (INN). Alternative sources are publications of nationally approved agencies (e.g. USAN) and well-known reference books, such as the Martindale - The Complete Drug Reference and the Merck Index.

National drug lists, selected by the countries participating in the WHO International Drug Monitoring Programme, or international reference books are used as sources for **proprietary names**, ie trade names of drugs.

Codes and IDs

The WHO Drug Dictionary Enhanced contains a large number of data fields that contain information about the Medicinal Products. This information is used to identify a product that should be coded in a database, e.g. for clinical trial data or drug safety data.

The WHO Drug Dictionary Enhanced contains two types of IDs that can be used as links between the case report in the Clinical trials database/Drug Safety database and the WHO Drug Dictionary Enhanced. The Medicinal Product ID identifies an entry in the dictionary. Many users also implement Drug Code in the case database, for historical reasons and as a way to improve querying performance.

In the new C Format of the dictionary both codes are used.

Medicinal Product ID

The Medicinal Product ID identifies a unique entry in the WHO Drug Dictionary Enhanced. The ID is just a 'numeric name' of the medicinal product and it has no intrinsic meaning. The Medicinal Product ID identifies a unique combination of the following data:

- Medicinal Product Name
- Drug Code (Drug Record Number + Sequence 1 + Sequence 2)
- Name Specifier
- Market Authorisation Holder
- Country
- Dosage form (available as Pharmaceutical Form in the Pharmaceutical Product table)
- Strength (available as amount and unit of active ingredient/s in the Ingredient table)

Example 1:

MP ID	Drug Code	Name	Name Specifier	MAH	Country	Dosage Form	Strength
000001	12345601002	DrugnameAA					
000002	12345601002	DrugnameAA	SR				
000003	12345601002	DrugnameAA		Company1	FRA		
000004	12345601002	DrugnameAA	SR	Company1	FRA		
000005	12345601002	DrugnameAA	SR	Company1	FRA	Tablet	
000006	12345601002	DrugnameAA	SR	Company1	USA	Tablet	
000007	12345601002	DrugnameAA	SR	Company1	FRA	Tablet	500 mg

In the example several entries are available for the drug called DrugnameAA. The entry with Medicinal Product ID 000001 holds only information about the name and the active ingredient(s) – through the Drug Code.

The entry with MP ID 000002 has a name specifier – SR. Entries 000003 – 000007 hold additional information in the different fields, so each entry is given a unique Medicinal Product ID.

Drug Code

The term Drug Code refers to the unique numeric key in the B Format of the dictionary. The B format is the old format of the dictionary and it is a dictionary of Drug Names. A Drug Code identifies a name, either a trade name or a generic Preferred Name. The Drug Code is used also in the C Format, where it is not a unique key but still has the same meaning as in the B Format.

The Drug Code is aggregated from Drug Record Number (Drecno), Sequence number 1 and Sequence number 2. The code differs from the Medicinal Product ID in that it has a meaning. The code is not only a unique identifier of a name – it also gives information about the active ingredient(s) and salt/ester form of the substance.

Drecno. A Drecno identifies a generic identification level. In most cases the generic identification level is the one active ingredient, but it can also identify a unique combination of active ingredients.

Example 2:

MP ID	Drecno	Seq 1	Seq 2	Name
000011	123456	01	001	Ampicillin
000012	234567	01	001	Paracetamol

The two examples above have different Drecnos which means that they contain different active ingredients – Ampicillin and Paracetamol.

Sequence number 1 identifies the salt or the ester of the active ingredient in single ingredient Drecnos. The number '01' identifies the base substance, without any salt or ester, and values above '01' will identify salts and esters. Drecnos that identify more than one active ingredient will have only one Sequence 1 with value '01'.

Example 3 :

MP ID	Drecno	Seq 1	Seq 2	Name
000011	123456	01	001	Ampicillin		
000013	123456	02	001	Ampicillin Sodium		
000014	123456	03	001	Ampicillin Trihydrate		

The three entries all have the same active ingredient – Ampicillin, but in different forms, Sodium and Trihydrate.

Sequence number 2 identifies trade names and in some cases a synonym to a generic name, e.g. Acetaminophen as a synonym to Paracetamol. The entry with Sequence number 2 value '001' identifies the name of the generic Drecno level – the Preferred Name. In single ingredient Drecnos this will be the INN name, in multi ingredient Drecnos it will be the trade name of the first product with the given combination that was entered into the dictionary.

Example 4:

MP ID	Drecno	Seq 1	Seq 2	Name
000011	123456	01	001	Ampicillin
000015	123456	01	002	DrugnameAB
000016	123456	01	003	DrugnameAC
000013	123456	02	001	Ampicillin Sodium
000017	123456	02	002	DrugnameAD
000018	123456	02	003	DrugnameAE

The entries with MP ID 000015 and 000016 both contain Ampicillin in its base form but the entries 000017 and 000018 contain Ampicillin Sodium.

Combination products – products with more than one active ingredient- needs to have a separate coding principle. It is not possible to include the names of all active ingredients in the name field, so the first trade name with the unique combination of ingredients will be the preferred name even though it is not a generic name.

Example 5:

MP ID	Drecno	Seq 1	Seq 2	Name	Generic
000019	345678	01	001	DrugnameAF	N
000020	345678	01	002	DrugnameAG	N

The entries 000019 and 000020 are combination products. The entry with seq 1 = 01 and seq 2 = 001 is the preferred name but it is not generic. The use of the column Generic will be explained in another section.

Generic synonyms are sometimes included in the dictionary.

Example 6:

MP ID	Drecno	Seq 1	Seq 2	Name	Generic
000012	234567	01	001	Paracetamol	Y
000021	234567	01	002	Acetaminophen	Y
000022	234567	01	003	DrugnameAH	N

Acetaminophen is a synonym to Paracetamol. It is a generic name but it is not the preferred name since it is not the name used in the INN standard. The Acetaminophen entry is therefore given a seq 2 higher than 001. The use of the column Generic will be explained in another section.

Use of codes in data analysis and retrieval

The identification levels are useful for querying and analysis of aggregated data.

- The Drecno can be used to identify all products with the same active ingredient(s)
- The Drecno + Sequence number 1 to identify different salts
- The Drecno + Sequence number 1 + Sequence number 2 to identify a trade name.

Versioning

The WHO Drug Dictionary Enhanced is updated on a quarterly basis. Each quarter a large number of drugs are being added to the dictionary, but changes are also made to existing entries. The changes are due to changes in composition, new ATC code assessment or annual ATC revision or modifications of erroneous entries.

Together with the dictionary a log of all changes is distributed. The log helps you identify the changes and make the appropriate actions. This data is available in the folder 'Changes' in the WHO DD distribution package.

The Changes tables contain the following types of changes:

A **list of changed Drug Code** (drug record number, sequence 1 and sequence 2), e.g.. when a product is coded under new salt - Ampicillin changed to Ampicillin Sodium

The list contains the Medicinal Product ID listed together with old and new drug codes.

A **list of deleted Medicinal Product IDs**. In rare cases an entry in the dictionary will be deleted; if an entry has been included with incorrect substance(s) or salt/esters, and if it also appears in the dictionary with the correct composition. In these cases a list will be produced with the old, now deleted Medicinal Product ID and the new.

The list contains the old and the new Medicinal Product ID listed together with the old and the new drug codes.

A **list of changed drug names in the B files**. The drug code is listed together with old and new drug names. Notice that the name of a drug in the B format might be different to the name in the C format.

Changes to ATC codes. The ATC classification is revised on an annual basis. Each year – in the March 1 version- the new version of the classification will come into effect in the WHO DD. A list of these changes is produced which shows changed ATC codes and deleted ATC codes.

The Chemical Abstract System numbers (CAS) are sometimes changed. This happens when a temporary number has been used until an official CAS number is created or when a CAS number is replaced with a Herbal Code Number for herbal remedies.

Changes

When a medicinal product in the dictionary changes its composition or when a misclassification is identified, two things can happen:

- If the product changes composition it will be given a new Drug Code. A table is produced each quarter to notify the users of changes. The table contains the Medicinal Product ID, the old Drug Code and the new Drug Code. If you use the Drug Code as a link to the case reports in the Clinical Trial/ Drug Safety database you need to identify these cases and replace the old Drug Code with the new.
- In rare cases an entry in the dictionary will be deleted; if an entry has been included with incorrect substance(s) or salt/esters, and if it also appears in the dictionary with the correct composition. In these cases a list will be produced with the old, now deleted Medicinal Product IDs and the new. You should identify all case reports that have a link to the old deleted IDs and replace it with the new.

Definitions - Main Files

Medicinal Product

A **Medicinal Product** is a product intended to be administered to human beings or animals for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions. [Definition from the European Economic Community - Directive 65/65 EEC - modified]

This is the main file in which most information about the product is recorded. A Medicinal Product entry represents one product as it is marketed in a specific country. The Medicinal Product file contains the unique identifier and the Trade Name. It also contains information about the company responsible for the product internationally and the company that markets the product in this given country, the Market Authorisation Holder. The concept Name Specifier is often used as a synonym to Strength, but it can also be used for text strings like 'Forte' or 'Sustained Release'. The type of product is also recorded, a majority of the entries are regular medicinal products, but an increasing number of herbal remedies and vaccines are recorded.

Pharmaceutical Product

The WHO Drug Dictionary Enhanced format allows for the use of a two-level structure of the product information. Some medicinal products contain more than one dosage form or more than one type of the same dosage form. For example: a suppository packaged together with a cream; oral contraceptives with three different types of tablets. The two level structure makes it possible to record both the Medicinal Product – the Product Name, Market Authorization Holder etc, and the Pharmaceutical Products with their individual ingredients.

Therapeutic Group

Each Medicinal Product can be coded to one or several Therapeutic Groups. The Therapeutic grouping uses the Anatomical Therapeutic Chemical classification (ATC). For more information about the ATC see the section "Therapeutic Group".

Ingredient

Each Pharmaceutical Product contains one or several Ingredients. In this file there is a link to the Substance database and the amount of each ingredient can be recorded here.

Definitions – Data Fields

Medicinal Product

Medicinalprod_Id /Drug record number /Sequence number 1 /Sequence number 2

For a description of the coding system please see section "Codes and IDs".

Generic

A Yes or No value. A Yes signifies that the drug entry is a generic level – a Preferred Name or a synonym to a Preferred name. E.g. Paracetamol and Acetaminophen are both flagged as generic. See also the example 5 and 6 in the Codes and IDs section.

Drug name

The field Drug Name contains the names of generic products as well as trade names of products. For more information please also read the Codes and IDs section.

Preferred Name

Drugs containing the same active ingredient(s) are found by reference to the Drug Record number, Drecno. The **Preferred name** is the name associated with the Drecno. In the case of single ingredient drugs, the INN (International Non-proprietary Name) in English is the Preferred name, but where no INN exists another non-proprietary name is used.

For multiple ingredient drugs, the first reported Drug Name of a given ingredient combination is chosen as the Preferred name. Any subsequently reported drug having the same combination of ingredients is sorted under the Preferred name. For any chemical substance that is an ingredient in a multiple ingredient drug, reference is given to all Preferred names where this substance is a constituent.

A Preferred Name is the text in the Drug Name field where the Sequence 2 equals '001'.

For more information about the coding system, see the section "Codes and IDs"

Medicinal Product Name

A name used in the identification of a medicinal product. It can be a made up name, a proprietary name or a non-proprietary name. We enter product names as similar to the original name as possible within our principles of coding, eg replacing special characters like ö and ä with oe and ae etc.

A Medicinal Product Name is the text in the Drug Name field where the Sequence 2 is higher than "001".

Additional information in the Name field

Sometimes the same trade name is used in more than one country with different active ingredients. This makes it necessary to differentiate the texts in the name field and this is done by adding the Drug Record Number as a part of the name field. The code will appear in positions 37-44. Slashes will appear in positions 36 and 45.

Example:

DrugnameAI /12345601/

Further investigation is necessary by the coder to find out which of the entries should be used.

Name Specifier

The Name Specifier is an additional element added to the Medicinal Product Name in order to distinguish Medicinal Products with the same Medicinal Product Name.

These Name Specifiers can be based on any possible property of a Medicinal Product, e.g. 'Sustained Release', a reference to dosage form or strength, or even be a proprietary combination of letters and/or numbers.

As a rule, pharmaceutical forms are not included in the Medicinal Product Name. However, in some cases entered in the old system this has been necessary in order to avoid ambiguity, for example where different pharmaceutical forms contain different salts of a substance. In the new system we have Pharmaceutical Form as a separate field.

The concept and the term Name Specified is also taken from the Directive 65/65 EEC.

Country

The country in which the product is marketed.

Company /MA Holder

The recorded Company and Market Authorization Holder of a drug is the one given in the source where the drug name was found. The Marketing Authorisation Holder is in possession of the licence

or marketing authorisation for a Medicinal Product within a given Country. The Company, or Main Company is the owner of the product world-wide. The Company is frequently also the holder of the Market Authorisation of the Medicinal Product.

Source code /Source country /Source year

These fields identifies the source from where the information about the drug entry has been taken. It is a National Drug Compendium or other reliable source. The country of the source and the year of the source are also recorded.

Product type

A Product Type can be a regular medicinal product, a herbal remedy, a vaccine etc.

Product group

The Product Group is a way to group products that are owned by the same company, contain the same substance(s) but are marketed under different names in different countries.

Note that this feature is NOT introduced yet. The file is prepared for the feature and it will be introduced when the User Community prioritises it.

Create date /Date changed

The date when the drug was first entered and the date of the latest change.

Pharmaceutical Product

The new format allows for the use of a two level structure of the product information. Some Medicinal Products contain more than one form, or more than one type of the same form. For example: a suppository is packaged together with a cream; oral contraceptives often contain three different types of tablets. The two level structure makes it possible to record both the Medicinal Product – the product name, Market Authorization Holder etc, and the Pharmaceutical Products with their individual ingredients.

It is however possible to connect the ingredients directly to the Medicinal Product because Medicinal Product ID is included in the Ingredient file.

Pharmaceutical Form

The pharmaceutical form is the form in which a Pharmaceutical Product is presented in a Medicinal Product. It is a synonym to galenic form. The look-up table is based on the New Form Code from EphMRA.

EXAMPLE: tablet, capsule, syrup, suspension, cream.

Number of ingredients

The number of ingredients of this Pharmaceutical Product.

Create date

The date when the Pharmaceutical Product entry was created.

Therapeutic Group

ATC code /Official ATC code

For coding of the therapeutic use of drugs, Anatomical Therapeutic Chemical classification (ATC) is used. Each drug is assigned at least one ATC code. Official ATC codes and instructions for coding are issued by the WHO Collaborating Centre for Drug Statistics Methodology, Oslo Norway.

Drug entries in the WHO Drug Dictionary Enhanced that have not been assigned official ATC codes by the Oslo Centre, have received provisional codes by *the* Uppsala Monitoring Centre staff. In

some instances drugs have been assigned provisional codes in addition to the official ATC codes, to meet the needs for classifications in the WHO Programme. In the C Format official ATC codes are marked by an Y next to the ATC code and ATC codes set by *the* UMC are marked with N. In the old B format the official codes are flagged with a *.

Each Medicinal Product is coded with the ATC code of its most common use. Sometimes more than one is needed but we try to limit the numbers of ATC codes as much as possible. This allows for a more flexible analysis and comparison of the drugs using the ATC classification. By using the ATC code assigned on the Preferred Name level a broader range of indications is covered, whereas using the ATC codes assigned on the product level limits the selection to the individual products for which a particular ATC reflects the product's main use.

For an example, see table below.

Type	Name	ATC code	Use	Form
Preferred Name	Atropine Sulfate	A03BA, S01FA		
Trade name	Atropine NM Pharma	A03BA	Antispasmodic	Injection substance
Trade name	Atropine Novartis	S01FA	Mydriatic and Cycloplegic	Eye drops

For general information about the ATC classification, see the document 'The ATC Classification'.

Create date

The date when the Therapeutic Group entry was created.

Ingredient

Substance_Id

The Ingredient file contains a link to the Substance file in which the name of the Substance can be found.

Only active substances are included (no excipients, colouring agents, filling agents etc.). The distinction between auxiliary ingredients (help substances) and active ingredients is not always clear, and the legislation varies between countries. Therefore auxiliary substances may be coded as active ingredients.

Substances are entered according to the source of information used. Substance names are always given in English.

Quantity /Unit /Strength

The amount/quantity of a substance is entered together with the unit (mg, ml etc).

The Strength is the amount and unit of the active ingredient(s).

Create date

The date when the Ingredient entry was created.



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PROPOSED NEW ENTRY TO THE WHO DRUG DICTIONARY

Reporter _____

Please mark the desired alternative below:

Company _____

Address _____

Country _____

Fax No. _____

Regular Updates

- Update in regular quarterly input
- No separate info on new entry
- No charge
- check if required

Expedited Updates

- Immediate update
- Info sent by fax or mail
- Charge 1000 SEK/hour, min. 500 SEK
- check if required

DRUG NAME			
Name Specifier			
COMPANY			
MaHolder			
SOURCE OF DRUG			
NAME (REFERENCE BOOK ETC.)			
ACTIVE INGREDIENTS			
Form			
Amount			
Unit			
THERAPEUTIC USE			
(ATC-CODE IF AVAILABLE)			

Drug names and active ingredients must be identifiable in international reference sources. If available, INN should be used for substances.