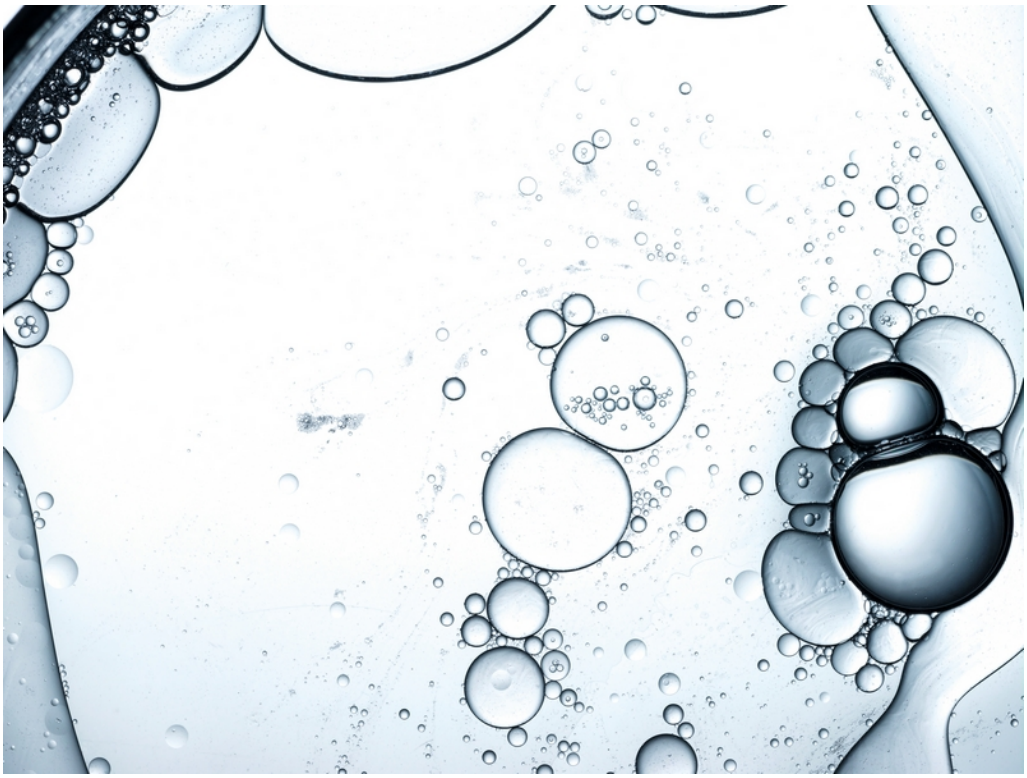
AkzoNobel Functional Chemicals
sBU Chelates

AkzoNobel
Tomorrow's Answers Today

Generic Exposure Scenarios

For Dissolvine® products

A short explanatory manual



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Introduction

In the new EU legislation on chemicals REACH, producers of chemicals have an obligation to communicate safe use of chemicals to their customers. The Exposure Scenario (ES) is the tool for this communication. Basically the ES contains all the do's and don'ts for a customer expressed as the conditions of use. For customers these conditions of use are legally binding.

AkzoNobel Functional Chemicals, sBU Chelates, requested TNO to develop generic and broad ES's suitable for its chelates portfolio as part of the Chemical Safety Assessment of such substances under REACH.

"Generic" meaning that an ES covers many commercial available Dissolvine® products.

"Broad" meaning that all known uses of chelating agents are covered by only a few ES's.

In this way we believe that we can offer a coherent and customer friendly ES system to our customers.

Goal

The goal of this manual is to facilitate proper communication and understanding on the AkzoNobel Exposure Scenarios (ES) for chelates between AkzoNobel and its customers.

The main part of this manual deals with a one-by-one explanation of all the rows of an Exposure Scenario. Per row information is presented on:

- What does it mean (technical background)
- What is the customer relevance
- Reference to source and/or additional information

Definitions

REACH: Acronym for Registration, Evaluation, and Authorization of Chemical substances. The REACH legislation came into force on 1st June 2007 and obligates companies like AkzoNobel, which import or produce chemical substances, to evaluate the risks connected with the use of substances and document how they may be used safely.

Exposure Scenario: The set of conditions that describe how the substance is used and how the manufacturer or importer controls risks and recommends downstream user to control the human health and environmental risks associated with the identified use(s) of a substance.

Derived No Effect Level (DNEL): The toxicological threshold value for human health through inhalation, oral uptake or dermal contact with substances. Dermal contact is not a relevant route of exposure to pure chelates because the substances do not have effects on the skin and are not taken up by the skin into the body. The risk managing methods (RMMs) needed to protect from skin and eye irritation due to the caustic (NaOH) impurity in some of the commercial available Dissolvine® products are described in detail in both the product SDS and the ESs.

For workers the oral uptake of substances is also not considered to be relevant.
The DNEL for inhalation represents the inhalable concentration in the air under which no health effects are to be expected. The DNEL for inhalation for chelates is presented in mg/m^3.
The DNEL for oral uptake (only relevant for consumers) represents the maximum amount of chelates that can be taken up through the oral route without human health effects to be expected. The DNEL for oral uptake is presented in mg/kg body weight/day.

Predicted No Effect Concentration (PNEC): The eco-toxicological threshold value for the environment. For chelates only concentrations in water are considered relevant and therefore only PNECs for water are derived.

Downstream Users: Any European person who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user.

Substance: A chemical element and its compounds with a CAS-number and/or EINECS number. A substance can cover more than one commercial available product. For example, the substance EDTA-Na4 (CAS number 64-02-8) covers Dissolvine® E-39, NA, 100-S, 220-S, NA-X.

Preparation: A mixture or solution composed of two or more substances.

Matrix: A continuous solid phase in which substances like chelates are embedded with limited possibility of release, for example rubber. The AkzoNobel ES for the building industry (ES 6) introduces the term matrix while considering chelates inside concrete. Only in case of mechanical work-up of concrete, chelates might be released into the environment and cause health effects.

Use: Any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization.

What is an Exposure Scenario?

A key element of the REACH registration of a substance is the demonstration and communication of safe use[1]. The manufacturer of the substance is responsible for the evaluation of hazards and risks of their substances and for communication of safe use trough the supply chain.

The demonstration of safe use for humans and the environment relies on two aspects: hazard and exposure. The REACH term for the value under which no adverse effects are expected for humans is the Derived No Effect level (DNEL); for the environment it is the Predicted No Effect Concentration (PNEC). When exposures are shown to be below the DNEL and PNEC respectively safe use is assumed, see figure 1 below.

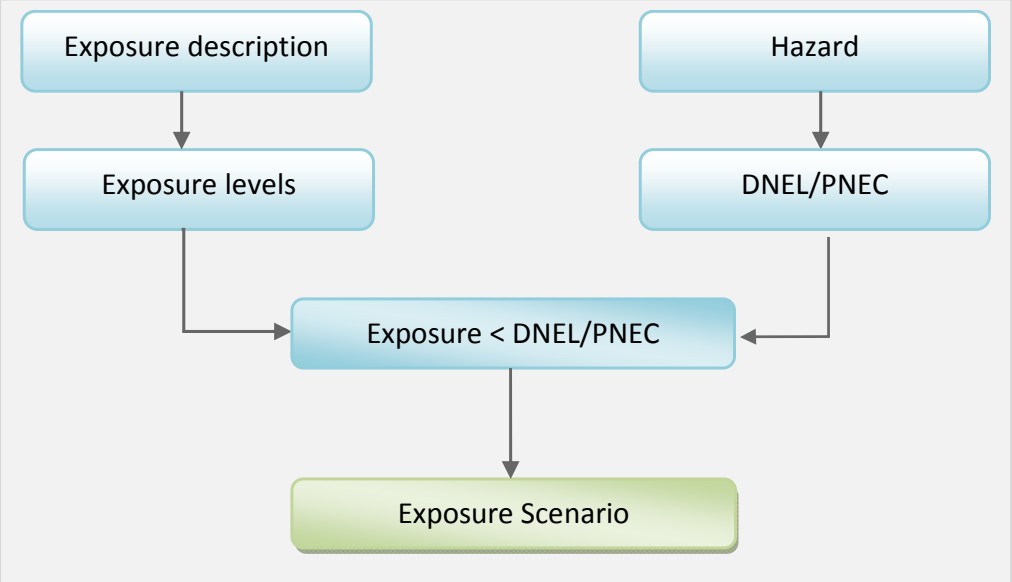

Figure 1: The technical background of a REACH Exposure Scenario: predictions of human exposure and environmental release assessment are compared with threshold values.

The main focus of the ES is on the Operational Conditions (OC) and Risks Management Measures (RMM) necessary to keep exposure levels below the relevant threshold values. In order words the 'do's and don'ts' to which a downstream users should adhere. These OCs and RMMs in an ES are legally binding for all downstream users.

[1] The official term used in the legal text and in the Guidance is 'control of risk'. Informally the term 'safe use' is an established expression.

The Exposure Scenario format

Figure 2 presents the index of a REACH Exposure Scenario (ES). It consists of four main chapters:

1. Title and covered activities: this chapter provides the possibility to give the ES an appropriate name and to report the so-called standard descriptors of use.
2. Operational conditions: aspects related to activity or process, surrounding, exposed population or situation that influence exposure and risk (excluding Risk Management Measures), for example:
   - Open or closed batch process
   - Duration of activity
   - Percentage of substance in the product
   - Amount used or use rate
3. Risk Management Measures: aspects related to the activity or process, the source, the surrounding, the situation or the exposed persons that are intended to limit emission, dispersion, exposure and risk, for example:
   - Local exhaust ventilation (LEV)
   - Personal Protective Equipment (PPE)
4. Reference to exposure estimation: guidance on how the exposure predictions were calculated and further guidance to a downstream user to check whether he is working inside or outside the boundaries of the ES.

Each of the 4 chapters is divided in two or more sections, which will be explained in detail in the following paragraphs. Figure 2 shows the current format of the ES as will be communicated by AkzoNobel for Dissolvine® products as annex to the Safety Data Sheet.

Title and covered activities	
1.	Short title for Exposure Scenario
2.	Processes and activities covered
Operational Conditions	
3.	Duration and frequency of use
4.1	Physical form of substance or preparation
4.2	Concentration of substance in preparation or article
4.3	Amount used per time or activity
5.	Other relevant operational conditions of use
Risk Management Measures	
6.1	Risk management related to human health (worker, consumer)
6.2	Risk management related to the environment
7.	Waste management measures
References to exposure estimation	
8.	Exposure prediction and reference to its source
9.	Guidance to the DU to check whether he is working within the ES

Figure 2: The REACH Exposure Scenario format as extension of the Safety Data Sheet.

Please note!
The format of the Exposure Scenario as illustrated is taken from the REACH guidance. Some changes might occur over time and other companies might use a different format.

Exposure Scenarios explained section-by-section

Header

In the header displayed on the first page an ES number (2-7) and title are given, for which more explanation is given below (see section 1).

Also the Dissolvine® products which are fully covered by these Generic Exposure Scenarios (GESs) are listed.

Boundaries

Each GES starts with a textbox containing the boundaries of the GES. These boundaries are important, because they define for what substances the GES is valid and for what substances it is not. The commercial Dissolvine® products given in the header all fit within these boundaries.

The first bullet concerns the inhalation Derived No Effect Level (DNEL) of a substances. This is the threshold value (as an average exposure level over an 8 hour full shift) for inhalation exposure that should not be exceeded. The DNEL used for workers is set arbitrary at 2 mg/m^3 and for consumer exposure at 0,12 mg/m^3. The Dissolvine® types listed in the header of the pages all have a DNEL equal or higher than this level and thus can be used safely within the limitations set further in the ES.

The second and third bullet deals with the Predicted No Effect Concentration for freshwater ($PNEC_{freshwater}$). This is the maximum safe environmental concentration of chelates in the freshwater. The limit for inherently biodegradable chelates is arbitrary set at 2.2 mg/l. This is based on the eco-toxicological properties of EDTA; this concentration should not exceed 2,2 mg EDTA-H_4 / L. When expressed as tetrasodium salt this would be 30% higher (= 2,86 mg EDTA-Na_4 / L)

All Operational Conditions and Risk Management Measures mentioned in the ES are directly related to these threshold values with the goal of keeping exposure and emission levels below the relevant DNELs and PNECs.

The fourth bullet concerns the dermal uptake of the chelates. From laboratory results it was concluded that Dissolvine® chelates do not penetrate the skin, and thus has a negligible dermal uptake into the body. This means that skin exposure to chelates is not considered being a risk and estimation of skin exposure levels is not needed. Regarding the skin & eye irritation due to NaOH impurities in commercial Dissolvine® products see text below under the last bullet.

The fifth bullet states that the validity of the GES is limited to those chelates unable to cause a very serious human or environmental health effect.

Under the Dangerous Substance Directive (DSD) NTA is classified as carcinogen in the lowest category (class 3). DTPA will be classified reprotoxic, also in the lowest class (=3) and so they fit both within the boundaries set.

The physical form of the chelates, as mentioned in the next to last bullet, is important as it has a major influence on the human exposure levels. The GES are applicable for chelates in liquids (solutions and dispersions) and solids (coarse dust).

The last bullet addresses the caustic (NaOH) impurity present in some of the commercial Dissolvine® products. This impurity (amongst other impurities) is part of the registered substance. When the NaOH level is higher than 0.5% and up to 1.9%, this causes labelling of the chelating product as skin and eye irritant. This is the reason that NaOH has to be mentioned separately in chapter 3 of the SDS.

It is important to state that all the Dissolvine® products listed in the heading of the first page are no preparations (or mixtures) of the chelating substance with NaOH. The risk managing methods (RMMs) needed to protect from skin and eye irritation due to this impurity are described in detail in both the product SDS and the ESs.

Section 1: Short title of the Exposure Scenario

This is a free text field allowing AkzoNobel to provide a title that should be instantly recognizable for a customer.

Seven ES are available for use of chelates with different titles. The title refers to the life cycle stage in the product chain in combination with the type of application and target group, as indicated in table 1.

Table 1: Exposure Scenarios and exposure/emission potential

Exposure Scenario:	Description:	Human exposure due to:	Environmental emission due to:
ES 1	**Production** of chelates (Only for AkzoNobel production plant)	Charging/discharging of pure chelates	Spillages due to the production process, cleaning processes
ES 2	Adding chelates to liquid and solid **formulations**	Charging/discharging of chelates	Minimal spillages
ES 3	**Use** of chelates in **industrial processes** in which the chelates are consumed	Charging/discharging of chelates	Emission to industrial activities to a sewer system
ES 4	Industrial and professional **use** of chelates in **spraying** formulations	Spraying of formulations	Wide dispersive use
ES 5	Industrial and professional **use** of chelates in **non-spraying** formulations	No relevant exposure moments	Wide dispersive use
ES 6	Industrial and professional **use** of chelates in **building** and construction	Sawing and grinding of concrete matrix	Wide dispersive use
ES 7	**Use** of chelates in **consumer** products	Spraying, washing etc.	Wide dispersive use

An overview with applications of chelates and the accompanying Exposure Scenarios to be applied is given in appendix 1.

ES 1: This is a scenario for the production of chelates by AkzoNobel only and not for downstream users.

ES 2: Is for making formulations by customers with our chelates. In this application our chelates leave the factory in products (and not in the sewer).

There are five scenarios for the end use of our chelates: ES3-ES7

ES 3: Is intended for the direct end use by our customer. The chelate leaves the plant via the sewer system.

ES 4, ES 5 and ES 6 are intended for the (industrial & professional) downstream users of our customer products.

ES 7: Is intended for the non-professional consumer use of the products of our customers.

Section 2: Processes and activities covered

This section is commonly used for defining the so-called Standard Descriptors of Use.

With the arrival of REACH and its focus on safe use of chemicals, the chemical industry, authorities and knowledge institutes jointly developed a system for uniform description of use. This methodology is called the "Use Descriptor System". Details on the Use Descriptor System may be found in Chapter R.12 of the REACH Technical Guidance documents available from the ECHA website: http://echa.europa.eu/

The purpose of the Use Descriptor System is to standardize the description of uses and to provide a starting point to the exposure assessment. Currently five formal descriptors of use are available:

SU (Sector of Use)

Defines the economic sector of the activity.

PC (Product category)

The product category describes the type of preparation (product) in which the substance is used.

PROC (Process Category)

The process category describes the industrial or professional process through which a worker may be exposed, for example the loading of chelates into a container or wiping a liquid formulation of chelates with a cloth.

AC (Article Category)

Defines the article in or on which a substance is present. On our chelates ESs ACs are not listed as they are not relevant for determining the exposure risk.

ERC (Environments Release Category)

Describing spilling / the release of chelating agents to the environment during manufacturing, formulation and end use.

Beside these ECHA Use Descriptors also the A.I.S.E. (the international Association for Soaps, Detergents and Maintenance Products) codes for activities that are covered are listed here.

Section 3: Duration and frequency of use

The duration and frequency of use are important parameters in the assessment of human exposure and environmental emission. For the duration, full shift (of 8 hours) during the whole year is used. Please note that the Personal Protective Equipment (PPE) mentioned is mandatory.

For the environmental emission into the air, water and soil compartments, the total number of emission days is an important parameter. The duration of use is presented per ERC as the minimum emission days per year. The minimum number of emission days is related to the yearly use tonnage of chelates by a customer as may be found in section 4.3. The following rule and reasoning applies: if a certain amount of chelates is used in less emission days, the higher the predicted daily emission to the compartments will be. Also if the same amount of chelates is used in more days, the total emission into the environment is spread over more days, thus the daily emission is predicted to be lower.

Section 4.1: Physical form of substances or preparation

The physical form of chelates in pure form or in a formulation is an important parameter in the exposure prediction. For example, the use of chelates in a liquid formation will not give rise to any inhalation exposure, as long as the formulation is not sprayed, due to the very low vapor pressure of chelates, whereas dust of the chelates in powder form might become available into the air depending on their dustiness.

The current ES for use of chelates cover three types of physical forms:

- Pure chelates as a powder/ coarse dust
- Liquid form: chelates in solution or dispersion (as produced by AkzoNobel) or in liquid formulations (as produced by customers of AkzoNobel) with a vapour pressure below 1 Pascal
- Chelates processed into tablets with a possibility for dust formation

Section 4.2: Concentration of substance in preparation or article

This section presents the maximum concentration of chelates in a liquid formulation or tablet.

For professional spray application (see ES 4) the base case or standard scenario is set at 10% chelates in a solution with a P2 filter mask. In case the concentration or the risk managing methods (see section 6 of ES4) are changed, exposure is changed. Alternate scenarios are presented in section 8 of the ES.

The use of chelates in hardened plaster, concrete or cement that is mechanically grinded, cut, drilled and/or sanded (ES 6). Due to the expected higher levels of exposure, the maximum concentration is set at 2%.

For consumer products (ES 7) the maximum concentration is limited as follows:

- (Dish-)washing tablets and other powdery detergents: a maximum of 40%.
- Liquid spray detergents: up to 10% aqueous solution
- Liquid non-spray detergents, glues and cosmetics: up to 100% aqueous solution

Section 4.3: Amount used per time or activity

This is an important input parameter for the calculation of environmental emissions. As can be expected the higher tonnage used per year, the higher the predicted emissions into the environment.

The type of Sewage Treatment Plant (STP) determines the maximum amount used per year. For example, in ES 2 (=adding chelates to liquid or solid formulations), the maximum amount used may be up to 1400 tonnes per year (of active material!) in case an adapted STP is used with an efficiency of 70%. In case a “standard” municipal STP is used the maximum amount is reduced to 420 tonnes of active material per year.

These amounts are based on calculations made under the assumption that the chelates contain 100% active (acid form) compound. In reality the percentage of active substance is likely to vary between 30- 98%. The amounts mentioned may be adjusted accordingly.

Section 5: Other relevant operational conditions

In this section other Operational Conditions than the ones mentioned under section 4.1. to 4.3. can be mentioned. In ES 7 it is stated that consumers should only pressure wash outside.

Section 6.1: Risk Management Measures related to human health

This section provides the Risk Management Measures that should be in place either for a professional worker or for a consumer. In case of worker exposure to chelates the ES refers to chapter 8 of the Material Safety Data Sheet for mandatory advice in good occupational hygiene.

Section 6.2: Risk Management Measures related to the environment

In all cases customers of AkzoNobel using chelates need to be connected to the municipal Sewage Treatment Plant (STP). In some cases a Long-term aerated Activated Sludge Plant (LAS), or adapted Sewage Treatment Plant is necessary. As explained under section 8 the maximum amount that can be used depends on the type of STP, the amount of emission days per year (standard 200), the sewage flow (standard 2000 m^3/d) and the river dilution factor (standard 10) and must be scaled up or down when diverting from these standard figures.

For consumers using chelates there are no specific risk management measures related to environmental protection, because the release is wide dispersive.

Section 7: Waste management measures

No specific waste management measures are of relevance for the use of chelates.

Section 8: Exposure prediction and reference to its source

This section presents the results of the exposure predictions and the assumptions used. All predictions of human exposure to and environmental emission of chelates are based on models. The model used to predict environmental emissions is the EUSES 2.1. model.
For human exposure two models were used:

- Stoffenmanager 4.0. (www.stoffenmanager.nl) for worker exposure assessment
- ConsExpo 4.1. (www.rivm.nl/en/healthanddisease/productsafety/ConsExpo.jsp) for consumer exposure assessment.

To allow a customer of Dissolvine® products flexibility in the use of their ES, alternative options for control of risk are presented. These alternative scenarios are also commonly known as scaling options. Each alternative scenario is presented as an option. Per option different assumptions are presented for percentage in the product, duration of exposure or type of Risk Management Measure.

Section 9: Guidance to downstream users on boundaries

This section mentions the models used to calculate exposure and emission and provides references for a Downstream User.

Appendix 1: Overview of applications and ESs

	Life cycle stage						
	Production	Formulation	End use				
	ES 1	**ES 2**	**ES 3**	**ES 4**	**ES 5**	**ES 6**	**ES 7**
Title	Generic ES for the production of chelates	Adding chelates to liquid and solid formulations	Use of chelates in industrial processes in which chelates are consumed	Industrial & professional use of chelates in spraying formulations	Industrial & professional use of chelates in non spraying formulations	Industrial & professional use of chelates in building and construction	Use of chelates in consumer products
PROCs covered	3, 8a/b	1, 2, 3, 4, 5, 6, 8a/b, 9, 10, 14, 19	1, 2, 3, 4, 5, 6, 8a/b, 9,13, 17, 18, 21	7, 8a/b, 11	1,2, 3, 4, 5, 6, 8a/b, 9, 10, 13, 14, 15, 17, 18, 19, 21	5, 24	not applicable
ERCs covered	1	2, 3	4, 5, 6, 7	4, 5, 6, 7, 8, 9	4, 5, 6, 7, 8, 9	3, 5, 6, 7, 8, 10a, 11a, 12	8, 9, 10, 11
PC covered	not applicable	all	all	all	all	0, 9b	1, 8, 9, 10, 12, 14, 15, 18, 20, 23, 24, 26, 28, 29, 30, 31, 32, 34, 35, 36, 37, 39
SU covered	8, 9	3,10	all	all	all	13, 19	21
X = exposure scenario to be handed over to customer (X) = less likely, but alternative route for our chelate depending on existence of an intermediate formulator							
Description							
Adhesives		**X**			**X**		**X**
Auto dish wash		**X**			**X**		**X**
Building & construct.		**X**		**(X)**	**(X)**	**X**	**(X)**
Cleaning boilers/ heat exchangers		**(X)**	**X**		**(X)**		
Cosmetics		**X**					**X**
Distributors		**X**	**X**	**X**	**X**	**X**	**X**
Functional Chemicals	**X**						
Feed additives		**X**					
Food		**X**					
Gas sweetening			**X**				
Herbicides		**X**					
Household cleaning		**X**					**X**
I&I cleaners		**X**	**(X)**	**X**	**X**		
Inks		**X**			**X**		
Leather		**(X)**	**X**				**(X)**
Fertilizers		**X**		**(X)**	**(X)**		**(X)**
Metal plating		**(X)**	**X**				
Metal working fluids		**(X)**	**X**				
Oilfield application		**X**	**(X)**		**X**		
Paint		**X**		**X**	**X**		**X**
Pharmaceuticals		**X**					
Polymers		**(X)**	**X**		**(X)**		
Photography		**X**			**X**		**(X)**
Pulp			**X**				
Soil cleaning			**X**				
Sugar industry			**X**				
Textile			**X**				
Water treatment		**(X)**	**X**		**(X)**		
Lab use		**X**			**X**		