

REPORT:

Multilingual Safety Data Sheets for Dangerous Chemical Products

Development of an Access database for authoring and updating multilingual safety data sheets for more than 28 countries worldwide – with focus on linguistic correctness and regulatory compliance

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1. Introduction

All companies that market dangerous chemical products are obliged to provide the professional user with a safety data sheet in the official language of the country in question containing regulatory and safety information. For export firms this often implies translation into many languages together with the obligation to provide the professional user with an updated version of the safety data sheet whenever it has been revised due to linguistic or legal amendments.

The safety data sheet contains information ensuring that the user can take the necessary precautions when handling, transporting and eliminating the product. In case of an accident, environmental authorities and medical staff can find the necessary information in the safety data sheet in order to initiate precautionary measures.

DTC has developed a special database for authoring and updating of multilingual safety data sheets.

SAFETY DATA SHEET					
Product name:	DEMO product Terpentine Alcohol, 96% vol.	Page:	1/6		
Last revised date:	2004-02-16	Print date:	2004-02-16		
Product No.:		SDS-ID:	GB/IRL/1.0		
1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY/ UNDERTAKING					
<u>Product name:</u>	DEMO product Terpentine Alcohol, 96% vol.				
<u>Application:</u>	For the preparation of paints and as a	<u>Container size:</u>	See heading 16.		
<u>Supplier:</u>	Danish Toxicology Centre Kogle Allé 2 DK-2970 Hørsholm Tel.: +45 4576 2055 Fax: +45 4576 2455 e-mail: DTC@DTC.dk				
2. COMPOSITION/INFORMATION ON INGREDIENTS					
The product contains: organic solvents.					
The following substances shall be indicated according to legislation:					
<u>%:</u>	<u>CAS-No.:</u>	<u>EC No.:</u>	<u>Chemical name:</u>	<u>Hazard classification:</u>	<u>Notes:</u>
93-95	64-17-5	200-578-6	Ethanol	F;R11	
0,1-<1	8006-64-2	232-350-7	Turpentine	R10 Xn;R20/21/22-65 R51/53	
3. HAZARDS IDENTIFICATION					
The product has been classified according to the legislation in force: F; R11					
<u>Physical and Chemical Hazards:</u>	The product is highly flammable and may be ignited even after short contact with an ignition source. The product may form explosive vapours/air mixtures even at normal temperatures.				
<u>Human health:</u>	Degreasing to skin. Vapours irritate the respiratory system, and may cause coughing difficulties in breathing. The product contains a small amount of sensitizing substance which may provoke which may provoke an allergic reaction among sensitive individuals.				
<u>Environment:</u>	The product contains volatile organic compounds (VOC) which will evaporate easily all surfaces volatile organic compounds which will evaporate easily from all surfaces.				
<u>Human health:</u>	Degreasing to skin. Vapours irritate the respiratory system, and may cause coughing difficulties in breathing. The product contains a small amount of sensitizing substance which may provoke which may provoke an allergic reaction among sensitive individuals.				

Figure 1: Safety Data Sheet

2. Project background

Since the early 80s, DTC has prepared safety data sheets on a client basis. Initially, DTC carried out the authoring of safety data sheets by using macros in Word Perfect and Word. It was a very time consuming task, as each safety data sheet for each country had to be typed in manually using the macro based system. This method gave rise to errors due to mistyping, and consequently quality checking of each document was also a time consuming task.

During 1996, DTC developed the first IT-based system in cooperation with computer programmers. This database is constantly being improved in order to meet both clients and internal users' needs and requirements, and in the near future it will be integrated with a database containing national regulatory data.

3. DTC's database for SDS authoring

3.1 Structure

The database consists of two parts, one containing the phrase library and one intended for authoring safety data sheets.

A safety data sheets contains 16 sections that the supplier of the chemical product has to fill in with relevant information. The 16 sections are:

1. Identification of the Substance/Preparation and Company/Undertaking
2. Composition/Information on Ingredients
3. Hazards Identification
4. First-Aid Measures
5. Fire-Fighting Measures
6. Accidental Release Measures
7. Handling and Storage
8. Exposure Controls/Personal Protection
9. Physical and Chemical Properties
10. Stability and Reactivity
11. Toxicological Information
12. Ecological Information
13. Disposal Considerations
14. Transport Information
15. Regulatory Information
16. Other Information

Development and maintenance of the database is carried out in close cooperation between DTC's regulatory experts and internal and external translators.

3.2 Contents and maintenance

The database contains a large number of so-called Master Core phrases in English, each with a unique identification number showing in which section and subsection it should be used. The phrases cover the information to be provided in the 16 sections mentioned above. Furthermore, the database contains the national versions of the Risk and Safety phrases that are used to describe the product's impact on health and environment and the classification and labelling of the product.

A substantial part of these phrases have been translated into all the languages handled by the database, presently 25 languages.

Languages

Chinese
Czech
Danish
Dutch
English
Estonian
German
Finnish
French
Greek
Hungarian
Icelandic
Italian
Korean
Latvian
Lithuanian
Norwegian
Polish
Portuguese
Russian
Slovakian
Slovenian
Spanish
Swedish
Turkish

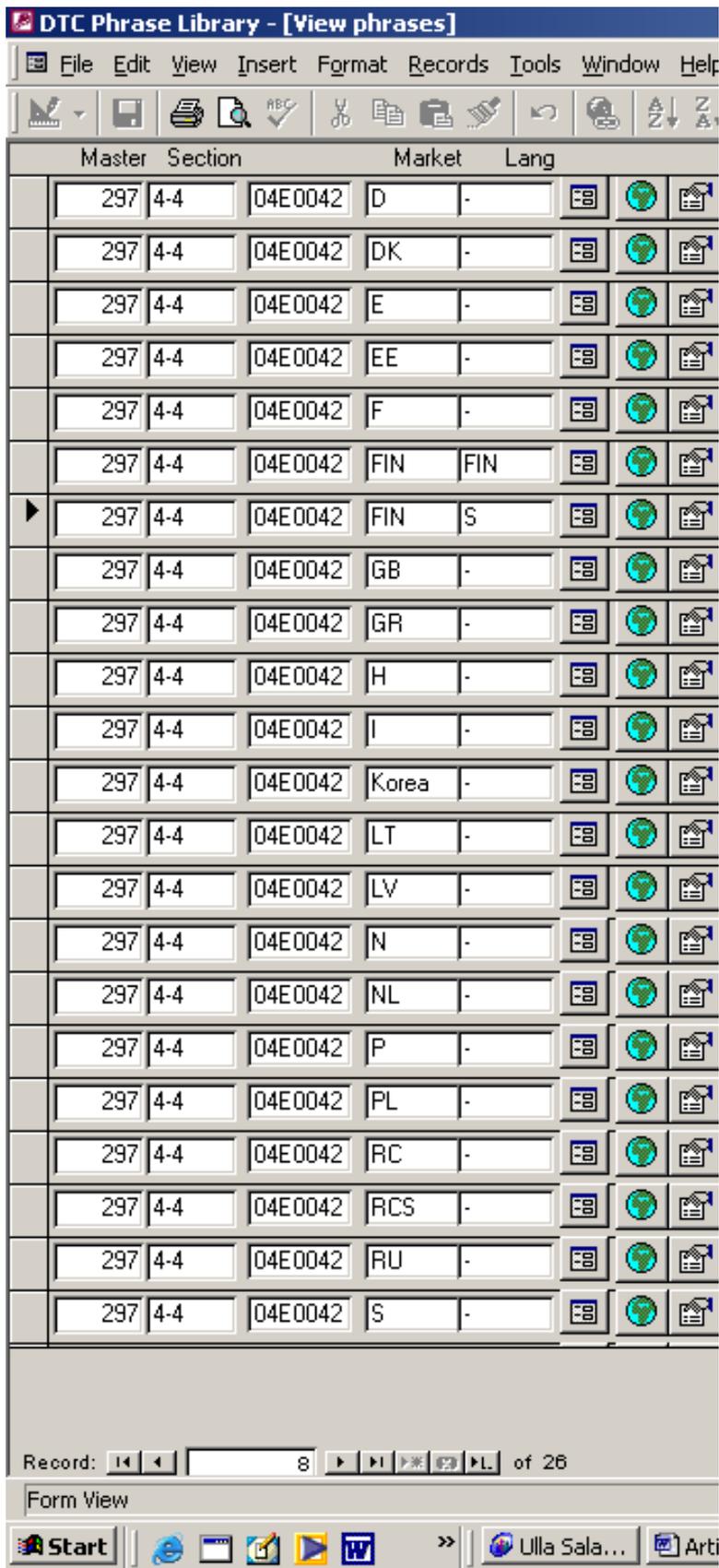


Figure 2a: Print screen from database with examples of the same phrase in 26 languages.

Language	Phrase	4	4	+	X!
German	Mit Wasser spülen. Arzt aufsuchen, falls Beschwerden anhalten.	4	4	+	X!
Danish	Skyl med vand. Søg lægehjælp ved fortsat ubehag.	4	4	+	X!
Spanish	Enjuague con agua. Póngase en contacto con un médico si el malestar persiste.	4	4	+	X!
Estonian	Loputada veega. Halva enesetunde jätkumisel pöörduda arsti poole.	4	4	+	X!
French	Rincer avec de l'eau. Consulter un médecin si les troubles persistent.	4	4	+	X!
Finnish	Huuhtelee vedellä. Ota yhteys lääkäriin, mikäli epämukava olo jatkuu.	4	4	+	X!
Swedish	Skölj med vatten. Kontakta läkare om besvär kvarstår.	4	4	+	X!
English	Rinse with water. Contact physician if discomfort continues.	4	4	+	X!
Greek	Ξπλύνετε με νερό. Εάν η δυσφορία συνεχίζεται συμβουλευτείτε γιατρό.	4	4	+	X!
Hungarian	Öblögesse vízzel. Forduljon orvoshoz, ha a kellemetlenség folytatódik.	4	4	+	X!
Italian	Sciacquare con acqua. Contattare un medico se il disturbo continua.	4	4	+	X!
Korean	물로 헹글 것. 불편함이 계속되면 의사의 진료를 받음.	4	4	+	X!
Lithuanian	Plauti vandeniu. Neprašėjus blogai savijautai, kviesti gydytoją.	4	4	+	X!
Latvian	Skaloj ar ūdeni. Griezties pie ārsta, ja slikā sajūta nepāriet.	4	4	+	X!
Norwegian	Skyll med vann. Kontakt lege hvis ubehaget vedvarer.	4	4	+	X!
Dutch	Met water spoelen. Bij aanhoudende klachten een arts raadplegen.	4	4	+	X!
Portuguese	Enxaguar com água. Contactar médico caso o mal-estar continue.	4	4	+	X!
Polish	Opłukać wodą. W przypadku utrzymującego się dyskomfortu skontaktować się z lekarzem.	4	4	+	X!
Chinese (Simplified)	用水冲洗, 若感到不适, 应与医生联系。	4	4	+	X!
Chinese (Traditional)	用水冲洗, 若感到不适, 应与医生联系。	4	4	+	X!
Russian	Прополоскать водой. Обратиться к врачу, если неприятные ощущения не проходят.	4	4	+	X!
Swedish (repeated)	Skölj med vatten. Kontakta läkare om besvär kvarstår.	4	4	+	X!

Figure 2b: Print screen from database with examples of the same phrase in 26 languages

The phrases are used for authoring safety data sheets for DTC's many Danish and international clients. DTC's consultants, mainly chemical engineers and pharmacists, prepare an English master template containing phrases common for all requested languages/countries. When the master is ready, the consultant marks the countries in which the safety data sheets is to be used and releases the master template. Within a few seconds, the safety data sheet is available in the requested languages, and all that remains for the consultant to do is to add the country specific regulatory references and phrases.

Should the consultant need a new phrase to describe the product, an electronic request is sent to DTC's in-house translators who creates the phrase in the database and provides for translation of the phrase.

4. Maintenance of Phrases and Quality Assurance

4.1 Terminology and Controlled Language

To the greatest possible extent the phrases are based on the wording used in the so-called Risk and Safety phrases (cf. paragraph 5) and in the below-mentioned safety data sheet directive. In this way it is ensured that the phrases contain the correct and generally known and accepted terminology.

To a certain extent DTC uses controlled language when creating new phrases. Wherever possible, DTC prefers short phrases and active constructions, e.g. *Repeated exposure may produce adverse effects on the lungs* versus *Adverse effects on the lungs may be produced by repeated exposure*.

The objective of focusing on the use of controlled language is to improve the consistency and readability and facilitate the translation into many languages.

4.1 Quality Assurance

DTC only uses experienced translators. They may either be state-authorized translators or other persons with a university degree in language studies or native chemists or specialists. Most of them have worked for DTC for many years and are very familiar with the terminology used in this specific field of work. They know the relevant EU directives and are also familiar with relevant national legislation.

Both DTC and the translators keep records of all translations, mostly in special translation tools such as Translator's Workbench or Transit. This aspect is very important in order to ensure the consistency.

As chemical translations are often rather complicated, the translators are in close contact with DTC in case of specific problems. Furthermore, if DTC identifies a specific translation problem, the translators are provided with reference material to help them translate correctly and to make sure that all the translators have the same understanding of the meaning of the phrase.

Before the translations are entered into the database, DTC's translators control that the translation is correct, i.e. by checking key terminology, translations of chemical substance names etc.

If new legislation or linguistic development makes a new translation of a word necessary, the translator revises all the phrases in which the word appears and the database is updated accordingly. The phrase corpus can therefore be compared with a live organism in constant change.

5. Regulatory Compliance

Both at EU-level and in the individual member states a substantial number of rules and guidelines exists regarding dangerous products, e.g. Commission Directive 2001/58/EC, the so-called safety data sheet directive, and Commission Directive 1999/45/EC, the so-called preparations directive. The continuous amendments of the directives have increased the requirements to the information given in the safety data sheet. On the other hand, this means that legislation has become more uniform in the member states, but there are still many national rules to be complied with.

In addition, countries outside the EU have their own regulatory demands which must be reflected in the safety data sheet. For many years DTC has compiled and systematized these rules and requirements so that the safety data sheets made by DTC meet relevant European and national requirements.

The regulatory information in the safety data sheets has to reflect current European and national legislation. Therefore, DTC follows the relevant EU directives and their implementations in the member states closely. This information appears from section 15, and the database includes specific phrases with references to legislation.

Chemical substance names are a chapter by itself. They are only translated if it is not possible to find an official designation in Council Directive 67/548/EEC regarding classification, packaging and labelling of dangerous substances (= Annex 1) via The European Chemicals Bureau's webpage or in other databases, e.g. Chemfinder.

The database also contains a number of so-called "regulatory related phrases" contained in the EU directives, e.g. the Risk and Safety phrases. The wording of the phrases must not be changed and the phrases have to be stated in the safety data sheet together with their specific number:

- R15 Contact with water liberates toxic, extremely flammable gas.
- R15 Reagiert mit Wasser unter Bildung hochentzündlicher Gase.
- R15 Em contacto com a água liberta gases extremamente inflamáveis.

- S24/25 Avoid contact with skin and eyes.
- S24/25 Berührung mit der Haut und den Augen vermeiden.
- S24/25 Evitar o contacto com a pele e os olhos.

Even though EU harmonization is well advanced in the field of chemical products, there are still a number of individual national regulations that must be complied with, and outside the EU regulations on safety data sheets are even more diversified.

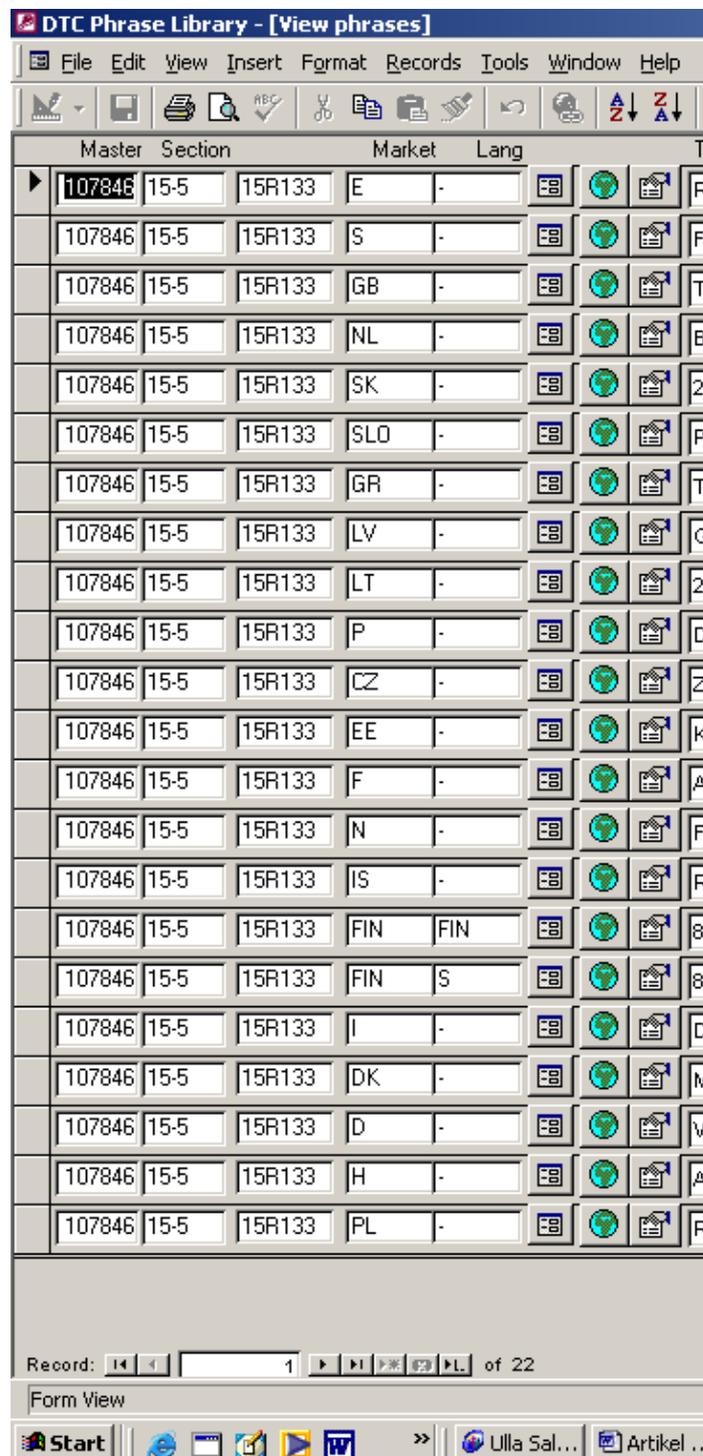


Figure 3a: Print screen of phrases with regulatory information.

Text			
Real Decreto 363/1995, de 10 de marzo, por el que se aprueba el Reglamento sobre Notificación de Sustanci-	15	5	+
Föreskrifter om ändring i Kemikalieinspektionens i föreskrifterna (KIFS 1994:12) om klassificering och märknin	15	5	+
The Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (S.I 2002 No. 1689).	15	5	+
Besluit van 14 oktober 1987 houdende regelen met betrekking tot de verpakking en aanduiding van milieugeve	15	5	+
2/2002 výnos Ministerstva hospodárstva Slovenskej republiky è. 2/2002 z 27. marca 2002, na vykonanie zák	15	5	+
Pravilnik o razvrščanju, pakiranju in označevanju nevarnih snovi (Ur.l. RS, št. 101/2002 in 22/2003).	15	5	+
Τροποποίηση της απόφασης ΑΧΣ 378/94, (ΦΕΚ 705/Β'/20.9.1994) σε εναρμόνιση προς την Οδηγία 2001/59/Ε	15	5	+
Grozījumi Ministru kabineta 2002.gada 12.marta noteikumos Nr.107 "Īmisko vielu un Īmisko produktu klasifikā	15	5	+
2002 m. taisyklės dėl chemikalų (Informacija apie pavojus ir tiekimui tinkamos pakuotės) (S.I 2002 Nr. 1689).	15	5	+
Decreto-Lei n.º 82/95 transpõe para a ordem jurídica interna várias directivas que alteram a Directiva n.º 67/5-	15	5	+
Zákon è. 356 ze dne 23. zán 2003 o chemických látkách a chemických přípravcích a o změně některých zák	15	5	+
Kemikaalide (ohutusteave ja pakendamise tamimiseks) eeskirjad 2002 (S.I 2002 nr 1689).	15	5	+
Arrêté du 30 juin 2001 modifiant l'arrêté du 20 avril 1994 relatif à la déclaration, la classification, l'emballage et l'	15	5	+
Forskrift om klassifisering, merking m.v. av farlige kjemikalier. Fastsatt av Miljøverndepartementet og Arbeids-	15	5	+
Reglugerð um breytingu á reglugerð nr. 236/1990, um flokkun, merkingu og meðferð eitrefna, hættulegra efna	15	5	+
807/2001 Sosiaali- ja terveysministeriön asetus kemikaalien luokitusperusteista ja merkintöjen tekemisestä, my	15	5	+
807/2001 Social- och hälsöförhållningsministeriets förordning om grunderna för klassificering samt märkning av kem	15	5	+
Decreto legislativo 16 luglio 1998, num. 285, recante: Attuazione di direttive comunitarie in materia di classifica:	15	5	+
Miljøministeriets bekendtgørelse nr. 329 af 16. maj 2002 om klassificering, emballering, mærkning, salg og opbr	15	5	+
Verordnung zum Schutz vor gefährlichen Stoffen (Gefahrstoffverordnung-GefStoffV) vom 15. November 1998	15	5	+
Az egészségügyi miniszter 44/2000 (XVI. 27.) EÜM rendelete a veszélyes anyagokkal és a veszélyes készítr	15	5	+
Rozporządzenie Ministra Zdrowia z dnia 11 lipca 2002 r. w sprawie kryteriów i sposobu klasyfikacji substancj	15	5	+

Figure 3a: Print screen of phrases with regulatory information.

5. Future development

The database will shortly be expanded to include Bulgarian and Rumanian, as Bulgaria and Rumania are expected to become members of the European Union in 2007. Turkish is already part of the database as well as Korean and simplified and traditional Chinese. Arab and Japanese may also be included in the near future.

Today, DTC's database is used for authoring safety data sheets and labeling proposals for chemical products, but the system is also suited for other types of translations of controlled texts such as package leaflets for medicinal products, toxicological descriptions and standardized technical documentation in general.

ABSTRACT

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and regulatory compliance**

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Companies marketing dangerous chemical products must provide the professional user of the product with a safety data sheet in the official language of the country in which the user has bought the product. In countries with more than one official language, the safety data sheet must be issued in all official languages. Therefore, a safety data sheet for Finland has to be issued in Finnish and Swedish, whereas a safety data sheet for Belgium must be available in French and Flamish. Furthermore, safety data sheets must comply with European and national legislation on safety data sheets and classification and labeling of chemical products.

The safety data sheet contains information ensuring that the user can take the necessary precautions when handling, transporting and eliminating the product. In case of an accident, environmental authorities and medical staff can find the necessary information in the safety data sheet in order to initiate precautionary measures.

This article describes the development and maintenance of a database designed to manage phrase libraries in presently 25 languages and regulatory information for more than 28 countries. Focus is placed on quality assurance of translations and regulatory compliance.
