



Conversion template REACH dossier into GPS Safety Summary



7 March 2011

Version 1: for publication

Preface

This document gives some practical advises as to what information could be provided and what are the possible sources for that information, assuming that a REACH registration has been done for the substance.

The GPS Safety Summary is intended for communication on safe use in a simple language. Under REACH the extended safety datasheet (eSDS) is to inform the Downstream Users on safe use of the chemicals. If an eSDS is available, this could serve as the first source of information. Other sources are the Chemical Safety Report and the IUCLID dossier. Be aware that not all that information is publicly available under REACH.

This document describes the different elements a company may decide to include in a safety summary. It is not a mandatory template.

Disclaimer

The information contained in this paper is intended as advice only and whilst the information is provided in utmost good faith and has been based on the best information currently available, is to be relied upon at the user's own risk.

No representations or warranties are made with regards to its completeness or accuracy and no liability will be accepted by (company name) for damages of any nature whatsoever resulting from the use of or reliance on the information.

SUBSTANCE NAME

Company decides what substance name to give here.
It could be brand name, chemical name, popular well known name etc.

GENERAL STATEMENT

This part is optional for companies to complete. It could give some high level description of the substance, its hazards and recommendations on safe use.

Possible source:
Company commercial persons, Product Manager, Product Steward, etc

CHEMICAL IDENTITY

Name: (popular well known name, recognised by public)

Brand names:

Chemical name (IUPAC):

CAS number(s):

Molecular formula (optional):

Structure (optional):

Possible source:
eSDS: section 1 of SDS
CSR: Part B section 1
IUCLID: Section 1
Company internal business units / experts / marketing departments/product stewards

USES AND APPLICATIONS

General high level description of product uses (no technical details) consistent with what has been registered under REACH - information gathered from CSR or company product database – e.g. *commonly used plasticiser and has a wide range of indoor and outdoor applications. Such as for construction and industrial applications, and durable goods (wire and cable, film and sheet, flooring, industrial hoses and tubing, footwear,*

High level description of the benefit of the chemical in certain applications – not focused on technical issues – specifically focused on benefits for consumer and society e.g. *smooth, tough surface of the upper wear layer which prevents dust and dirt from building up and microbes breeding, robust surfaces cut down the need for cleaning and the use of polish, etc.*

Consumer use should be addressed in this section, either by informing about the use or by stating that the substance is not in consumer products.

Possible source:
 eSDS: section 1.2 of SDS and section 1 of the Exposure Scenario
 CSR: Part B section 2 and section 9
 IUCLID: section 3.5
 Product Manager, Product Steward, company database with product info, Sector of use, Article category, marketing department

PHYSICAL/CHEMICAL PROPERTIES

Phys/Chem Safety Assessment

General statement on colour, physical state, odour, melting point, vapour pressure, solubility in water, flammability.

Possible source:
 eSDS: section 9 of SDS
 CSR: part B section 1
 IUCLID section 4

Property	Value
Form	
Physical state	Liquid/solid/gaseous
Colour	
Odour	
Density	
Melting / boiling point	
Flammability (optional)	H statement in case classified
Explosive properties	
Self-ignition temperature	
Vapor pressure	
Mol weight	
Water solubility	
Flash point	
Octanol-water partition coefficient (LogKow)	

Possible source:
 eSDS: section 9 of SDS and section 2 of Exposure Scenario
 CSR: part B section 1
 IUCLID section 4

HEALTH EFFECTS

Human Health Safety Assessment

- » **Consumer:** High level statement (no detailed toxicological data referenced) on safe use of consumer products e.g. consumer exposure is very unlikely as the substance is manufactured and handled in industrial settings in closed systems (used as chemical intermediate or as monomer in polymerization) – or - **consumers will not come into contact with harmful levels of XXX the substance is only used in acceptable concentrations as**
- » **Worker:** e.g. *Workers will not come into contact with XXX, as the substance is manufactured and handled in industrial settings in closed systems. In case of unintended exposure during maintenance, sampling, testing, or other procedures workers should follow the recommended safety measures in the Extended Safety Data Sheet (eSDS).*

Effect Assessment ¹	Result
Acute Toxicity Oral / inhalation / dermal	e.g. virtually not toxic after
Irritation / corrosion Skin / eye/ respiratory tract	H-statements in case classified Causes skin irritation. May cause respiratory irritation.
Sensitisation	e.g. not considered to be sensitizing
Toxicity after repeated exposure Oral / inhalation / dermal	
Genotoxicity / Mutagenicity	e.g. not mutagenic
Carcinogenicity	e.g. not considered as carcinogenic based on oral and dermal data
Toxicity for reproduction	e.g. based on available data no developmental toxicity or reprotoxicity to be anticipated

Possible source

eSDS: sections 2 and 11 of SDS and section 4 of Exposure Scenario

CSR Chapter 5 and 6 and 10

IUCLID: section 7

ENVIRONMENTAL EFFECTS

Environment Safety Assessment

- » High level statement (no toxicological data referenced) e.g. *based on available data for the pure substance, XXX is toxic to aquatic organisms. The amount of the substance released into the aquatic environment, however, is low indicating no risk for the aquatic environment. This is confirmed by an environmental exposure assessment showing that the substance can be handled safe during all steps of*

¹ Only in case data is available

manufacture, industrial and consumer end use. Furthermore it does not bioaccumulate, is readily biodegradable and will not persist in the environment.

Effect Assessment	Result
Aquatic Toxicity	e.g. H statement in case classified

Fate and behaviour	Result
Biodegradation	e.g. Readily biodegradable
Bioaccumulation potential	e.g. Not bioaccumulative
PBT / vPvB conclusion	e.g. Not considered to be either PBT nor vPvB.

Possible source
 eSDS: sections 2 and 12 of SDS and section 4 of Exposure Scenario
 CSR: Chapter 4, 7, 8 and 10
 IUCLID: sections 5 and 6

EXPOSURE

Human health

Indication of industrial, professional or consumer use. High level statement on exposure potential e.g. *consumers will not come into contact with XXX as it is manufactured in a closed process which also minimizes employee exposure potential. Exposure to XXX of personnel in manufacturing facilities is also considered very low because the process, storage and handling operations are enclosed. Workers who might accidentally come in contact with the non formulated, undiluted substance should follow the safety measures recommended in the Extended Safety Data Sheet (eSDS) – or – e.g. the exposure of consumers to XX in end products is at safe levels. However, workers who might come in contact with the non formulated, undiluted substance should follow the safety measures recommended in the eSDS, as the non formulated, undiluted substance causes e.g. skin and eye irritations. In the environmental hazard assessment XXXX was assessed as safe for the environment during all stages of manufacture, industrial uses and consumer.*

Environment

Information about possible direct and indirect releases to the different compartments in the environment (water including sediment, soil and air)
 e.g. *the manufacture is a closed and automated process with no aqueous effluent neither gaseous effluent released to the environment. During the industrial use of the substance there is also a “No release” policy with all effluent being stored in special containers dedicated to incineration.*
 Assure that the content of this section is consistent with sections 5 and 6 of this Safety Summary!

Possible source
 eSDS: section 1 of Exposure Scenario
 CSR chapter 9 (and chapter 2)

RISK MANAGEMENT RECOMMENDATIONS

e.g. *When using chemicals make sure that there is adequate ventilation. Always use appropriate chemical resistant gloves to protect your hands and skin and always wear eye protection such as chemical goggles. Do not eat, drink, or smoke where chemicals are handled, processed, or stored. Wash hands and skin following contact. If the substance gets into your eyes, rinse eyes thoroughly for at least 15 minutes with tap water and seek medical attention.*

e.g. *All effluent releases that may include the substance must be directed to a (municipal) waste water treatment plant that removes the substance from the final releases to the receiving water. Releases to air are not expected and therefore no specific recommendations are required.*

Possible source

eSDS: section 8 of SDS and section 2 of the Exposure Scenario

CSR chapters 9 and 10

Generic text on normal hygiene measures and environmental recommendations– the same for all Safety Summaries

Generic text on informing and training of workers referring to the extended SDS

STATE AGENCY REVIEW

Indicate whether this substance has been reviewed by any regulatory program, like OECD HPV, Canadian DSL, US HPV etc

E.g. *this substance has been registered under REACH*

Possible source:

OECD Portal, ICCA Portal, internet etc

REGULATORY INFORMATION / CLASSIFICATION AND LABELLING

Under GHS substances are classified according to their physical, health, and environmental hazards. The hazards are communicated via specific labels and the eSDS. GHS attempts to standardize hazard communication so that the intended audience (workers, consumers, transport workers, and emergency responders) can better understand the hazards of the chemicals in use.

- » **Visuals and H-Statements on EU GHS classification consistent to CSR (this is a specific request from regulatory bodies to be included in Safety Summaries)**

Possible source:

eSDS: section 2

CSR: section B chapter 3

CONCLUSION

Possible source
Up to company

CONTACT INFORMATION WITHIN COMPANY

For further information on this substance or product safety summaries in general, please contact:

- » Functional e-mail or contact person Reference to company web site where additional information can be found
- » Make reference to ICCA portal for additional information:
<http://www.icca-chem.org/en/Home/ICCA-initiatives/global-product-strategy/>

GLOSSARY

Acute toxicity	harmful effects after a single exposure
Biodegradable	breakdown of materials by a physiological environment
Bioaccumulation	accumulation of substances in the environment
Carcinogenicity	effects causing cancer
Chronic toxicity	harmful effects after repeated exposures
Clastogen	a substance that causes breaks in chromosomes
Embryotoxicity	harmful effects on foetal health
GHS	Global Harmonized System
Hazard	situation bearing a threat to health and environment
Mutagenicity	effects that change genes
Reprotoxicity	combining teratogenicity, embryotoxicity and harmful effects on fertility
Sensitising	allergenic
Teratogenic	effects on foetal morphology

DATE OF ISSUE

REVISION

ADDITIONAL INFORMATION

Up to the company

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