

Safety Data Sheets as communication instrument

Recap regarding SDS “new style”
Compliance check: practical experiences

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Part 1

Recap SDS “new style”

**Requirements for the “new” SDS
according to REACH**



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Function of the Safety Data Sheet

The SDS is the key instrument for the information flow down the supply chain, because:

- it informs the downstream user about the dangerous properties & potential hazards during normal handling and use
- it recommends necessary measures to manage the risk to health & environment (storage, use, disposal)
- it provides the basis for the assessment of hazards / risks

**Fulfillment of all legal requirements of Article 31 REACH
addressed to suppliers & downstream users**

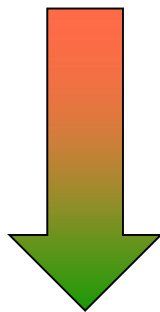


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When should a Safety Data Sheet be provided?



System:

- unsolicitedly - Art. 31(1) REACH
- on request - Art. 31(3) REACH
- on a voluntary basis

“to be made available” →

**Customers must be informed about
down-load options in written form!**

Means in this context, that
it is not sufficient to simply
offer the SDS via the Internet!

**SDS complete and in correct format in accordance with
REACH Art. 31 and Annex II (Amended 453/2010)**




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When should a SDS be provided unsolicitedly? (REACH Art. 31.1)

Requirements for SDSs:

- a) if a substance / mixture meets the criteria for classification as hazardous according to (EC) No 1272/2008 or 1999/45/EC
- b) if a substance is PBT or vPvB 
- c) if the substance was identified as an SVHC and was taken up in the candidate list, according to the criteria in Art. 57.f



Example: Endocrine Disrupting Chemicals

The SDS has to be provided at the latest at the time of first delivery



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When should a SDS be provided upon request? (REACH Art. 31.3)

Requirements for SDSs

The consumer may request a SDS if a mixture is not classified by DPD (1999/45/EC) as dangerous, but contains:

- a) a harmful or environmentally hazardous material in a concentration ≥ 1 weight percent for non-gaseous mixtures or ≥ 0.2 percents by volume for gaseous mixtures
- b) PBT- or vPvB material in an individual concentration ≥ 0.1 weight percent for non-gaseous mixtures respectively $> 0,2$ volume percent for gaseous mixtures
- c) a substance for which a Community workplace exposure limit has been established

the consumer may request a SDS.



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When will it be useful to draft and provide a SDS on voluntary basis?

A SDS may be provided for mixtures which are not classified as dangerous, but:

- which - based on experience - often prompt questions
- which call for the communication of other dangers (suffocation frostbite, inclination for formation of dust ... (see selection 2.3 "other hazards")
- are descendants of other information duty, if not required by SDS
- as basis for its own assessment of dangers.

an SDS can be provided on voluntary basis
or
a free format sufficient for communicating essential information



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When to update an SDS ? (REACH Art. 31.9)

- **Suppliers have to modify an SDS (Annex 31(9)) if:**
 - new information is available, which may have effects on risk management measures!
 - an authorization for SVHC was given or denied!
 - a limitation for the substance was issued

The correct version must be made available to all customers who were served within the last 12 months

- **But minor changes, like changed address of the Producer, do not trigger requirement to inform all customers**



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Part 2

SDS Control Steps

Step 1: Control of general requirements

Step 2: Control of hazard identification and composition

Step 3: Consistency check of the information in the different sections of SDS

Step 4: Consistency check with Exposure Scenario sections



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Step 1: Control of general requirements

- Language requirement;
- Number of sections;
- Date of issue of the current version of SDS;
- Identification of the substance/mixture in section 1 of SDS;
- Registration number of substance, if applicable;
- Identified uses and uses advised against in section 1 of SDS;
- Is the attached ES relevant for this concrete use?
- Details of the supplier of the SDS
- Emergency phone number



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SDS example of Xylene for formulator of varnishes

Safety data sheet

Product : MIXED-XYLENE
ATOF-010

Version (en) nr : 11.1

Page : 1/15
Revised : 15/11/2010
Supersedes : 17/11/2009

GHS02 GHS07 GHS08

1. Identification of the substance / preparation and of the company / undertaking

IDENTIFICATION OF THE SUBSTANCE

Trade name: Aromatic hydrocarbons, C8
SDS number: MIXED-XYLENE
CAS number: ATOF-010
EINECS or ELINCS number: 90089-38-1
INDEX nr: 292-694-9
Reach Number: 648-010-00-X

MATERIAL USE

TP France UGO (01-2119486136-34-0000) - Petrofina (01-2119486136-34-0001)

RECOMMENDED USES AND RESTRICTIONS

Manufacture of substances
Distribution of substances and mixtures
Synthesis intermediate product
Uses in Coatings
Use as binders and release agents
Propellants
Agrochemical uses
Polymer production
Restricted to professional users

RESPONSIBLE FOR PLACING ON THE MARKET

Trade name of the firm: see below this page.

EMERGENCY NUMBER

Email address: Petrochemicals.felr-sds@total.com

Emergency call TOTAL PETROCHEMICALS:
• for English speaking countries: +44 (0) 1235 239 670
• for Europe (in local languages): +33 1 49 00 00 49
• for Africa and Middle East: +44 (0) 1235 239 671 • for China:
+86 10 5100 3039
• for Asia Pacific (Hong-Kong, Singapore, Taiwan, Philippines, India, Vietnam, Sri Lanka, Japan, Korea, Malaysia, Indonesia, Thailand):
+65 3158 1074

Official advisory body

The UK National Poisons Emergency number is 0870 600 6266 (Outside the UK: +44 870 600 6266)

Step 2: Control of hazard identification and composition

Example of Xylene for formulator of varnishes

Section 3. Composition / information on ingredients				
Identification name	CAS nr.	Weight % content (or range)	EC-GHS Class	67/548/EEC & 1999/45/EC Class
Ethylbenzene	100-41-4	< 20%	Flam. Liq. 2, H225 Acute Tox. 4, H332	F; Xn R - 11-20
Xylene (mixture of isomers)	1330-20-7	> 80%	Flam. Liq. 3, H226 Acute Tox. 4, H312, H332 Skin Irrit. 2, H315	Xn R - 10-20/21-38
Toluene	108-88-3	< 0.5%	Flam. Liq. 2, H225 Repr. 2, H361d Asp. Tox. 1, H304 STOT RE 2, H373 Skin Irrit.2, H315 STOT SE 3, H336	F; R11 Repr.Cat.3;R63 Xn; R48/20-65 Xi; R38 R67

Investigation of sections 3 & 2 – control of classification and labeling

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2. Hazards identification

Classification & Labelling		Label elements	
EC-GHS	Classification according to the regulation EC 1272/2008 (EC-GHS) and ATP The substance contains less than 0.1 % benzene (Einescs 200-753-7); it needs not to be classified as T, R-45: "May cause cancer" (nota J & P)	EC-GHS	Classification according to the regulation EC 1272/2008 (EC-GHS) and ATP The substance contains less than 0.1 % benzene (Einescs 200-753-7); it needs not to be classified as T, R-45: "May cause cancer" (nota J & P)
Class	Flam. Liq. 3 Asp. Tox. 1 Acute Tox. 4 Skin Irrit. 2	Signal word	Danger
H Phrase(s)	H226, H304, H312, H315, H332	Pictogram(s)	GHS02, GHS07, GHS08
67548/EEC & 1999/45/EC	Classification according to directives 67548/EEC and 1999/45/EC: The substance contains less than 0.1 % benzene (Einescs 200-753-7); it needs not to be classified as T, R-45: "May cause cancer" (nota J & P)	H Phrase(s)	H226 - Flammable liquid and vapour. H304 - May be fatal if swallowed and enters airways. H312 - Harmful in contact with skin. H315 - Causes skin irritation. H332 - Harmful if inhaled.
Symbols EC	Flammable Xn - Harmful	P Phrase(s)	P210 - Keep away from heat/sparks/open flames/hot surfaces. —No smoking. P262 - Do not get in eyes, on skin, or on clothing. P273 - Avoid release to the environment. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P301/310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. P331 - Do NOT induce vomiting. P309/311 - IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.
R Phrase(s)	R 10 - Flammable. R 20/21 - Harmful by inhalation and in contact with skin. R 38 - Irritating to skin. R 65 - Harmful may cause lung damage if swallowed.	Other hazards	no information available
S Phrase(s)	S 16 - Keep away from sources of ignition - No smoking. S 24/25 - Avoid contact with skin and eyes. S 62 - If swallowed, do not induce vomiting; seek medical advice immediately and show this container or label.		



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Step 3: Consistency check of the information in the different sections of SDS (few examples)

Each example will be introduced by illustrating the links between the different sections of the SDS


As case is used the e-SDS for Ammonium nitrate 34,8% N as distributed by PETROKEMIJA, version 3 of 13-11-2013



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	SAFETY DATA SHEET AMMONIUM NITRATE 34,8% N According to Regulation (EC) No 1907/2006	Sheet : 1/30 Date : 13.11.2013. Revision : 3
	SECTION 1: Identification of the substance/mixture and of the company/undertaking	
1.1. Product identifier Product names (codes): AMMONIUM NITRATE 34,8 % N high density (2603252); AMMONIUM NITRATE 34,8 % N porous, absorption 6 (2603260); AMMONIUM NITRATE 34,8 % N porous, absorption 12 (2606446); AMMONIUM NITRATE 34,8 % N porous, not amminized (2606594). Substance name: ammonium nitrate EC No: 229-347-8 REACH registration reference No: 01-2119490981-27-0048 CAS No: 6484-52-2 CLP (Annex VI) index No: none.		
1.2. Relevant identified uses of the substance or mixture and uses advised against Relevant identified uses: <ul style="list-style-type: none"> • Manufacturing of the substance, including handling, storage and quality control, • Use of ammonium nitrate in the manufacturing of formulations for adhesives and sealants, explosives and water treatment chemicals, • Use of ammonium nitrate as an intermediate to synthesise other substances: Uses advised against: No uses specifically advised against.		
1.3. Details of the supplier of the safety data sheet Manufacturer: Petrokemija Plc. Fertilizer Company, Aleja Vukovar 4, HR-44320 Kutina, Croatia Telephone number: 00 385 44 647 122 E-mail address: safety.data.sheet@petrokemija.hr		
1.4. Emergency telephone numbers Emergency (EU, Croatia): 112		
SECTION 2: Hazards identification The most important adverse physicochemical, human health and environmental effects: <ul style="list-style-type: none"> • The substance is a strong oxidiser, contact with combustible material may cause fire (see section 10). • When nitrates are involved in a fire, nitrous fumes may be formed, • Ammonium nitrate is irritating to eyes. 		


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First page of a 30 pages e-SDS for Ammonium nitrate 34,8% N from Petrokemija showing sections 1 and part of section 2.

Note that the e-SDS is REACH compliant; based on a joint registration

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2.2. Label elements Labelling according to Regulation (EC) No 1272/2008 [CLP/GHS] <u>Hazard pictograms</u>  GHS03  GHS07 <u>Signal word:</u> Warning <u>Hazard statements:</u> H272: May intensify fire; oxidiser. H319: Causes serious eye irritation.
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Section 2.2 Labelling

- Many registrations submitted with varying voluntary C&L
- Presumably based on variability in tox. info
- So found ...

- H315: causes skin irritation (skin irritant 2)
- H335: may cause respiratory irritation (STOT SE 3, respiratory tract),
- H370: causes damage to the liver via ingestion (STOT SE 1)

with GHS08



Maybe no harmonised C&L established; so variation may remain.
 Up to the SIEF to come to an agreement, because no priority under CLP

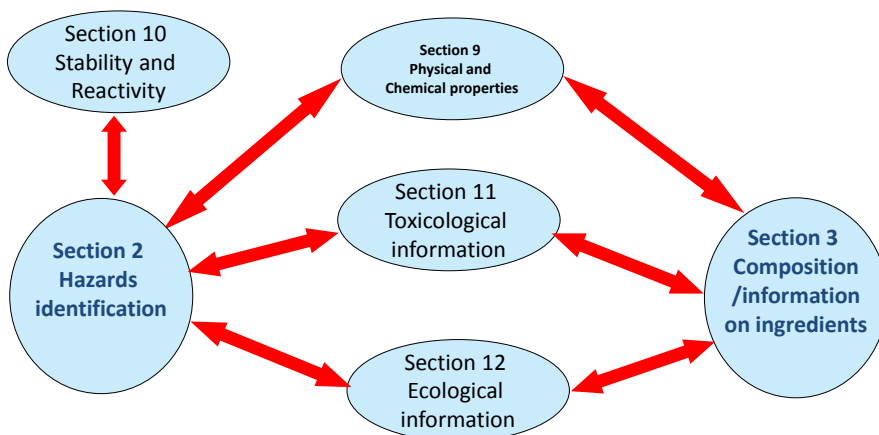


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SDS sections 2 & 3 needs to be checked for consistency with the following sections:



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Sections 2, 4, 9, 11 and ES

11.1. Information on toxicological effects	
(b) skin corrosion/irritation	
Classification: Conclusive but not sufficient for classification.	
9.1. Information on basic physical and chemical properties	
Appearance	Solid (prills, no inhalable fraction, granulation between 0,5 -5 ,0 mm), transparent to white colour at 20 °C and 1013 hPa.
Following skin contact	
Remove any contaminated clothing. Immediately flush exposed area with copious amounts of tepid water for at least 15 minutes followed by washing area thoroughly with soap and water.	
Delayed effects after exposure: get medical attention if irritation develops or persists	
ANNEX TO EXTENDED SAFETY DATA SHEET (eSDS)	
EXPOSURE SCENARIO 1	
1. Exposure Scenario Title	



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Sections 2, 4, 9, 11 and ES

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... but in ES the following recommendation ...

Personal protective equipment (PPE)	
<p>Type of PPE (gloves, respirator, face-shield etc) required under regular working conditions.</p> <p>Remark: Reference on PPE is non exhaustive list, other appropriate PPE list can exist but according to regulations.</p>	<ul style="list-style-type: none"> Selected specifically for the workplace, depending on concentrations and quantities of the substance handled. Those dealing with major releases should wear full protective clothing including respiratory protection. Avoid skin and eye contact. Respiratory protection: respiratory protection is good practice for normal handling, use half-mask with filter type P1 (EN 149) for dust and half-gas-mask (EN 140). Hand protection: in case of dermal contact, use impervious chemical resistant protective rubber gloves complying with EN 374 (required). Eye protection: wear chemical safety goggles or face shield, visor (EN 166) to reduce exposure of the eye to a negligible level.



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My questions

- **Not classified regarding skin and no toxicological indications**
- **Why still RMM for high level of preventing dermal exposure?**
- **Is more toxicological information available, but not expressed in the SDS of Petrokemija?**
- **Note that ...**
 - Ammonium nitrate is jointly registered totally in quantity of 10,000 to 100,000 tonnes per year
 - Consequently, chronic exposure (long term) animal studies should have been submitted or extrapolated by registrants, if > 100 tonnes/year
 - So, what is the status at Petrokemija? (registration type, volume, manufactured/marketed/intermediate use on site or transported)



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Section 11: Toxicological information

(a) acute toxicity

Classification: Conclusive but not sufficient for classification.

(b) skin corrosion/irritation

Classification: Conclusive but not sufficient for classification.

(d) respiratory or skin sensitisation

Classification: Conclusive but not sufficient for classification.

(e) germ cell mutagenicity

Classification: Conclusive but not sufficient for classification.

(f) carcinogenicity

Classification: Conclusive but not sufficient for classification.

(g) reproductive toxicity

Classification: Conclusive but not sufficient for classification.

(h) STOT-single exposure

Classification: Conclusive but not sufficient for classification.

(i) STOT-repeated exposure

Classification: Conclusive but not sufficient for classification.

Applied standard phrase to express “not classified” is unclear and might create confusion.

**Suggestion:
“conclusive; no evidence requiring classification”**

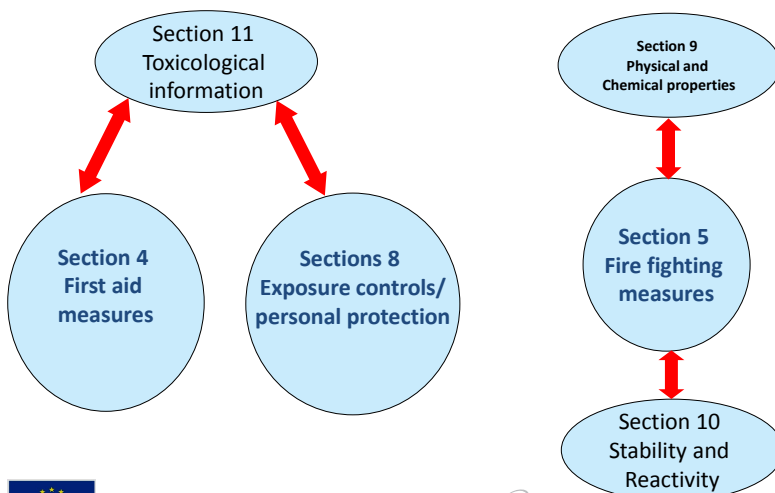


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SDS sections 4, 5 & 8 needs to be checked for consistency with the following sections:



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Sections 8 and 11

SECTION 11: Toxicological information

11.1. Information on toxicological effects

11.1.1. Substances

... but ...

Section 11 does not contain data from chronic exposure animal studies; maybe not required according to


8.1.2. DNEL/PNEC values


Selection of values derived from qualitative/semi-quantitative health effects:

Where these data coming from? Extrapolation not reported; source data not mentioned.

DNELs - Ammonium nitrate

DNELs for workers	DNELs for the general population	Exposure route	Exposure frequency	Remark
21.3 mg/kg bw/day	12.8 mg/kg bw/day	Dermal Oral	Long term - systemic effects	Route-to-route extrapolation has been performed.
37.6 mg/m ³	11.1 mg/m ³	Inhalation	Long term - systemic effects	Route-to-route extrapolation has been performed.

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Section 8 and Exposure Scenarios

8.1.2. DNEL/PNEC values

Selection of values derived from qualitative/semi-quantitative health effects:

Why exposure not assessed? Why not using estimated DNELs?

After checking ECHA database I found the following figures:

For workers:

- DNEL-dermal/oral 5,12 mg/kg bw/day
- DNEL-inhalation 36 mg/m³

For general population:

- DNEL-dermal/oral 2,56 mg/kg bw/day
- DNEL-inhalation 8,9 mg/m³


Has lead registration been updated after 13-11-2013, or is this registration an opt-out? Important to know the exposure at the workplace!


... but in Exposure scenario ...

4. Exposure estimation

4.1. Professional users exposure

Not performed, qualitative assessment.

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Some odd observations in ES

3.2. Risk management measures related to environment

An environmental assessment has not been performed for ammonium nitrate.

Exposure of humans through environment is not relevant as no environmental assessment was done and the leading effect is eye irritation which should not be considered relevant for the route man exposed via the environment. ?

3. Risk management measures

3.1. Risk management measures related to workers

Table 1.2. Risk management measures related to professional and consumer end users

Remark: Additional good practices (Operational Conditions and Risk Management Measures) beyond the REACH Chemical Safety Assessment established within Chemical Industry are also advised and communicated through Safety Data Sheets but are not necessarily required to control risk as laid out above.

It is responsibility of consumers and downstream users (DU) to inform producer of a new specific identified use that is not listed in this SDS. It is responsibility of a producer to include new informations on identified uses received from consumers and downstream users in next revision of SDS.

1. Consumers have no responsibility to inform new use
2. Better "to inform the supplier up the supply chain". It includes also the manufacturer



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Disclaimer

- I am only an observer
- My observations might be clarified
- I could make mistakes, but better to put forward (stupid) questions than wait and see
- I have only access to public data at ECHA website; confidential data might explain some observations
- Hopefully illustrative for you



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THANKS FOR YOUR ATTENTION

QUESTIONS / COMMENTS ?



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