



TECHNICAL GUIDANCE DOCUMENT FOR PREPARING THE CHEMICAL SAFETY ASSESSMENT

Chapter R.9 : Physicochemical Hazard Assessment

**“Technical Guidance Documents in support of the New EU Chemicals Legislation (REACH) –
V: Development of a Technical Guidance Document for preparing the Chemical Safety
Assessment (REACH Implementation Project 3.2-2)”**

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1 **R.9 PHYSICOCHEMICAL HAZARD ASSESSMENT**

2 This chapter focuses on the human health hazard assessment of physico-chemical properties.
3 According to REACH the potential effects to human health shall be assessed for at least the
4 following physicochemical properties:

- 5 • Flammability (Section R.7.1.10)
- 6 • Explosivity (Section R.7.1.11)
- 7 • Oxidizing properties (Section R.7.1.13)

8 For these physicochemical properties the following activities are required:

- 9 • For every physicochemical property, the assessment shall entail an evaluation of the inherent
10 capacity of the substance to cause the effect.
- 11 • The appropriate classification and labelling developed in accordance with the criteria in
12 Directive 67/548 shall be presented and justified.
- 13 • Indicate and justify the actions or decisions taken if information on physicochemical data is not
14 adequate or available to make an hazard assessment
- 15 • Documentation of the assessment of each effect, to be presented under the relevant heading of
16 the Chemical Safety Report (Section 6) and where required summarised in the Safety Data
17 Sheet under heading 9.

18 Although it is assumed that the need for detailing exposure scenarios will be mainly driven by the
19 environment and health concerns it should be ensured that these exposure scenarios are in-line with
20 the precautions needed in relation to the physico-chemical hazards.

21 When a hazard exists, steps should be taken to eliminate or control it. If the hazard cannot be
22 eliminated or reasonably controlled through technical means appropriate control mechanism (e.g.
23 ventilation, specific work processes (e.g. permit-to-work) or specifically trained staff) or protective
24 equipment (e.g. PPE), detection devices or monitoring should be used to avoid human health
25 hazard.

26 **R.9.1 Evaluation of data**

27 Aim

28 The evaluation of data comprises two steps

- 29 • Evaluation of all available data and
- 30 • Identification of the study or studies giving rise to the highest concern (key studies)

31 Background

32 All available information about the relevant hazard properties of the substance must be collected.
33 Information regarding a substance can be results of laboratory tests and investigations in relevant
34 data banks but it may also comprise information obtained via non-test methods (e.g. QSAR, SAR,
35 read-across). It is assumed that as a minimum, all hazard data for physicochemical hazard endpoints
36 specified in Annex VI and VII are available. Additional information may be available which can be
37 used to further specify the hazards having led to i) a classification of the substance and ii) the
38 assignment to a hazard class. See Section R.7.1 for more information on the individual endpoints.

39 If there are several test results addressing the same property, then the valid and most relevant result
40 or results which are giving rise to the highest concern in the situations encountered shall be used to
41 draw a conclusion and a documentation of the data and underpinning arguments (e.g. robust test

42 summary or copy of the cited study) used for the classification shall be prepared for that result or
 43 results and included as part of the registration dossier.

44 Input

Parameter	Description	Source
All available data on the substance, as a minimum: <ul style="list-style-type: none"> • Flammability (Section R.7.1.10) • Explosivity (Section R.7.1.11) • Oxidizing properties (Section R.7.1.13) 	All data used to assess a specific physico-chemical property for hazards to human health shall be briefly presented in the CSR (Section 6) by the relevant test results and test conditions (e.g., physical form, test guideline) and other relevant information	Studies owned by the registrant Other studies to which the registrant has access Publicly available data (publications, data bases, etc.) Information obtained by non-testing methods

45 Output

Parameter	Description	Use
Key studies for required endpoints	The valid value for each endpoint given the highest concern, to develop the appropriate classification and labeling in accordance with the criteria in Directive 67/548	Technical Dossier [cf. Art. 9 (a) (vi) and (vii)] The assessment of each effect shall be presented under the relevant heading of the Chemical Safety Report (Section 6) and where required and in accordance with Article 29, summarised in the Safety Data Sheet under heading 9.

46 **R.9.1.1 Assessment of likelihood of an event**

47 Hazards on the basis of flammable, explosive or oxidizing properties of a substance can be e.g.
 48 generated by leakages of gases, liquids or powders from technical equipment during normal
 49 operation or maintenance activities, spillages during storage or filling/emptying of transportation
 50 containers or during open application of flammable substances or preparations (e.g. during
 51 applications like cleaning processes) thus generating solvent vapours and flammable atmosphere.
 52 Production facilities manufacturing substances with such properties in significant quantities are in
 53 general falling under the requirements of the SEVESO II Directive (98/82/EC, see further
 54 guidance¹) which includes a hazard identification and evaluation process to avoid major accidents.
 55 For activities within the supply chain which are not covered by this directive the registrant should
 56 conduct an assessment of the activities to identify potential hazards and to define measures suitable
 57 to prevent minor accidents which might occur at the workplace or during consumer use. This can
 58 comprise

- 59 ▪ Eliminating the hazard by inherently safe technical design (e.g. leakage prevention, double
 60 sealing, enclosure)
- 61 ▪ Preventive measure to reduce the likelihood of an event (e.g. exclusion of ignition sources,
 62 maintenance / inspection plans)

¹ <http://mahbsrv.jrc.it/GuidanceDocs-SafetyManagementSystems.html#Section3-2>

- 63 ▪ Implementing detection meters to indicate presence of flammable/explosive atmosphere
- 64 ▪ Controlling the scale, intensity and duration of an event (e.g. shut-down procedures,)
- 65 ▪ Mitigating adverse health effects (e.g. active fire protection equipment, safe control rooms)
- 66 ▪ Handling and disposal of contaminated material (e.g. absorbent material, residues, waste).
- 67 ▪ Safety advice and clear instructions for handling of a substance as such or in a preparation

68 The likelihood of an event can be further minimized by keeping the concentration of a flammable or
69 explosive substance outside the explosive limits (LEL or UEL) or e.g. to avoid process or handling
70 temperatures exceeding the flashpoint of a flammable liquid.

71 A simplified methodology to assess the risk of accident, fire or explosion is explained in Part E,
72 based on a questionnaire and methodological approach developed by DG EMPL.

73 The registrant should list the physicochemical properties and endpoints (with reference to the
74 testing methods applied) resulting in a hazard classification and the measures recommended to
75 minimize the likelihood of an event in section 6 of the CSR. Further specification of relevant
76 information will be given in the following sections.

77 **R.9.1.2 Flammability**

78 Based on the information collected (see definitions and testing information in Section B.7.1.9) a
79 distinction can be made in the classification and labelling of flammable substances and its potential
80 source of ignition (e.g. contact with water, electrostatic sparks, welding/ soldering) which - in
81 combination - can create serious effects for human health. Depending on the spontaneity of ignition
82 a distinction can be made according to directive 67/548/EEC ²between

- 83 ▪ Flammable substances
- 84 ▪ Highly flammable substances
- 85 ▪ Extremely flammable substances

86 The assignment to the respective hazard class will further determine the technical means to be taken
87 to avoid dangerous events which, in combination with other endpoints like i) explosive limits, ii)
88 flash points (applicable only for liquids) or iii) self-ignition temperature, can lead to clear
89 restrictions in the conditions of use. The relevant data are to be communicated via the SDS (chapter
90 9).

91 Depending on the likelihood that flammable substances/gases can be released (un-/intentionally)
92 during manufacturing and use preventive measures to avoid ignition should be taken. These can be
93 technically or organisational measures like:

² <http://ecb.jrc.it/classification-labelling/>

- 94 ▪ Prevent explosive / flammable atmosphere by e.g.
 - 95 ○ Define maximum operation temperature
 - 96 ○ Implement better ventilation
 - 97 ○ Use inertisation to exclude e.g. air as oxidizing material
 - 98 ○ Prevent accumulation of flammable material (e.g. discharge of organic phase to sink
 - 99 or sewer)
- 100 ▪ Avoid ignition sources by e.g.
 - 101 ○ Through safe electrical equipment or tools
 - 102 ○ earthing of equipment
 - 103 ○ use of antistatic material
- 104 ▪ Minimize the consequences of ignition by e.g.
 - 105 ○ Injection of extinguishing agents
 - 106 ○ Pressure relief devices / blow-down systems
- 107 ▪ Establish “permit-to-work” system for handling open flames or electrical equipment during
- 108 maintenance / construction operation.
- 109 ▪ Implement monitoring systems

110 Although the absence of ignition source may prevent immediate acute risks through flames and
111 open fire for workers or consumers (e.g. burns or poisoning by decomposition gases (e.g. CO)) the
112 gas or vapour may accumulate in a confined space and can have acute health effects like irritation,
113 narcosis or anaesthesia thus influencing a person’s ability to escape unaided from this space.

114 As flammable substances are broadly used in consumer applications clear labelling and safety
115 instructions are necessary to alert the user to the potential hazard.

116 **R.9.1.3 Explosivity**

117 Due to the destructive potential of explosions, the EU has published Directive 94/9/EC on
118 equipment and protective systems intended for use in potentially explosive atmospheres and
119 Directive 1999/92/EC (ATEX)³ on work in explosive atmospheres. For the latter the EU council
120 has issued a “non-binding guidance of good practice for implementation of the directive” for the
121 prevention of formation of explosive atmospheres at the workplace, avoiding ignition of explosive
122 atmospheres and controlling the effects of explosion. Other obligations for safe use of explosive
123 substances are addressed under Directive 96/82/EC (see. Section R.9.1.1).

124 It may be expected either that the substance being classified as “explosive” based on the physical
125 data (see Section B.7.1.10) is of no immediate concern (e.g. all technical equipment, storage and
126 handling at the workplace allows to conclude that the substance can be handled safely) or that risk

³ Further information can be found in
http://ec.europa.eu/employment_social/emplweb/publications/publication_en.cfm?id=56).

127 reduction measures need to be recommended and implemented at the workplace. Specific
128 consideration besides those already mentioned above should be given to e.g.

- 129 ▪ explosive potential of fine powders (dust explosion)
- 130 ▪ simultaneous generation of explosive atmosphere and electrostatic sparks during open bottling
131 from plastic containers.
- 132 ▪ Explosive gases heavier than air forming clouds close to potential ignition sources (e.g. hot
133 exhaust pipes of cars)

134 For consumer use appropriate control mechanisms should be applied in the design of the product
135 (e.g. limited concentrations or package size) or by clear instructions for use which ensure safe
136 handling under foreseeable conditions of use. Possible adverse effects and appropriate measures to
137 avoid these effects should be reported in the CSR.

138 It should be stated, however, that this guidance does not invalidate existing protection goals realized
139 under other legislation (e.g. ATEX 137) which needs to be followed accordingly.

140 **R.9.1.4 Oxidizing Properties**

141 Substances with oxidizing properties can give rise to a highly exothermic reaction in contact with
142 other substances, in particular with flammable substances (see 9.1.1). They can in principle have
143 irritating effects to skin, eyes and to the respiratory tract as they can react with the human tissue
144 under formation of high temperatures thus destructing biological material. Appropriate good
145 housekeeping practices and PPE may need to be considered during normal use, whereas consumer
146 products containing such substances should have upper concentration limits which ensure limitation
147 of risks

148 Not all substances that have oxidizing properties are indeed hazardous; some will be mildly
149 oxidizing only and present very little hazard. To distinguish those that are hazardous, a substance's
150 oxidizing properties are compared to those of standard reference substances.

151 Due to the possible effect of reacting with other substances warehousing and transportation of
152 substances with oxidizing properties together with e.g. flammable substances are regulated under
153 Directive 96/82/EC or international agreement on transportation of dangerous goods (ADR⁴). Such
154 limitations should be indicated in the eSDS communication and documented in the CSR
155 respectively.

156 **R.9.2 Classification and labelling**

157 The objective of the hazard assessment for physicochemical properties shall be to determine the
158 classification and labelling of a substance in accordance with Directive 67/548. This should be done
159 by comparing the data against the criteria given in the classification and labelling rules (further
160 guidance will be developed in RIP 3.6). If the data are inadequate to decide whether a substance
161 should be classified for a particular end-point, the registrant shall indicate and justify the action or
162 decision he has taken as a result.

163

⁴ <http://www.unece.org/trans/danger/publi/adr2007/07ContentsE.html>

164 It needs mentioning that based on the implementation of GHS additional hazard classes will be
165 introduced which will further differentiate the hazards to be expected by flammable or explosive
166 properties. This will be reflected by establishing additional risk phrases⁵ to be used in the SDS
167 communication.

168 **R.9.3 Documentation in the CSR and SDS**

169 The safety assessment to be presented in the Chemical Safety Report shall document that the risks
170 are adequately controlled and the associated hazards communicated by the ensuing classification
171 and labelling. This should cover the capacity of hazardous chemical agents to cause accidents, in
172 particular fires, explosions or other hazardous chemical reactions:

- 173 • hazards resulting from the physicochemical nature of the chemical agents,
 - 174 • risk factors identified in their storage, transport and use, and
 - 175 • the estimated consequences in the event of occurrence.
- 176

177 As REACH does not cover the major-accident hazards of certain industrial activities as defined by
178 Directive 96/82/EC only minor accident scenarios should be considered which might occur in the
179 workplace and those related to consumer use. As it is therefore unreasonable to expect catastrophic
180 consequences to result from such accidents, simplified assessments, based on questionnaires and/or
181 check lists, can be used to evaluate whether the risk is adequately controlled. In general, the aim of
182 these simplified assessments is not to calculate the absolute value of the risk but, in the interests of
183 simplicity, to provide only an approximation of the magnitude of the risk. This will often be
184 sufficient to establish a risk hierarchy and thus determine the priorities in the preventive action.

185 One can either conclude that the use of the substance and the normal risk reduction measures
186 invoked by classification and labelling of the hazard can be considered of no immediate concern for
187 workers and consumers or that recommendation for risk reduction are necessary. Many of the
188 preventive measures which may be triggered by toxicological effects of the same substance or other
189 substances in a preparation will serve the same purpose and can already help eliminating or
190 minimizing the effects of physicochemical hazards. Such measures or additionally proposed actions
191 (see also sections 9.1.1 – 9.1.3) should be described in a narrative format and included in the CSR
192 (see table R.9.1) whereas information about substance specific properties and RMMs should be
193 addressed in the SDS under the respective headings (see Chapter G).

⁵ See comparison of risk phrases http://ecb.jrc.it/classlab/15004_physchem_EU-GHS.doc

194
195**Table R.9-1: Information and description of measures to be documented in CSR and SDS**

Information	CSR	SDS
Physicochemical properties (e.g. flammability, explosivity, oxidizing potential, flash point, explosive limits...)	X	X
Classification based on phys-chem hazards	X	X
Description of activities which may cause minor accidents at workplace or during consumer use (e.g. during maintenance, cleaning of equipment, open use)	X	
Estimation of severity in the event of occurrence (qualitatively based on assumed amount during event, operational conditions of use and volatility of the substance)	X	
Measures taken to avoid dangerous situations (e.g. inherently safe equipment, exclusion of ignition sources by organisational measures, ventilation ...)	X	
Recommended risk management measures to avoid occurrence of event	X	X
Measures to be taken if event occurs (e.g. fire fighting...)		X
Restrictions in transportation and storage		X
R-phrases		X

196 Any measures / RMMs regarding physicochemical hazards which haven't been addressed already
197 by other health or environmental considerations should be included in the SDS under heading 8.

198 As a consequence of such assessment the registrant may

- 199 • define specific process operating conditions and workplace practices
- 200 • specifies appropriate labelling and information e.g. on the packaging material if substance with
201 physicochemical hazard will be used in consumer products (e.g. flammable propellants in
202 sprays)
- 203 • state marketing restrictions (e.g. no use in consumer products) which may need to be addressed
204 in the eSDS under heading 16 as "use advised against"

205 Where it is judged to be the case a conclusion of no concern should be drawn and documented in
206 the CSR. Such an approach was endorsed by the Competent Authorities for the implementation of
207 Regulation 793/93 at their 16th Meeting November, 1999.